Background and Document Organization

The goal of the U.S. Food and Drug Administration's (FDA or Agency) Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) project is to support structuring eCTD product quality concepts that are amenable to structuring and bring value to the quality review process as structured data elements. It is not intended to migrate the entirety of eCTD Module 3 to a structured form.

The submission of structured data in a standardized format will increase the efficiency of FDA's review of PQ/CMC data contained in the Module 3 of eCTD submissions for a New Drug Application (NDA), an Investigational New Drug Application (IND), a Biologics License Application (BLA), an Abbreviated New Drug Application (ANDA), a New Animal Drug Application (NADA), an Abbreviated New Animal Drug Application (ANADA), an Investigational New Animal Drug (INAD), Generic Investigational New Animal Drugs (JINADs), and a Master File (MF).

Industry will submit this PQ/CMC information in the Common Technical Document (CTD) as defined by the International Council for Harmonisation's (ICH) CTD.[1]

For consistency of product quality data across FDA centers, the draft standardized data elements and terminologies were created by an Agency workgroup comprised of Subject Matter Experts (SMEs) from the Center for Drug Evaluation and Research (CDER), the Center for Veterinary Medicine (CVM), and the Center for Biologics Evaluation and Research (CBER). Please note that data element definitions provided here have been developed for purposes of review of information in Module 3 of the eCTD.[2]

For the most current information on the PQ/CMC effort, please visit FDA's PQ/CMC page.

"Living Document" Organization

FDA has previously released documents for comment related to data elements and terminologies for PQ/CMC as part of individual Federal Register Notices (FRNs). Since FDA is planning to ask for comment on additional PQ/CMC data elements and terminologies over time, an open docket is being created where this document will be updated on a periodic basis. Updates will be made with the addition of new "Chapters" covering new and/or revised data elements and terminologies while still retaining the sections previously published.

Unless otherwise stated, FDA will *ask for comment on only the newly added Chapter(s)* of the document.

[1] The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality – M4Q (R1)
[2] Electronic Common Technical Document v3.2.2

Document Version History and Directions for Public Comment

Version Number	Description of Changes and Reason for Change

1.0	Initial document containing 2 chapters
	• Chapter 1: The text of the Document "Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange" which was published for comment in March 2022. *FDA is NOT requesting further comment on this section.*
	  ○ Note that all references to the representation of these data elements in the HL7 FHIR (Fast Healthcare Interoperability Resources) standard have been removed since the that is out of the scope of this living document. You can still see the original document with references to FHIR in the published document at the link above.
	• **Chapter 2:** A *new* chapter describing data elements and terminologies covering
	  ○ Enhancements to support solid oral dosage form component and composition: multi-layer tablets and capsules.
	  ○ Drug product manufacturing scoped to solid oral dosage forms

FDA is requesting comment on ONLY Chapter 2. Public comment on previous Chapter(s) has already been received.

Contents

CHAPTER 1: Foundational Data Standards and Terminology for PQ/CMC

Document version 1.0: FDA is NOT requesting comment on Chapter 1.

Please proceed to Chapter 2 to view material for which FDA seeks public comment.

Scope of this Chapter

The PQ/CMC domain scope for this entire effort has been divided into two phases.

Phase 1 covers the following topics: Drug Product definition, Drug Substance definition, Quality Specification, Batch Formula, Batch Analysis and Stability.
Phase 2 data standards are under development, and will cover the following topics: Drug Product Manufacturing and Drug Substance Manufacturing.
The scope of this document is limited to Phase 1 domains only. FDA will provide the structuring of Phase 2 domains in the near future.

This draft document is organized into the following eight sections:

Each data element section describes the PQ/CMC data elements.

The table in each section identifies the structured data elements and their details that are in scope of that section. The majority of the content of the Data Elements table is the same as was published by FDA as part of the FRN in 2017. There are updates based on industry feedback as well as further clarification, refinement, and structuring. The data elements have been grouped together under a larger logical grouping. The columns in the data element tables are as follows:

- **Data Element Name Definition:** Represents the description of the data element and is intended to provide the semantic clarity for the data element. To further clarify the definition, examples and additional notes have been provided. Also, the source of the definition has been captured and added after the definition. Where possible authoritative sources such as the CFR, USP or ICH were relied on. The source most often documented is "Subject Matter Expert (SME) Defined." The SMEs for this effort are the PQ/CMC reviewers from CDER, CVM and CBER.
- **Data Type:** Identifies the data format or representation and can contain a range of values or specific types. For example, date, text.
- **Cardinality:** The number of occurrences of the element.
- **Business Rule (BR)/Comments:** Provides element specific business rules where relevant or any other additional comments for clarification.

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

Section 1: Drug Substance Data Elements

This section covers the properties of drug substance nomenclature, characterization, control of materials and impurities. This information is typically submitted in eCTD sections -- 3.2.S.1.1; 3.2.S.1.2; 3.2.S.3.1; 3.2.S.2.3; 3.2.S.2.4 (for intermediates ONLY); 3.2.S.3.2

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Substance Name**	A commonly used name or a systematic name assigned to the material or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N- (4-hydroxyphenyl)-; 4-hydroxyacetanilide; rituximab, OkT3	Text	0..*	BR: Substance Name and the following identifiers (CAS, INN, USAN, IUPAC) collectively are providing the name, depending on the Substance Type (in IDMP), one of these identifiers is mandatory.
2	**CAS Number**	Chemical Abstract Service (CAS) Registry Numbers (often referred to as CAS RNs or CAS Numbers) are used to provide identifiers for chemical substances. A CAS Registry Number itself has no inherent chemical significance but provides a way to identify a chemical substance or molecular structure when there are many possible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Example: CAS [103-90-2]	Text	0..1	
3	**INN**	International Nonproprietary Names (INN) is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name. Note: International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients [Source: http://www.who.int/medicines/services/inn/en/] Example: Paracetamol	Text	0..1	
4	**USAN**	A unique nonproprietary name assigned to drugs and biologics and assigned by the United States Adopted Names Council [Source: SME Defined] Example: acetaminophen	Text	0..1	

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
5	**IUPAC Name**	A name assigned to a chemical substance according to the systematic nomenclature rules defined by the International Union of Pure and Applied Chemistry (IUPAC) [Source: SME Defined] Example: N- (4-hydroxyphenyl)acetamide	Text	0..1	
6	**UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Example: 362O9ITL9D Note: If a UNII does not exist, please go to http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/	Text	0..1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
7	**ISBT 128**	It is the global standard for the terminology, identification, coding and labeling of medical products of human origin (including blood, cell, tissue, milk, and organ products). [Source: https://www.iccbba.org/]	Text	0..1	BR: Applicable to blood products.
8	**Company Code**	An internal identifier assigned by the sponsor to this drug substance. [Source: SME Defined]	Text	0..*	

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
9	**Molecular Weight**	The average mass of a molecule of a compound compared to $^{1}/_{12}$ the mass of carbon 12 and calculated as the sum of the atomic weights of the constituent atoms. [Source: Merriam Webster]	Numeric	0..1	
10	**Molecular Weight UOM**	The labeled unit of measure for the molecular weight. [Source: Adapted for NCI EVS C117055]	Code	0..1	BR: Required if Molecular Weight is not null.
11	**Molecular Formula**	An expression which states the number and type of atoms present in a molecule of a substance or sequence for biotechnology products. [Source: SME Defined]	Text	0..1	
12	**Substance Structure Graphic**	A pictorial representation of the structure of the drug substance. [Source: SME Defined] Note: Refer to the "Acceptable File Formats for use in eCTD" Example: This is the representation of the molecule CH3OH, or the sequence SHLVEALALVAGERG.	Graphic	0..1	BR: Required for Small Molecules.
13	**Structural Representation**	A machine-readable representation of the structure of the chemical. [Source: SME Defined] Examples: SDF, MOLFILE, InChI file (small molecule), PDB, mmCIF (large molecules), HELM.	Text	0..*	
14	**Structural Representation Type**	A format name or abbreviation that identifies a file structure. [Source: SME Defined] Examples: SMILES, MOLFILE, HELM.	Code	0..1	BR: Required if Structural Representation is provided.
15	**Polymorphic Form Identification**	The designation of the polymorphs present in the drug substance. [Source: SME Defined] Example: Polymorph A	Text	0..*	
16	**Substance Characterization Technique**	The technique used to elucidate the structure or characterization of the drug substance. [Source: SME Defined] Examples: x-ray, HPLC, NMR, peptide mapping, ligand binding assay.	Text	1	

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
17	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram. Note: Refer to the "Acceptable File Formats for use in eCTD" Example: This is the representation of the instrumental output for the molecule -- CH3OH	Graphic	0..*	BR: Multiple graphics are typically seen more often in Biologics. Some techniques produce multiple graphics.
18	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined] Example: JCAMP, ADX, ADF.	Text/ Binary	0..*	
19	**Analytical Instrument Data File Type**	A format name or abbreviation that identifies a file structure. [Source: SME Defined] Examples: Joint Committee on Atomic and Molecular Physical Data (JCAMP), Analytical Information Markup Language (AnIML).	Text	0..1	BR: Required if Analytical Instrument Data File is provided.
20	**Substance Component Name**	Any raw material intended for use in the manufacture of a drug substance. [Source: SME Defined] Note: for use as an agent in manufacture of a drug substance	Text	1..*	
21	**Quality Standard**	The established benchmark to which the component complies. [Source: SME Defined] Examples: USP/NF, EP, Company Standard	Code	1..*	
22	**UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please go to http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/	Text	1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
23	**CAS Number**	Chemical Abstract Service (CAS) Registry Numbers (often referred to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical substances. A CAS Registry Number itself has no inherent chemical significance but provides a way to identify a chemical substance or molecular structure when there are many possible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Example: CAS [103-90-2]	Text	0..1	
24	**Drug Substance Component Supplier Name**	The name of the entity that was the source for the component. It may be different from the manufacturer of the component. [Source: SME Defined] Note: Supplier is synonymous to a Distributor	Text	0..1	BR: For raw materials, supplier information is not required, but if a supplier is identified then a supplier name must be provided.
25	**Drug Substance Component Supplier Address**	The complete address for the supplier. [Source: SME Defined]	Text	0..1	BR: For raw materials, supplier information is not required, but if a supplier is identified then a supplier address must be provided.

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
26	**Drug Substance Component Manufacturer Name**	The name of the entity that created, made, produced, or fabricated the component. [Source: SME Defined]	Text	0..*	BR: For raw materials, manufacturer information is not required, but if a manufacturer is identified then a manufacturer name must be provided.
27	**Drug Substance Component Manufacturer Address**	The complete address for the manufacturer of the component. [Source: SME Defined]	Text	0..*	BR: For raw materials, manufacturer information is not required, but if a manufacturer is identified then a manufacturer address must be provided.
28	**Source Type**	A classification that provides the origin of the raw material. [Source: SME Defined]	Code	1	IF raw material source type equals Microbial, Animal, Plant, Insect or Human THEN the 4 source related attributes and the manufacturer and supplier information is "highly desirable" (optional from system point of view)
29	**Source Organism**	The name, genus or genus and species of the organism from which the material is derived. [Source: SME Defined] Examples: human or Homo Sapiens, chicken, dog or canine, cow or bovine, rat or rattus.	Text	0..1	

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
30	**Source Organism Part**	A fragment of the source organism. [Source: SME Defined] Examples: secretions, material from a specific organ, tissue, or portion of the organism such as liver, pancreas, blood or from bark or seed of a plant. IDMP 11238 definition & examples: Entity of anatomical origin of source material within an organism. Cartilage, Root and Stolon, whole plant is considered as a part, Aerial part of the plant, Leaf, Tuberous Root, whole animal	Text	0..1	
31	**Source Organism Country of Origin**	The name of the country where the organism was reared. [Source: SME Defined]	Code	0..1	
32	**Drug Substance Impurity Name**	Any component of the drug substance which is not the chemical entity defined as the drug substance. [Source: ICH Q6A] Examples: CHO cell protein, QQ201234, Residual DNA, gentamicin. Note: For example, this could also be a common name, systematic name or a company code	Text	1..*	
33	**UNII (of the Impurity)**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please go to http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/	Text	0..1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
34	**Impurity Classification**	A categorization of impurities based on its origin. [Source: SME Defined] Examples: Degradation Product, Inorganic, Process Related/Process, Product Related, Leachables.	Code	1..*	
35	**Impurity Chemical Structure Data File**	A machine-readable representation of the structure of the chemical. [Source: SME Defined] Examples: Structured Data File (SDF), MDL MOLFILE, IUPAC Chemical Identifier (InChI) file.	Text/ Binary	0..1	
36	**Impurity Structure Graphic**	A pictorial representation of the structure of the impurity. [Source: SME Defined]	Graphic	0..1	
37	**Drug Substance Impurity Method Type**	The technique used to elucidate the structure or characterization of the impurity. [Source: SME Defined]	Code/ Text	0..*	
38	**Impurity Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	0..*	
39	**Impurity Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/ Binary	0..*	

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#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
40	**Impurity Analytical Instrument Data File Type**	A format name or abbreviation that identifies a file structure. [Source: SME Defined] Examples: JCAMP, AnIML.	Text	0..1	BR: Required if Impurity Analytical Instrument Data File is provided.

END OF SECTION 1

Section 2: Drug Product Data Elements

This section covers the properties of drug product component & composition; control of excipients and impurities. This information is typically submitted in eCTD sections -- 3.2.P.1; 3.2.P.4.1; 3.2.P.5.5.

Refer to Appendix A for several detailed examples that illustrate how to provide the strength of the ingredient using the PQ/CMC strength-related data elements.

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Product Proprietary Name**	The exclusive name of a drug product owned by a company under trademark law regardless of registration status with the Patent and Trademark Office (PTO). [Source: SME Defined] Note: Excludes dosage form, route of administration and strength. Example: Tylenol	Text	0..1	
2	**Product Non-proprietary Name**	A name unprotected by trademark rights that is entirely in the public domain. It may be used without restriction by the public at large, both lay and professional. [Source: SME Defined]	Text	1	
3	**Co-Packaged Indicator**	A property that identifies whether a drug product has been supplied along with an additional item, such as another drug product, a placebo, a diluent or an adjuvant. [Source: SME Defined] Note: Any component that is dispensed separately or external to the drug product is not considered co-packaged. Example -- Alka Seltzer. Since water is not supplied by the sponsor it is not considered as a co-packaged component.	Code	1	
4	**Dosage Form**	The form in which active and/or inert ingredient (s) are physically present. [Source: NCI EVS - C42636] Examples: tablet, capsule, solution, cream that contains a drug substance generally, but not necessarily, in association with excipients. [Source: ICH Q1A (R2)] Note: If there is a new dosage form that does not exist in the controlled	Code	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		terminology, then propose this new dosage form during sponsor meetings with FDA.			
5	**Route of Administration**	Designation of the part of the body through which or into which, or the way in which, the medicinal product is intended to be introduced. In some cases, a medicinal product can be intended for more than one route and/or method of administration. [Source: NCI EVS C38114]	Code	1	
6	**Strength Type**	A physical (content) or activity measurement of the strength of the ingredient. [Source: SME Defined] Example: Mass, Activity	Code	1	When Strength Type =Activity - IF UOM is UCUM Arbitrary Unit [arb'U], need to describe the Units in Strength Text data element IF Strength Type = Mass THEN Strength Numeric and Strength UOM are Mandatory IF Strength Type = Activity THEN Strength Textual, Strength UOM ([arb'U]) and Strength Operator are applicable data elements. Strength Textual and Strength UOM will be Mandatory and Operator will be Optional
7	**StrengthNumericNumerator**	The content of an ingredient expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dosage form. This should be the strength as listed on the label. [Source: Adapted from NCI EVS C53294]	Number	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		Note: Strength can also be referred to as potency in biologics and other products. This information may be captured on the label.			
8	**StrengthNumericNumerator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055]	Code	0..1	BR: Required if StrengthNumericNumerator is provided.
9	**StrengthNumericDenominator**	Specifies the quantity of the ingredient (s) consistent with a single unit dose or as expressed on the label. [Source: SME Defined] Note: Kg value is only applicable for veterinary applications. Note: This is the denominator value when expressing the strength for APIs Example: 5 mg per 100 mL	Code	0..1	
10	**StrengthNumericDenominator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055]	Code	0..1	BR: Required if StrengthNumericDenominator is provided.
11	**Strength Textual**	A written description of the strength of the ingredient. [Source: SME Defined] Note: This is typically applicable to biologics Example: International Units for Enzymes	Text	0..1	BR: If the UOM is UCUM Arbitrary Unit [arb'U], you need to describe the units in the Strength Text data element.
12	**Strength Operator**	A mathematical symbol that denotes equality or inequality between two values. [Source: SME Defined] Examples: LT, EQ, NMT. Note: This is typically applicable to biologics	Code	0..1	BR: See Strength Type BR
13	**Drug Product Description**	A textual narrative describing the drug product or products. [Source: SME Defined] Examples: dosage form, container closure system, purpose.	Text	1..*	
14	**Container Closure System Description**	Any textual comments that describe the sum of container closure system (CCS) components that together contain and protect the dosage form or drug substance. [Source: Adapted from Q1A (R2)-ICH Glossary] Example: White opaque, round 50 mL HDPE bottle with a fitted 33 mm child resistant black polypropylene threaded cap closure, aluminum sealed, and	Text	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		containing molecular sieve canister 2 gm (CAN TRISORB 2G) as desiccant. Note: This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug substance or the drug product. A packaging system is equivalent to a container closure system. [Source: Adapted from Q1A (R2)-ICH Glossary]			
15	**Container Type**	The kind of container that drug substances and finished dosage forms are contained in, which could include both the immediate (or primary) and secondary containers [Source: Adapted from NCI Thesaurus C43164]	Code	1	
16	**Closure Type**	The kind of closures used for the container in which the drug substances and finished dosage forms are stored. [Source: SME Defined]	Code	1	
17	**Product Component Name**	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. [Source: (21 CFR 210.3 (b) (3)) PAC-ATLS 1998]	Text	1	
18	**UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please contact fda-srs@fda.hhs.gov	Text	1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
19	**Drug Product Component Function Category**	A high-level classification that identifies the purpose of that material. [Source: SME Defined] Example: Active Ingredient, Inactive Ingredient, Adjuvant.	Code	1	
20	**Drug Product Component Function**	A sub-classification of components identifying its purpose/role in the drug product. [Source: SME Defined] Examples: Filler, Surfactant.	Code	1..*	If Drug Product Component Function Category is Active Ingredient or Adjuvant THEN Drug Product Component Function will be NA If Drug Product Component Function Category is Inactive Ingredient (excipient) THEN Drug Product Component Function must be from the value list.
21	**Content (%)**	The percentage of the component in the drug product. [Source: SME Defined]	Numerical Percent	0..1	
22	**Quality**	The established benchmark to which the component complies. [Source: SME Defined]	Code	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Standard	Examples: USP/NF, EP, Company Standard			
23	**Drug Product Component Additional Information**	A placeholder for providing any comments that are relevant to the component. [Source: SME Defined] Examples: removed during process, adjusted for loss on drying.	Text	0..*	
24	**Source Type**	A classification that provides the origin of the raw material. [Source: SME Defined] Example: cat hair would be an Animal source type	Code	1	
25	**Source Organism**	The name, genus or genus and species of the organism from which the material is derived. [Source: SME Defined] Examples: human or Homo Sapiens, chicken, dog or canine, cow or bovine, rat or rattus.	Text	0..1	
26	**Source Organism Part**	A fragment of the source organism. [Source: SME Defined] Examples: secretions, material from a specific organ, tissue or portion of the organism such as liver, pancreas, blood or from bark or seed of a plant. IDMP 11238 definition & examples: Entity of anatomical origin of source material within an organism. Cartilage, Root and Stolon, whole plant is considered as a part, Aerial part of the plant, Leaf, Tuberous Root, whole animal	Text	0..1	
27	**Source Organism Country of Origin**	The name of the country where the organism was reared. [Source: SME Defined]	Code	0..1	
28	**Drug Product Impurity Name**	Any component of the drug product which is not the chemical entity defined as the drug substance or an excipient in the drug product. [Source: ICH Q6A] Examples: QQ201234, Residual DNA, Aggregates & degradants. Note: For example, this could also be a common name, systematic name or a company code	Text	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
29	**UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please go to http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/	Text	0..1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
30	**CAS Number**	Chemical Abstract Service (CAS) Registry Numbers (often referred to as CAS RNs or CAS Numbers) are used to provide unmistakable identifiers for chemical substances. A CAS Registry Number itself has no inherent chemical significance but provides a way to identify a chemical substance or molecular structure when there are many possible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Example: CAS [103-90-2]	Text	0..1	

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
31	**Impurity Classification**	A categorization of impurities based on its origin. [Source: SME Defined] Examples: Degradation Product, Inorganic, Process Related/Process, Product Related, Leachables.	Code	1..*	
32	**Chemical Structure Data File**	A machine-readable representation of the structure of the chemical. [Source: SME Defined] Examples: SDF, MOLFILE, InChI file, cdx.	Text/Binary	0..1	
33	**Impurity Structure Graphic**	A pictorial representation of the structure of the impurity. [Source: SME Defined]	Graphic	0..1	
34	**Drug Product Impurity Method Type**	The technique used to elucidate the structure or characterize the impurity. [Source: SME Defined] Examples: NMR, Mass Spectrometry.	Text	0..*	
35	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	0..*	
36	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/Binary	0..*	
37	**Analytical Instrument Data File Type**	A value that identifies the file format. [Source: SME Defined] Examples: JCAMP, AnIML.	Text	0..1	BR: Required if Analytical Instrument Data File is provided.

END OF SECTION 2

Section 3: Batch Formula Data Elements

This section covers the properties of batch formula for a drug product. This information is typically submitted in eCTD sections -- 3.2.P.3.2

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Quantity**	The amount of material in a specific batch size [Source: SME Defined] Example: 1000 kg	Numeric	1	
2	**Quantity UOM**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709]	Code	1	
3	**Batch Formula Additional Information**	A placeholder for providing any comments that are relevant to the batch formula. [Source: SME Defined] Examples: Water for wet granulation -- removed during processing; adjusted for assay.	Text	0..*	
4	**Overage Percent**	Overage is the percent of a drug substance in excess of the label claim to compensate for the loss, such as manufacturing or other. [Source: SME Defined] Note: This is not for stability loss, and generally not permitted Example: 3% overage of drug that has a label claim of 10mg of active (API) - the formulation would have 10.3 mg. A batch formula for 100 kg would contain 103 kg of API.	Numeric Percent	0..1	
5	**Overage Justification**	The rationale for use of excess drug substance during manufacturing of the drug product [Source: SME Defined]	Text	0..1	
6	**Component Quantity Per Batch**	Specifies the amount of the component per batch size of the drug product. [Source: SME Defined]	Numeric	1	
7	**Quantity Percent**	The percentage of the component in the batch [Source: SME Defined]	Numeric	1	
8	**Component Additional Information**	A placeholder for providing any comments relevant to the component. [Source: SME Defined] Examples: Water for wet granulation - removed during process; adjusted for loss on drying.	Text	0..*	
9	**Product Proprietary**	See details of this element in Drug Product section 2			

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Name				
10	**Strength Textual**	See details of this element in Drug Product section 2			
11	**Quality Standard**	See details of this element in Drug Product section 2			

END OF SECTION 3

Section 4: Quality Specification Data Elements

This section covers the properties of a quality specification. This information is typically submitted in eCTD sections -- 3.2.S.4.1, 3.2.P.5.1. Also used with Batch Information (3.2.S.4.4 and 3.2.P.5.4), Stability Data (3.2.S.7.3; 3.2.P.8.3) and Annual Report 1.13
NOTE: A quality specification is for a drug product or a drug substance, excipient, or raw material. This Quality Specification profile references the Drug Product or the Drug Substance Profile. Not all the data elements from the Drug Product and Drug Substance profiles are needed while building the Quality Specification Profile. The specific elements from the referenced profiles are identified in the FHIR Mapping table.

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Specification Title**	The textual identification for the specification. [Source: SME Defined] Example: <drug name> 75 mg chewable tablets Note: This may include the name of the drug substance, product or the raw material/excipients.	Text	1	
2	**Specification Subtitle**	An additional textual identification for the specification [Source: SME Defined].	Text	0..1	Some sponsors provide an additional title for the specification -- a subtitle.
3	**Specification Type**	A classification of specification related to the kind of the entity it is referencing. [Source: SME Defined] Examples: Drug product, Drug substance.	Code	1	
4	**Specification Version**	The alphanumeric text assigned by the sponsor to a particular edition of a specification. [Source: SME Defined] Examples: 2.1, 13.2, ST1, 00001, 00002, <companyname>001. Note: This value should be unique across all specifications for a given material, not just those with the same name	Text	1..*	A Specification can have one or more versions.
5	**Specification Version Date**	The date when the sponsor assigned a date to a specific version. [Source: SME Defined] Note: This is the date a particular version of the specification was internally accepted by the submitter.	Date	1	
6	**Specification Status**	The current FDA regulatory status of the specification. [Source: SME Defined] Examples: Approved, Not Approved, Reported in a CBE or AR.	Code	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		Note: There are instances when FDA does approve the Specifications in a supplement or an amendment where other information in the dossier has not changed. Note: This is different from Application Status			
7	**Specification Status Date**	The date on which the FDA approval status for a specification became effective. [Source: SME Defined] Note: If the application is not yet approved, then this is the date of the current submission OR the date of the complete response (CR). Note: This is not the application approval status date.	Date	1	
8	**Specification Additional Information**	Placeholder for providing any comments that are relevant to the specification. [Source: SME Defined] Examples: replaces method ABC, using the XYZ facility.	Text	0..1	
9	**Test Name**	The textual description of a procedure or analytical method. [Source: SME Defined] Examples: Assay by HPLC, moisture by Karl Fischer, analysis for impurities. Note: as defined by the sponsor	Text	1	
10	**Test Method Origin**	A coded value specifying the source of the method. [Source: SME Defined] Example: Compendial	Code	1	
11	**Test Category**	A high-level grouping of quality attributes for products, substances, raw materials, excipients, intermediates and reagents. [Source: SME Defined]. Examples: Assay, Biological Properties.	Code	1	
12	**Analytical Procedure**	The name of the technique used to determine the nature of a characteristic. [Source: SME Defined]. Note: The full descriptor of the technique is part of the next data element - Reference to Procedure	Text	1	
13	**Reference to**	A sponsor/applicant provided alphanumeric code that identifies the procedure. [Source: SME Defined]. Example: HP1234-2008	Text	1	

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Procedure	Note: This could also be a transferred lab method.			
14	**Relative Retention Time**	The ratio of the retention time of a component relative to that of another used as a reference obtained under identical conditions as an alias for the name of the unidentified impurities. [Source: Adapted from USP] Example: 1:23 (a ratio) Note: This is the title or name of the impurity (sometimes expressed as a ratio) and not the value.	Text	0..1	
15	**Test Additional Information**	Placeholder for providing any comments that are relevant to the Test. [Source: SME Defined].	Text	0..*	
16	**Test Order**	The sequential number assigned to each Test to specify the order of display on the Quality Specification. [Source: SME Defined]	Numeric	1	
17	**Stage Name**	A textual description and/or a number that identifies a level within a sequential test. [Source: SME Defined] Examples – Single Stage, Stage 1, Stage 2 (sometimes referred to as L1, L2 L3 or A1, A2 as in USP <711>) Note: A Stage may or may not provide a conditional sequence with associated acceptance criteria. [Source: SME Defined] (e.g., dissolution test, pyrogen test - USP <151>; 21 CFR 610.13 (b) Test for pyrogenic substances)	Text	1	
18	**Stage Sequence Order**	The order of the stages in regular succession. [Source: SME Defined] Examples: 1, 2, 3.	Numeric	1	
19	**Stage Additional Information**	Placeholder for providing any comments that are relevant to the Test. [Source: SME Defined]	Text	0..*	
20	**Value**	The acceptable qualitative or text value of the result of the test. [Source: SME Defined]	Text	0..1	
21	**ValueNumeric**	The acceptable quantitative or numeric value for the result of the test. [Source: SME Defined]	Numeric	0..1	

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
22	**ValueNumeric UOM**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709]	Code	0..1	BR: Required if ValueNumeric is not null.
23	**Original Text**	The text of the acceptance criteria as provided in the specification. [Source: SME Defined] Examples: White to off-white cake; 22.5 - 27.5 mg/ml Note: This is the text as it appears in the Specification.	Text	1	
24	**Acceptance Criteria Usage**	A coded value specifying when a particular analytical procedure or measurement is being performed on a substance or a product. [Source: SME Defined]. Examples: Release, Stability. Note: The concept of "In-Process" is subsumed by the Release code.	Code	1..*	
25	**Interpretation Code**	A code that describes how to relate the given value to an acceptance value. [Source: SME Defined] Note: When result value is numeric there is a controlled vocabulary; when result value is textual the vocabulary is Pass/Fail.	Code	1	
26	**Acceptance Criteria Additional Information**	A textual field to provide any additional information about the acceptance criteria. [Source: SME Defined] Example: value changed from 4% to 5% on 01/01/2010	Text	0..*	

END OF SECTION 4

Section 5: Batch Analysis Data Elements

This section covers the properties of a batch analysis. This information is typically submitted in eCTD sections -- 3.2.S.4.4 and 3.2.P.5.4. Also used with Stability Data (3.2.S.7.3; 3.2.P.8.3) and Annual Report 1.13

NOTE: A batch analysis is on a drug product or a drug substance for a given quality specification. This Batch Analysis profile references the Drug Product or the Drug Substance and the identifier and the version of the Quality Specification. Not all the data elements from the Drug Product and Dug Substance profiles are needed while building the Batch Analysis Profile. The specific elements from the referenced profiles are identified in the FHIR Mapping table.

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Batch or Lot Number (Bulk Batch ID)**	A combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined. [Source: Adapted reference: 21 CFR 210.3 Definitions (4/1/2014)]	Text	1	
2	**Batch Size**	The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval. [Source: ICH Q7 - Part of the definition of Batch]	Numeric	1	
3	**Batch Size Unit**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709]	Code	1	
4	**Retest Date**	The date after which samples of the drug substance should be examined to ensure compliance with the specification and thus suitable for use in the manufacture of a given drug product [Source: Adapted from Q1A (R2)]	Date	0..1	BR: For Substances and some biologics. Does not apply to Products and therefore optional.
5	**Retest Date Classification**	The endorsement of the Retest date that clarifies whether this date has been approved by the FDA or is being proposed by the sponsor/applicant for a drug substance. [Source: SME Defined]	Code	1	This classification applies to ALL substances. * For an original MF/application, Retest Date Classification is "Proposed".

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					* After an MF/application has been approved, Retest Date Classification is "Approved". * For a Supplement that's changing the Retest Date that is already classified as "Approved" for the drug product or drug substance, the changed Retest Date Classification would be "Proposed". *For substances that do not have a Retest Date, the Retest Date Classification will be "NA". "Approved" applies to product AND "Adequate" applies to substances.
6	**Manufacturing Date**	The date associated with manufacturing a batch. [Source: SME Defined] Note: See Manufacturing Date Description element.	Date	1	
7	**Manufacturing Date Description**	A textual description that provides a rationale for the selection of the manufacturing date. [Source: SME Defined] Note: This description should include the specific operation/step in the manufacturing process associated with the assigned manufacturing date, for example fill step or filtration step.	Text	1	
8	**Manufacturing Site Name**	The name of the establishment (facilities) which manufacture, prepare, propagate, compound, process or package drugs that are commercially distributed in the U.S. or offered for import to the U.S. [Source: Adapted from FDA Drug Establishment Current Registration Site]	Text	1..*	
9	**Manufacturing Site Unique Identifier**	A unique identifier assigned to the establishment (facility) which manufactures, prepares, propagates, compounds or processes drugs. [Source: Adapted from FDA Drug Establishment Current Registration Site]	Text	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
10	**Manufacturing Site Unique Identifier Type**	A value that identifies the source of the unique identifier. [Source: SME Defined] Examples: Data Universal Number System (DUNS), Facility Establishment Identifiers (FEI), etc.	Code	1	BR: For every Manufacturing Site Unique Identifier there will only be one type.
11	**Manufacturing Site Physical Address**	The complete address for the supplier [Source: SME Defined]	Text	0..1	
12	**Expiration Date**	The date the manufacturer guarantees the full potency and safety of a particular batch/lot of medicinal product. The complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format. [Source: ISO IDMP 11615-2017]	Date	0..1	BR: Required if the marketing application has been approved. Applies for Products. Also applies to some antibiotic substances. Expiration date would not apply when the FDA has not yet approved the marketing application. BR: When Batch Lot is Bulk, the expiration date is the Hold time.
13	**Expiration Date Classification**	The endorsement of the expiration date that clarifies whether this date has been approved by the FDA or is being proposed by the sponsor/applicant. [Source: SME Defined]	Code	1	This classification applies to all products and some substances. * For an original application, Expiration Date Classification is "Proposed". * After an application has been approved, Expiration date classification is "Approved". * For a Supplement that's changing the expiration date that is already classified as "Approved" for the drug product or drug substance, the changed Expiration Date Classification would be "Proposed". * For substances that do not have an Expiration Date, the Expiration Date Classification is "NA".

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					"Approved" applies to product AND "Adequate" applies to substances.
14	**Batch Utilization**	A categorization of the batch that identifies its usage. [Source: SME Defined] Examples: commercial, development.	Code	1..*	
15	**Batch Analysis Release Date**	The date at which the drug substance or drug product is released by the quality assurance unit of the sponsor/applicant. [Source: SME Defined] Note: A single release date per batch.	Date	0..1	
16	**Drug Substance Lot Number**	Lot number of the drug substance used in manufacturing a drug product batch. [Source: SME Defined]	Text	1..*	
17	**Container Lot Number**	A combination of letters, numbers, or symbols, or any combination of them to uniquely identify the container's manufacturing lot. Note: This is different from the drug product batch/lot number. Example: Company A makes batch of bottles (container) -- need a lot number on the container (bottle) assigned by the manufacturer of the bottle (container). This requirement becomes critical when the dosing and delivery of the drug is impacted by the container (bottle).	Text	0..1	BR: When container is critical to dosing and delivery, the container lot number would be mandatory. Example, when the container is a nebulizer.
18	**Container Closure System Description**	Any textual comments that describe the sum of container closure system (CCS) components that together contain and protect the dosage form or drug substance. [Source: Adapted from Q1A (R2)-ICH Glossary] Example: White opaque, round 50 mL HDPE bottle with a fitted 33 mm child resistant black polypropylene threaded cap closure, aluminum sealed, and containing molecular sieve canister 2 gm (CAN TRISORB 2G) as desiccant. Note: This includes primary packaging components and	Text	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		secondary packaging components, if the latter are intended to provide additional protection to the drug substance or the drug product. A packaging system is equivalent to a container closure system. [Source: Adapted from Q1A (R2)-ICH Glossary]			
19	**Container Type**	The kind of container that drug substances and finished dosage forms are contained in, which could include both the immediate (or primary) and secondary containers [Source: Adapted from NCI Thesaurus C43164]	Code	1	
20	**Closure Type**	The kind of closures used for the container in which the drug substances and finished dosage forms are stored. [Source: SME Defined]	Code	1	
21	**Container Size**	The volume or physical proportions or dimension of the container. [Source: SME Defined] Example: 250 (mL) Note: may not apply to all container types, for example – single dose container sizes	Numeric	1	
22	**Container Size Unit**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709] Examples: mL, L, cc.	Code	1	
23	**Container Fill**	Amount or volume of the drug product in the container. [Source: SME Defined]. Examples: 100 tablets; 10 mL, 1 transdermal system, 1 sachet. Note: the examples include both the Container Fill and the Container Fill Unit	Numeric	1	
24	**Container Fill Unit**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709] Examples: tablets, mL.	Code	1	
25	**Additional Information**	A placeholder for providing any comments that are relevant to the Batch. [Source: SME Defined] Examples: first batch manufactured at a new facility; first batch manufactured using a new Active Pharmaceutical	Text	0..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		Ingredient (API) source, new process, new container closure.			
26	**Conformance to Criteria**	A coded value specifying whether the results of a particular test on a given batch of a drug substance or a drug product comply with the acceptance criteria. [Source: SME Defined] Examples: Conforms, Does not Conform	Code	1	
27	**Test Date**	The date when a particular test was performed. [Source: SME Defined]	Date	1	
28	**Result**	The outcome of a test performed on a batch. [Source: SME Defined] Examples: 98% for Assay; 7.1 for pH.	Text Numeric	1	BR: When result is quantitative, then numeric Results, Result Unit of Measure and Conformance to criteria data elements are "Mandatory". When Result is qualitative, Results and Results Unit of Measure data elements are "Optional" and Conformance to criteria data element is "Mandatory"
29	**Result Unit of Measure**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709]	Code	0..1	
30	**Replicate Number**	An identification number for a member of the set of results for a test, usually the sequence order in which the test was executed. Individual test are executed on multiple samples to give greater validity to the findings. [Source: SME Defined] Examples: Prepare six aliquots from the sample. Test 8 samples. If any fall above 110%, test an additional 7 samples. Record all replicate values as stated in the method.	Numeric	1	
31	**Testing Site Unique Identifier**	A unique identifier assigned to the establishment (facility) which performs the testing. [Source: SME Defined]	Text	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
32	**Testing Site Unique Identifier Type**	A value that identifies the source of the unique identifier. [Source: SME Defined] Examples: DUNS, FEI.	Code	1	BR - For every Testing Site Unique Identifier there will only be one type.
33	**Testing Site Name**	The name of the establishment (facility) which tests the raw materials, intermediates, drug substance, drug product, packaging components. [Source: SME Defined]	Text	1	
34	**Testing Site Address**	The complete address for the testing site. [Source: SME defined]	Text	1	
35	**Test Name**	See details of this element in Quality Specification section 4			
36	**Test Category**	See details of this element in Quality Specification section 4			
37	**Analytical Procedure**	See details of this element in Quality Specification section 4			
38	**Relative Retention Time**	See details of this element in Quality Specification section 4			
39	**Test Additional Information**	See details of this element in Quality Specification section 4			
40	**Test Order**	See details of this element in Quality Specification section 4			
41	**Stage Name**	See details of this element in Quality Specification section 4			
42	**Stage Sequence Order**	See details of this element in Quality Specification section 4			
43	**Stage Additional Information**	See details of this element in Quality Specification section 4			
44	**Value**	See details of this element in Quality Specification section 4			

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
45	**ValueNumeric**	See details of this element in Quality Specification section 4			
46	**ValueNumeric UOM**	See details of this element in Quality Specification section 4			
47	**Original Text**	See details of this element in Quality Specification section 4			
48	**Acceptance Criteria Usage**	See details of this element in Quality Specification section 4			
49	**Interpretation Code**	See details of this element in Quality Specification section 4			
50	**Additional Information**	See details of this element in Quality Specification section 4			

END OF SECTION 5

Section 6: Stability Data Elements

This section covers the properties of a stability study. This information is typically submitted in eCTD sections -- 3.2.S.7.3, 3.2.P.8.3.
NOTE: A Stability study is on a drug product or a drug substance for compliance with a given quality specification. This Stability Study profile references the Drug Product or the Drug Substance and includes some referential elements from Batch Analysis and Quality Specification. Not all the data elements from the Drug Product and Dug Substance profiles are needed while building the Stability Study Profile.

The main study is the collection and has its stated study purpose for the collection. The Sub-study is used to designate the conditions for the samples. The Diagnostic Report resource collects all the observations for a study time point/pull date

NOTE: In the Data Elements table for this section, the last column includes additional information besides the business rules. Since the business requirement exists to support both Primary (study) and Secondary (sub-study) studies, "Both" indicates the element is required for both the primary/study and the secondary/sub-study.

PQ/CMC Data Elements

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study
1	**Study Identifier**	An alphanumeric identifier assigned to a study as executed by the sponsoring organization. [Source: SME Defined] Example: Study Number- 565758	Text	1	Both
2	**Study Name**	A non-unique textual identifier given to the drug stability study by the sponsoring organization. [Source: SME Defined] Example: 00001 - Testing methotrexate as a pill tablet under the storage conditions of 25 deg C/65% RH.	Text	0..1	Both
3	**Study Sub Title**	Additional name or title. [Source: SME Defined]	Text	0..1	
4	**Study Design**	A textual description providing the details of the study plan which includes tests, time points, storage conditions, method. [Source: SME Defined]	Text	0..1	Study
5	**Study Purpose**	A textual description intended to provide a high level objective and rationale for the study. [Source: SME Defined] Example: The purpose of this study EX 2010PRD5758 is to confirm the stability of BellaVie ™ (2 AMINOBUTYROLE ACID, DL) 2.0 mg, Pink Film	Text	1	Study

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study
		Coated Extended Release Tablets (Product 54321) per the NDA post approval stability commitments.			
6	**Study Reason**	The rationale for submitting the stability data. [Source: SME Defined] Examples: Annual Report, NDA, Pre-market approval.	Code	1..*	Study
7	**Study Start Date**	The date the product or substance is put into the stability chamber for a given set of storage conditions [Source: SME Defined]	Date	1	Both
8	**Study End Date**	The date the study or sub-study completes or terminates. [Source: SME Defined]	Date	0..1	Both
9	**Protocol Identifier**	An alphanumeric identifier assigned to a prospective protocol plan by the sponsoring organization. [Source: SME Defined] Note: A given Protocol can have multiple studies.	Text	0..1	Study
10	**Protocol Version**	The alphanumeric text assigned by the sponsor to a particular edition of a stability study that is sequential. [Source: SME Defined] Examples: 2.1, 2.2 or A1, A2 or P1, P2.	Text	0..1	Study
11	**Sub Study Type**	A categorization of studies that identifies whether there are single or multiple phases of the study sometimes simulating the periods of use. [Source: SME Defined] Examples: Standard, Cycled-simple.	Code	1	Sub-study
12	**Storage Conditions Temp.RH**	The temperature and the relative humidity under which the study was performed. [Source: SME Defined]	Code	0..1 1	Study Sub-study
13	**Study Additional Comment**	A placeholder for providing comments about the stability study. [Source: SME Defined]	Text	0..1	Both
14	**Container Orientation**	The placement of a container during storage to understand the interactions between the product and the closure. [Source: SME Defined] Examples: horizontal, upright.	Code	0..1	Sub-study
15	**Quality Specification Identifier**	See details of this element in Quality Specification section 4			Sub-study

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study
16	**Quality Specification Version**	See details of this element in Quality Specification section 4			Sub-study
17	**Pull Date**	The date when a particular sample of the batch lot was pulled from the stability chamber. [Source: SME Defined]	Date	1	Sub-study Results BR: Mandatory when Batch Utilization = "Stability Study"
18	**Interval**	Storage time of the batch in a climatic chamber. [Source: eStability Implementation Guide]	Numeric	1	Sub-study Results BR: Mandatory when Batch Utilization = "Stability Study"
19	**Interval Unit**	The partitions of the study pause. [Source: eStability Implementation Guide]	Code	1	Sub-study Results BR: Mandatory when Batch Utilization = "Stability Study"
20	**Interval Description Code**	This code describes any "delay" that happened during testing, e.g., none (Immediate) or freeze sample (Delayed Frozen). [Source: NCIt]	Code	1	Sub-study Results BR: Mandatory when Batch Utilization = "Stability Study"
21	**Reason Stopped**	The rationale for why the Stability study was terminated. [Source: SME Defined]	Text	0..1	Both

END OF SECTION 6

Section 7: Terminology

The table in section 7A and 7B contain the controlled terminology/vocabulary defined by FDA SMEs for a set of coded PQ/CMC data elements. The controlled terminology table contains only those PQ/CMC data elements for which a value set has been defined. The terminology table below has been alphabetically presented by the data element name.

- **PQ/CMC Data Element Name:** Denotes the name of the PQ/CMC element.
- **NCIt Concept Codes:** The unique identifier assigned to each concept by NCI EVS to permanently track a specific meaning.
- **Valid Value:** The allowable values for a given PQ/CMC data element.
- **Valid Value Meaning:** The description of the allowable value for the given PQ/CMC data element.

A: PQ/CMC Controlled Terminology

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
1	**Batch Utilization**	commercial	C133990	A product batch intended for marketing.
		development	C133991	A batch produced during the characterization and process definition for the desired product.
		clinical	C133992	A batch produced for use in clinical trials.
		validation	C133993	A batch intended for use in verification and demonstration of suitability of the designed process. A collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. [Source: Process Validation Guidance -- https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf]
		bioequivalence	C133994	A batch produced and used for the purposes of determining bioequivalence of the product.
		stability study	C185328	A batch placed under study to determine the maintained performance parameters over time.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
2	**Chemical Structure Data File Type**	SMILES	C54684	Simplified Molecular Input Line Entry System
		SDF	C133996	Structure Data File
		MOLFILE	C133910	MDL Molfile
		InChI File (small molecule)	C54683	IUPAC Chemical Identifier
		PDB	C49039	Protein Data Bank
		mmCIF (large molecules)	C133997	macromolecular Crystallographic Information Framework
3	**Closure Type**	NCIt Codes are available in section 7-B		
4	**Conformance to Criteria**	Conforms	C80262	The result complies with the acceptance criteria for the given test
		Does not conform	C133998	The result does not comply with the acceptance criteria for the given test
5	**Container Orientation**	horizontal	C25241	parallel to the surface
		upright	C86043	closure-up orientation

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		inverted	C133999	closure down orientation
		valve-up	C133914	dispenser (valve) pointing upwards for inhalers
		valve- down	C133915	dispenser (valve) pointing downwards for inhalers
6	**Container Type**	NCIt Codes are available in section 7-B		
7	**Co-Packaged Indicator**	Yes	C49488	Yes
		No	C49487	No
8	**Dosage Form**	See link in next column		http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm
9	**Drug Product Component Function Category**	Active Ingredient	C82533	Active ingredient – ingredient that has the pharmacological action.
		Adjuvant	C2140	Adjuvant – an ingredient(s) which augments or promotes the pharmacological effect of the active ingredient(s) without itself being considered active (typically used with vaccines).

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Inactive Ingredient	C42637	Inactive ingredient, i.e., ingredients added for a purpose other than the intended pharmacological action. Inactive Ingredient is also referred to as excipient.
10	**Drug Product Component Function**	NCIt Codes are available in section 7-B		
11	**Expiration Date Classification/Retest Date Classification**	Approved	C185182	After an application has been approved, then the Expiration date classification is set to "Approved". Approved is only applicable to Drug Products.
		Adequate	C185186	The applicant has appropriate process understanding to demonstrate that the quality of the subsequent API can be satisfactorily controlled.
		Proposed	C185188	For a Supplement that's changing the expiration date that is already classified as "Approved" for the drug product or drug substance, the changed expiration date classification would be "Proposed"
		NA	C48660	Not Applicable
12	**Impurity Classification**	Degradation Product	C176816	A molecule resulting from a chemical change brought about over time and/or by the action of something (e.g., light, temperature, pH, water, or by reaction with an excipient and/or the immediate container/closure system). [Source: SME Defined] Examples: decomposition product, oxidation product, hydrolysis, etc.
		Elemental Impurities	C185190	Elements that are found in the environment or that are used or introduced in the manufacture of drug substances or excipients. [Source: USP STIMULI

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				Article, https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/elementalImpuritiesInformation.pdf]
		Residual Solvent	C176815	Inorganic or organic liquids remaining during the manufacturing process. [Source: Adapted from ICH Q3A(R2)]
		Inorganic	C134001	Materials that are not carbon-based and are generated during a manufacturing process that are not part of elemental impurity specification. [Source: SME Defined]
		Process Related/Process	C176812	Impurities that are derived from the manufacturing process. [Source: SME defined - Reviewed ICH - Q6A and Q3] Examples: Small molecules -- starting materials, intermediates, antibiotics, or media components, by-products, etc. Large molecules -- They may be derived from cell substrates (e.g., host cell proteins, host cell DNA), cell culture (e.g., inducers, antibiotics, or media components), or downstream processing (e.g., processing reagents or resin leachables).
		Leachables	C185192	Materials that can migrate from manufacturing systems, container-closure systems and drug-delivery components. [Source: Adapted from ICH Q3E Concept Paper]
		Product Related	C176813	Molecular variants of the desired product (e.g., precursors, certain degradation products arising during manufacture and/or storage) which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety. [Source ICH Q6B]
		Microbiological	C92081	Microorganism contamination of the cell culture or starting/raw materials that are objectionable due to their detrimental effect on products or potential harm to patients or due to the total number of organisms. [Source: 21CFR211 Preamble] Examples: bacteria, fungi, mollicutes (mycoplasmas or spiroplasmas), mycobacteria, rickettsia, protozoa, parasites, agents causing TSEs and viruses. [Source: Adapted from 21CFR211 Preamble]

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
13	**Interpretation Code (numeric)**	NMT (not more than)	C61586	The value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to”.
		NLT (not less than)	C61583	The value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to”.
		MT (more than)	C61584	The value should not be smaller than the given value excluding the given value, which is equivalent to “greater than”.
		LT (less than)	C61585	The value should not be greater than the given value excluding the given value, which is equivalent to “less than”.
		EQ	C48793	A person or thing equal to another in value or measure or force or effect or significance, etc.; being essentially equal to something.
		NA	C48660	Not Applicable
14	**Manufacturing Site Unique Identifier Type/Testing Site Unique Identifier Type**	DUNS	C134003	Data Universal Number System
		FEI	C134004	Facility Establishment Identifiers
		CFN	C134005	Central File Number
		Unknown	C17998	Unknown
15	**Quality Standard**	USP/NF	C134006	United States Pharmacopeia/National Formulary
		EP	C134007	European Pharmacopoeia

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		JP	C134008	Japanese Pharmacopoeia
		BP	C176793	British Pharmacopoeia
		Company Standard	C134009	A proprietary standard internal to the organization. Note: If pharmacopeia's other than the 4 listed are used, identify them as Company Standard.
16	**Route of Administration**	See link in the next column		https://www.fda.gov/industry/structured-product-labeling-resources/route-administration
17	**Source Organism country of origin**	NCIt Codes are available in section 7-D		
18	**Source Type**	Chemical	C48807	A substance with a defined atomic or molecular structure that results from, or takes part in, reactions involving changes in its structure, composition, or properties. [Source: NCI EVS C48807]
		Animal	C14182	A living organism that has membranous cell walls, requires oxygen and organic foods, and is capable of voluntary movement, as distinguished from a plant or mineral. [Source: NCI EVS C14182]
		Microbial	C14329	A microscopic organism. [Source: Adapted from NCI EVS C14329]
		Plant	C14258	Any living organism that typically synthesizes its food from inorganic substances, possesses cellulose cell walls, responds slowly and often permanently to a stimulus, lacks specialized sense organs and nervous system, and has no powers of locomotion. (EPA Terminology Reference System) [Source: NCI EVS C14258]

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Insect	C14227	A taxonomic class of arthropods that includes praying mantises, dragonflies, grasshoppers, true bugs, flies, bees, wasps, ants, butterflies, moths, and beetles. [Source: NCI EVS C14227]
		Human	C14225	The bipedal primate mammal, Homo sapiens; belonging to man or mankind; pertaining to man or to the race of man; use of man as experimental subject or unit of analysis in research. [Source: NCI EVS C14225]
		Animal-derived indirectly	C18634	A material for which an earlier process step (or an ancillary process) in the manufacturing of the material whose input materials involved animal-derived materials. [Source: SME Defined] – Example: Magnesium Stearate from animal source, BSA
19	**Specification Status**	Approved	C25425	A specification that has met the requirements for approval Note: Applies for NDA, NADA, ANDA, ANADA, BLA
		Tentatively Approved	C134010	A specification that met the requirements for approval, but the application could not be approved for reasons such as patents and exclusivity. Note: Applies for 351A BLA, 351K BLA, ANDA
		Not Approved	C134011	A specification that has not yet been approved. Note: Applies for NDA, NADA, ANDA, ANADA, BLA
		Reported in a CBE or AR	C134012	The specification may be used without prior approval and was submitted in a change being affected (CBE) supplement or an annual report (AR). Note: Applies for NDA, NADA, ANDA, ANADA, BLA
		Not Applicable	C48660	Determination of a value is not relevant in the current context. Note: Master files and INDs have the same information and are reviewed in the same way, but the FDA terminologies and the processing/encoding is slightly different. Applies for INDs, INAD, JINAD, MF
20	**Specification Type**	Drug Product	C134021	The specification which is applied to the drug product.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Drug Substance	C134022	The specification which is applied to the drug substance.
		Raw Materials /Excipients/Intermediates/Reagents	C133931	The specification which is applied to the raw materials, excipients, intermediates or reagents.
21	**Storage Conditions**	25 ± 2 °C /60% ± 5% RH	C134014	Storage at 25 degrees Celsius plus or minus 2 degrees Celsius, along with 60 percent relative humidity plus or minus 5 percent relative humidity.
		30 ± 2 °C /65% ± 5% RH	C134015	Storage at 30 degrees Celsius plus or minus 2 degrees Celsius, along with 65 percent relative humidity plus or minus 5 percent relative humidity.
		40 ± 2 °C /75% ± 5% RH	C134016	Storage at 40 degrees Celsius plus or minus 2 degrees Celsius, along with 75 percent relative humidity plus or minus 5 percent relative humidity.
		5 ± 3 °C	C133935	Storage at 5 degrees Celsius plus or minus 3 degrees Celsius.
		-20 ± 5°C	C133936	Storage at minus 20 degrees Celsius plus or minus 5 degrees Celsius.
		Proprietary	C96148	Storage conditions that are custom and unique to the product being tested
		30 ± 2 °C /75% ± 5% RH	C134017	Storage at 30 degrees Celsius plus or minus 2 degrees Celsius, along with 75 percent relative humidity plus or minus 5 percent relative humidity.
		25 ± 2 °C /40% ± 5% RH	C134018	Storage at 25 degrees Celsius plus or minus 2 degrees Celsius, along with 40 percent relative humidity plus or minus 5 percent relative humidity.
		30 ± 2 °C/35% RH ± 5% RH	C134019	Storage at 30 degrees Celsius plus or minus 2 degrees Celsius, along with 35 percent relative humidity plus or minus 5 percent relative humidity. Note: Only for semi-permeable containers
		40 ± 2 °C/not more than (NMT) 25% RH	C133940	Storage at 40 degrees Celsius plus or minus 2 degrees Celsius, along with not more than 25 percent relative humidity. Note: Only for semi-permeable containers

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
22	**Strength Type**	Mass	C168628	A physical measurement (e.g., weight, genome titer)
		Activity	C45420	Measurement of a property related to therapeutic or biological effect. Examples, enzyme activity, international units, plaque forming units (PFU), radioactivity (MBql)
23	**Strength Operator**	NMT (not more than)	C61586	The value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to”.
		NLT (not less than)	C61583	The value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to”.
		MT (more than)	C61584	The value should not be smaller than the given value excluding the given value, which is equivalent to “greater than”.
		LT (less than)	C61585	The value should not be greater than the given value excluding the given value, which is equivalent to “less than”.
		EQ	C48793	A person or thing equal to another in value or measure or force or effect or significance etc.; being essentially equal to something.
		NA	C48660	Not Applicable
24	**Study Reason**	Abbreviated New Animal Drug Application	C115123	PQCMC data submitted to an abbreviated (generic) new animal drug application.
		Abbreviated New Drug Application	C73113	PQCMC data submitted to an abbreviated (generic) new human drug application.
		Biologics License Application	C71778	PQCMC data submitted to a biologics license application.
		Generic Investigational New Animal Drug File	C115122	PQCMC data submitted to a generic investigational new animal drug file.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Humanitarian Device Exemption (HDE)	C80440	PQCMC data submitted for an HDE application.
		Investigational Device Exemption	C82667	PQCMC data submitted to an investigational device exemption.
		Investigational New Animal Drug File	C96091	PQCMC data submitted to an investigational new animal drug file.
		Investigational New Drug Application	C96090	PQCMC data submitted to an investigational new human drug application.
		New Active Ingredient	C96092	PQCMC data submitted for an active ingredient, could be PQCMC data for an active ingredient submitted in a drug application, or a Master File.
		New Animal Drug Application	C72901	PQCMC data submitted to a new animal drug application.
		New Drug Application	C72899	PQCMC data submitted to a new human drug application.
		Premarket Approval	C70880	PQCMC data submitted for a PMA application.
		Premarket Notification 510 (K)	C80442	PQCMC data submitted for a premarket 510 (k) submission.
		Master File	C70877	to be added to NCI EVS
25	**Study Type**	Standard	C134026	A single set of environmental conditions. Example: 25 degree C, 60% RH.
		Cycled-Simple	C134027	A set of two alternating environmental conditions. Example: freeze-thaw cycled study.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Complex	C134028	Multiple phases with different set of environmental conditions. Note: It is standard study if there is only one storage condition. If there are multiple storage conditions, then this will be classified as Complex study. Transport Studies are considered Complex studies. Examples: typically for inhalers, nebulizers; transportation studies. Note: Complex studies MUST have associated studies
		Photostability	C96087	Studies that evaluate the light sensitivity and stability of drugs. [Refer to ICH Q1B]
26	**Test Category**	Assay	C60819	Tests which measure the content of the active ingredient in the drug substance or drug product. Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug product. [Source: Adapted from ICH Q6A and Q6B] Note: chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio.
		Biological Properties	C158425	Any effect a given material has on a living organism (e.g., microbial limits, endotoxin).
		Description	C138990	An assessment of the physical state (e.g., color, shape, size) of the drug substance or product. [Source: Adapted from ICH Q6A]
		Identification	C138993	Tests that establish the characteristic and uniqueness of the substance of interest and should be able to discriminate between compounds of closely related structures which are likely to be present. [Source: ICH Q6A]
		Impurities	C158423	Analytical procedures that determine the presence of a component of the material that is not the chemical entity defined as the material.
		Physico-Chemical Properties	C176811	Assessments of the characteristics of a material that are not associated with a change in its composition and basic nature, including but not limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity and density. A characteristic of a material that is observed during a reaction in which the

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				chemical composition or identity of the material is changed (e.g., combustibility, solubility, acidity/basicity).
		Microbiological Properties	C176810	The characteristics of, or the effects of a material on a microorganism or microbiome.
27	**Test Method Origin**	CFR	C96164	Method defined in the Code of Federal Regulation (CFR)
		Proprietary	C96103	Method identified/defined by the sponsor/applicant (not recognized in CFR or any compendium)
		Compendial	C96102	Method defined in any recognized compendium (e.g., USP, EP, BP, JP).
28	**Test Usage**	Release	C134029	For determination of acceptability for use of a material, drug or a drug substance. NOTE: The "use" could be for distribution, marketing, further manufacturing stages.
		Stability	C134030	For determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.
29	**Testing Site Unique Identifier**	DUNS	C134003	Data Universal Number System
		FEI	C134004	Facility Establishment Identifiers
		CFN	C134005	Central File Number
		Unknown	C17998	Unknown
30	**Interval**	Delayed Testing	C96151	Sample is not tested immediately.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Description Code			
		Immediate Testing	C96150	Sample is tested immediately.
		Ambient Delayed Testing	C96154	Sample is stored at ambient conditions and not tested immediately.
		Frozen Delayed Testing	C96153	Sample is frozen and not tested immediately.
		Refrigerated Delayed Testing	C96155	Sample is refrigerated and not tested immediately.
31	**Unit of Measure: ValueNumeric UOM; Batch Size Unit; Container Size Unit; Container Fill Unit; Strength Unit of Measure; Amount Per Unit; Diluent UOM; Amount UOM**	Look at the NCIt Codes in section 7-C		

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

B: Terminologies for Closure Type, Container Type, Component Function

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
1	**Closure Type**	Child-resistant, Metal	C96113	Metal closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
2	**Closure Type**	Child-resistant, Plastic	C96114	Plastic closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
3	**Closure Type**	Continuous Thread, Metal	C96115	Metal closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic or metal.
4	**Closure Type**	Continuous Thread, Plastic	C96116	Plastic closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic or metal.
5	**Closure Type**	Crown, Metal	C96125	A non-threaded shallow draw metal closure that normally has 21 corrugations on the outer edge, which function to engage the container when applied. The crown is only 1/4" high when manufactured and does not have a rolled edge or wire. The crown is manufactured 26mm worldwide and can be applied to either a threaded finish or a solid ring pry-off finish.
6	**Closure Type**	Flip-Top (Dispensing), Plastic	C96128	A hinged single or dual flap closure for controlled product dispensing.
7	**Closure Type**	Hinged (Dispensing), Plastic	C96129	A closure with a lid that is hinged to the top of a closure and opens to expose a dispensing orifice.
8	**Closure Type**	Linerless, Plastic	C96130	A closure that incorporates a specific molded-in feature such as rings, plugs or flexible sections. These features achieve a seal by conforming to one or more of the sealing surfaces on the container neck finish.
9	**Closure Type**	Lug, Metal	C96126	Closure with an ability to be applied and removed with a partial turn. The closure can also be produced with vacuum buttons that can clearly indicate to the packer if a vacuum has been effectively drawn following the closure application.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
10	**Closure Type**	Press-on, Composite	C96124	A metal/plastic composite cap composed of a plastisol lined metal disk, assembled to a plastic band. The closure requires a simple glass bead finish common on bowls, tumblers and carafes.
11	**Closure Type**	Press-on/twist-off, Metal	C96123	Closure with a stepped, skirted drawn shell with an inside curl. The closure is lined with an annular plastisol material designed to provide a proper seal along the top and side surfaces of the glass container finish. The closure uses a special plastisol material that, following application, takes a permanent impression of the glass threads ensuring cam-off and reseal.
12	**Closure Type**	Pump (Dispensing), Plastic	C96131	Closure dispensing pumps are used to dispense product from containers.
13	**Closure Type**	Push-pull (Dispensing), Plastic	C96132	A two-piece dispensing closure that includes a base member the lower portion of which is designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. The spout member may be moved upward and downward to open and close the dispensing passageway.
14	**Closure Type**	Roll-on, Metal	C96127	A tamper-evident closure produced as an unthreaded shell containing a liner. It is applied to the proper finish on a plastic or glass container by the bottler, using a roll-on capping machine that forms a thread in the closure matching the bottle thread.
15	**Closure Type**	Snap-on Cap, Plastic	C96133	A non-threaded closure that is pressed onto the package finish with a protruding feature that mates with a similar protruding feature on the closure to secure the closure to the package.
16	**Closure Type**	Snip-tip (Dispensing), Plastic	C96134	Conical closure that is turned onto a container. The tip is cut off to open the container.
17	**Closure Type**	Stopper	C96139	Object used to plug opening of container.
18	**Closure Type**	Tamper-evident, Composite	C96120	Composite tamper-evident closures usually consist of a metal disk with a plastic skirt. The plastic skirt is perforated or weakened in some manner so that when the closure is removed, this section is designed to break and either

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				remain on the container or attached to the closure to indicate the package has been opened.
19	**Closure Type**	Tamper-evident, Metal	C96117	A closure/finish of a closure/container system designed to make it difficult to achieve the first removal of a closure from a container without it being detectable by subsequent users that the package seal has been breached (e.g., aluminum overseal).
20	**Closure Type**	Tamper-evident, Plastic	C96118	A closure that shows the package has been opened and the product has been exposed to the outside environment.
21	**Closure Type**	Tie	C96140	Line, ribbon, or cord used for fastening, or drawing the container closed.
22	**Closure Type**	Toggle-swing (Dispensing), Plastic	C96135	A closure with a lower part attaches securely and seals the container. The upper part provides a second movable portion which functions in a rocker-like pivotal motion between an open and a closed position.
23	**Closure Type**	Trigger Sprayer (Dispensing), Plastic	C96136	Closure designed to dispense product from containers by spraying the product when a trigger is pulled.
24	**Closure Type**	Twist Open/Close (Dispensing), Plastic	C96137	Two-piece dispensing closure that has a lower portion designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. Rotating the spout member opens and closed the container.
25	**Closure Type**	Vacuum, Composite	C96122	Metal/Plastic closures used on packages where the pressure inside the package is less than atmospheric.
26	**Closure Type**	Vacuum, Metal	C96119	Metal closures used on packages where the pressure inside the package is less than atmospheric.
27	**Closure Type**	Vacuum, Plastic	C96121	Plastic closures used on packages where the pressure inside the package is less than atmospheric.
28	**Closure Type**	Valved (Dispensing), Plastic	C96138	Dispensing closure incorporating a product-flow controlling valve within the orifice. Product will not dispense from the package until sufficient squeezing pressure is applied to the flexible container to cause the valve to open.
29	**Container Type**	AMPULE	C43165	A container capable of being hermetically sealed, intended to hold sterile materials.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
30	**Container Type**	APPLICATOR	C43166	A pre-filled non-injectable pipette, syringe or tube.
31	**Container Type**	BAG	C43167	A sac or pouch.
32	**Container Type**	BLISTER PACK	C43168	A package that consists of molded plastic or laminate that has indentations (viewed as 'blisters' when flipped) into which a dosage form, is placed. A covering, usually of laminated material, is then sealed to the molded part. A strip pack is a specialized type of blister pack where there are no pre-formed or molded parts; in this case there are two flexible layers that are sealed with the dosage form in between. Suppositories that are strip packed between two layers of foil are also considered a blister pack.
34	**Container Type**	BOTTLE	C43169	A vessel with a narrow neck designed to accept a specific closure.
35	**Container Type**	BOTTLE, DISPENSING	C43170	A bottle that is used by the pharmacist to dispense the prescribed medication. It includes preparations for which a dropper accompanies the bottle.
36	**Container Type**	BOTTLE, DROPPER	C43171	A bottle that has a device specifically intended for the application of a liquid in a drop by drop manner, or a device intended for the delivery of an exact dose (e.g., calibrated dropper for oral medications).
37	**Container Type**	BOTTLE, GLASS	C43172	A glass vessel with a narrow neck designed to accept a specific closure.
38	**Container Type**	BOTTLE, PLASTIC	C43173	A plastic vessel with a narrow neck designed to accept a specific closure.
39	**Container Type**	BOTTLE, PUMP	C43174	A bottle that is fitted with a pumping mechanism for the administration of drug product.
40	**Container Type**	BOTTLE, SPRAY	C43175	A bottle that is fitted with an atomizer or a device which produces finely divided liquid carried by air.
41	**Container Type**	BOTTLE, UNIT-DOSE	C43176	A bottle that contains a single whole dose of a non-parenteral drug product.
42	**Container Type**	BOTTLE, WITH APPLICATOR	C43177	A bottle which includes a device for applying its contents.
43	**Container Type**	BOX	C43178	A square or rectangular vessel, usually made of cardboard or plastic.
44	**Container Type**	BOX, UNIT-DOSE	C43179	A box that contains a single dose of a non-parenteral drug product. [Note: Boxes that contain 100 unit dose blister packs should be classified under

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				blister pack, since this is the immediate container into which the dosage form is placed.]
45	**Container Type**	CAN	C43180	A cylindrical vessel, usually made of metal.
46	**Container Type**	CANISTER	C43181	A type of can for holding a drug product.
47	**Container Type**	Canisters, lined	C96143	A round container that has an inner layer of a material different from what the canister is composed of.
48	**Container Type**	CAPSULE	C92708	A drug packaging type usually in a cylindrical shape with rounded ends. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials, may be soft or hard, and are filled with solid or liquid drug products. It is not intended to be swallowed (like the dosage form) but instead is holding the drug such as for an inhalation powder or for oral granules intended only for sprinkling.
49	**Container Type**	CARTON	C43182	A cardboard box or container which is usually considered a secondary packaging component.
50	**Container Type**	CARTRIDGE	C43183	A container consisting of a cylinder with a septum at one end, and a seal at the other end, which is inserted into a device to form a syringe which contains a single dose of a parenteral drug product.
51	**Container Type**	CASE	C43184	A receptacle for holding something (e.g., that into which some oral contraceptive blister packs are placed).
52	**Container Type**	CELLO PACK	C43185	A plastic 'clamshell' [thin plastic pre-formed structure for a device].
53	**Container Type**	CONTAINER	C43186	An object that can be used to hold things.
54	**Container Type**	CUP	C43187	A bowl-shaped container.
55	**Container Type**	CUP, UNIT-DOSE	C43188	A cup intended to hold a single dose of a non-parenteral drug product.
56	**Container Type**	CYLINDER	C43189	A container designed specifically to hold gases.
57	**Container Type**	DEWAR	C43190	A container, usually made of glass or metal, that has at least two walls with the space between each wall evacuated so as to prevent the transfer of heat. The inside of the container often has a coating (as silvering) on the inside to reduce

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				heat transfer, and is used especially for storing liquefied gases or for experiments at low temperatures. The size can vary from that of a small thermos bottle up to that which may be mounted upon a large truck (also known as a 'cryogenic truck').
58	**Container Type**	DIALPACK	C43191	A dose pack container designed to assist with patient compliance. The patient turns a dial to the correct day and the correct dose is made available and the container indicates that the dose has been removed.
59	**Container Type**	Dish, Petri	C96141	A shallow dish with a lid used to culture cells.
60	**Container Type**	DOSE PACK	C43192	A container in which a preselected dose or dose regimen of the medication is placed.
61	**Container Type**	DRUM	C43193	A straight-sided cylindrical shipping container with flat ends; one of which can be opened/closed.
62	**Container Type**	Flask	C96144	A container with a base wider than the narrow neck traditionally used for holding liquids.
63	**Container Type**	FLEXIBLE INTERMEDIATE BULK CONTAINER	C79135	A receptacle with a body constructed of film, woven plastic, woven fabric, paper or combination thereof, together with any appropriate service equipment and handling devices, and if necessary, an inner coating or liner.
64	**Container Type**	INHALER	C16738	A device by means of which a medicinal product can be administered by inspiration through the nose or the mouth.
65	**Container Type**	INHALER, REFILL	C43194	A container of medication intended to refill an inhaler.
66	**Container Type**	JAR	C43195	A rigid container having a wide mouth and often no neck which typically holds solid or semisolid drug products.
67	**Container Type**	JUG	C43196	A large, deep container that has a narrow mouth, is typically fitted with a handle, and is used to hold liquids.
68	**Container Type**	KIT	C43197	A packaged set of related pharmaceutical or and/or drug delivery devices used for a particular medical activity or procedure including required documentation for kit components and the entire kit.
69	**Container Type**	NOT STATED	C48626	The package type is not stated or is unavailable.
70	**Container Type**	PACKAGE	C43233	The drug product container with any accompanying materials or components. This may include the protective packaging, labeling, administration devices.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
71	**Container Type**	PACKAGE, COMBINATION	C43198	A package in which two or more drug products that are normally available separately are now available together.
72	**Container Type**	PACKET	C43199	An envelope into which only one dose of a drug product, usually in the form of granules or powder, has been directly placed. Examples include aluminum foil packets into which alcohol swabs and pledgets are placed.
73	**Container Type**	PAIL	C79136	A watertight vessel, often cylindrical, that is usually fitted with a handle, and that may have a lid.
74	**Container Type**	PATCH	C82332	A drug delivery system that often contains an adhesive backing that is usually applied to an external site on the body. Its ingredients either passively diffuse from, or are actively transported from, some portion of the patch. Depending upon the patch, the ingredients are either delivered to the outer surface of the body or into the body.
75	**Container Type**	Plate, Microwell	C96142	A flat dish type device with multiple wells for testing cellular material.
76	**Container Type**	POUCH	C43200	A flexible container used to protect or hold one or more doses of a drug product (e.g. a pouch into which oral contraceptive blister packs are inserted, and an overwrap pouch for large volume parenterals).
77	**Container Type**	SUPERSACK	C43201	A multilayer paper bag for shipping some solid bulk excipients, usually in the form of powder or granules.
78	**Container Type**	SYRINGE	C43202	A device for the administration of drug products that consists of a rigid barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.
79	**Container Type**	SYRINGE, GLASS	C43203	A device for the administration of parenteral drug products that consists of a rigid glass barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.
80	**Container Type**	SYRINGE, PLASTIC	C43204	A device for the administration of parenteral drug products that consists of a rigid plastic barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.
81	**Container Type**	TABMINDER	C43205	A specialized package; it registers each time it is opened and is used for checking patient compliance to prescribed medication regimens.

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82	**Container Type**	TANK	C43206	A large receptacle used for holding, transporting, or storing liquids or gases, and often referred to as a reservoir.
83	**Container Type**	TRAY	C53438	A shallow flat receptacle, with a raised edge or rim, used for carrying, holding, or displaying finished drug product in its primary or market package. A tray and its contents may be encased in shrink-wrapped plastic for shipping, or with a cover or an overwrap as part of a unit of use package or kit.
84	**Container Type**	TUBE	C42794	A flexible container for semisolid drug products which is flattened and crimped or sealed at one end and has a reclosable opening at the other.
85	**Container Type**	TUBE, WITH APPLICATOR	C43207	A tube which is provided with a device (the applicator) for administering the dosage form. The applicator may be part of the tube closure or be separate.
86	**Container Type**	VIAL	C43226	A container designed for use with parenteral drug products.
87	**Container Type**	VIAL, DISPENSING	C43208	A vial that is used by the pharmacist to dispense the prescribed medication.
88	**Container Type**	VIAL, GLASS	C43209	A glass container designed for use with parenteral drug products.
89	**Container Type**	VIAL, MULTI-DOSE	C43210	A vial intended to contain more than one dose of the drug product.
90	**Container Type**	VIAL, PATENT DELIVERY SYSTEM	C43211	A vial that has a patented delivery system.
91	**Container Type**	VIAL, PHARMACY BULK PACKAGE	C43212	A container of a sterile preparation whose contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.
92	**Container Type**	VIAL, PIGGYBACK	C43213	A vial that contains a parenteral preparation that can be attached directly to the tubing of a parenterally administered fluid.
93	**Container Type**	VIAL, PLASTIC	C43214	A plastic container designed for use with parenteral drug products.
94	**Container Type**	VIAL, SINGLE-DOSE	C43215	A vial containing a single unit of a parenteral drug product.
95	**Container Type**	VIAL, SINGLE-USE	C43216	A vial where a single dose of a parenteral drug product can be removed, and then the vial and its remaining contents can be disposed.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
96	**Drug Product Component Function**	Absorption modifier	C176637	An excipient included in formulations to improve the absorption of a pharmacologically active drug (e.g. permeation enhancer; transmucosal absorption enhancer; intestinal permeation enhancer; delivery agent; penetration enhancer; transdermal delivery agent).
97	**Drug Product Component Function**	Adhesive	C89528	Substance capable of bonding together two surfaces (e.g. bioadhesive material).
98	**Drug Product Component Function**	Adsorbent	C176642	Agent used to bind another component from within a formulation, acting as a carrier, reservoir or sequestrant (e.g. water-absorbing agent). (Adapted from Medicinescomplete)
99	**Drug Product Component Function**	Air displacement	C176643	Agent used to replace air in a product or pack with a gas phase of known composition during manufacturing. Example is widely used In reactors/mixing tanks with liquid products (e.g. air overlay; gas blanket). (Adapted from Medicinescomplete)
100	**Drug Product Component Function**	Anticaking agent	C42654	Agent added to improve powder flow. Used to promote powder flow and to reduce the caking or clumping that can occur when powders are stored in bulk. In addition, glidants and anticaking agents reduce the incidence of bridging during the emptying of powder hoppers and during powder processing. (e.g. glidant). (Adapted from Medicinescomplete)
101	**Drug Product Component Function**	Antioxidant	C275	Agent used to stabilize a system against oxidative degradation. (Adapted from Medicinescomplete)
102	**Drug Product Component Function**	Binder	C42647	Impart cohesive qualities to powdered material (e.g. binding agent or wet binder). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
103	**Drug Product Component Function**	Buffering agent	C70815	Agent used to stabilize pH within a defined range. (Adapted from Medicinescomplete)
104	**Drug Product Component Function**	Bulking agent	C176644	To provide a pharmaceutically elegant freeze-dried cake. (Adapted from USP <1059>)
105	**Drug Product Component Function**	CAPSULE	C92708	A drug packaging type usually in a cylindrical shape with rounded ends. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials, may be soft or hard, and are filled with solid or liquid drug products.
106	**Drug Product Component Function**	Carrier	C176645	Agents designed to interact with, and enhance the properties, of active pharmaceutical ingredients (APIs). Carrier excipients promote various ingredient qualities and have become a valuable asset for drug formulators. Used to help deposit the active ingredient in the lung and may have a secondary role in diluting the active to ensure that dosages can be properly metered (e.g. solid carrier; sorbent; carbon dioxide). (Adapted from American Pharmaceutical Review)
107	**Drug Product Component Function**	Chelating agent	C360	Used to sequester ions from solution and to form stable complexes (e.g. sequestering agent). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
108	**Drug Product Component Function**	Coloring agent	C42656	Agent to impart hue to a component (e.g. color retention agent, dye).
109	**Drug Product Component Function**	Complexing agent	C176646	Agent added to combine with another component, commonly to maintain or improve solubility or chemical stability. (Adapted from Medicinescomplete)
110	**Drug Product Component**	Cryoprotectant	C53306	Agent added to prevent cell damage during freeze-drying. (Adapted from Medicinescomplete)

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Function			
111	**Drug Product Component Function**	Denaturant	C176647	Agent added to make unfit to drink an ethanol containing product.
112	**Drug Product Component Function**	Disintegrant	C42648	An agent used to facilitate breakup or disintegration after administration. Functional components that are added to formulations to promote rapid disintegration into smaller units and to allow a drug substance to dissolve more rapidly. (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
113	**Drug Product Component Function**	Dispersing agent	C42662	Agent added to prevent aggregation in liquid formulations. (Adapted from Medicinescomplete)
114	**Drug Product Component Function**	Effervescent agent	C176638	Effervescent excipients are used in powders and tablets. They are commonly used with acidic agents to cause a reaction that produces carbon dioxide. The carbon dioxide leads to a fizzing of the effervescent powder. (Adapted from American Pharmaceutical Review)
115	**Drug Product Component Function**	Emollient	C176632	Agent added to topical formulations to promote softening of the skin. Used in topical preparations to impart lubrication, spreading ease, texture, and softening of the skin and to counter the potentially drying/irritating effect of surfactants on the skin (e.g. skin protectant). (Adapted from Medicinescomplete)
116	**Drug Product Component Function**	Emulsifying Excipient	C73477	Agent added to promote mixing of immiscible phases (e.g. fluorocarbon emulsifying agent; emulsifier; emulsifying salt). (Adapted from Medicinescomplete)
117	**Drug Product Component Function**	Emulsion stabilizing agent	C176633	Agent added to improve stability against phase separation. (Adapted from Medicinescomplete)

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
118	**Drug Product Component Function**	Filler	C42650	Make up the bulk of solid unit dosage forms when drug itself is inadequate to produce the bulk. Components that are incorporated into tablet or capsule dosage forms to increase dosage form volume or weight (e.g. diluent; dry powder inhalation; bulking agent). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
119	**Drug Product Component Function**	Film coating agent	C176648	Agent used to produce a cosmetic or functional layer on the outer surface of a dosage form. Agents used to mask unpleasant tastes or odors, improve ingestion and appearance, protect active ingredients from the environment, and modify the release of the active ingredient or product subcomponent (e.g. coating agent; film-forming agent; film former; granulating agent; granulating fluid; film-coating dispersion medium). (Adapted from Medicinescomplete)
120	**Drug Product Component Function**	Foam stabilizing agent	C176634	Agent added to improve physical stability of foam (e.g. foaming agent). (Adapted from Medicinescomplete)
121	**Drug Product Component Function**	Free radical scavenger	C176649	Used to preferentially interact with oxidative or reductive free radicals that otherwise would result in degradation of formulation components. (Adapted from USP <1059>)
122	**Drug Product Component Function**	Gelling agent	C176650	Agent added to produce a gel texture in a product. (Adapted from Medicinescomplete)
123	**Drug Product Component Function**	Humectant	C176651	Humectants can be used in topical dosage forms to increase the solubility of a chemical compound's active ingredients, increasing the active ingredients' ability to penetrate skin, or its activity time. Examples: propylene glycol, sorbitol solution, ammonium alginate, cyclomethicone, glycerin, polydextrose, sodium hyaluronate, and sodium lactate.
124	**Drug Product Component Function**	Ink	C42657	A colored fluid or paste used for writing, drawing, typically used to identify a product and its strength.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
125	**Drug Product Component Function**	Lubricant	C42653	Agent added to reduce friction effects during processing or use. Used to reduce the frictional forces between particles and between particles and metal-contact surfaces of manufacturing equipment (e.g. tablet ejection; antiadherent; antistat; glidant). (Adapted from Medicinescomplete)
126	**Drug Product Component Function**	Lyophilization aid	C176652	Agent added to produce suitable physical properties in a freeze-dried product. (Adapted from Medicinescomplete)
127	**Drug Product Component Function**	Matrix-forming agent	C176653	Polymers added to sustained release formulations to control and maintain the rigidity of the matrix over a prolonged period (e.g., sustained-release agent; matrix for sustained release; rate-controlling polymer for sustained release). (Adapted from "The Role of Oral Controlled Release Matrix Tablets in Drug Delivery Systems", Ali Nokhodchi1, Shaista Raja1, Pryia Patel1, Kofi Asare-Addo BioImpacts, 2012, 2 (4), 175-187)
128	**Drug Product Component Function**	Microencapsulating agent	C176654	Agent used to form microcapsules with desirable physical properties. (Adapted from Medicinescomplete)
129	**Drug Product Component Function**	Ointment base	C176655	A nonaqueous vehicle for topical products. The major component of an ointment and controls its physical properties. (Adapted from Medicinescomplete)
130	**Drug Product Component Function**	Opacifier	C176656	Agent added to reduce light transmission in a product (e.g., opacifying agent). (Adapted from Medicinescomplete)
131	**Drug Product Component Function**	Organoleptic agent	C176635	An agent added to modify color, flavor, taste (e.g., flavoring agent; flavor enhancer; sweetening agent; taste-masking agent).
132	**Drug Product Component**	Osmotic agent	C176657	Material used to provide osmotic pressure differential in osmotic pump-based drug product delivery systems.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Function			
133	**Drug Product Component Function**	pH modifier	C176658	Substance added to alter the acidity or basicity (e.g., acidity regulator; acidifying agent/alkalizing agent; acid; base).
134	**Drug Product Component Function**	Plasticizer	C55826	Agent added to promote flexibility of films or coatings (e.g., plasticizing agent). (Adapted from Medicinescomplete)
135	**Drug Product Component Function**	Polishing agent	C176659	Agent used to impart an attractive sheen to coated tablets (e.g., tablet polishing agent).
136	**Drug Product Component Function**	Polymers for ophthalmic use	C176660	Used in ophthalmic preparations to enhance the retention of active ingredients by reducing the amount of product that is lost from the eye when the patient blinks. In addition, polymers also can be components of artificial tears. (Adapted from USP <1059>)
137	**Drug Product Component Function**	Preservative	C42659	An agent added to extend the shelf-life of a formulation (e.g., antibacterial agent; antifungal agent preservative; fungicides; antimicrobial preservative; antiviral agent preservative; viricides; sterilizing agent; glazing agent).
138	**Drug Product Component Function**	Propellant	C176661	Developing pressure in container which expels the product. Used in pharmaceuticals (nasal sprays and respiratory and topical formulations), cosmetics, and foods to provide force to expel contents from a container (e.g., aerosol propellant). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
139	**Drug Product Component Function**	Reducing agent	C176639	Reduces oxidation state of product component to produce desired active component/ingredient.

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
140	**Drug Product Component Function**	Release modifying agent	C176662	Substances added to the formulation to alter the release profile of the active substance (e.g., release modifier; release agent; modifying agent; extended release agent; controlled release agent; latex particle coating agent).
141	**Drug Product Component Function**	Solubilizing agent	C176640	Enhance solubility of the active substance. (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India.)
142	**Drug Product Component Function**	Solvent	C45790	The liquid in which a solute is dissolved to form a solution.
143	**Drug Product Component Function**	Stabilizer	C176636	Agent added to preserve product integrity and prevent degradation (e.g., stabilizing agent; colloid stabilizing agent).
144	**Drug Product Component Function**	Suppository base	C176663	Agent used as the carrier for other ingredients in suppository formulations. Used in the manufacture of suppositories (for rectal administration) and pessaries (for vaginal administration). They can be hydrophobic or hydrophilic, (Adapted from Medicinescomplete)
145	**Drug Product Component Function**	Surfactant	C42739	Substances used to enhance stability by reducing surface tension (e.g., anionic surfactant; cationic surfactant; nonionic surfactant).
146	**Drug Product Component Function**	Suspending agent	C42660	A non-surface active polymer or a surface-active substance added to a suspension, to improve the separation of particles and to prevent settling or clumping (e.g. dispersing agent).
147	**Drug Product Component Function**	Tonicity agent	C176641	Agent added to alter osmotic potential of liquid formulations. (Adapted from Medicinescomplete)

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#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
148	**Drug Product Component Function**	Transdermal delivery component	C176664	A component of a transdermal system otherwise not covered by other terms.
149	**Drug Product Component Function**	Transfer ligand	C176665	Used in the preparation radiopharmaceuticals to transfer a relatively weak chelating ligand to the principal chelating ligand or complexing moiety. (USP <1059>)
150	**Drug Product Component Function**	Vehicle	C927	A substance that facilitates the use of a drug, or other material mixed with it, not covered by other terms (e.g., oleaginous vehicle).
151	**Drug Product Component Function**	Viscosity modifier	C176666	Viscosity modifiers are designed to change the thickness or texture of pharmaceutical ingredients. Viscosity modifiers can include such products as thickeners, texturizers, gelation agents and stiffening agents (e.g., stiffening agent; thickener; thickening agent; viscosity-increasing agent; firming agent). (Adapted from American Pharmaceutical Review)
152	**Drug Product Component Function**	Water-repelling agent	C176667	An agent used to enhance hydrophobic properties.
153	**Drug Product Component Function**	Wetting agent	C176668	An agent added to a liquid to reduce its surface tension and make it more effective in spreading over and penetrating surfaces.

C: Terminologies for Units Of Measure

All units of measure for quantitative values must use the FHIR unit value set. See https://build.fhir.org/valueset-ucum-units.html

for a list of values. The following table lists the common UCUM codes used in PQ/CMC. This is the value set that will constrain the profiles in the IG. The code system will be UCUM in compliance with the FHIR standard. If the acceptance criterium is a qualitative value, then no unit is needed.

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
1	Unit of Measure	%	Percent Unit	C48570
2	Unit of Measure	%{VolumeToVolume}	Percent Volume per Volume	C48571
3	Unit of Measure	%{WeightToVolume}	Percent Mass per Volume	C48527
4	Unit of Measure	%{WeightToWeight}	Percent Mass per Mass	C48528
5	Unit of Measure	(m2.d)	Unit per Square Meter per Day	C73783
6	Unit of Measure	[Btu]	British Thermal Unit	C67196
7	Unit of Measure	[CFU]	Colony Forming Unit	C68742
8	Unit of Measure	[degF]	Degree Fahrenheit	C44277
9	Unit of Measure	[EU]	Ehrlich Unit	C96599
10	Unit of Measure	[in_i]	Inch	C48500
11	Unit of Measure	[IU]	International Unit	C48579
12	Unit of Measure	[lb_av]	Pound	C48531
13	Unit of Measure	[lbf_av]	Linear Foot Pound	C139134
14	Unit of Measure	[oz_av]	Ounce	C48519
15	Unit of Measure	[pH]	pH	C45997
16	Unit of Measure	[ppb]	Part Per Billion	C70565
17	Unit of Measure	[ppm]	Part Per Million	C48523
18	Unit of Measure	[ppth]	Part per Thousand	C69112
19	Unit of Measure	[pptr]	Part Per Trillion	C70566
20	Unit of Measure	[psi]	Pound per Square Inch	C67334
21	Unit of Measure	[pt_us]	Pint	C48529
22	Unit of Measure	[qt_us]	Quart Dry US	C69118
23	Unit of Measure	{actuation}	Actuation Dosing Unit	C122629
24	Unit of Measure	{can}	Can Dosing Unit	C48479
25	Unit of Measure	{tbl}	Tablet Dosing Unit	C48542
26	Unit of Measure	{tot}	Particle Total Count	C171022
27	Unit of Measure	{vial}	Vial Dosing Unit	C48551

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#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
28	Unit of Measure	a	Year	C29848
29	Unit of Measure	Cel	Degree Celsius	C42559
30	Unit of Measure	cm	Centimeter	C49668
31	Unit of Measure	mL	Milliliter	C28254
32	Unit of Measure	d	Day	C25301
33	Unit of Measure	deg	Degree Unit of Plane Angle	C68667
34	Unit of Measure	g	Gram	C48155
35	Unit of Measure	gal	Gallon US	C48580
36	Unit of Measure	h	Hour	C25529
37	Unit of Measure	K	Kelvin	C42537
38	Unit of Measure	kg	Kilogram	C28252
39	Unit of Measure	kgf	Kilogram-Force	C70471
40	Unit of Measure	ku	Kilodalton	C105491
41	Unit of Measure	L	Liter	C48505
42	Unit of Measure	m	Meter	C41139
43	Unit of Measure	m2	Square Meter	C42569
44	Unit of Measure	m3	Cubic Meter	C42570
45	Unit of Measure	mg	Milligram	C28253
46	Unit of Measure	mg%	Milligram per Deciliter	C67015
47	Unit of Measure	min	Minute	C48154
48	Unit of Measure	mm	Millimeter	C28251
49	Unit of Measure	mmol	Millimole	C48513
50	Unit of Measure	mo	Month	C29846
51	Unit of Measure	mol	Mole	C42539
52	Unit of Measure	mosm	Milliosmole	C67318
53	Unit of Measure	ms	Millisiemens	C176690
54	Unit of Measure	N	Newton	C42546
55	Unit of Measure	ng	Nanogram	C48516
56	Unit of Measure	nm	Nanometer	C67328
57	Unit of Measure	nmol	Nanomole	C48517
58	Unit of Measure	pg	Picogram	C64551
59	Unit of Measure	pmol	Picomole	C65045

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
60	Unit of Measure	rad	Radian	C42543
61	Unit of Measure	s	Second	C42535
62	Unit of Measure	u	Unified Atomic Mass Unit	C41127
63	Unit of Measure	u	Atomic Mass Unit	C64559
64	Unit of Measure	U	Enzyme Unit	C64778
65	Unit of Measure	ug	Microgram	C48152
66	Unit of Measure	uL	Microliter	C48153
67	Unit of Measure	um	Micron	C48510
68	Unit of Measure	umho	Microsiemens	C154859
69	Unit of Measure	umol	Micromole	C48509
70	Unit of Measure	wk	Week	C29844

D: Terminologies for NCIt GENC Country Codes

All Country Codes used in PQ/CMC are available via the spreadsheet on the NCIt site at https://evs.nci.nih.gov/ftp1/FDA/PQCMC/PQCMC_NCIt_Subsets.xls.
The GENC country codes are available in the GENC worksheet of the above spreadsheet.

END OF SECTION 7

Section 8: Glossary

Acronym	Description
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
APhA	American Pharmacists Association
BLA	Biologics License Application
CAS	Chemical Abstract Service
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CMC	Chemistry Manufacturing & Controls
CFR	Code of Federal Regulations
CTD	Common Technical Document
CVM	Center for Veterinary Medicine
eCTD	Electronic Common Technical Document
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
FHIR	Fast Health Interoperability Resources
HL7	Health Level Seven
ICH	International Council for Harmonisation
ISO IDMP	International Organization for Standardization Identification of Medicinal Products
INN	International Nonproprietary Name
INAD	Investigational New Animal Drug
IND	Investigational New Drug Application
IUPAC	International Union of Pure and Applied Chemistry
JINAD	Generic Investigational New Animal Drugs

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

Acronym	Description
MF	Master Files
NADA	New Animal Drug Application
NDA	New Drug Application
NCI EVS	National Cancer Institute – Enterprise Vocabulary Service
PQ/CMC	Pharmaceutical Quality/Chemistry, Manufacturing & Controls
SME	Subject Matter Expert
SPL	Structured Product Labeling
UNII	Unique Ingredient Identifier
USAN	United States Adopted Name
WHO	World Health Organization

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

Appendix A: Examples of PQ/CMC Drug Product Strength

	(10 mg/5 mL)	(5 mg per unit)	(5 mg per 100 mL)	(2 mg of lypholized powder per vial)	EQ 0.33% BASE Gel - .5mg/gm	DPI (Dry Powder Inhalator) products are listed as : mg/INH (mg per inhalation	Autoinjector products are listed as: EG 0.3 mg/(.3 mL Delivery (Epi pen)	(serotype A > 4500)	(pancrelipase (Test) – 2500 USP units)
Strength Type	Mass	Mass	Mass	Mass	Mass	Mass	Mass	Activity	Activity
Strength Numeric Numerator	10	5	5	2	0.5	1	0.3	4500	2500
Strength Numeric Numerator UOM	mg	mg	mg	mg	mg	mg	mg	[arb'U]	arb'U
Strength Numeric Denominator	5	1	1	1	1	1	0.3		
Strength Numeric Denominator UOM	mL	unit	mL	vial	gm	Actuation	mL		
Strength Textual	NA	NA	NA	NA	NA	NA	NA	serotype A	USP Lipase units
Strength Operator	NA	NA	NA	NA	NA	NA	NA	GT	NA

END OF CHAPTER 1

FDA is NOT requesting comment on this Chapter. It has been released for public comment previously. Please proceed to Chapter 2 to view material for which FDA seeks public comment.

CHAPTER 2: Enhancements to support solid oral dosage form component and composition: multi-layer tablets and capsules; Support for drug product manufacturing of solid oral dosage forms

Document version 1.0: ***FDA IS REQUESTING COMMENT ON THIS CHAPTER***.

Scope of Chapter 2

- Data standards enhancements to support drug product component and composition in support of requirements for multi-layer tablets and capsules.
- Introduction of new structured data elements and controlled terminology to support Drug Product Manufacturing scoped to **solid oral dosage forms**.
- Note
    - The content of this Chapter is limited to the two use cases above. The previously published PQ/CMC data elements (outside of the scope of these two use cases) were published in previously released versions of this document and previous FRNs, which are available on the FDA PQ/CMC website.
    - The mapping of the data elements in this Chapter to HL7 FHIR is in progress and will eventually be represented in a PQ/CMC FHIR IG. The purpose of this Chapter is to solicit comments specifically on the structured data elements and the supporting controlled terminology for the above mentioned two use cases.

Target Audience

The FDA suggests that review of the elements and definitions introduced in this Chapter be conducted by pharmaceutical company personnel who will be able to determine if the element definitions and controlled terminologies are understandable and meaningful in the context of a CTD Quality submission.

The reviewer/reader should have a sound understanding of the PQ/CMC Data elements and supporting controlled terminologies in Chapter 1 of this document and the PQ/CMC FRNs published in 2017 and 2022.

Information technology personnel at the pharmaceutical companies are encouraged to actively participate in the HL7 BR&R Workgroup. This workgroup collaboratively determines the HL7 FHIR representation and mapping of the PQ/CMC semantics.

Chapter Organization

Chapter 2 is organized into the following sections:

- detailed examples that illustrate how to provide the weight/amount information using the PQ/CMC data elements.

- detailed examples that illustrate the use of the new PQ/CMC data elements to provide the composition details of various drug products.

Section 1: Drug Product Composition Data Elements (solid oral-focused)

This section covers the properties of drug product component and composition, control of excipients, and impurities for solid oral dosage forms. This information is typically submitted in eCTD sections: 3.2.P.1 [Description and Composition of the Drug Product]; 3.2.P.4.1 [Control of Excipients - Specification]; 3.2.P.5.5 [Control of Drug Products – Characterisation of Impurities].

Background

Since the previous FDA PQ/CMC FRN was published in March 2022, the component and composition-related data elements have been enhanced to support the use case of multi-layer tablets and multi-component capsules. The business requirement driving the enhancements is to have the component and composition of the ingredients specified per layer (or per capsule constituent), not just per the entire drug product. Support for this use case has resulted in some additional and complex structured data elements. This enhanced set of data elements supports a deeper level of granularity in the component and composition section.

Below is a set of examples, with illustrations and descriptions, to aid in understanding the new set of data elements. The FDA suggests that the examples be reviewed prior to reviewing the data elements to ensure a baseline understanding of the terms by which the data elements are named. Please view the examples below concurrently with the composition tables in Appendix B.

Note: The examples presented do not represent actual dosage forms and are presented for illustration only; some quantities and formulations may not be conventional.

Introduction to new terms and concepts with examples

Figure 1: a two-layer Drug Product; a tablet with a purple layer and a white layer

- The **Drug Product** is the whole tablet (pictured in Figure 1)
- Each layer of the tablet is referred to as a **Product Part**
    - Every **Drug Product** has one or more **Product Part(s)**
- Each **Product Part** contains **Product Part Ingredients**
    - Each **Product Part Ingredient** has an amount and one or more functions in the context of the **Product Part**

The four examples below illustrate how the drug product component and composition sections of PQ/CMC can be presented for multi-layer tablets and capsules using the proposed enhanced PQ/CMC

data elements.

Multi-layer Tablet

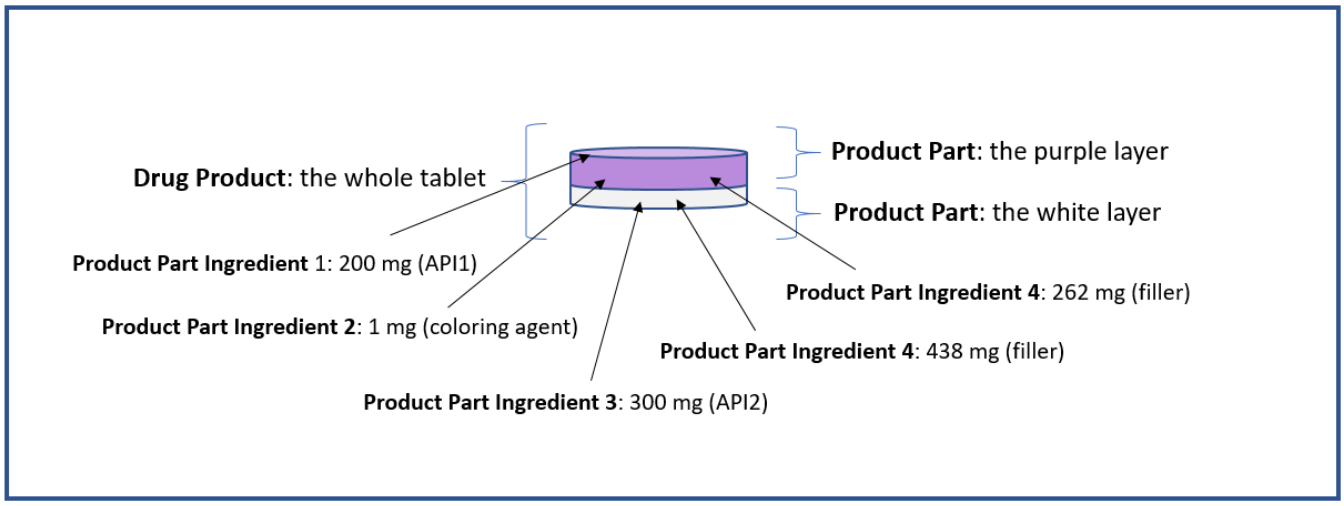


Figure 2: Illustration of multi-layer tablet (Drug Product) broken down into Product Parts and Product Part Ingredients

Drug Product: Example1Drug, is a tablet composed of two **Product Parts** and has 2 APIs

- **Product Part**: **Layer A** is purple colored and is composed of 3 ingredients
  - **Product Part Ingredient**: Ingredient 1: 200 mg, is API1
  - **Product Part Ingredient**: Ingredient 2: 1 mg, is a coloring agent
  - **Product Part Ingredient**: Ingredient 4: 262 mg, is a filler
- **Product Part**: **Layer B** is white colored and is composed of 2 ingredients
  - **Product Part Ingredient**: Ingredient 3: 300 mg, is API2
  - **Product Part Ingredient**: Ingredient 4: 438 mg, is a filler

A capsule filled with a tablet and one bead type

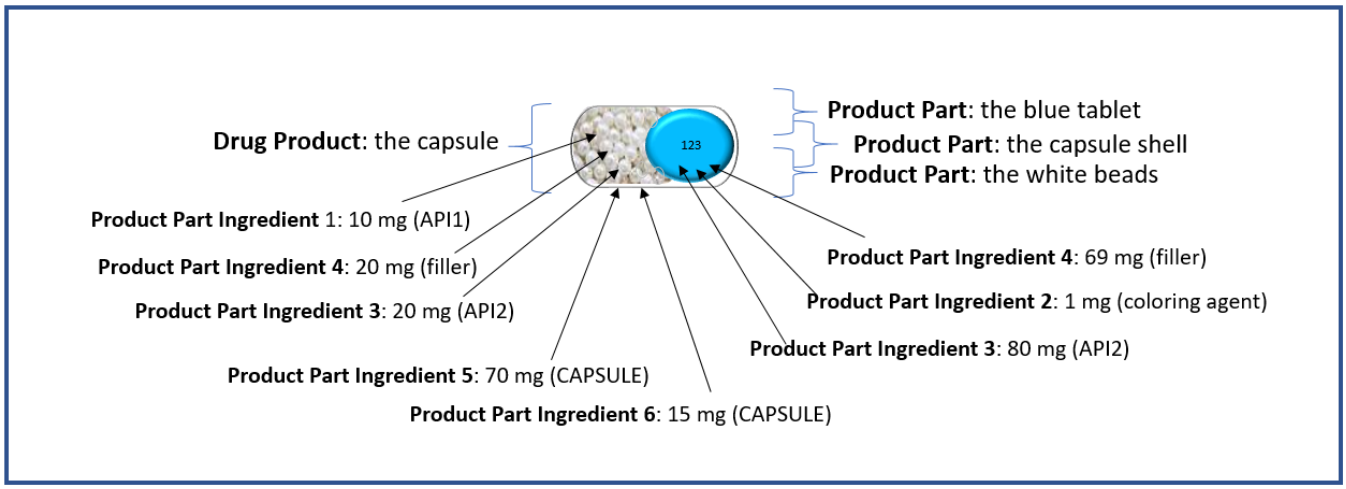


Figure 3:Illustration of a capsule (Drug Product) broken down into Product Parts and Product Part Ingredients

Drug Product: Example2Drug, is a hard hydroxypropylmethylcellulose (HPMC) capsule composed of three **Product Parts** and has 2 APIs

- **Product Part: Capsule Shell** is a Hard HPMC capsule
  - **Product Part Ingredient:** Ingredient 5: 70 mg, is the capsule
  - **Product Part Ingredient:** Ingredient 6: 15 mg, is the capsule
- **Product Part: Tablet** is bright blue colored and consists of 3 ingredients
  - **Product Part Ingredient:** Ingredient 3: 80 mg, is API2
  - **Product Part Ingredient:** Ingredient 2: 1 mg, is a coloring agent
  - **Product Part Ingredient:** Ingredient 4: 69 mg, is a filler
- **Product Part: White Beads** is composed of 3 ingredients
  - **Product Part Ingredient:** Ingredient 1: 10 mg, is API1
  - **Product Part Ingredient:** Ingredient 3: 20 mg, is API2
  - **Product Part Ingredient:** Ingredient 4: 20 mg, is a filler

Tablet with two Coatings

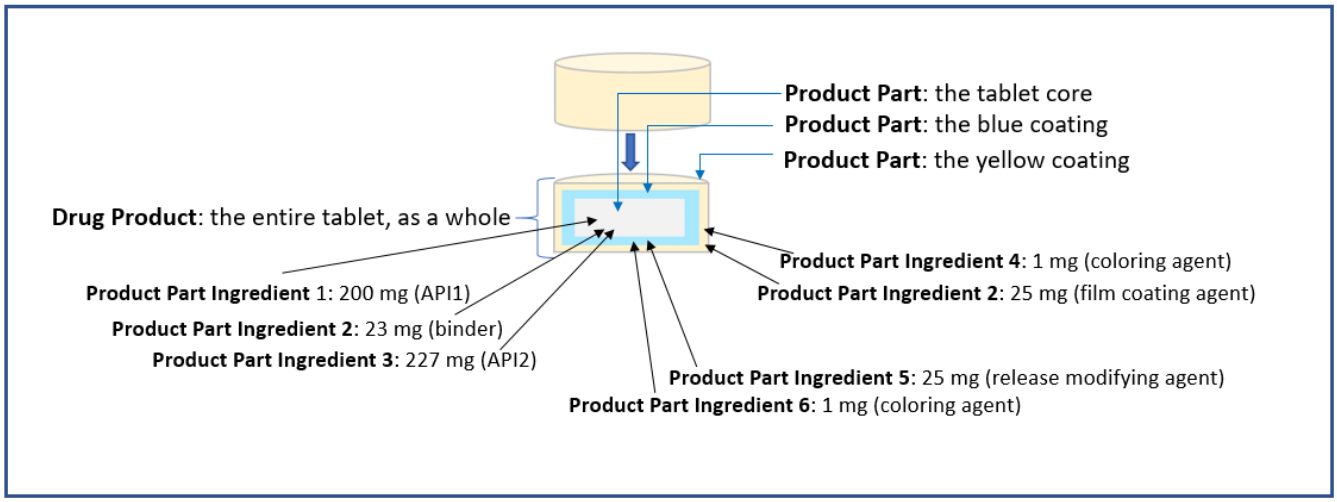


Figure 4:Illustration of tablet with two coatings (Drug Product) broken down into Product Parts and Product Part Ingredients

Drug Product: Example3Drug, is a tablet composed of three **Product Parts** and has 2 APIs

- **Product Part: Tablet** is a "single layer" tablet and consists of 3 ingredients
  - **Product Part Ingredient:** Ingredient 1: 200 mg, is API1
  - **Product Part Ingredient:** Ingredient 3: 227 mg, is API2
  - **Product Part Ingredient:** Ingredient 2: 23 mg, is a binder
- **Product Part: Coating** is the blue coating and consists of 2 ingredients
  - **Product Part Ingredient:** Ingredient 5: 25 mg, is a release modifying agent
  - **Product Part Ingredient:** Ingredient 6: 1 mg, is a coloring agent
- **Product Part: Coating** is the yellow outermost coating and consists of 2 ingredients
  - **Product Part Ingredient:** Ingredient 4: 1 mg, is a coloring agent
  - **Product Part Ingredient:** Ingredient 2: 25 mg, is a film coating agent

Coated Tablet containing one Bead type; each bead has two coatings

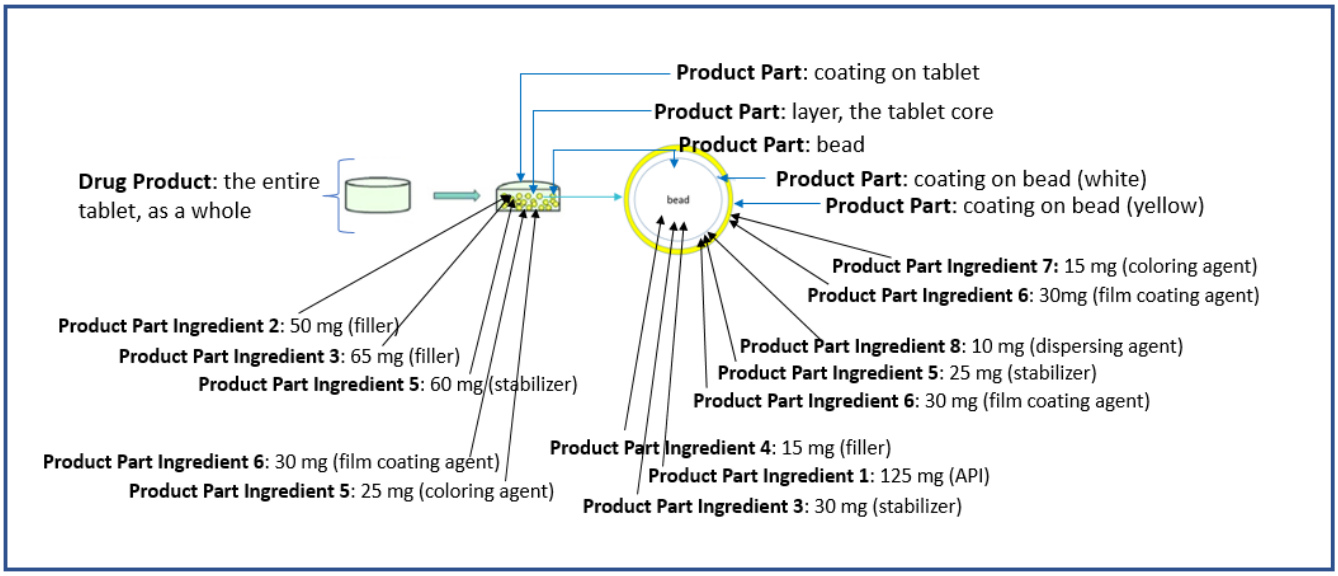


Figure 5: Illustration of a coated tablet with one bead type & bead with two coatings (Drug Product) into Product Parts and Product Part Ingredients

Drug Product: Example4Drug, is a tablet composed of five **Product Parts** and has 1 API

- **Product Part: Yellow Bead** is composed of 3 ingredients
  - **Product Part Ingredient:** Ingredient 1: 125 mg, is API
  - **Product Part Ingredient:** Ingredient 4: 15 mg, is a filler
  - **Product Part Ingredient:** Ingredient 3: 30 mg, is a stabilizer
- **Product Part: Tablet core** is composed of 3 ingredients
  - **Product Part Ingredient:** Ingredient 2: 50 mg, is a filler
  - **Product Part Ingredient:** Ingredient 3: 65 mg, is a filler
  - **Product Part Ingredient:** Ingredient 5: 60 mg, is a stabilizer
- **Product Part: Coating** is the green coating on the tablet and consists of 2 ingredients
  - **Product Part Ingredient:** Ingredient 5: 25 mg, is a coloring agent
  - **Product Part Ingredient:** Ingredient 6: 30 mg, is a film coating agent
- **Product Part: Coating** is the white coating on the bead and is composed of 3 ingredients
  - **Product Part Ingredient:** Ingredient 8: 10 mg, is a dispersing agent
  - **Product Part Ingredient:** Ingredient 5: 25 mg, is a stabilizer
  - **Product Part Ingredient:** Ingredient 6: 30 mg, is a film coating agent
- **Product Part: Coating** is the yellow outermost coating and consists of 2 ingredients
  - **Product Part Ingredient:** Ingredient 7: 15 mg, is a coloring agent
  - **Product Part Ingredient:** Ingredient 6: 30 mg, is a film coating agent

Drug Product Composition Table

The table below identifies the structured data elements that support drug product composition. The columns in the data element tables are as follows:

- **#**: A data element identifier in the content of the section of this document, that provides a mechanism to easily reference the data element.
    - The RED asterisk (*) indicates that the data element is NEW; introduced in this chapter. The data elements that do not have a RED asterisk were published in Chapter 1, which was originally announced in a previous FRN.
- **Data Element Name Definition:** Provides semantic clarity for the data element. To further clarify the definition, examples and additional notes are frequently provided, and the source of the definition is identified. Where possible, authoritative sources such as the CFR, USP or ICH are relied on. The source most often documented is "Subject Matter Expert (SME) Defined." The SMEs for this effort are PQ/CMC reviewers from CDER, CVM and CBER.
- **Data Type:** Identifies the data format or representation of the data element, and can contain a range of values or specific types. The data type of PQ/CMC elements may be: boolean, code, date, graphic, integer, number, numeric percent, text.
- **Cardinality:** The number of occurrences of the data element.
    - 1: the element must have exactly 1 value
    - 0..1: the element may have 0 or 1 value(s)
    - 0..*: the element may have 0 or many value(s)
    - 1..*: the element must at least 1 value, but may have many value(s)
- **Business Rule (BR)/Comments:** Provides data element specific business rules where relevant. Examples include identifying the conditions under which an attribute that is defined as optional may be mandatory, dependencies between values of multiple elements, etc.

Appendix A provides detailed examples that illustrate the use of the PQ/CMC elements to structure total product weight, product part weight, and product part ingredient amounts.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
The elements in this section are used to specify the Drug Product.					
1	**Product Proprietary Name**	The exclusive name of a drug product owned by a company under trademark law regardless of registration status with the US Patent and Trademark Office (PTO). [Source: SME Defined] Note: Excludes dosage form, route of administration and strength. Example: Tylenol	Text	0..1	
2	**Product Non-proprietary Name**	A name unprotected by trademark rights that is entirely in the public domain. It may be used without restriction by the public at large, both lay and professional. [Source: SME Defined]	Text	1	
3	**Product Co-Packaged Cross Reference**	A property that identifies whether a drug product has been supplied along with an additional item, such as another drug product, a placebo, a diluent, or an adjuvant. [Source: SME Defined] Note: Any component that is dispensed separately or external to the drug product is not considered co-packaged. For example, for Alka Selzer, since water is not supplied by the sponsor, it is not considered as a co-packaged product.	Text	0..*	If the product is a co-packaged product, then the co-packaged products must be identified. *Named Co-packaged Indicator in Chapter 1*
4	**Product Dosage Form**	The form in which active and/or inert ingredient (s) are physically presented as indicated on the packaging according to the USP. [Source: NCI EVS - C42636] Examples: tablet, capsule, solution, cream that contains a drug substance generally, but not necessarily, in association with excipients. [Source: ICH Q1A (R2)] See also 21 CFR 314.3. Note: If there is a new dosage form that does not exist in the controlled terminology, then propose this new dosage form during sponsor meetings with FDA.	Code	1	
5	**Product Route of Administration**	Designation of the part of the body through which or into which, or the way in which, the medicinal product is intended to be introduced. In some cases, a medicinal product can be intended for more than one route and/or method of administration. [Source: NCI EVS C38114]	Code	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
6	**Product Description**	A textual narrative describing the drug product or products. [Source: SME Defined] Examples: red-banded capsule, imprinted with DD1234A	Text	1..*	
7	**Product Container Closure System Description**	Any textual comments that describe the sum of container closure system (CCS) components that together contain and protect the dosage form or drug substance. [Source: Adapted from Q1A (R2)-ICH Glossary] Example: White opaque, round 50 mL HDPE bottle with a fitted 33 mm child resistant black polypropylene threaded cap closure, aluminum sealed, and containing molecular sieve canister 2 gm (CAN TRISORB 2G) as desiccant. Note: This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug substance or the drug product. A packaging system is equivalent to a container closure system. [Source: Adapted from Q1A (R2)-ICH Glossary]	Text	1	
8	**Product Container Type**	The kind of container that drug substances or finished dosage forms are contained in, which could include both the immediate (or primary) and secondary containers [Source: Adapted from NCI Thesaurus C43164]	Code	1	
9	**Product Closure Type**	The kind of closures used for the container in which the drug substances or finished dosage forms are stored. [Source: SME Defined]	Code	1	
10	**Product Quality Standard**	The established benchmark to which the drug product complies. [Source: SME Defined]	Code	1..*	
11 *	**Product Overall Release Profile**	The behavior in which drug substance migrates from a dosage form to the surrounding environment (e.g., biological fluids, dissolution media, etc.) [Source: SME Defined]	Code	1	
12 *	**Product Overall Release Mechanism**	The method employed to realize the specified drug product release type. [Source: SME Defined] Example: osmotic pump to achieve extended release	Code	0..1	Mandatory when Product Overall Release Profile = 'ER', otherwise null.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
13 *	**Product Coating Indicator**	A property that identifies whether the drug product contains any coatings. [Source: SME Defined]	Boolean	1	
14 *	**Product Tablet Layer Count**	The total number of layers in the tablet. [Source: SME Defined] Note: Non-layered tablets will be considered as one layer tablets.	Integer	0..1	Mandatory when Dosage Form = 'Tablet', otherwise null. When not null, must be greater than or equal to 1.
15 *	**Product Tablet Bead Type Count**	The total number of type of beads present in a tablet [Source: SME Defined] Example: For the case of a 1- layer tablet containing 2 types of beads, Tablet Bead Type Count = 2.	Integer	0..1	Mandatory when Dosage Form = 'Tablet', otherwise null. When not null, must be greater than or equal to 0.
16 *	**Product Capsule Constituent Count**	The number of distinct constituents contained in the capsule shell of the drug product. [Source: SME Defined] Example: For the case of a capsule shell filled with one type of bead and a minitablet, Constituent Type Count = 2.	Integer	0..1	Mandatory when Dosage Form = 'Capsule', otherwise null. When not null, must be greater than or equal to 1.
17 *	**Product Schematic**	The pictorial representation of the drug product. [Source: SME Defined]	Graphic	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
18 *	**Product Weight Type**	A physical (content) or activity measurement of the weight of the drug product unit. [Source: SME Defined] Example: Mass, Activity	Code	1	When Weight Type =Activity - IF UOM = UCUM Arbitrary Unit [arb'U], need to describe the units in Weight Textual IF Weight Type = Mass THEN Weight Numeric and Weight UOM are mandatory IF Weight Type = Activity THEN Weight Textual, Weight UOM ([arb'U]) and Weight Operator are applicable data elements. Weight Textual and Weight UOM are mandatory, and Weight Operator is optional
19 *	**Product Total Weight Numeric Numerator**	Specifies the total quantity of all ingredients in a single unit of the drug product. [Source: SME Defined] Note: a single unit of a solid oral dose form could be a tablet or a capsule	Number	0..1	
20 *	**Product Total Weight Numeric Numerator**	The labeled unit of measure for the content of the drug product, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Example: mg	Code	0..1	Mandatory if Product Total Weight Numeric Numerator is provided.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	UOM				
21 *	**Product Total Weight Numeric Denominator**	Specifies the quantity of the ingredient (s) consistent with a single unit dose or as expressed on the label. [Source: SME Defined] Note: For solid oral dose forms, by definition this is 1	Number	0..1	Product Total Weight Numeric Denominator = 1 for solid oral dose forms.
22 *	**Product Total Weight Numeric Denominator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Note: For solid oral dose forms, by definition this is "unit"	Code	0..1	Mandatory if Product Total Weight Numeric Denominator is provided. Product Total Weight Numeric Denominator UOM = "unit" for solid oral dose forms.
23 *	**Product Total Weight Textual**	A written description of the weight of the drug product. [Source: SME Defined] Note: This is typically applicable to biologics Example: International Units for Enzymes	Text	0..1	If the UOM is UCUM Arbitrary Unit [arb'U], units must be described in Weight Textual
24 *	**Product Total Weight Operator**	A mathematical symbol that denotes equality or inequality between two values. [Source: SME Defined] Examples: LT, EQ, NMT. Note: This is typically applicable to biologics	Code	0..1	See Product Weight Type
The elements in this section are used to specify the Product Part(s)					
25 *	**Product Part Type**	Identifies the kind of element, based on the design the applicant develops to achieve the desired drug product and overall release profile. [Source: SME Defined] Example: Layer, Bead, Minitablet, Capsule Shell, Coating	Code	1	When Coating Indicator = 'Yes', then at least 1 Product Part must have type = 'Coating'.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					When Dosage Form = 'Capsule', then at least 1 Product Part must have type = 'Capsule Shell' When Dosage Form = 'Tablet', then at least 1 part of the Product Part must have type = 'Layer'.
26 *	**Product Part Identifier**	A submitter designated identifier that uniquely identifies the part within the drug product. [Source: SME Defined] Examples: 1, A1, Red bead, Blue minitablet	Text	1	
27 *	**Product Part Identifier Reference**	Identifies the parent or outer-level product part. [Source: SME Defined] Example: A bead (Product Part Identifier = "B1") has a seal coating (Product Part Identifier = "SCoat") and is contained in a Hard HPMC capsule shell (Product Part Identifier "Cap Shell"). For the seal coating, Product Part Identifier Reference = "B1", because the seal coat is applied to the bead.	Text	0..1	The value of Product Part Identifier Reference is limited to the Product Part Identifier(s) for the elements of the Product or null. When Product Part Identifier Reference is null, the part is considered to be part of the Product. For example: Product Part Identifier Reference will be null for the layer of a tablet, and for a minitablet in a capsule, and for an outer coating of a tablet.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					For any Product Part, the Product Part Identifier Reference cannot be equal to the Product Part Identifier.
28 *	**Product Part Release Profile**	The behavior in which drug substance migrates from the drug product part to the surrounding environment (e.g., biological fluids, dissolution media, etc.) [Source: SME Defined]	Code	1	When part does not include an API, then Part Release Profile = 'Not Applicable' When part includes an API, then Part Release Profile cannot = 'Not Applicable'
29 *	**Product Part Release Mechanism**	The method employed to realize the specified part release profile. [Source: SME Defined] Example: matrix or reservoir	Code	0..1	Mandatory when Part Release Profile = 'ER', otherwise null.
30 *	**Coating Product Part Purpose**	The reason the coating or covering was added. [Source: SME Defined] Examples: rate-controlling, color, release type, protective, taste masking.	Code	0..*	Mandatory when Part Type = 'Coating', otherwise null.
31 *	**Tablet Product Part Function Description**	The main purpose for the part in the solid oral tablet. [Source: SME Defined] Example: Push, Target	Text	0..1	Mandatory when Dosage Form = 'Tablet' and Part Type is not 'Coating', otherwise null
32 *	**Capsule Shell Part Classification Category**	Categorization of the capsule shell based on factors such as the shell's barrier to water and oxygen, reactivity, and the material it is made of. [Source: SME Defined]	Code	0..1	Mandatory when Dosage Form = 'Capsule', and Part Type = 'Capsule Shell', otherwise null.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
33 *	**Product Part Color Description**	The hue or the tint of the drug product part. [Source: SME Defined] Examples: yellow, pink, blue, pale yellow.	Text	0..1	
34 *	**Product Part Total Weight Numeric Numerator**	Specifies the total quantity of all ingredients in a single part of the drug product. [Source: SME Defined] Note: a single unit of a solid oral dose form could be a layer of a tablet or a minitablet in a capsule	Number	1	
35 *	**Product Part Total Weight Numeric Numerator UOM**	The labeled unit of measure for the content of the drug product, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Example: mg	Code	1	
36 *	**Product Part Total Weight Numeric Denominator**	Specifies the quantity of the ingredient (s) consistent with a single part of a drug product. [Source: SME Defined] Note: For solid oral dose forms, by definition this is 1	Number	1	Product Part Total Weight Numeric Denominator = 1 for solid oral dose forms.
37 *	**Product Part Total Weight Numeric Denominator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per drug product part. [Source: Adapted for NCI EVS C117055] Note: For solid oral dose forms, by definition this is “unit”	Code	1	Product Total Weight Numeric Denominator UOM = ‘unit’ for solid oral dose forms.
38 *	**Product Part Content Percent**	The percentage of the drug product as a whole, that is represented by this part. [Source: SME Defined] Example: total tablet weight = 400 mg, total weight of layer = 250 mg, then Content Percent for the layer = 62.5	Numerical Percent	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
39 *	**Product Part Additional Information**	A placeholder for providing any comments that are relevant to the drug product component. [Source: SME Defined] Examples: removed during process, adjusted for loss on drying.	Text	0..1	
The elements in this section are used to specify the Product Part Ingredients; they parallel Drug Substance (published in previous Chapter).					
40	**Product Part Ingredient Name**	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. [Source: (see Component 21 CFR 210.3 (b) (3)), PAC-ATLS 1998]	Text	1..*	*Named Product Component Name in Chapter 1*
41 *	**Product Part Ingredient Name Type**	Identifies the source that assigned the product ingredient name. [Source: SME Defined] Examples: GSRS Preferred Term, Systematic Name, INN, USP/NF	Code	1	Each Product Part Ingredient Name must have 1 Product Part Ingredient Name Type. For Active Ingredients: FDA expects names submitted to include: • Systematic Name • GSRS Preferred Term, except in the case of an IND or INAD For Inactive Ingredients: FDA expects names submitted to include: • GSRS Preferred Term • USP/NF *In Chapter 1 there were distinct elements for CAS Number, INN,*

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					USAN, IUPAC Name, ISBT 128; in this Chapter, these 4 elements are supported by Name/Name Type.
42	**Product Part Ingredient UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source: http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please contact fda-srs@fda.hhs.gov	Text	0..1	UNIIs are not required for: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products. *Named UNII in Chapter 1*

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
43	**Product Part Ingredient Function Category**	A high-level classification that identifies the purpose of that material. [Source: SME Defined] Examples: Active Ingredient, Inactive Ingredient	Code	1	*Named Drug Product Component Function Category Chapter 1*
44	**Product Part Ingredient Quality Standard**	The established benchmark to which the component complies. [Source: SME Defined] Examples: USP/NF, EP, Company Standard	Code	1..*	*Named Quality Standard in Chapter 1*
45	**Product Part Ingredient Source Type**	A classification that provides the origin of the raw material. [Source: SME Defined] Example: cat hair and porcine gelatin would have Animal source type	Code	1	*Named Source Type in Chapter 1*
46	**Product Part Ingredient Source Organism**	The name, genus or genus and species of the organism from which the material is derived. [Source: SME Defined] Examples: human or Homo Sapiens, chicken, dog or canine, cow or bovine, rat or rattus. Note: When Source Type = 'Plant', Source Organism should be found in Kew Gardens Medicinal Plant Names Services (https://mpns.science.kew.org/). When Source Type = 'Animal', 'Microbial', 'Insect', 'Human', Source Organism should be found in NLM NCBI Taxonomy (https://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi)	Text	0..1	*Named Source Organism in Chapter 1*
47	**Product Part Ingredient Source Organism Part**	A fragment of the source organism. [Source: SME Defined] Examples: secretions, material from a specific organ, tissue or portion of the organism, such as liver, pancreas, blood or from bark or seed of a plant, CHO cell lines. IDMP 11238 definition & examples: Entity of anatomical origin of source material within an organism. Cartilage, Root and Stolon, whole plant is considered as a part; Aerial part of the plant, Leaf, Tuberous Root, whole animal	Text	0..1	*Named Source Organism Part in Chapter 1*

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
48	**Product Part Ingredient Source Organism Country of Origin**	The name of the country where the organism was reared. [Source: SME Defined]	Code	0..1	*Named Source Organism Country of Origin in Chapter 1*
49	**Product Part Ingredient Additional Information**	A placeholder for providing any comments that are relevant to the ingredient. [Source: SME Defined]	Text	0..*	*Named Drug Product Component Additional Information in Chapter 1*
50	**Product Part Ingredient Function**	A sub-classification of part ingredients identifying its purpose/role in the drug product part (e.g., in the layer, bead, minitablet). [Source: SME Defined] Examples: Filler, Surfactant.	Code	0..*	Mandatory when Product Ingredient Function Category = 'Inactive Ingredient'. Null when Product Ingredient Function Category = 'Active Ingredient' or 'Adjuvant'. *Named Drug Product Component Function in Chapter 1*
51 *	**Product Part Ingredient Physical Location**	Identifies where the ingredient physically resides within the product part. [Source: SME Defined] Examples: Intragranular, Extragranular, Blend	Code	0..1	Mandatory when Product Part Type is not 'Coating'.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					When the Product Part Type = 'Coating', value is null.
52 *	**Product Part Ingredient Amount Numeric Numerator**	Specifies the quantity of an ingredient in a single part of the drug product. [Source: SME Defined] Note: a single part of a solid oral dose form could be a layer of a tablet or a minitablet in a capsule Note: Amount can also be referred to as potency in biologics and other products.	Number	1	
53 *	**Product Part Ingredient Amount Numeric Numerator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per product part. [Source: Adapted for NCI EVS C117055]	Code	1	
54 *	**Product Part Ingredient Amount Numeric Denominator**	Specifies the quantity of the ingredient (s) consistent with this single product part. [Source: SME Defined]	Number	1	Product Part Ingredient Amount Numeric Denominator = 1 for solid oral dose forms.
55 *	**Product Part Ingredient Amount Numeric Denominator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per drug product part. [Source: Adapted for NCI EVS C117055] Note: For solid oral dose forms, by definition this the product part	Code	1	Product Ingredient Amount Numeric Denominator UOM = UCUM Arbitrary Unit for solid oral dose forms. The units must be described in Product Part Ingredient Amount Textual.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
56 *	**Product Part Ingredient Amount Textual**	A written description of the amount of the ingredient. [Source: SME Defined] Note: This is typically applicable to biologics Example: International Units for Enzymes	Text	0..1	If the UOM is UCUM Arbitrary Unit [arb'U] then, Product Part Ingredient Amount Textual is mandatory (describe the units).
57 *	**Product Part Ingredient Amount Operator**	A mathematical symbol that denotes equality or inequality between two values. [Source: SME Defined] Examples: LT, EQ, NMT. Note: This is typically applicable to biologics	Code	0..1	
58 *	**Product Part Ingredient Content Percent**	The percentage of the component in the drug product part. [Source: SME Defined] Example: Product Part Total Weight = 2 mg and Product Part Ingredient Amount = 0.5 mg, so Product Part Ingredient Content Percent = 25 Example: total weight of layer = 250 mg, amount of ingredient = 150 mg, then Content Percent for the ingredient = 60	Numerical Percent	1	
The elements in this section are used to specify the product composition per unit dose.					
59	**Product Ingredient Amount Numeric Numerator**	Specifies the quantity of an ingredient in a single dose unit (e.g., one tablet, capsule) of the drug product. [Source: SME Defined] Example: if the tablet contains 325 mg of the ingredient in each unit dose, then Product Ingredient Numeric Numerator = 325	Number	1	*Named StrengthNumericNumerator in Chapter 1*
60	**Product Ingredient Amount Numeric Numerator UOM**	The labeled unit of measure for the content of the drug product, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Example: mg	Code	1	*Named StrengthNumericNumerator UOM in Chapter 1*

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
61	**Product Ingredient Amount Numeric Denominator**	Specifies the quantity of the ingredient(s) consistent with this single dose unit (e.g., one tablet, capsule) of drug product. [Source: SME Defined] Example: if the tablet contains 325 mg of the ingredient in each unit dose, then Product Ingredient Numeric Denominator = 1	Number	1	*Named StrengthNumericDenominator in Chapter 1*
62	**Product Ingredient Amount Numeric Denominator UOM**	The labeled unit of measure for the content of an ingredient, expressed quantitatively per drug product. [Source: Adapted for NCI EVS C117055] Note: For solid oral dose forms, by definition this is "unit"	Code	1	*Named StrengthNumericDenominator UOM in Chapter 1*
63	**Product Ingredient Content Percent**	The percentage of the component in a single dose unit (e.g., one tablet, capsule) of the drug product. [Source: SME Defined] Example: Product Total Weight = 1200 mg and Product Ingredient Amount = 325 mg, so Product Ingredient Content Percent = 27.08	Numerical Percent	1	*Named Content (%) in Chapter 1*
The elements in this section are used to specify Drug Product impurities; these are unchanged from the previous Chapter and are included here for completeness.					
64	**Product Impurity Name**	Any component of the drug product which is not the chemical entity defined as the drug substance or an excipient in the drug product. [Source: ICH Q6A] Examples: QQ201234, Residual DNA, Aggregates & degradants. Note: For example, this could also be a common name, systematic name, or a company code	Text	1..*	
65	**Product Impurity Name Type**	Identifies the source of the name of the ingredient. [Source: SME Defined]ed] Examples: GSRS Preferred Term, Systematic Name, INN, USP/NF	Code	1	Each Drug Product Impurity Name must have 1 Product Impurity Name Type.
66	**Product Impurity UNII**	The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. [Source:	Text	0..1	UNIIs are not required for: Human Cells, Tissues

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/] Note: If a UNII does not exist, please go to http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/			and Cellular and Tissue-Based Products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271. Blood and blood components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122 (circular of information)), or labeling associated with licensed in vitro diagnostic (IVD), Blood Grouping Reagents (BGR) products.
67	**Impurity Classification**	A categorization of impurities based on its origin. [Source: SME Defined] Examples: Degradation Product, Inorganic, Process Related/Process, Product Related, Leachables.	Code	1..*	
68	**Chemical Structure Data File**	A machine-readable representation of the structure of the chemical. [Source: SME Defined] Examples: SDF, MOLFILE, InChI file, cdx.	Text/Binary	0..1	
69	**Impurity Structure Graphic**	A pictorial representation of the structure of the impurity. [Source: SME Defined]	Graphic	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
70	**Drug Product Impurity Method Type**	The technique used to elucidate the structure or characterize the impurity. [Source: SME Defined] Examples: NMR, Mass Spectrometry.	Text	0..*	
71	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	0..*	
72	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/Binary	0..*	
73	**Analytical Instrument Data File Type**	A value that identifies the file format. [Source: SME Defined] Examples: JCAMP, AnIML.	Text	0..1	Mandatory if Analytical Instrument Data File is not null.
74	**Analytical Instrument Data File Type Narrative Text**	The description or justification in support of the interpretation of the data file. [Source: SME Defined].	Text	0..*	

END OF SECTION 1

Section 2: Drug Product Manufacturing Data Elements (solid oral-focused)

This section provides the NEW structured data elements in support of drug product manufacturing for solid oral dosage form (SODF). This information is typically submitted in the following eCTD sections: 3.2.P.3.1 [Manufacturer(s)], 3.2.P.3.3 [Description of Manufacturing Process and Process Controls], and 3.2.P.3.4 [Control of Critical Steps and Intermediates].

Drug Product Manufacturing Table

The table below identifies the NEW structured data elements that support drug product manufacturing for solid orals dosage forms (SODF). The columns in the data element tables are as follows:

- **#**: A data element identifier in the content of the section of this document, that provides a mechanism to easily reference the data element.
    - The RED asterisk (*) indicates that the data element is NEW; introduced in this FRN. The data elements that do not have a RED asterisk were published in the previous PQ/CMC FRNs.
- **Data Element Name Definition:** Provides semantic clarity for the data element. To further clarify the definition, examples and additional notes are frequently provided, and the source of the definition is identified. Where possible authoritative sources such as the CFR, USP or ICH are relied on. The source most often documented is "Subject Matter Expert (SME) Defined." The SMEs for this effort are PQ/CMC reviewers from CDER, CVM and CBER.
- **Data Type:** Identifies the data format or representation of the data element and can contain a range of values or specific types. The data type of PQ/CMC elements may be: boolean, code, date, graphic, integer, number, numeric percent, text.
- **Cardinality:** The number of occurrences of the data element.
    - 1: the element must have exactly 1 value
    - 0..1: the element may have 0 or 1 value(s)
    - 0..*: the element may have 0 or many value(s)
    - 1..*: the element must at least 1 value, but may have many value(s)
- **Business Rule (BR)/Comments:** Provides data element specific business rules where relevant. Examples include identifying the conditions under which an attribute that is defined as optional may be mandatory; dependencies between values of multiple elements, etc.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
1	**Manufacturing Site Name**	The name of the establishment (facilities) which manufacture, prepare, propagate, compound, process or package drugs that are commercially distributed in the U.S. or offered for import to the U.S. [Source: Adapted from FDA Drug Establishment Current Registration Site]	Text	1..*	
2	**Manufacturing Site Unique Identifier**	A unique identifier assigned to the establishment (facility) which manufactures, prepares, propagates, compounds or processes drugs. [Source: Adapted from FDA Drug Establishment Current Registration Site]	Text	1..*	
3	**Manufacturing Site Unique Identifier Type**	A value that identifies the source of the unique identifier. [Source: SME Defined] Examples: Data Universal Number System (DUNS), Facility Establishment Identifiers (FEI), etc.	Code	1	Each Manufacturing Site Unique Identifier must have 1 Manufacturing Site Unique Identifier Type.
4	**Manufacturing Site Physical Address**	The complete address for the supplier [Source: SME Defined]	Text	1	
5 *	**Manufacturing Site Contact Person Name**	A word or set of words by which a responsible individual, who is known, addressed, or referred to for the named facility. [Source: Adapted from Oxford Dictionary]	Text	0..1	CDER: mandatory except for CDER-led BLA CVM: mandatory
6 *	**Manufacturing Site Contact Person Role**	A description specifying the function of the person in the context of this manufacturing site who could be contacted. Examples: Director of manufacturing, Direction of quality control, etc. [Source: SME Defined]	Text	0..1	
7 *	**Manufacturing Site Contact Person Mailing Address**	The contact point used to send physical form of communication to the site person. Note: this may be different from the manufacturing site physical address. [Source: SME Defined]	Text	0..1	
8 *	**Manufacturing Site Contact Person**	A unique identifier associated with the site person which is used to send and receive messages over the internet. [Source: SME Defined]	Text	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Email				
9 *	**Manufacturing Site Contact Person Phone Number**	A sequence of digits or characters to identify a particular telephone number for the site contact person. [Source: SME Defined]	Text	0..1	
10 *	**Manufacturing Site Contact Person Fax Number**	A sequence of digits, typically a phone number, used to identify a machine in a telephone network that enables people to send and receive copies of documents to the site contact person. [Source: SME Defined]	Text	0..1	
11 *	**Manufacturing Site Responsibility Category**	A high-level classification of manufacturing sites based on the functions or services provided. [Source: SME Defined]	Code	1..*	
12 *	**Manufacturing Site Responsibility Subcategory**	An additional classification to further specify the services provided by the manufacturing site. [Source: SME Defined}	Code	0..*	When Manufacturing Site Responsibility Category = 'Testing' or 'Packaging', then Manufacturing Site Responsibility Subcategory is mandatory (at least 1 must be specified). When Manufacturing Site Responsibility Category = 'Manufacturing' or 'Other', then value is null.
13 *	**Manufacturing Site Responsibility Description**	A textual narrative related to manufacturing site function(s). [Source: SME Defined]	Text	0..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
14 *	**Manufacturing Site Utilization**	A categorization of the manufacturing site, with respect to the associated application, that identifies whether its activities are involved in development or commercial usage of the drug product. [Source: SME Defined] For example, if a manufacturing site has the following responsibilities: Manufacturing and Biological Potency Testing, then the utilization for each responsibility category/subcategory should be specified. e.g., Manufacturing: Both commercial and non-commercial; Biological Potency Testing: Commercial	Code	0..*	CDER: Mandatory for ANDA, NDA and CDER-led BLA. CBER: Mandatory except for CBER-led BLA CVM: Mandatory for ANADA and NADA.
15 *	**US Agent Name**	A non-unique textual identifier for the person identified by the foreign establishment as the point of contact for official communication, scheduling FDA inspections and other responsibilities. [Source: Adapted from FDA: https://www.fda.gov/medical-devices/device-registration-and-listing/us-agents]	Text	0..1	Mandatory when the sponsoring establishment is outside the US. US Agent information is mandatory on FDA Form 356h and is required for facility registration. [Source: 21 CFR 207.40] US Agent information is also mandatory on the CVM eSubmitter form.
16 *	**US Agent Title**	A description specifying the function or occupational title of the US Agent. [Source: SME Defined]	Text	0..1	Mandatory when the sponsoring establishment is outside the US.
17 *	**US Agent Physical Address**	The contact point used to send physical form of communication to the US Agent. [Source: SME Defined] Note: this may be different from the sponsor physical address.	Text	0..1	Mandatory when the sponsoring establishment is outside the US.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
18 *	**US Agent Email**	A unique identifier associated with the US Agent which is used to send and receive messages over the internet. [Source: SME Defined]	Text	0..1	Mandatory when the sponsoring establishment is outside the US.
19 *	**US Agent Phone Number**	A sequence of digits or characters to identify a particular telephone number for the US Agent. [Source: SME Defined]	Text	0..1	
20 *	**US Agent Fax Number**	A sequence of digits, typically a phone number, used to identify a machine in a telephone network that enables people to send and receive copies of documents to the US Agent. [Source: SME Defined]	Text	0..1	
21 *	**Manufacturing Process Flow Diagram**	Diagram(s) illustrating the flow of the operations involved in the manufacture of the drug product. [Source: SME Defined] Note: At a minimum, the FDA requires the Manufacturing Process Flow diagram for the Proposed Commercial batch. It can be helpful to include the flow diagram(s) for relevant development lots.	Graphic	1..*	
22 *	**Continuous Manufacturing Indicator**	A property that identifies whether the manufacturing process of this drug product is continuous. [Source: SME Defined] Note: A manufacturing process is considered continuous if any two or more steps are combined. See Q13 *Continuous Manufacturing of Drug Substances and Drug Products*.	Boolean	1	
23 *	**Manufacturing Process Additional Information**	A placeholder for providing any comments that are relevant to the manufacturing process [Source: SME Defined]	Text	0..1	
24 *	**Step Identifier**	A unique, within the manufacturing process, alphanumeric identifier assigned to a particular phase or process step in the manufacturing cycle. [Source: SME Defined]	Text	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
25 *	**Subsequent Step Identifier**	The unique alphanumeric identifier that is assigned to the next process step in the manufacturing cycle. [Source: SME Defined]. Example: A manufacturing process consists of 3 steps in the order: Sieve (Step Identifier = '00A'), Mixing (Step Identifier = '002'), and Packaging (Step Identifier = 'C'). For the Sieve step, Subsequent Step Identifier = '002' (Mixing); for the Mixing step, Subsequent Step Identifier = 'C' (Packaging); for the Packaging step, Subsequent Step Identifier is null because it is the last step in the cycle.	Text	0..1	Mandatory, except for the last step in the cycle which has no subsequent step.
26 *	**Step Description**	A narrative summary providing details of a particular step in the manufacturing cycle. [Source: SME Defined] Note: The purpose of the step can be included in the Step Description, or it can be documented in the PDR (Pharmaceutical Development Report).	Text	1	
27 *	**Unit Operation Category**	One part of a potentially multiple-step process which can be considered to have a single function that results in a physical change or a chemical transformation. [Source: SME Defined] Examples: Granulation, Particle size reduction, Drying, Coating	Code	1	
28 *	**Unit Operation Subcategory**	The operating principle associated with the unit operation category that further specifies the process details. [Source: SME Defined] Examples: subcategories of Granulation include: Dry Granulation, Wet High-Shear Granulation, Extrusion Granulation; subcategories of Particle size reduction include: Impact Milling, Cutting, Screening Note: not all unit operation categories have subcategories	Code	0..1	
29 *	**Unit Operation Purpose**	The rationale or function of this unit operation. [Source: SME Defined] Examples: for API Layering, to mask taste, for Seal Coating	Text	0..1	Mandatory when Unit Operation Category = 'Coating'
30 *	**Unit Operation Critical Indicator**	A property that identifies whether the unit operation is considered critical in the drug manufacturing process. [Source: SME Defined]	Boolean	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
31 *	**Unit Operation Hold Time**	Hold time is the established limit on the time period for which materials (dispensed raw materials, intermediates, and bulk dosage from awaiting final packaging) may be held under specified conditions and will remain within the defined specifications. [Source: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-manufacture-finished-dosage-form-revision-1_en.pdf]	Numeric	1	
32 *	**Unit Operation Hold Time UOM**	The labeled unit of measure for the unit operation hold time. [Source: Adapted for NCI EVS C117055] Examples: days, hours, minutes	Code	1	
33 *	**Unit Operation Equipment Classification**	The type of the machine used in the manufacturing step. [Source: SME Defined] Examples: Fluid bed dryer, Diffusion mixer, Cage blender	Text	1	
34 *	**Equipment Manufacturer Name**	The name of the organization/company who made the equipment [Source: SME Defined]	Text	1	
35 *	**Equipment Model Number**	A uniquely identifies a kind of machine, as assigned by the manufacturer, that was/will be used to perform the unit operation. [Source: SME Defined]	Text	1	
36 *	**Equipment Identifier**	A unique identifier assigned by the applicant to the machinery used to perform the unit operation. [Source: SME Defined] Example: A1, V2, FBD1	Text	1	
37 *	**Equipment Size**	The capacity of the equipment as designated by the manufacturer. [Source: SME Defined] Examples: 1000 kg (for blender); 500 L (for liquids), 1500 kg/hr (for extruder)	Text	0..1	
38 *	**Equipment Working Capacity**	The maximum amount of material that the equipment is capable of or rated for processing. [Source: SME Defined] Examples: for a blender, 800 kg; for liquids, 500 L for liquids; for an extruder, 1500 kg/hr	Text	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
39 *	**Equipment Utilization Percent**	The percent used or proposed based on the equipment's working capacity for this manufacturing step. [Source: SME Defined] Examples: 500 kg of a blender with 800 kg capacity is used, therefore the utilization percent is 63; 250 L of 500 L capacity is used, therefore utilization percent is 50; ran extruder at 1000 kg/hr even through capacity is 1500 kg/hr, therefore utilization percent is 67.	Numeric Percent	0..1	
40 *	**Unit Operation Equipment Process Parameter Name**	The attributes of a pharmaceutical manufacturing system which are usually the characteristics of the equipment or processes which is being monitored or controlled. [Source: SME Defined] Examples: speed, time, temperature	Text	1	
41 *	**Unit Operation Equipment Process Parameter UoM**	The labeled unit of measure for the process parameter. [Source: Adapted for NCI EVS C117055] Examples: rpm, °C Note: units in which the Target Value and/or Target Range are measured.	Code	1	
42 *	**Critical Process Parameter Indicator**	A property that identifies whether the process parameter is considered critical in the drug manufacturing process. [Source: SME Defined] Note: A critical process parameter is one whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality. [Source: ICH Q8]	Boolean	1	
43 *	**Process Parameter Target Value**	The expected and/or acceptable qualitative or quantitative value of the process parameter. [Source: SME Defined] Examples: 15 (rpm); 60(°C), slow	Text	0..1	Both Process Parameter Target Value and Process Parameter Target Range cannot be null.
44 *	**Process Parameter Target Range**	The expected and/or acceptable variability or the spread of the process parameter. [Source: SME Defined] Examples: 10-25 (rpm); 65-70(°C); slow-medium	Text	0..1	Both Process Parameter Target Value and Process Parameter Target Range cannot be null.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
45 *	**Process Parameter Target Change Rationale**	The justification for why a process parameter target value or target range was modified. [Source: SME Defined] Examples: equipment capacity may be modified to support a larger batch; a range may be tightened based on new or historical information	Text	0..1	
46 *	**IPC Time Point**	An instance of time identifying when an in-process control (IPC) will be performed with respect to the unit operation. [Source: SME Defined] Examples: Before, After	Code	1	
47 *	**IPC Name**	The textual moniker associated with the in-process control (IPC) to be performed on the unit operation, that signifies what characteristic is to be tested. [Source: SME Defined] Examples: Loss on drying, Particle size distribution, Blend uniformity	Text	1	
48 *	**IPC Test Category**	A high-level grouping of intermediate process controls. [Source: SME Defined]. Examples: Assay, Material Properties/Measurements	Code	1	
49 *	**IPC Test Subcategory**	A secondary grouping of intermediate process controls. [Source: SME Defined].	Code	0..1	
50 *	**IPC Analytical Procedure**	The name of the technique used to determine the nature of a characteristic. [Source: SME Defined]. Examples: HPLC, Karl Fischer titration Note: The full descriptor of the technique is the IPC Reference to Analytical Procedure data element	Text	0..1	Mandatory when Unit Operation Critical Indicator = True.
51 *	**IPC Reference to Analytical Procedure**	The reference to the actual file of the analytical procedure. [Source: SME Defined] Note: this is the file path to the procedure document.	Text	0..1	Mandatory when Unit Operation Critical Indicator = True.
52	**Value**	The acceptable qualitative or text value of the result of the test. [Source: SME Defined]	Text	0..1	
53	**ValueNumeric**	The acceptable quantitative or numeric value for the result of the test. [Source: SME Defined]	Numeric	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
54	**ValueNumeric UOM**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709]	Code	0..1	Mandatory when ValueNumeric is not null.
55	**Original Text**	The text of the acceptance criteria as provided in the specification. [Source: SME Defined] Examples: White to off-white cake; 22.5 - 27.5 mg/ml Note: This is the text as it appears in the Specification.	Text	1	
56	**Acceptance Criteria Usage**	A coded value specifying when a particular analytical procedure or measurement is being performed on a substance or a product. [Source: SME Defined]. Examples: Release, Stability. Note: The concept of "In-Process" is subsumed by the Release code.	Code	1..*	
57	**Interpretation Code**	A code that describes how to relate the given value to an acceptance value. [Source: SME Defined] Note: When result value is numeric there is a controlled vocabulary; when result value is textual the vocabulary is Pass/Fail.	Code	1	
58	**Acceptance Criteria Additional Information**	A textual field to provide any additional information about the acceptance criteria. [Source: SME Defined] Example: value changed from 4% to 5% on 01/01/2010	Text	0..*	
59 *	**Sampling Timing/Frequency**	The occurrence indicating how often material from the lot (sample(s) of the lot) are extracted for testing during the manufacturing step. [Source: SME Defined]	Text	0..1	FDA recommends that Industry use applicable guidance and best practices based on the appropriate unit operation when providing the sampling frequency.
60 *	**Sampling Location**	The place or the spot in the manufacturing equipment or the immediate environment (e.g., air in the room) from where the	Text	0..1	FDA recommends that Industry use applicable guidance and best

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		material from the lot (sample of the lot) was extracted for testing during a manufacturing step. [Source: SME Defined]			practices based on the appropriate unit operation when providing the location information.
61 *	**Sampling Quantity**	The amount of material taken from the lot to be inspected to determine if the entire lot will be accepted or rejected based on the quality of the sample size. [Source: SME Defined] Examples: 10, 200	Text	0..1	
62 *	**Sampling Quantity Unit of Measure**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS - C25709] Examples: tablets (or units), ml, mg	Code	0..1	Mandatory when Sampling Quantity is not null.
63 *	**IPC Batch Usage**	A categorization of the batch that identifies its usage. [Source: SME Defined] Examples: commercial, development.	Code	1..*	This is the same as Batch Utilization published in the previous Chapter document, but is in the context of IPC.

END OF SECTION 2

Section 3: Controlled Terminology

The tables below contain the controlled terminology/vocabulary defined by FDA SMEs for the data elements that have a "code" data type in the data element tables above. The columns in the controlled terminology table are as follows:

- **#:** A value list identifier in the content of the section of this document, that provides a mechanism to easily reference the value list.
    - The RED asterisk (*) indicates that the list is NEW; introduced in this FRN. The lists that do not have a RED asterisk were published in the previous PQ/CMC FRNs.
- **PQ/CMC Data Element Name:** Denotes the name of the PQ/CMC element.
- **Valid Value:** The allowable values for a given PQ/CMC data element.
- **NCIt Concept Codes:** The unique identifier assigned to each concept by NCI EVS to permanently track a specific meaning.
    - A blank NCIt Concept Code indicates that the valid value has not been registered with NCI EVS at the time this document was published. Once the valid values are finalized, they will all be registered and assigned NCIt Concept Codes.
- **Valid Value Meaning:** The description of the allowable value for the given PQ/CMC data element.

Note: The Controlled Terminology has been broken into six tables

- Table A: Data elements with limited number of valid values (less than 15 valid values)
- Table B: Closure Type, Container Type, and Ingredient Function. Separate table due to large number of valid values.
- Table C: Unit of Measure. Refers to UCUM, an external standard
- Table D: Country Code. Refers to NCIt GENC, an external standard
- Table E: IPC Test Category and IPC Test Subcategory to present the relationship between values of the two elements
- Table F: Unit Operation Category and Unit Operation Subcategory to present the relationship between the values of the two elements

A: Data elements with limited number of valid values

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
1	**Acceptance Criteria Usage**	Release	C134029	For determination of acceptability for use of a material, drug or a drug substance. NOTE: The "use" could be for distribution, marketing, further manufacturing stages.
		Stability	C134030	For determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.
2	**Batch Usage** (IPC Batch Usage)	commercial	C133990	A product batch intended for commercial scale and/or marketing.
		development	C133991	A batch produced during the characterization and process definition for the desired product. Note: This covers trial batches, exhibit batches
		Clinical	C133992	A batch produced for use in clinical trials.
		validation	C133993	A batch intended for use in verification and demonstration of suitability of the designed process. A collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. [Source: Process Validation Guidance -- https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf]
		bioequivalence	C133994	A batch produced and used for the purposes of determining bioequivalence of the product. Note: Also called bio-batch
		stability study	C185328	A batch placed under study to determine the maintained performance parameters over time.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
3 *	**Capsule Shell Part Classification Category**	Hard Gelatin Capsule		A cylindrical shaped shell with rounded ends consisting of two parts, a body and cap, and composed largely of gelatin in which one or more drug substances and/or inert materials are enclosed.
		Hard HPMC Capsule		A cylindrical shaped shell with rounded ends consisting of two parts, a body and cap, and composed largely of hydroxypropyl methylcellulose (HPMC) in which one or more drug substances and/or inert materials are enclosed.
		Hard Pullulan Capsule		A cylindrical shaped shell with rounded ends consisting of two parts, a body and cap, and composed largely of pullulan in which one or more drug substances and/or inert materials are enclosed.
		Hard Starch Capsule		A cylindrical shaped shell with rounded ends consisting of two parts, a body and cap, and composed largely of starch in which one or more drug substances and/or inert materials are enclosed.
		Hard PVA Capsule		A cylindrical shaped shell with rounded ends consisting of two parts, a body and cap, and composed largely of polyvinyl alcohol (PVA) copolymer in which one or more drug substances and/or inert materials are enclosed.
		Soft Gelatin Capsule		A one-piece, hermetically sealed soft gelatin shell with liquid, suspension, or semisolid materials enclosed.
4 *	**Coating Product Part Purpose**	Appearance/Identification		A coating applied for the purpose of achieving a specific presentation.
		Consumption Enhancement		A coating applied to facilitate swallowing (e.g., making the tablet smoother, etc.).
		Content Isolation		A coating applied to a component(s) of the tablet (e.g., beads or granules) to mitigate interaction with each other and/or other components. Comment: it is unlikely that a layer in a multilayer tablet would be coated, but if a tablet contains beads or granules, the beads or granules could have coatings. In

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				multi-layer tableting the individual layers must bind/adhere to each other or delamination defects can occur.
		Delayed Release		A coating applied for the purpose of achieving a delayed release profile.
		Drug Layering		A coating applied to deposit API(s) on a surface (i.e., tablet, bead, blend, or other intermediates).
		Extended Release		A coating applied for the purpose of achieving an extended-release profile.
		Irritant Suppression		A coating applied to reduce dispersion within the GI (e.g., prevention of drug-induced irritation at a specific site such as NSAIDs with an enteric coating).
		Odor Masking		A coating applied for the purpose of obscuring or enhancing olfaction.
		Protective		A coating applied for the purpose of ensuring the properties of the contents are not impacted prior to administration (e.g., by moisture, air, light, handling, transportation, etc.) and after administration (e.g., by inactivation of drug in the stomach (acid-labile APIs).
		Site of Action		A coating applied to ensure delivery of API to the site of action (e.g., colon delivery).
		Seal or Non-functional		A coating applied to improve drug product appearance, handling, and/or stability of the dosage form, but has no measurable effect on biopharmaceutical properties of the dosage form.
		Taste Masking		A coating applied for the purpose of obscuring or enhancing gustation.
5	**Dosage Form**	See link in next column		http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm
6	**Ingredient Function Category** (Product	Active Ingredient	C82533	Active ingredient – ingredient that has the pharmacological action.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Part Ingredient Function Category)			
		Adjuvant	C2140	Adjuvant – an ingredient(s) which augments or promotes the pharmacological effect of the active ingredient(s) without itself being considered active (typically used with vaccines).
		Inactive Ingredient	C42637	Inactive ingredient, i.e., ingredients added for a purpose other than the intended pharmacological action. Inactive Ingredient is also referred to as excipient.
7	**Impurity Classification**	Degradation Product	C176816	A molecule resulting from a chemical change brought about over time and/or by the action of something (e.g., light, temperature, pH, water, or by reaction with an excipient and/or the immediate container/closure system). [Source: SME Defined] Examples: decomposition product, oxidation product, hydrolysis, etc.
		Elemental Impurities	C185190	Elements that are found in the environment or that are used or introduced in the manufacture of drug substances or excipients. [Source: USP STIMULI Article, https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/elementalImpuritiesInformation.pdf]
		Residual Solvent	C176815	Inorganic or organic liquids remaining during the manufacturing process. [Source: Adapted from ICH Q3A(R2)]
		Inorganic	C134001	Materials that are not carbon-based and are generated during a manufacturing process that are not part of elemental impurity specification. [Source: SME Defined]
		Process Related/Process	C176812	Impurities that are derived from the manufacturing process. [Source: SME defined - Reviewed ICH - Q6A and Q3] Examples: Small molecules -- starting materials, intermediates, antibiotics, or media components, by-products, etc. Large molecules -- They may be derived from cell substrates (e.g., host cell proteins, host cell DNA), cell culture (e.g., inducers, antibiotics, or media

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				components), or downstream processing (e.g., processing reagents or resin leachables).
		Leachables	C185192	Materials that can migrate from manufacturing systems, container-closure systems, and drug-delivery components. [Source: Adapted from ICH Q3E Concept Paper]
		Product Related	C176813	Molecular variants of the desired product (e.g., precursors, certain degradation products arising during manufacture and/or storage) which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety. [Source ICH Q6B]
		Microbiological	C92081	Microorganism contamination of the cell culture or starting/raw materials that are objectionable due to their detrimental effect on products or potential harm to patients or due to the total number of organisms. [Source: 21CFR211 Preamble] Examples: bacteria, fungi, mollicutes (mycoplasmas or spiroplasmas), mycobacteria, rickettsia, protozoa, parasites, agents causing TSEs and viruses. [Source: Adapted from 21CFR211 Preamble]
8	**Interpretation Code**	NMT (not more than)	C61586	The value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to.”
		NLT (not less than)	C61583	The value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to.”
		MT (more than)	C61584	The value should not be smaller than the given value excluding the given value, which is equivalent to “greater than.”
		LT (less than)	C61585	The value should not be greater than the given value excluding the given value, which is equivalent to “less than.”
		EQ	C48793	A person or thing equal to another in value or measure or force or effect or significance, etc.; being essentially equal to something.
		NA	C48660	Not Applicable

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
9 *	**IPC Time Point**	After		Following a specified step or activity.
		Before		Preceding a specified step or activity.
		During		In concurrence with a specified step or activity.
10	**Manufacturing Site Unique Identifier Type**	DUNS	C134003	Data Universal Number System
		FEI	C134004	Facility Establishment Identifiers
		CFN	C134005	Central File Number
		Unknown	C17998	Unknown
11 *	**Manufacturing Site Responsibility Category**	Manufacturing		A facility that makes a drug product. [Source: SME Defined] Note: This does not include packaging. This is intended to be the intermediate or the bulk drug product and not the finished product. Note: This is referred to as manufactured item in IDMP 11615.
		Packaging		A facility that provides packaging services to protect the drug product against all adverse external influences that may affect its quality or potency as well as prevent leakage and spilling. [Source: SME Defined]
		Testing		A facility that provides drug product related analytic services. For example, release and stability testing, microbiological testing, etc. [Source: SME Defined]
		Other		Any other services provided by the manufacturing site that cannot be classified under Manufacturing, Testing or Packaging. [Source: SME Defined]

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
12 *	**Manufacturing Site Responsibility Subcategory** *(for Packaging)*	Primary Packaging		A Packaging component that is in direct contact with or may come into direct contact with the article. [Source: USP <659>]
		Secondary Packaging		A packaging component that is in direct contact with a primary packaging component and may provide additional protection for the article. [Source: USP <659>]
13 *	**Manufacturing Site Responsibility Subcategory** *(for Testing)*	Chemical/Physical Testing		Procedures that assess the characteristics of a material that are not associated with a change in its composition and basic nature including but not limited to its texture, smell, freezing point, boiling point, melting point, opacity, viscosity, and density. This includes assay. [Source: SME Defined]
		Microbiological testing of nonsterile product		A procedure to determine the bioburden of nonsterile products. [Source: SME Defined] Note: Refer to USP <61> for further clarification.
		Sterility Testing		A procedure to demonstrate the absence of viable contaminating microorganisms. [Source: Adapted from 21 CFR 610.12(b)(3)]
		Biological Potency Testing		The specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				[Source: Guidance for Industry -- Potency Tests for Cellular and Gene Therapy Products].
14 *	**Manufacturing Site Utilization**	Commercial		A facility that is focused on manufacturing drug products only for marketing and distribution purposes for a given function (manufacturing site responsibility category and sub-category).
		Non-commercial		A facility that is focused on manufacturing drug products for development.
		Both commercial and non-commercial		A facility that provides services to manufacture both marketable and development drug products.
15 *	**Product Part Ingredient Name Type**	Brand		The part of the name or logo associated with a specific product or service identifying and distinguishing it from varieties of the same product or service marketed by competing companies.
		CAS Number		A unique numerical identifier assigned, by the Chemical Abstract Service (CAS), a division of the American Chemical Society, to chemical compounds, polymers, biological sequences, mixtures, and alloys. [Source: NCI Thesaurus]
		Generic		A non-branded nor registered name that meant for common use.
		Common		The generally used, literal identifier of the entity.
		Company ID/Code		Identifier or code assigned by the company.
		GSRS Preferred Term		Default display name identified within FDA Global Substance Registration System (GSRS).

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		INN		International Nonproprietary Names (INN) is a unique name that is globally recognized and is public property. Note: International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients [Source: http://www.who.int/medicines/services/inn/en/]
		ISBT 128		It is the global standard for the terminology, identification, coding and labeling of medical products of human origin (including blood, cell, tissue, milk, and organ products). [Source: Information Standard for Blood and Transplant (ISBT) https://www.iccbba.org/]
		IUPAC		A name assigned to a chemical substance according to the systematic nomenclature rules defined by the International Union of Pure and Applied Chemistry (IUPAC) [Source: SME Defined]
		Systematic		A name derived directly from the chemical structure. [Source: SME Defined]
		USAN		A unique nonproprietary name assigned to drugs and biologics and assigned by the United States Adopted Names (USAN) Council [Source: SME Defined]
		USP/NF		A unique nonproprietary name assigned to drugs and biologics and assigned by the United States Pharmacopeia (USP) and excipients by the National Formulary (NF). [Source: SME Defined]
16 *	**Product Part Ingredient Physical Location**	Active core/granulate		A granule, bead or tablet formed from API and other excipients with no applied coating.
		Extragranular		Material resulting from a granulation process (wet or dry) In which the ingredients (e.g., API and excipients) are added externally to the granules (granulates).
		Intragranular		Material resulting from a granulation process (wet or dry) in which the ingredients (e.g., API and excipients) are added to form granules (granulates).

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
17 *	**Product Part Type**	Blend		A constituent composed of a dry mixture of ingredients (e.g., API and/or excipients) mixed in pharmaceutical processing equipment.
		Bead		A constituent composed of small sphere(s). Beads can also be referred to as pellets.
		Capsule Shell		An outer skin in which a medicinal substance is contained.
		Coating		A constituent composed of a thin layer covering the outer surface.
		Dispersion		A constituent in which particles are uniformly distributed throughout a liquid.
		Granules		A constituent composed of dry aggregates of powder particles that may contain one or more APIs, with or without other ingredients.
		Layer		A sheet, quantity, or thickness of material, typically one of several.
		Minitablet		A constituent composed of small tablets that are filled into capsules.
		Solution		A constituent that is a clear, homogeneous liquid containing one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.
		Tablet		A constituent prepared from powders or granules by compaction (with or without API and/or excipients). The tablet may be coated or uncoated.
18	**Quality Standard** (Drug Product Quality Standard; Product Part Ingredient Quality Standard)	USP/NF	C134006	United States Pharmacopeia/National Formulary
		EP	C134007	European Pharmacopoeia

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		JP	C134008	Japanese Pharmacopoeia
		BP	C176793	British Pharmacopoeia
		Company Standard	C134009	A proprietary standard internal to the organization; often also referred to as 'In-house'. Note: If pharmacopeia's other than the 4 listed are used, identify them as Company Standard.
19 *	**Release Profile** (Drug Product Overall Release Profile; Product Part Release Profile)	DR		Delayed-release (DR) products are deliberately modified to delay release of the drug substance for some period of time after initial administration.
		ER		Extended-release (ER) products are formulated in a manner that makes the drug substance available over an extended period of time following administration, compared to that observed or anticipated for an immediate-release dosage form.
		IR		Descriptive term for a dosage form in which no deliberate effort has been made to modify the API release rate (i.e., immediate release [IR]). In the case of capsules and tablets, the inclusion or exclusion of a disintegrating agent is not interpreted as a modification.
		Not Applicable		Determination of a value is not relevant in the current context.
20 *	**Release Mechanism** (Drug Product Overall Release Mechanism;	Matrix		A mechanism that controls drug release by homogeneously distributing the drug throughout a matrix. Drug molecules are released as the matrix dissolves.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Product Part Release Mechanism)			
		Osmotic Pump		A mechanism that contains an osmotic agent that acts to imbibe water from the surrounding medium via a semipermeable membrane which is permeable to water but impermeable to drug. The delivery of the active agent from the device is controlled by water influx across the semipermeable membrane. The drug is forced out of an orifice in the device.
		Reservoir		A mechanism that controls drug release by the thickness and the dissolution rate of the encapsulating membrane surrounding the drug core.
21	**Route of Administration**	See link in the valid value meaning column		https://www.fda.gov/industry/structured-product-labeling-resources/route-administration
22	**Source Type**	Chemical	C48807	A substance with a defined atomic or molecular structure that results from, or takes part in, reactions involving changes in its structure, composition, or properties. [Source: NCI EVS C48807]
		Animal	C14182	A living organism that has membranous cell walls, requires oxygen and organic foods, and is capable of voluntary movement, as distinguished from a plant or mineral. [Source: NCI EVS C14182]
		Microbial	C14329	A microscopic organism. [Source: Adapted from NCI EVS C14329]
		Plant	C14258	Any living organism that typically synthesizes its food from inorganic substances, possesses cellulose cell walls, responds slowly and often permanently to a stimulus, lacks specialized sense organs and nervous system, and has no powers of locomotion. (EPA Terminology Reference System) [Source: NCI EVS C14258]

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		Insect	C14227	A taxonomic class of arthropods that includes praying mantises, dragonflies, grasshoppers, true bugs, flies, bees, wasps, ants, butterflies, moths, and beetles. [Source: NCI EVS C14227]
		Human	C14225	The bipedal primate mammal, Homo sapiens; belonging to man or mankind; pertaining to man or to the race of man; use of man as experimental subject or unit of analysis in research. [Source: NCI EVS C14225]
		Animal-derived indirectly	C18634	A material for which an earlier process step (or an ancillary process) in the manufacturing of the material whose input materials involved animal-derived materials. [Source: SME Defined] – Example: Magnesium Stearate from animal source, BSA
23	**Weight Type** (Drug Product Weight Type)	Mass	C168628	A physical measurement (e.g., weight, genome titer)
		Activity	C45420	Measurement of a property related to therapeutic or biological effect. Examples, enzyme activity, international units, plaque forming units (PFU), radioactivity (MBql)
24	**Weight Operator** (Drug Product Total Weight Operator; Product Part Ingredient Amount Operator)	NMT (not more than)	C61586	The value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to.”
		NLT (not less than)	C61583	The value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to.”
		MT (more than)	C61584	The value should not be smaller than the given value excluding the given value, which is equivalent to “greater than.”

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		LT (less than)	C61585	The value should not be greater than the given value excluding the given value, which is equivalent to “less than.”
		EQ	C48793	A person or thing equal to another in value or measure or force or effect or significance etc.; being essentially equal to something.
		NA	C48660	Not Applicable

B: Controlled Terminologies for Closure Type, Container Type, Product Part Ingredient Function

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
1	**Closure Type**	Child-resistant, Metal	C96113	Metal closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
2	**Closure Type**	Child-resistant, Plastic	C96114	Plastic closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
3	**Closure Type**	Continuous Thread, Metal	C96115	Metal closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic, or metal.
4	**Closure Type**	Continuous Thread, Plastic	C96116	Plastic closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic, or metal.
5	**Closure Type**	Crown, Metal	C96125	A non-threaded shallow draw metal closure that normally has 21 corrugations on the outer edge, which function to engage the container when applied. The crown is only 1/4" high when manufactured and does not have a rolled edge or wire. The crown is manufactured 26mm worldwide and can be applied to either a threaded finish or a solid ring pry-off finish.
6	**Closure Type**	Flip-Top (Dispensing), Plastic	C96128	A hinged single or dual flap closure for controlled product dispensing.
7	**Closure Type**	Hinged (Dispensing), Plastic	C96129	A closure with a lid that is hinged to the top of a closure and opens to expose a dispensing orifice.
8	**Closure Type**	Linerless, Plastic	C96130	A closure that incorporates a specific molded-in feature such as rings, plugs or flexible sections. These features achieve a seal by conforming to one or more of the sealing surfaces on the container neck finish.
9	**Closure Type**	Lug, Metal	C96126	Closure with an ability to be applied and removed with a partial turn. The closure can also be produced with vacuum buttons that can clearly indicate to the packer if a vacuum has been effectively drawn following the closure application.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
10	**Closure Type**	Press-on, Composite	C96124	A metal/plastic composite cap composed of a plastisol lined metal disk, assembled to a plastic band. The closure requires a simple glass bead finish common on bowls, tumblers, and carafes.
11	**Closure Type**	Press-on/twist-off, Metal	C96123	Closure with a stepped, skirted drawn shell with an inside curl. The closure is lined with an annular plastisol material designed to provide a proper seal along the top and side surfaces of the glass container finish. The closure uses a special plastisol material that, following application, takes a permanent impression of the glass threads ensuring cam-off and reseal.
12	**Closure Type**	Pump (Dispensing), Plastic	C96131	Closure dispensing pumps are used to dispense product from containers.
13	**Closure Type**	Push-pull (Dispensing), Plastic	C96132	A two-piece dispensing closure that includes a base member the lower portion of which is designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. The spout member may be moved upward and downward to open and close the dispensing passageway.
14	**Closure Type**	Roll-on, Metal	C96127	A tamper-evident closure produced as an unthreaded shell containing a liner. It is applied to the proper finish on a plastic or glass container by the bottler, using a roll-on capping machine that forms a thread in the closure matching the bottle thread.
15	**Closure Type**	Snap-on Cap, Plastic	C96133	A non-threaded closure that is pressed onto the package finish with a protruding feature that mates with a similar protruding feature on the closure to secure the closure to the package.
16	**Closure Type**	Snip-tip (Dispensing), Plastic	C96134	Conical closure that is turned onto a container. The tip is cut off to open the container.
17	**Closure Type**	Stopper	C96139	Object used to plug opening of container.
18	**Closure Type**	Tamper-evident, Composite	C96120	Composite tamper-evident closures usually consist of a metal disk with a plastic skirt. The plastic skirt is perforated or weakened in some manner so that when the closure is removed, this section is designed to break and either remain on the container or attached to the closure to indicate the package has been opened.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
19	**Closure Type**	Tamper-evident, Metal	C96117	A closure/finish of a closure/container system designed to make it difficult to achieve the first removal of a closure from a container without it being detectable by subsequent users that the package seal has been breached (e.g., aluminum overseal).
20	**Closure Type**	Tamper-evident, Plastic	C96118	A closure that shows the package has been opened and the product has been exposed to the outside environment.
21	**Closure Type**	Tie	C96140	Line, ribbon, or cord used for fastening, or drawing the container closed.
22	**Closure Type**	Toggle-swing (Dispensing), Plastic	C96135	A closure with a lower part attaches securely and seals the container. The upper part provides a second movable portion which functions in a rocker-like pivotal motion between an open and a closed position.
23	**Closure Type**	Trigger Sprayer (Dispensing), Plastic	C96136	Closure designed to dispense product from containers by spraying the product when a trigger is pulled.
24	**Closure Type**	Twist Open/Close (Dispensing), Plastic	C96137	Two-piece dispensing closure that has a lower portion designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. Rotating the spout member opens and closed the container.
25	**Closure Type**	Vacuum, Composite	C96122	Metal/Plastic closures used on packages where the pressure inside the package is less than atmospheric.
26	**Closure Type**	Vacuum, Metal	C96119	Metal closures used on packages where the pressure inside the package is less than atmospheric.
27	**Closure Type**	Vacuum, Plastic	C96121	Plastic closures used on packages where the pressure inside the package is less than atmospheric.
28	**Closure Type**	Valved (Dispensing), Plastic	C96138	Dispensing closure incorporating a product-flow controlling valve within the orifice. Product will not dispense from the package until sufficient squeezing pressure is applied to the flexible container to cause the valve to open.
29	**Container Type**	AMPULE	C43165	A container capable of being hermetically sealed, intended to hold sterile materials.
30	**Container Type**	APPLICATOR	C43166	A pre-filled non-injectable pipette, syringe, or tube.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
31	**Container Type**	BAG	C43167	A sac or pouch.
32	**Container Type**	BLISTER PACK	C43168	A package that consists of molded plastic or laminate that has indentations (viewed as 'blisters' when flipped) into which a dosage form, is placed. A covering, usually of laminated material, is then sealed to the molded part. A strip pack is a specialized type of blister pack where there are no pre-formed or molded parts; in this case there are two flexible layers that are sealed with the dosage form in between. Suppositories that are strip packed between two layers of foil are also considered a blister pack.
34	**Container Type**	BOTTLE	C43169	A vessel with a narrow neck designed to accept a specific closure.
35	**Container Type**	BOTTLE, DISPENSING	C43170	A bottle that is used by the pharmacist to dispense the prescribed medication. It includes preparations for which a dropper accompanies the bottle.
36	**Container Type**	BOTTLE, DROPPER	C43171	A bottle that has a device specifically intended for the application of a liquid in a drop-by-drop manner, or a device intended for the delivery of an exact dose (e.g., calibrated dropper for oral medications).
37	**Container Type**	BOTTLE, GLASS	C43172	A glass vessel with a narrow neck designed to accept a specific closure.
38	**Container Type**	BOTTLE, PLASTIC	C43173	A plastic vessel with a narrow neck designed to accept a specific closure.
39	**Container Type**	BOTTLE, PUMP	C43174	A bottle that is fitted with a pumping mechanism for the administration of drug product.
40	**Container Type**	BOTTLE, SPRAY	C43175	A bottle that is fitted with an atomizer or a device which produces finely divided liquid carried by air.
41	**Container Type**	BOTTLE, UNIT-DOSE	C43176	A bottle that contains a single whole dose of a non-parenteral drug product.
42	**Container Type**	BOTTLE, WITH APPLICATOR	C43177	A bottle which includes a device for applying its contents.
43	**Container Type**	BOX	C43178	A square or rectangular vessel, usually made of cardboard or plastic.
44	**Container Type**	BOX, UNIT-DOSE	C43179	A box that contains a single dose of a non-parenteral drug product. [Note: Boxes that contain 100 unit dose blister packs should be classified under

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				blister pack, since this is the immediate container into which the dosage form is placed.]
45	**Container Type**	CAN	C43180	A cylindrical vessel, usually made of metal.
46	**Container Type**	CANISTER	C43181	A type of can for holding a drug product.
47	**Container Type**	Canisters, lined	C96143	A round container that has an inner layer of a material different from what the canister is composed of.
48	**Container Type**	CAPSULE	C92708	A drug packaging type usually in a cylindrical shape with rounded ends. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials, may be soft or hard, and are filled with solid or liquid drug products. It is not intended to be swallowed (like the dosage form) but instead is holding the drug such as for an inhalation powder or for oral granules intended only for sprinkling.
49	**Container Type**	CARTON	C43182	A cardboard box or container which is usually considered a secondary packaging component.
50	**Container Type**	CARTRIDGE	C43183	A container consisting of a cylinder with a septum at one end, and a seal at the other end, which is inserted into a device to form a syringe which contains a single dose of a parenteral drug product.
51	**Container Type**	CASE	C43184	A receptacle for holding something (e.g., that into which some oral contraceptive blister packs are placed).
52	**Container Type**	CELLO PACK	C43185	A plastic 'clamshell' [thin plastic pre-formed structure for a device].
53	**Container Type**	CONTAINER	C43186	An object that can be used to hold things.
54	**Container Type**	CUP	C43187	A bowl-shaped container.
55	**Container Type**	CUP, UNIT-DOSE	C43188	A cup intended to hold a single dose of a non-parenteral drug product.
56	**Container Type**	CYLINDER	C43189	A container designed specifically to hold gases.
57	**Container Type**	DEWAR	C43190	A container, usually made of glass or metal, that has at least two walls with the space between each wall evacuated to prevent the transfer of heat. The inside of the container often has a coating (as silvering) on the inside to reduce heat

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				transfer, and is used especially for storing liquefied gases or for experiments at low temperatures. The size can vary from that of a small thermos bottle up to that which may be mounted upon a large truck (also known as a 'cryogenic truck').
58	**Container Type**	DIALPACK	C43191	A dose pack container designed to assist with patient compliance. The patient turns a dial to the correct day and the correct dose is made available and the container indicates that the dose has been removed.
59	**Container Type**	Dish, Petri	C96141	A shallow dish with a lid used to culture cells.
60	**Container Type**	DOSE PACK	C43192	A container in which a preselected dose or dose regimen of the medication is placed.
61	**Container Type**	DRUM	C43193	A straight-sided cylindrical shipping container with flat ends; one of which can be opened/closed.
62	**Container Type**	Flask	C96144	A container with a base wider than the narrow neck traditionally used for holding liquids.
63	**Container Type**	FLEXIBLE INTERMEDIATE BULK CONTAINER	C79135	A receptacle with a body constructed of film, woven plastic, woven fabric, paper, or combination thereof, together with any appropriate service equipment and handling devices, and if necessary, an inner coating or liner.
64	**Container Type**	INHALER	C16738	A device by means of which a medicinal product can be administered by inspiration through the nose or the mouth.
65	**Container Type**	INHALER, REFILL	C43194	A container of medication intended to refill an inhaler.
66	**Container Type**	JAR	C43195	A rigid container having a wide mouth and often no neck which typically holds solid or semisolid drug products.
67	**Container Type**	JUG	C43196	A large, deep container that has a narrow mouth, is typically fitted with a handle, and is used to hold liquids.
68	**Container Type**	KIT	C43197	A packaged set of related pharmaceutical or and/or drug delivery devices used for a particular medical activity or procedure including required documentation for kit components and the entire kit.
69	**Container Type**	NOT STATED	C48626	The package type is not stated or is unavailable.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
70	**Container Type**	PACKAGE	C43233	The drug product container with any accompanying materials or components. This may include the protective packaging, labeling, administration devices.
71	**Container Type**	PACKAGE, COMBINATION	C43198	A package in which two or more drug products that are normally available separately are now available together.
72	**Container Type**	PACKET	C43199	An envelope into which only one dose of a drug product, usually in the form of granules or powder, has been directly placed. Examples include aluminum foil packets into which alcohol swabs and pledgets are placed.
73	**Container Type**	PAIL	C79136	A watertight vessel, often cylindrical, that is usually fitted with a handle, and that may have a lid.
74	**Container Type**	PATCH	C82332	A drug delivery system that often contains an adhesive backing that is usually applied to an external site on the body. Its ingredients either passively diffuse from, or are actively transported from, some portion of the patch. Depending upon the patch, the ingredients are either delivered to the outer surface of the body or into the body.
75	**Container Type**	Plate, Microwell	C96142	A flat dish type device with multiple wells for testing cellular material.
76	**Container Type**	POUCH	C43200	A flexible container used to protect or hold one or more doses of a drug product (e.g., a pouch into which oral contraceptive blister packs are inserted, and an overwrap pouch for large volume parenterals).
77	**Container Type**	SUPERSACK	C43201	A multilayer paper bag for shipping some solid bulk excipients, usually in the form of powder or granules.
78	**Container Type**	SYRINGE	C43202	A device for the administration of drug products that consists of a rigid barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.
79	**Container Type**	SYRINGE, GLASS	C43203	A device for the administration of parenteral drug products that consists of a rigid glass barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.
80	**Container Type**	SYRINGE, PLASTIC	C43204	A device for the administration of parenteral drug products that consists of a rigid plastic barrel fitted with septum with a plunger at one end and a seal or

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				needle at the other end. The needle assembly may be part of the device or separate.
81	**Container Type**	TABMINDER	C43205	A specialized package; it registers each time it is opened and is used for checking patient compliance to prescribed medication regimens.
82	**Container Type**	TANK	C43206	A large receptacle used for holding, transporting, or storing liquids or gases, and often referred to as a reservoir.
83	**Container Type**	TRAY	C53438	A shallow flat receptacle, with a raised edge or rim, used for carrying, holding, or displaying finished drug product in its primary or market package. A tray and its contents may be encased in shrink-wrapped plastic for shipping, or with a cover or an overwrap as part of a unit of use package or kit.
84	**Container Type**	TUBE	C42794	A flexible container for semisolid drug products which is flattened and crimped or sealed at one end and has a reclosable opening at the other.
85	**Container Type**	TUBE, WITH APPLICATOR	C43207	A tube which is provided with a device (the applicator) for administering the dosage form. The applicator may be part of the tube closure or be separate.
86	**Container Type**	VIAL	C43226	A container designed for use with parenteral drug products.
87	**Container Type**	VIAL, DISPENSING	C43208	A vial that is used by the pharmacist to dispense the prescribed medication.
88	**Container Type**	VIAL, GLASS	C43209	A glass container designed for use with parenteral drug products.
89	**Container Type**	VIAL, MULTI-DOSE	C43210	A vial intended to contain more than one dose of the drug product.
90	**Container Type**	VIAL, PATENT DELIVERY SYSTEM	C43211	A vial that has a patented delivery system.
91	**Container Type**	VIAL, PHARMACY BULK PACKAGE	C43212	A container of a sterile preparation whose contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.
92	**Container Type**	VIAL, PIGGYBACK	C43213	A vial that contains a parenteral preparation that can be attached directly to the tubing of a parenterally administered fluid.
93	**Container Type**	VIAL, PLASTIC	C43214	A plastic container designed for use with parenteral drug products.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
94	**Container Type**	VIAL, SINGLE-DOSE	C43215	A vial containing a single unit of a parenteral drug product.
95	**Container Type**	VIAL, SINGLE-USE	C43216	A vial where a single dose of a parenteral drug product can be removed, and then the vial and its remaining contents can be disposed.
96	**Product Part Ingredient Function**	Absorption modifier	C176637	An excipient included in formulations to improve the absorption of a pharmacologically active drug (e.g., permeation enhancer; transmucosal absorption enhancer; intestinal permeation enhancer; delivery agent; penetration enhancer; transdermal delivery agent).
97	**Product Part Ingredient Function**	Adhesive	C89528	Substance capable of bonding together two surfaces (e.g., bioadhesive material).
98	**Product Part Ingredient Function**	Adsorbent	C176642	Agent used to bind another component from within a formulation, acting as a carrier, reservoir or sequestrant (e.g., water-absorbing agent). (Adapted from Medicinescomplete)
99	**Product Part Ingredient Function**	Air displacement	C176643	Agent used to replace air in a product or pack with a gas phase of known composition during manufacturing. Example is widely used In reactors/mixing tanks with liquid products (e.g., air overlay; gas blanket). (Adapted from Medicinescomplete)
100	**Product Part Ingredient Function**	Anticaking agent	C42654	Agent added to improve powder flow. Used to promote powder flow and to reduce the caking or clumping that can occur when powders are stored in bulk. In addition, glidants and anticaking agents reduce the incidence of bridging during the emptying of powder hoppers and during powder processing. (e.g., glidant). (Adapted from Medicinescomplete)
101	**Product Part Ingredient Function**	Antioxidant	C275	Agent used to stabilize a system against oxidative degradation. (Adapted from Medicinescomplete)
102	**Product Part Ingredient Function**	Binder	C42647	Impart cohesive qualities to powdered material (e.g., binding agent or wet binder). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
103	**Product Part Ingredient Function**	Buffering agent	C70815	Agent used to stabilize pH within a defined range. (Adapted from Medicinescomplete)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
104	**Product Part Ingredient Function**	Bulking agent	C176644	To provide a pharmaceutically elegant freeze-dried cake. (Adapted from USP <1059>)
105	**Product Part Ingredient Function**	CAPSULE	C92708	A drug packaging type usually in a cylindrical shape with rounded ends. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials, may be soft or hard, and are filled with solid or liquid drug products.
106	**Product Part Ingredient Function**	Carrier	C176645	Agents designed to interact with, and enhance the properties, of active pharmaceutical ingredients (APIs). Carrier excipients promote various ingredient qualities and have become a valuable asset for drug formulators. Used to help deposit the active ingredient in the lung and may have a secondary role in diluting the active to ensure that dosages can be properly metered (e.g., solid carrier; sorbent; carbon dioxide). (Adapted from American Pharmaceutical Review)
107	**Product Part Ingredient Function**	Chelating agent	C360	Used to sequester ions from solution and to form stable complexes (e.g., sequestering agent). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
108	**Product Part Ingredient Function**	Coloring agent	C42656	Agent to impart hue to a component (e.g., color retention agent, dye).
109	**Product Part Ingredient Function**	Complexing agent	C176646	Agent added to combine with another component, commonly to maintain or improve solubility or chemical stability. (Adapted from Medicinescomplete)
110	**Product Part Ingredient Function**	Cryoprotectant	C53306	Agent added to prevent cell damage during freeze-drying. (Adapted from Medicinescomplete)
111	**Product Part Ingredient Function**	Denaturant	C176647	Agent added to make unfit to drink an ethanol containing product.
112	**Product Part Ingredient Function**	Disintegrant	C42648	An agent used to facilitate breakup or disintegration after administration. Functional components that are added to formulations to promote rapid disintegration into smaller units and to allow a drug substance to dissolve more rapidly. (Pharmaceutical Excipients: A review Shilpa P Chaudhari and

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
113	**Product Part Ingredient Function**	Dispersing agent	C42662	Agent added to prevent aggregation in liquid formulations. (Adapted from Medicinescomplete)
114	**Product Part Ingredient Function**	Effervescent agent	C176638	Effervescent excipients are used in powders and tablets. They are commonly used with acidic agents to cause a reaction that produces carbon dioxide. The carbon dioxide leads to a fizzing of the effervescent powder. (Adapted from American Pharmaceutical Review)
115	**Product Part Ingredient Function**	Emollient	C176632	Agent added to topical formulations to promote softening of the skin. Used in topical preparations to impart lubrication, spreading ease, texture, and softening of the skin and to counter the potentially drying/irritating effect of surfactants on the skin (e.g., skin protectant). (Adapted from Medicinescomplete)
116	**Product Part Ingredient Function**	Emulsifying Excipient	C73477	Agent added to promote mixing of immiscible phases (e.g., fluorocarbon emulsifying agent; emulsifier; emulsifying salt). (Adapted from Medicinescomplete)
117	**Product Part Ingredient Function**	Emulsion stabilizing agent	C176633	Agent added to improve stability against phase separation. (Adapted from Medicinescomplete)
118	**Product Part Ingredient Function**	Filler	C42650	Make up the bulk of solid unit dosage forms when drug itself is inadequate to produce the bulk. Components that are incorporated into tablet or capsule dosage forms to increase dosage form volume or weight (e.g., diluent; dry powder inhalation; bulking agent). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)
119	**Product Part Ingredient Function**	Film coating agent	C176648	Agent used to produce a cosmetic or functional layer on the outer surface of a dosage form. Agents used to mask unpleasant tastes or odors, improve ingestion and appearance, protect active ingredients from the environment, and modify the release of the active ingredient or product subcomponent (e.g., coating agent; film-forming agent; film former; granulating agent; granulating fluid; film-coating dispersion medium). (Adapted from Medicinescomplete)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
120	**Product Part Ingredient Function**	Foam stabilizing agent	C176634	Agent added to improve physical stability of foam (e.g., foaming agent). (Adapted from Medicinescomplete)
121	**Product Part Ingredient Function**	Free radical scavenger	C176649	Used to preferentially interact with oxidative or reductive free radicals that otherwise would result in degradation of formulation components. (Adapted from USP <1059>)
122	**Product Part Ingredient Function**	Gelling agent	C176650	Agent added to produce a gel texture in a product. (Adapted from Medicinescomplete)
123	**Product Part Ingredient Function**	Humectant	C176651	Humectants can be used in topical dosage forms to increase the solubility of a chemical compound's active ingredients, increasing the active ingredients' ability to penetrate skin, or its activity time. Examples: propylene glycol, sorbitol solution, ammonium alginate, cyclomethicone, glycerin, polydextrose, sodium hyaluronate, and sodium lactate.
124	**Product Part Ingredient Function**	Ink	C42657	A colored fluid or paste used for writing, drawing, typically used to identify a product and its strength.
125	**Product Part Ingredient Function**	Lubricant	C42653	Agent added to reduce friction effects during processing or use. Used to reduce the frictional forces between particles and between particles and metal-contact surfaces of manufacturing equipment (e.g., tablet ejection; antiadherent; antistat; glidant). (Adapted from Medicinescomplete)
126	**Product Part Ingredient Function**	Lyophilization aid	C176652	Agent added to produce suitable physical properties in a freeze-dried product. (Adapted from Medicinescomplete)
127	**Product Part Ingredient Function**	Matrix-forming agent	C176653	Polymers added to sustained release formulations to control and maintain the rigidity of the matrix over a prolonged period (e.g., sustained-release agent; matrix for sustained release; rate-controlling polymer for sustained release). (Adapted from "The Role of Oral Controlled Release Matrix Tablets in Drug Delivery Systems", Ali Nokhodchi1, Shaista Raja1, Pryia Patel1, Kofi Asare-Addo BioImpacts, 2012, 2 (4), 175-187)
128	**Product Part Ingredient Function**	Microencapsulating agent	C176654	Agent used to form microcapsules with desirable physical properties. (Adapted from Medicinescomplete)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
129	**Product Part Ingredient Function**	Ointment base	C176655	A nonaqueous vehicle for topical products. The major component of an ointment and controls its physical properties. (Adapted from Medicinescomplete)
130	**Product Part Ingredient Function**	Opacifier	C176656	Agent added to reduce light transmission in a product (e.g., opacifying agent). (Adapted from Medicinescomplete)
131	**Product Part Ingredient Function**	Organoleptic agent	C176635	An agent added to modify color, flavor, taste (e.g., flavoring agent; flavor enhancer; sweetening agent; taste-masking agent).
132	**Product Part Ingredient Function**	Osmotic agent	C176657	Material used to provide osmotic pressure differential in osmotic pump-based drug product delivery systems.
133	**Product Part Ingredient Function**	pH modifier	C176658	Substance added to alter the acidity or basicity (e.g., acidity regulator; acidifying agent/alkalizing agent; acid; base).
134	**Product Part Ingredient Function**	Plasticizer	C55826	Agent added to promote flexibility of films or coatings (e.g., plasticizing agent). (Adapted from Medicinescomplete)
135	**Product Part Ingredient Function**	Polishing agent	C176659	Agent used to impart an attractive sheen to coated tablets (e.g., tablet polishing agent).
136	**Product Part Ingredient Function**	Polymers for ophthalmic use	C176660	Used in ophthalmic preparations to enhance the retention of active ingredients by reducing the amount of product that is lost from the eye when the patient blinks. In addition, polymers also can be components of artificial tears. (Adapted from USP <1059>)
137	**Product Part Ingredient Function**	Preservative	C42659	An agent added to extend the shelf-life of a formulation (e.g., antibacterial agent; antifungal agent preservative; fungicides; antimicrobial preservative; antiviral agent preservative; viricides; sterilizing agent; glazing agent).
138	**Product Part Ingredient Function**	Propellant	C176661	Developing pressure in container which expels the product. Used in pharmaceuticals (nasal sprays and respiratory and topical formulations), cosmetics, and foods to provide force to expel contents from a container (e.g., aerosol propellant). (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India. USP <1059>)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
139	**Product Part Ingredient Function**	Reducing agent	C176639	Reduces oxidation state of product component to produce desired active component/ingredient.
140	**Product Part Ingredient Function**	Release modifying agent	C176662	Substances added to the formulation to alter the release profile of the active substance (e.g., release modifier; release agent; modifying agent; extended-release agent; controlled release agent; latex particle coating agent).
141	**Product Part Ingredient Function**	Solubilizing agent	C176640	Enhance solubility of the active substance. (Pharmaceutical Excipients: A review Shilpa P Chaudhari and Pradeep S Patil Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune, Maharashtra, India.)
142	**Product Part Ingredient Function**	Solvent	C45790	The liquid in which a solute is dissolved to form a solution.
143	**Product Part Ingredient Function**	Stabilizer	C176636	Agent added to preserve product integrity and prevent degradation (e.g., stabilizing agent; colloid stabilizing agent).
144	**Product Part Ingredient Function**	Suppository base	C176663	Agent used as the carrier for other ingredients in suppository formulations. Used in the manufacture of suppositories (for rectal administration) and pessaries (for vaginal administration). They can be hydrophobic or hydrophilic, (Adapted from Medicinescomplete)
145	**Product Part Ingredient Function**	Surfactant	C42739	Substances used to enhance stability by reducing surface tension (e.g., anionic surfactant; cationic surfactant; nonionic surfactant).
146	**Product Part Ingredient Function**	Suspending agent	C42660	A non-surface active polymer or a surface-active substance added to a suspension, to improve the separation of particles and to prevent settling or clumping (e.g., dispersing agent).
147	**Product Part Ingredient Function**	Tonicity agent	C176641	Agent added to alter osmotic potential of liquid formulations. (Adapted from Medicinescomplete)
148	**Product Part Ingredient Function**	Transdermal delivery component	C176664	A component of a transdermal system otherwise not covered by other terms.
149	**Product Part Ingredient Function**	Transfer ligand	C176665	Used in the preparation radiopharmaceuticals to transfer a relatively weak chelating ligand to the principal chelating ligand or complexing moiety. (USP <1059>)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
150	**Product Part Ingredient Function**	Vehicle	C927	A substance that facilitates the use of a drug, or other material mixed with it, not covered by other terms (e.g., oleaginous vehicle).
151	**Product Part Ingredient Function**	Viscosity modifier	C176666	Viscosity modifiers are designed to change the thickness or texture of pharmaceutical ingredients. Viscosity modifiers can include such products as thickeners, texturizers, gelation agents and stiffening agents (e.g., stiffening agent; thickener; thickening agent; viscosity-increasing agent; firming agent). (Adapted from American Pharmaceutical Review)
152	**Product Part Ingredient Function**	Water-repelling agent	C176667	An agent used to enhance hydrophobic properties.
153	**Product Part Ingredient Function**	Wetting agent	C176668	An agent added to a liquid to reduce its surface tension and make it more effective in spreading over and penetrating surfaces.

C: Controlled Terminologies for Units Of Measure

PQ/CMC uses the UCUM standard for expressing units of measure. The table below identifies a subset of UCUM values commonly used in CMC submissions, but is not comprehensive list.

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
1	Unit of Measure	%	Percent Unit	C48570
2	Unit of Measure	%{VolumeToVolume}	Percent Volume per Volume	C48571
3	Unit of Measure	%{WeightToVolume}	Percent Mass per Volume	C48527
4	Unit of Measure	%{WeightToWeight}	Percent Mass per Mass	C48528
5	Unit of Measure	(m2.d)	Unit per Square Meter per Day	C73783
6	Unit of Measure	[Btu]	British Thermal Unit	C67196
7	Unit of Measure	[CFU]	Colony Forming Unit	C68742
8	Unit of Measure	[degF]	Degree Fahrenheit	C44277
9	Unit of Measure	[EU]	Ehrlich Unit	C96599
10	Unit of Measure	[in_i]	Inch	C48500
11	Unit of Measure	[IU]	International Unit	C48579
12	Unit of Measure	[lb_av]	Pound	C48531
13	Unit of Measure	[lbf_av]	Linear Foot Pound	C139134
14	Unit of Measure	[oz_av]	Ounce	C48519
15	Unit of Measure	[pH]	pH	C45997
16	Unit of Measure	[ppb]	Part Per Billion	C70565
17	Unit of Measure	[ppm]	Part Per Million	C48523
18	Unit of Measure	[ppth]	Part per Thousand	C69112
19	Unit of Measure	[pptr]	Part Per Trillion	C70566
20	Unit of Measure	[psi]	Pound per Square Inch	C67334
21	Unit of Measure	[pt_us]	Pint	C48529
22	Unit of Measure	[qt_us]	Quart Dry US	C69118
23	Unit of Measure	{actuation}	Actuation Dosing Unit	C122629
24	Unit of Measure	{can}	Can Dosing Unit	C48479
25	Unit of Measure	{tbl}	Tablet Dosing Unit	C48542
26	Unit of Measure	{tot}	Particle Total Count	C171022
27	Unit of Measure	{vial}	Vial Dosing Unit	C48551

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
28	Unit of Measure	a	Year	C29848
29	Unit of Measure	Cel	Degree Celsius	C42559
30	Unit of Measure	cm	Centimeter	C49668
31	Unit of Measure	mL	Milliliter	C28254
32	Unit of Measure	d	Day	C25301
33	Unit of Measure	deg	Degree Unit of Plane Angle	C68667
34	Unit of Measure	g	Gram	C48155
35	Unit of Measure	gal	Gallon US	C48580
36	Unit of Measure	h	Hour	C25529
37	Unit of Measure	K	Kelvin	C42537
38	Unit of Measure	kg	Kilogram	C28252
39	Unit of Measure	kgf	Kilogram-Force	C70471
40	Unit of Measure	ku	Kilodalton	C105491
41	Unit of Measure	L	Liter	C48505
42	Unit of Measure	m	Meter	C41139
43	Unit of Measure	m2	Square Meter	C42569
44	Unit of Measure	m3	Cubic Meter	C42570
45	Unit of Measure	mg	Milligram	C28253
46	Unit of Measure	mg%	Milligram per Deciliter	C67015
47	Unit of Measure	min	Minute	C48154
48	Unit of Measure	mm	Millimeter	C28251
49	Unit of Measure	mmol	Millimole	C48513
50	Unit of Measure	mo	Month	C29846
51	Unit of Measure	mol	Mole	C42539
52	Unit of Measure	mosm	Milliosmole	C67318
53	Unit of Measure	ms	Millisiemens	C176690
54	Unit of Measure	N	Newton	C42546
55	Unit of Measure	ng	Nanogram	C48516
56	Unit of Measure	nm	Nanometer	C67328
57	Unit of Measure	nmol	Nanomole	C48517
58	Unit of Measure	pg	Picogram	C64551
59	Unit of Measure	pmol	Picomole	C65045

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
60	Unit of Measure	rad	Radian	C42543
61	Unit of Measure	s	Second	C42535
62	Unit of Measure	u	Unified Atomic Mass Unit	C41127
63	Unit of Measure	u	Atomic Mass Unit	C64559
64	Unit of Measure	U	Enzyme Unit	C64778
65	Unit of Measure	ug	Microgram	C48152
66	Unit of Measure	uL	Microliter	C48153
67	Unit of Measure	um	Micron	C48510
68	Unit of Measure	umho	Microsiemens	C154859
69	Unit of Measure	umol	Micromole	C48509
70	Unit of Measure	wk	Week	C29844

D: Controlled Terminologies for NCIt GENC Country Codes

All Country Codes used in PQ/CMC are available via the spreadsheet on the NCIt site at: https://evs.nci.nih.gov/ftp1/FDA/PQCMC/PQCMC_NCIt_Subsets.xls.

The Geopolitical Entities, Names, and Codes (GENC) country codes are available in the GENC worksheet of the spreadsheet linked above.

E: Controlled Terminologies for IPC Test Category and IPC Test Subcategory

These value lists have not yet been registered in NCI Thesaurus and therefore the NCIt concept codes are not presented in the table below.

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
1	**Assay**	Tests which measure the content of the active ingredient in the drug substance or drug product of a substance. Synonymous with strength or purity which is commonly used of define the content of the active ingredient in a drug product. Note: chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio	Active ingredient	Tests that verify the content and potency of a pharmaceutical substance that is intended effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.
			Adventitious agents (safety)	In vitro and in vivo assays for detection of unintended agents such as viral, bacterial, fungal agents which have undesirable adverse impact on patient's health.
			Amino acid content	Methodology used to determine the amino acid composition or content of proteins, peptides, and other pharmaceutical preparations

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Bioburden	Test that screens for aerobic mesophilic bacteria and fungi.
			Cell and gene therapy Product characterization assay	Tests to determine Cell and Gene therapy product properties. Examples: Viability, Cell number, Morphology, Cell surface markers, Secreted molecules, Gene expression, Genetic stability, percent recovery, gene expression, cell surface marker expression, proliferation capacity, total cell number, cell morphology, cell distribution in scaffold, total volume of scaffold, cellular pattern, vector genome concentration, vector infectious titer assay, replication competence assay, DNA homogeneity, transduction efficiency, vector genome concentration, vector infectious titer assay, Replication competence assay [Source: SME Defined]
			Counterion content	Tests that measure the secondary ion of a drug salt.
			Excipient	Testing of the amount of material other than the active or adjuvant.
			Host cell DNA	Measurement of DNA that comes from cell substrate used to make the viral particles.
			In-vitro or in-vivo test for viral contaminants	Test used to measure viral contamination both by in vitro and in vivo assays

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Nucleic acid content	Tests designed to reveal the presence of a particular nucleic acid from a test sample.
			Percent conjugate	Test to determine the percentage of total protein that functions in interaction with other (non-polypeptide) chemical groups attached by covalent bonding.
			Purity	Testing methods to identify actives and indirectly measure impurities that may be present in a medicine. Examples of analytical procedures for this test subcategory include SDS-PAGE and HPLC.
			Solvate content	Identification of hydrates or solvates by the assay of water of crystallization or solvent found in the crystal.
			Total protein	Test to determine total protein concentration in the product
2	**Bulk Density**	Tests that determine the ratio of the mass of an untapped powder sample and its volume including the contribution of the interparticulate void volume.		
3	**Conductivity**	Electrical conductivity is a measure of the ion-facilitated electron flow through it.		
4	**Container Closure Integrity**	Tests for the adequacy of pharmaceutical packaging and container closures.		

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
5	**Crystallinity**	The detection and/or quantification of the amount of amorphous material within a highly crystalline substance.		
6	**Cytotoxicity**	Test methods designed to evaluate the acute adverse biological effects of extractables from medical device materials.		
7	**Deliverable Volume/Fill Volume**	Tests designed to provide assurance that oral liquids will, when transferred from the original container, deliver the volume of dosage form that is declared on the label of the article.		
8	**Disintegration**	Test to determine whether tablets capsules disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions.		
9	**Dissolution**	Test to determine compliance with the requirements of the material of interest dissolving into solution. A dosage unit is defined as 1 tablet or 1 capsule or the amount specified.		
10	**Droplet Size**	Tests that determine the size of the liquid drop [Source: SME Defined]		
11	**Elemental Analysis**	The relative proportion of elements present		
12	**Foreign and Particulate Matter**	Tests for injections or infusions to check for insoluble particles to confirm that they are not present in excess of specified	Metal detection	Tests for metallic particles to confirm that they are not present in excess of specified levels. [Source: SME Defined]

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
		levels in the solutions [Source: Adapted from ICH Q4B Annex 3(R1)].		
13	**Friability**	The percent loss of a tablet due to mechanical action that results in fracture or breaking during the test		
14	**Functional Assays**	Functional assay used to quantify functioning of an active substance rather than just its quantity. Common uses are: showing that a drug target fits the desired functionality and quality profile before moving on to the next stage of development; and comparison of biosimilars with innovator products.		
15	**Hardness**	A test used to identify the ability of a material to resist mechanical deformation such as scratching or penetration by other substances.		
16	**Identification**	Tests that establish the characteristic and uniqueness of the substance of interest and should be able to discriminate between compounds of closely related structures which are likely to be present. [Source: ICH Q6A]		
17	**Impurity**	Analytical procedures to establish material purity by determining the presence of a material or component of a material that is not defined as the material.	Elemental impurity	Analytical procedures that determine the amount of single elements in drug products or drug product components.

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Identified impurity under IT that is monitored as unspecified	Identification (chemical name and/or UNII code) of all the identified (known) impurities that are being controlled as "unspecified impurities" rather than "Specified Identified Impurity" due to the level being consistently below the ICH identification threshold (IT) value. Note: this includes degradation products for tests conducted on drug products. [Source: SME Defined]
			Impurities/Degradation Products/Related Substances	Tests that establish the characteristic and uniqueness of the substance of interest and should be able to discriminate between compounds of closely related structures which are likely to be present. Includes leachables and extractables.
			Impurity chemical	Analytical procedures to establish chemical purity by determining the presence of a component of the material that is not the chemical entity defined as the material.
			Residual solvent	Tests performed to determine if organic volatile chemicals that are used or produced in manufacture of drug substance or excipients, or in the preparation of drug products are present in the pharmaceuticals. [Source: Adapted from USP <467>] BACKGROUND: For pharmacopeial purposes, residual solvents in pharmaceuticals are defined as organic

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
				volatile chemicals that are used or produced in the manufacture of drug substances or excipients, or in the preparation of drug products.
			Specified identified impurity	Testing for an impurity that is individually listed and limited with a specific acceptance criterion in the new drug substance or drug product specification and for which a structured characterization has been achieved. Note: this includes degradation products for tests conducted on drug products. [adapted from ICH Q3A (R2) & Q3B (R2)]
			Specified unidentified impurity	Testing for an impurity that is individually listed and limited with a specific acceptance criterion in the new drug substance or drug product specification and that is defined solely by qualitative analytical properties (e.g., chromatographic retention time) due to the lack of achieving a structured characterization. Note: this includes degradation products for tests conducted on drug products. [adapted from ICH Q3A (R2) & Q3B (R2)]
			Total impurities	The sum of all impurities at a level greater than (>) the reporting threshold. Note: this includes degradation products for tests conducted on drug products. [adapted from ICH Q3A (R2) & Q3B (R2)]

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Total unknown Impurities	The sum of unknown (unidentified) impurities in a new drug substance or drug product specification. Note: Total impurities includes all impurities while Total Unknown impurities only includes all the unknown impurities. [Source: SME Defined]
			Unspecified impurity	Testing for an impurity that is limited by a general acceptance criterion, but not individually listed with its own specific acceptance criterion, in the new drug substance or drug product specification. Note: this includes degradation products for tests conducted on drug products. [adapted from ICH Q3A (R2) & Q3B (R2)]
18	**Loss on Drying**	Analytical procedures to determine the amount of volatile matter of any kind that is driven off under the conditions specified.		
19	**Material Properties/ Measurements**	Dimensions and physical properties of the material of interest including tablets, capsule, soft gel capsule, granulate or pellet, etc.	Drilled side (single or double)	An observation if one or both sides of the unit dose has been drilled. [Source: SME Defined]
20	**Material Properties/ Measurements**		Group/Average Fill Weight	The sum total weights of material of interest across multiple units divided by the number of units included in the sum. Example: 790-810 mg, 100 mg (weight of 10 tablets), 10 mg (per tablet) note: for a QS or IPC this is likely a range

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
				but as a result it would be a single value Note: the unit would indicate if the value represents a total weight of the group or the average weight across the group - both values could be provided [Source: SME Defined]
			Group/Average Weight	The sum total weights of the material of interest units or sum total of the material of interest divided by the number of units included in the sum. Example: 790-810 mg, 100 mg (per 10), 10 mg (per tablet) note: for a QS or IPC this is likely a range but as a result it would be a single value Note: the unit would indicate if the value represents a total weight of the group or the average weight across the group - both values could be provided [Source: SME Defined]
			Individual Fill Weight	The weight of material of interest within a single unit. Example: 1 gram (in each vial), 200 mg (in each capsule) note: could be a capsule, vial, or bottle note: for a QS or IPC this is likely a range but as a result it would be a single value [Source: SME Defined]
			Individual Weight	The weight of a single unit of the material of interest. Examples: 800 mg (a tablet) [Source: SME Defined]
			Lock length	The length of a straight line measurement from the longest edge-to-edge distance

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
				through a Capsule body and cap that have been coupled such that the locking rings are sealed as designed. [Source: SME Defined]
			Number of orifices	The total count of holes drilled in the unit dose [Source: SME Defined]
			Orifice depth	The measurement of the penetration of the hole drilled in the unit dose as measured from the outer edge to the deepest point of penetration. [Source: SME Defined]
			Orifice diameter	The length of a straight line measurement across the center of the hole drilled in the unit dose. [Source: SME Defined]
			Orifice location	The position of hole drilled in the unit dose. [Source: SME Defined]
			Ribbon density	The compactness of a continuous sheet of compressed material in preparation for subsequent processing [Source: adapted from NCIt Density]
			Ribbon thickness	The dimension between two surfaces of a continuous sheet of compressed material in preparation for subsequent processing. [Source: adapted from NCIt Thickness]
			Seam thickness	The measurement of overlap common to two edges of the same material joined together. Example: 1 mm [Source: SME Defined]

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Shell weight	The weight of outer casing ("shell") into which material of interest is filled. Example: 20 mg [Source: SME Defined]
			Tablet thickness	The length of a straight line measurement from the shortest edge-to-edge distance through a Tablet. [Source: SME Defined]
			Tablet/Capsule diameter	The length of a straight line measurement across the circular center of a Tablet/Capsule. [Source: SME Defined]
			Tablet/Capsule length	The length of a straight line measurement from the longest edge-to-edge distance through the Tablet/Capsule. [Source: SME Defined]
			Target group weight gain %	A predetermined percentage weight increases for a set of units resulting from of an action such as coating. Example: 3% (weight gain after coating) note: this can be associated with a bulk material or a single unit [Source: SME Defined]
			Weight variation	The difference in weights of the material of interest. Examples: 2%, 5 mg, 2.5 % note: may be a percent, a value, or a percent relative standard deviation [Source: SME Defined]
21	**Mechanical Integrity**	Test that measures what amount of force is needed to alter the mechanical integrity of a construct.		

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
22	**Melting Point**	The temperature at the which a substance changes from solid to a liquid state at atmospheric pressure.		
23	**Microbial Limits**	Tests for the estimation of the number of viable aerobic microorganisms present and for the freedom from designated microbial species in the pharmaceutical articles of all kinds, from raw materials to the finished forms.		
24	**Optical Rotation**	A property of many pharmaceutical substances to rotate an incident plane of polarized light so that the transmitted light emerges at a measurable angle to the plane of the incident light. [Source: Adapted from USP <781>]		
25	**Organoleptic**	Evaluation via the senses—including taste, sight, smell, and touch.	Clarity of Solution	Measurement of the turbidity of the solution or; Qualitative or quantitative measurement of degree of opalescence of a solution. Instrumental measurement of the light reflected by the solution.
			Color of solution	The use of visual perception to indicate of purity and/or a means to identify contamination.
			Description/Appearance	Tests using visual inspection to assess the physical state and color of the drug substance or product.
			Odor	Testing via the sense of smell.

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
26	**Osmolality/ Osmolarity**	Osmolality and osmolarity are measurements of the solute concentration of a solution. Osmolality is expressed in terms of the weight of the solvent and osmolarity is expressed in terms of solvent volume.		
27	**Particle Size Distribution**	Analytical procedures that utilize mechanical sieving for deducing the particle-size distribution of a powdered solid.		
28	**pH**	The measure of acidity or alkalinity of an aqueous solution.		
29	**Plume Geometry**	A test that measures the spray pattern characteristics, including shape and size of the evolving spray cloud under defined experimental and instrumental test conditions.		
30	**Polymorphism**	Tests to determine the different crystalline forms of a given drug substance		
31	**Post-translational modifications**	Test to measure if the protein undergoing post translational modification which include glycosylation etc.	Glycosylation	Post translation modification due to addition of sugar
			Thrombin Peptide Map	Map of peptides derived from digestion of protein with thrombin
			Sialylation	Post translational modification of proteins by sialylation

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			Amidation	Testing for and acid containing residue conversion to an amide.
			Deamidation	Testing for an amide residue conversion to an acid.
32	**Porosity**	Tests that measure the empty spaces/voids in the material.		
33	**Potency**	Tests to measure the biological activity using a suitably quantitative biological assay (also called potency assay or bioassay), based on the attribute of the product which is linked to the relevant biological properties.		
34	**Pyrogenicity /Endotoxin**	Tests designed to limit to an acceptable level the risks of febrile reaction in the patient to the administration, by injection, of the product concerned. The test involves measuring the rise in temperature of rabbits following the intravenous injection of a test solution and is designed for products that can be tolerated by the test rabbit in a dose not to exceed 10 mL/kg injected intravenously within a period of NMT 10 min.		
35	**Reconstitution Time**	Measurement of how long it takes to restore something dried to its original state of liquid.		

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
36	**Redispersibility**	Testing of oral suspensions that settle on storage (produce sediment) to measure the time required to achieve resuspension.		
37	**Refractive Index**	Tests performed to determine the ratio of velocity of light in air to the velocity of light in the substance.		
38	**Residue on Ignition**	Tests to measure the amount of residual substance not volatilized from a sample when the sample is ignited in the presence of sulfuric acid. This test is usually used for determining the content of inorganic impurities in an organic substance.		
39	**Solubility**	A chemical property referring to the ability for a given substance, the solute, to dissolve in a solvent. It is measured in terms of the maximum amount of solute dissolved in a solvent at equilibrium.		
40	**Specific Gravity**	The ratio of the density of any substance to the density of some other substance taken as standard, water being the standard for liquids and solids, and hydrogen or air being the standard for gases.		
41	**Spray Pattern**	Tests to determine the size of the mist formed by spraying. The measurement is made for the longest axis (x axis), and the		

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
		ratio of longest to shortest axes (x/y ratio).		
42	**Sterility**	Tests done under aseptic conditions to ensure that there are no contaminating micro-organism present in the sample.		
43	**Surface Area**	Total surface area of a 2D or 3D material		
44	**Syringe Functionality**	Tests performed on syringes to ensure that It operates as specified		
45	**Tap Density**	An increased bulk density attained after mechanically tapping the container containing the powder sample. (aka - tapped density)		
46	**Total Organic Carbon**	An indirect measure of organic molecules present in pharmaceutical waters measured as carbon		
47	**Turbidity**	Measurement of the clarity and degree of opalescence of liquids by comparison of the solutions in diffused daylight after preparation of the reference suspension.		
48	**Transdermal Properties**	Tests that determine the physical properties of transdermal systems Example, Peel adhesion test, Tack test, Cold Flow test, etc.		
49	**Uniformity**	Tests to ensure the consistency of the API in the formulation. Test may be done as an IPC, release, or stability test.	Uniformity of dosage unit	Tests of the variability of the dosage unit including dispensed dose.

#	IPC Test Category Valid Values	IPC Test Category Valid Value Meaning	IPC Test Subcategory Valid Values	IPC Test Subcategory Valid Value Meaning
			IPC Content uniformity	Tests of the variability of the dosage unit including dispensed dose. Note: as informed by ASTM 2810
			Blend Uniformity	Test to ensure the adequacy of the mixing of active pharmaceutical ingredients (APIs) with other components of the drug product.
			Uniformity in containers	Content Uniformity based for multi-use containers, tubes, and jars.
50	**Viscosity/ Rheological Properties**	A property of liquids that is closely related to the resistance to flow.		

F: Terminologies for Unit Operation Category and Unit Operations Subcategory

For Unit Operation Category/Subcategory, FDA leveraged the SUPAC Unit Operation to inform the PQ/CMC value lists. These valid value lists have not yet been registered in NCI Thesaurus and therefore the NCIt concept codes are not presented in the table below.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
1	**Particle Size Reduction**	The mechanical process of breaking particles into smaller pieces via one or more particle size reduction mechanisms. The mechanical process used generally is referred to as milling.	Fluid Energy Milling	Particles are reduced in size as a result of high-speed particle-to-particle impact and/or attrition; also known as micronizing.
			Impact Milling	Particles are reduced in size by high-speed mechanical impact or impact with other particles; also known as milling, pulverizing, or comminuting.
			Cutting	Particles are reduced in size by mechanical shearing.
			Compression Milling	Particles are reduced in size by compression stress and shear between two surfaces.
			Screening	Particles are reduced in size by mechanically induced attrition through a screen. This process commonly is referred to as milling or deagglomeration.
			Tumble Milling	Particles are reduced in size by attrition utilizing grinding media.
2	**Particle Separation**	Particle size classification according to particle size alone.	Separating	Particles are segregated based upon particle size alone and without any significant particle size reduction. This process commonly is referred to as screening or bolting.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
3	**Blending and Mixing**	The reorientation of particles relative to one another to achieve uniformity.	Diffusion Blending (Tumble)	Particles are reoriented in relation to one another when they are placed in random motion and interparticular friction is reduced as the result of bed expansion (usually within a rotating container); also known as tumble blending.
			Convection Mixing	Particles are reoriented in relation to one another as a result of mechanical movement; also known as paddle or plow mixing.
			Pneumatic Mixing	Particles are reoriented in relation to one another as a result of the expansion of a powder bed by gas.
4	**Granulation**	The process of creating granules. The powder morphology is modified through the use of either a liquid that causes particles to bind through capillary forces or dry compaction forces. The process will result in one or more of the following powder properties: enhanced flow; increased compressibility; densification; alteration of physical appearance to more spherical, uniform, or larger particles; and/or enhanced hydrophilic surface properties.	Dry Granulation	Dry powder densification and/or agglomeration by direct physical compaction.
			Wet High-Shear Granulation	Powder densification and/or agglomeration by the incorporation of a granulation fluid into the powder with high-power-per-unit mass, through rotating high-shear forces.
			Wet Low-Shear Granulation	Powder densification and/or agglomeration by the incorporation of a granulation fluid into

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
				the powder with low-power-per-unit mass, through rotating low-shear forces.
			Low-Shear Tumble Granulation	Powder densification and/or agglomeration by the incorporation of a granulation fluid into the powder with low-power-per-unit mass, through rotation of the container vessel and/or intensifier bar.
			Extrusion Granulation	Plasticization of solids or wetted mass of solids and granulation fluid with linear shear through a sized orifice using a pressure gradient.
			Rotary Granulation	Spheronization, agglomeration, and/or densification of a wetted or non-wetted powder or extruded material. This is accomplished by centrifugal or rotational forces from a central rotating disk, rotating walls, or both. The process may include the incorporation and/or drying of a granulation fluid.
			Fluid Bed Granulation	Powder densification and/or agglomeration with little or no shear by direct granulation fluid atomization and impingement on solids, while suspended by a controlled gas stream, with simultaneous drying.
			Spray Dry Granulation	A pumpable granulating liquid containing solids (in solution or suspension) is atomized in a drying chamber and rapidly dried by a controlled gas stream, producing a dry powder.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
			Hot-melt Granulation	An agglomeration process that utilizes a molten liquid as a binder(s) or granulation matrix in which the active pharmaceutical ingredient (API) is mixed and then cooled down followed by milling into powder. This is usually accomplished in a temperature controlled jacketed high shear granulating tank or using a heated nozzle that sprays the molten binders(s) onto the fluidizing bed of the API and other inactive ingredients.
			Melt Extrusion	A process that involves melting and mixing API and an excipient (generally a polymer) using low or high shear kneading screws followed by cooling and then milling into granules. Thermal energy for melting is usually supplied by the electric/water heater placed on the barrel. Materials are either premixed or fed into an extruder separately. Melt extruder subclasses primarily are distinguished by the configuration of the screw.
5	**Drying**	The removal of a liquid from a solid by evaporation.	Direct Heating, Static Solids Bed	Heat transfer is accomplished by direct contact between the wet solids and hot gases. The vaporized liquid is carried away by the drying gases. There is no relative motion among solid particles. The solids bed exists as a dense bed, with the particles resting upon one another.
			Direct Heating, Moving Solids Bed	Heat transfer is accomplished by direct contact between the wet solids and hot gases. The vaporized liquid is carried away by the

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
				drying gases. Solid motion is achieved by either mechanical agitation or gravity force, which slightly expands the bed enough to flow one particle over another.
			Direct Heating, Fluidized Solids Bed	Heat transfer is accomplished by direct contact between the wet solids and hot gases. The vaporized liquid is carried away by the drying gases. The solids are in an expanded condition, with the particles supported by drag forces caused by the gas phase. The solids and gases intermix and behave like a boiling liquid. This process commonly is referred to as fluid bed drying.
			Direct Heating, Dilute Solids Bed, Spray Drying	Heat transfer is accomplished by direct contact between a highly dispersed liquid and hot gases. The feed liquid may be a solution, slurry, emulsion, gel or paste, provided it is pumpable and capable of being atomized. The fluid is dispersed as fine droplets into a moving stream of hot gases, where they evaporate rapidly before reaching the wall of the drying chamber. The vaporized liquid is carried away by the drying gases. The solids are fully expanded and so widely separated that they exert essentially no influence on one another.
			Direct Heating, Dilute Solids Bed, Flash Drying	Heat transfer is accomplished by direct contact between wet solids and hot gases. The solid mass is suspended in a finely divided state in a high-velocity and high-temperature

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
				gas stream. The vaporized liquid is carried away by the drying gases.
			Indirect Conduction, Moving Solids Bed	Heat transfer to the wet solid is through a retaining wall. The vaporized liquid is removed independently from the heating medium. Solids motion is achieved by either mechanical agitation or gravity force, which slightly expands the bed enough to flow one particle over another.
			Indirect Conduction, Static Solids Bed	Heat transfer to the wet solid is through a retaining wall. The vaporized liquid is removed independently from the heating medium. There is no relative motion among solid particles. The solids bed exists as a dense bed, with the particles resting upon one another.
			Indirect Conduction, Lyophilization	Drying in which the water vapor sublimes from the product after freezing.
			Gas Stripping	Heat transfer is a combination of direct and indirect heating. The solids motion is achieved by agitation and the bed is partially fluidized.
			Indirect Radiant, Moving Solids Bed	Heat transfer is accomplished with varying wavelengths of energy. Vaporized liquid is removed independently from the solids bed. The solids motion is achieved by mechanical agitation, which slightly expands the bed enough to flow one particle over one another. This process commonly is referred to as microwave drying.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
6	**Unit Dosing**	The division of a powder blend into uniform single portions for delivery to patients.	Tabletting	The division of a powder blend in which compression force is applied to form a single unit dose. (note: embossing is covered here)
			Encapsulating	The division of material into a hard gelatin capsule. Encapsulators should all have the following operating principles in common: rectification (orientation of the hard gelatin capsules), separation of capsule caps from bodies, dosing of fill material/formulation, rejoining of caps and bodies, and ejection of filled capsules.
			Powder Filling	The division of a powder blend into a container closure system.
7	**Soft Gel Mass Preparation**	The manufacture of a homogeneous, degassed liquid mass (solution) of gelatin, plasticizer, water, and other additives, either in solution or suspension, such as colorants, pigments, flavors, preservatives, etc., that comprise a unique functional gel shell formation. The operation may be performed in discreet steps or by continuous processing. Minor components can be added after the liquid gel mass is made.	-	
8	**Soft gel, Fill Mixing**	The mixing of either liquids or solids with other liquids to form a solution; blending of limited solubility solid(s) with a liquid carrier and suspending agents used to stabilize the blend to form a suspension; or the uniform combination of dry inert and drug active	Mixing	The combination of solid and liquid components, including suspending aid(s) at either ambient or elevated temperatures to form a solution, suspension, or dry powder blend for the manufacture of gel mass or fill material. Mixing also includes the

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
		substances to form a dry powder fill suitable for encapsulation. The reader should refer to the other sections of this document for dry fill manufacture.		incorporation of minor components into the liquid gel mass.
			Deaggregation	The removal of aggregates using a suitable homogenizer/mill to provide a pumpable fill material. The procedure has minimal effect on the particle size distribution of the initial solid component(s), and is viewed as a processing aid. (Carstensen, J. T., Theory of Pharmaceutical Systems, Volume 11 Heterogeneous Systems, Academic Press, New York, NY, 1973, p 51.)
			Deaeration	The removal of entrapped air from either the gel mass or fill material, solution, or suspension. This process can take place in either the mixing vessel, through the application of vacuum, or a separate off-line step.
			Holding	The storage of liquid gel mass or fill material in a vessel, with a mixer or without, prior to encapsulation, which also may be equipped with a jacket for either heating or cooling.
9	**Soft gel, Encapsulation**	The continuous casting of gel ribbons, with liquid fill material being injected between the gel ribbons using a positive displacement pump or, for dry materials being gravity or force fed with capsule formation using a rotary die.	Encapsulation	The formation of capsules using a rotary die machine. (Lachman, L., H. A. Lieberman, and J. L. Kanig (Eds.), The Theory and Practice of Industrial Pharmacy, Chapter 3, p. 359 (Stanley, J. P.), Philadelphia Lea & Febiger, 1971; Tyle, P. (Ed.), Specialized Drug Delivery Systems, Manufacturing and Production

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
				Technology, Chapter 10, p. 409 (Wilkinson, P.K. and F.S. Hom), New York; M. Dekker, 1990; Porter, S., Remington's Pharmaceutical Sciences, Edition 18, Chapter 89, pp. 1662 - 1665, Easton, Penn.: Mack Publishing Co.)
10	**Soft gel Washing**	The continuous removal of a lubricant material from the outside of the formed capsule. The washing operation is unique to each manufacturer's operation and generally uses in-house fabricated equipment. This equipment will not be discussed in this guidance document.	-	
11	**Soft gel, Drying**	The removal of the majority of water from the capsule's gel shell by tumbling and subsequent tray drying using conditioned air, which enhances the size, shape, and shell physical properties of the final product. The drying operation is unique to each manufacturer's operation and generally uses in-house fabricated equipment. This equipment will not be discussed in this guidance document.	-	
12	**Soft gel, Inspection/Sorting**	The process wherein undesirable capsules are removed, including misshapen, leaking, and unfilled capsules as well as agglomerates of capsules.	Inspection/Sorting	The physical removal of misshapen, leaking, or agglomerated capsules, using either a manual or automatic operation.
13	**Coating**	The uniform deposition of a layer of material on or around a solid dosage form, or component thereof.	Pan Coating	The uniform deposition of coating material onto the surface of a solid dosage form, or component thereof, while being translated via a rotating vessel.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
			Gas Suspension	The application of a coating material onto a solid dosage form, or component thereof, while being entrained in a process gas stream. Alternatively, this may be accomplished simultaneously by spraying the coating material and substrate into a process gas stream.
			Vacuum Film Coating	This technique uses a jacketed pan equipped with a baffle system. Tablets are placed into the sealed pan, an inert gas (i.e., nitrogen) is used to displace the air and then a vacuum is drawn.
			Dip Coating	Coating is applied to the substrate by dipping it into the coating material. Drying is accomplished using pan coating equipment.
			Electrostatic Coating	A strong electrostatic charge is applied to the surface of the substrate. The coating material containing oppositely charged ionic species is sprayed onto the substrate.
			Compression Coating	A coating process where a dry coatings blend is applied on a previously compressed core tablet using a tablet compression machine. Therefore, this process is also known as a dry coating process that does not involve any water or any other solvent in the coating process.
14	**Printing**	The marking of a capsule or tablet surface for the purpose of product identification. Printing may be accomplished by either the	Ink-Based Printing	The application of contrasting colored polymer (ink) onto the surface of a tablet or capsule.

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
		application of a contrasting colored polymer (ink) onto the surface of a capsule or tablet, or by the use of laser etching.		
			Laser Etching	The application of identifying markings onto the surface of a tablet or capsule using laser-based technology.
15	**Drilling**	The drilling or ablating of a hole or holes through the polymeric film coating shell on the surfaces of a solid oral dosage form using a laser. The polymeric film shell is not soluble in vivo. The hole or holes allow for the modified release of the drug from the core of the dosage form.	Laser Drilling	A drilling system typically is a custom built unit consisting of a material handling system to orient and hold the solid dosage form, a laser (or lasers), and optics (lenses, mirrors, deflectors, etc.) to ablate the hole or holes, and controls. The drilling unit may include debris extraction and inspection systems as well. The sorting, orienting, and holding equipment commonly is provided by dosage form printing equipment manufacturers, and is considered ancillary in this use.
16	**Packaging (non-sterile products)/ Holding**	The process of storing product after completion of manufacturing process and prior to filling final primary packs.	Holding	The storage of liquid, semi-solids, or product materials in a vessel that may or may not have temperature control and/or agitation.
17	**Packaging (non-sterile products)/ Transfer**	The process of relocating bulk finished product from holding to filling equipment using pipe, hose, pumps and/or other associated components.	Transfer	The controlled movement or transfer of materials from one location to another.
18	**Packaging (non-sterile products)/ Filling**	The delivery of target weight or volume of bulk finished product to primary pack containers	Filling	Filling operating principles involve several associated subprinciples. The primary package can be precleaned to remove particulates or other materials by the use of ionized air, vacuum, or inversion. A holding vessel

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
				equipped with an auger, gravity, or pressure material feeding system should be used. The vessel may or may not be able to control temperature and/or agitation. Actual filling of the dosage form into primary containers can involve a metering system based on an auger, gear, orifice, peristaltic, or piston pump. A head-space blanketing system can also be used.
19	**Packaging (non-sterile products)/ Sealing**	A device or process for closing and/or sealing primary pack containers following the filling process.	Sealing	Primary packages can be sealed using a variety of methods, including conducted heat and electromagnetic (induction or microwave) or mechanical manipulation (crimping or torquing).
			Capping	The provision of a protective or obstructive covering on a container. Source: TheFreedictionary.com medical dictionary (https://medical-dictionary.thefreedictionary.com/)
			Visual Inspection	The assessment and physical removal of misshapen or leaking packages using a manual operation. Source: derived from Unit Operation Subcategory "inspection/sorting"
			Assembly (PFS, MDI, etc.)	A process in which all parts, components, and fasteners as defined in and assembled according to the manufacturer's assembly and installation instructions. Source: Law Insider Dictionary (https://www.lawinsider.com/dictionary)

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
20	**Labelling**	The action of affixing an identifier to an item or the container for an item. Source: NCI C84732 SPL Business Operation Terminology	Labelling	
21	**Temperature Conditioning**	The process of treating air to control its temperature to meet the requirement of conditioned space. Source: derived from "air conditioning" in Law Insider Dictionary (https://www.lawinsider.com/dictionary)	Freezing	The act or event which causes the transition from a liquid to solid matter phase when the temperature is lowered. Source: NCI C48160
			Cryopreservation	Storage at very low temperature, usually in liquid nitrogen or the vapor phase of liquid nitrogen. Source: NCI C16475 FDA eManufacturing Terminology
22	**Scaffold**	Porous substrate for impregnation with active materials, such as cells.	Scaffold	
23	**Filtration**	The process of passing a substance through a porous material to remove impurities and solid particles. Source: derived from definition of 'filtered' in Collins English Dictionary (https://www.collinsdictionary.com/us/dictionary/english/filtered)	Filtration	
24	**Sterilization**	Validated process used to render product free from viable microorganisms. See ISO/TS 11139. Source: NCI C84382 SPL Business Operation Terminology	Terminal Sterilization	Sterilization following production using steam, gas, dry heat, water, or radiation. Source: NCI C113071 FDA eManufacturing Terminology

#	Unit Operation Category Valid Values	Unit Operation Category Valid Value Meaning	Unit Operation Subcategory Valid Values	Unit Operation Subcategory Valid Value Meaning
			Aseptic Sterilization (Filtration)	The process of passing a substance through a porous material to remove living organisms. Source: derived from definition of "filtration"
25	**Filling or Aseptic Processing**	A method of preparing pharmaceutical and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container, and closure of the container under at least ISO Class 5 conditions and using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing. Source: Law Insider Dictionary (https://www.lawinsider.com/dictionary)		

END OF SECTION 3

Section 4: Glossary

Acronym	Description
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
APhA	American Pharmacists Association
API	Active Pharmaceutical Ingredient
ASTM	American Society for Testing and Materials
BLA	Biologics License Application
CAS	Chemical Abstract Service
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CMC	Chemistry Manufacturing & Controls
CFR	Code of Federal Regulations
CTD	Common Technical Document
CVM	Center for Veterinary Medicine
eCTD	Electronic Common Technical Document
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
FHIR	Fast Health Interoperability Resources
GENC	Geopolitical Entities, Names, and Codes
HL7	Health Level Seven
ICH	International Council for Harmonisation
ISBT	Information Standard for Blood and Transplant
ISO IDMP	International Organization for Standardization Identification of Medicinal Products
INN	International Nonproprietary Name
INAD	Investigational New Animal Drug
IND	Investigational New Drug Application
IUPAC	International Union of Pure and Applied Chemistry
JINAD	Generic Investigational New Animal Drugs
MF	Master Files
NADA	New Animal Drug Application
NCIt	National Cancer Institute (NCI) Thesaurus

Acronym	Description
NCI EVS	National Cancer Institute – Enterprise Vocabulary Service
NDA	New Drug Application
PQ/CMC	Pharmaceutical Quality/Chemistry, Manufacturing & Controls
SME	Subject Matter Expert
SPL	Structured Product Labeling
UNII	Unique Ingredient Identifier
USAN	United States Adopted Name
USP/NF	United States Pharmacopeia (USP) and the National Formulary (NF)
WHO	World Health Organization

END OF SECTION 4

Appendix A: Examples PQ/CMC Drug Product Weight Representation

	(10 mg/5 mL)	(5 mg per unit)	(5 mg per 100 mL)
Weight Type	Mass	Mass	Mass
Weight Numeric Numerator	10	5	5
Weight Numeric Numerator UOM	mg	mg	mg
Weight Numeric Denominator	5	1	100
Weight Numeric Denominator UOM	mL	unit	mL
Weight Textual	NA	NA	NA
Weight Operator	NA	NA	NA

END OF APPENDIX A

Appendix B: Examples of PQ/CMC Drug Product Composition

1. Multi-layer tablet

Drug Product: an immediate release tablet composed of 2 layers	
Dosage Form	tablet
Drug Product Overall Release Profile	IR
Drug Product Overall Release Mechanism	*NULL*
Drug Product Coating Indicator	No
Drug Product Schematic	
Drug Product Tablet Layer Count	2
Drug Product Tablet Bead Type Count	0
Drug Product Total Weight Type	Mass
Drug Product Total Weight Numeric Numerator	1201
Drug Product Total Weight Numeric Numerator UOM	mg
Drug Product Total Weight Numeric Denominator	1
Drug Product Total Weight Numeric Denominator UOM	unit

Product Composition per unit dose					
Product Part Ingredient Name	**Product Ingredient Amount Numeric Numerator**	**Product Ingredient Amount Numeric Numerator UOM**	**Product Ingredient Amount Numeric Denominator**	**Product Ingredient Amount Numeric Denominator UOM**	**Product Ingredient Content Percent**
Ingredient 1	200	mg	1	unit	16.65
Ingredient 2	1	mg	1	unit	0.09
Ingredient 3	300	mg	1	unit	24.98
Ingredient 4	700	mg	1	unit	58.28

Product Parts		
Product Part Type	Layer	Layer
Product Part Identifier	A	B
Product Part Release Profile	IR	IR
Product Part Release Mechanism	*NULL*	*NULL*
Tablet Product Part Function Description	delivers API	delivers API
Product Part Color Description	purple	white
Product Part Total Weight Numeric Numerator	463	738
Product Part Total Weight Numeric Numerator UOM	mg	mg
Product Part Total Weight Numeric Denominator	1	1
Product Part Total Weight Numeric Denominator UOM	unit	unit
Product Part Content Percent	38.55	61.45

Product Part Ingredients			
Product Part Identifier: A			
Product Part Ingredient Name	Ingredient 1	Ingredient 2	Ingredient 4
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	12345XYZ	67890ABC	889PXY
Product Part Ingredient Function Category	Active Ingredient	Inactive Ingredient	Inactive
Product Part Ingredient Function	*NULL*	coloring agent	filler
Product Part Ingredient Physical Location	Active core/granulate	Intragranular	Intragranular
Product Part Ingredient Amount Numeric Numerator	200	1	262
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	layer	layer	layer
Product Part Ingredient Content Percent	43.19	0.22	56.59
Product Part Identifier: B			
Product Part Ingredient Name	Ingredient 3	Ingredient 4	
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	
Product Part Ingredient UNII	00234PPX	978XYZ	
Product Part Ingredient Function Category	Active Ingredient	Inactive Ingredient	
Product Part Ingredient Function	*NULL*	filler	
Product Part Ingredient Physical Location	Active core/granulate	Extragranular	
Product Part Ingredient Amount Numeric Numerator	300	438	
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	
Product Part Ingredient Amount Numeric Denominator	1	1	
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	
Product Part Ingredient Amount Textual	layer	layer	
Product Part Ingredient Content Percent	40.65	59.35	

2. Capsule filled with 2 constituents

Drug Product: an extended release capsule filled with 2 constituent types; beads and a tablet	
Dosage Form	capsule
Drug Product Overall Release Profile	ER
Drug Product Overall Release Mechanism	Osmotic Pump
Drug Product Coating Indicator	No
Drug Product Schematic	
Drug Product Tablet Layer Count	0
Drug Product Total Weight Type	Mass
Drug Product Total Weight Numeric Numerator	285
Drug Product Total Weight Numeric Numerator UOM	mg
Drug Product Total Weight Numeric Denominator	1
Drug Product Total Weight Numeric Denominator UOM	unit

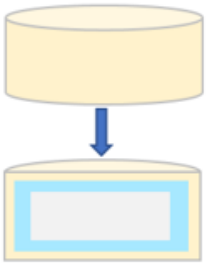
Product Composition per unit dose					
Product Part Ingredient Name	**Product Ingredient Amount Numeric Numerator**	**Product Ingredient Amount Numeric Numerator UOM**	**Product Ingredient Amount Numeric Denominator**	**Product Ingredient Amount Numeric Denominator UOM**	**Product Ingredient Content Percent**
Ingredient 1	10	mg	1	unit	3.51
Ingredient 2	1	mg	1	unit	0.35
Ingredient 3	100	mg	1	unit	35.09
Ingredient 4	89	mg	1	unit	31.23
Ingredient 5	70	mg	1	unit	24.56
Ingredient 6	15	mg	1	unit	5.26

Product Parts			
Product Part Type	Capsule Shell	Tablet	Beads
Product Part Identifier	P0	P1	P2
Product Part Release Profile	Not Applicable	ER	IR
Product Part Release Mechanism	*NULL*	Osmotic Pump	*NULL*
Tablet Product Part Function Description	*NULL*	delivers API	delivers API
Capsule Shell Part Classification Category	Hard HPMC Capsule	*NULL*	*NULL*
Product Part Color Description	clear	blue	white
Product Part Total Weight Numeric Numerator	85	150	50
Product Part Total Weight Numeric Numerator UOM	mg	mg	mg
Product Part Total Weight Numeric Denominator	1	1	1
Product Part Total Weight Numeric Denominator UOM	unit	unit	unit
Product Part Content Percent	29.82	52.63	17.54

Product Part Ingredients			
Product Part Identifier: P0			
Product Part Ingredient Name	Ingredient 5	Ingredient 6	
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	
Product Part Ingredient UNII	00234PPY	99876XXY	
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	
Product Part Ingredient Function	CAPSULE	CAPSULE	
Product Part Ingredient Physical Location	Active core/granulate	Active core/granulate	
Product Part Ingredient Amount Numeric Numerator	70	15	
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	
Product Part Ingredient Amount Numeric Denominator	1	1	
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	
Product Part Ingredient Amount Textual	capsule shell	capsule shell	
Product Part Ingredient Content Percent	82.35	17.65	
Product Part Identifier: P1			
Product Part Ingredient Name	Ingredient 2	Ingredient 3	Ingredient 4
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	00234PPX	978XYZ	999HIJ
Product Part Ingredient Function Category	Inactive Ingredient	Active Ingredient	Inactive Ingredient
Product Part Ingredient Function	coloring agent	*NULL*	filler
Product Part Ingredient Physical Location	Active core/granulate	Active core/granulate	Intragranular
Product Part Ingredient Amount Numeric Numerator	1	80	69
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	tablet	tablet	tablet
Product Part Ingredient Content Percent	0.67	53.33	46
Product Part Identifier: P2			
Product Part Ingredient Name	Ingredient 3	Ingredient 1	Ingredient 4
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	111UVWX	345STUV	999HIJ
Product Part Ingredient Function Category	Active Ingredient	Active Ingredient	Inactive Ingredient
Product Part Ingredient Function	NULL	NULL	filler
Product Part Ingredient Physical Location	Active core/granulate	Intragranular	Intragranular
Product Part Ingredient Amount Numeric Numerator	20	10	20
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	bead	bead	bead
Product Part Ingredient Content Percent	40	20	40

3. Tablet with two coatings

Drug Product: an delayed release tablet; with an enteric coating and a taste-masking coating	
Dosage Form	tablet
Drug Product Overall Release Profile	DR
Drug Product Overall Release Mechanism	*NULL*
Drug Product Coating Indicator	Yes
Drug Product Schematic	
Drug Product Tablet Layer Count	1
Drug Product Tablet Bead Type Count	0
Drug Product Total Weight Type	Mass
Drug Product Total Weight Numeric Numerator	502
Drug Product Total Weight Numeric Numerator UOM	mg
Drug Product Total Weight Numeric Denominator	1
Drug Product Total Weight Numeric Denominator UOM	unit



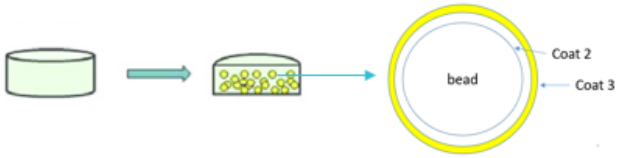
Product Composition per unit dose					
Product Part Ingredient Name	**Product Ingredient Amount Numeric Numerator**	**Product Ingredient Amount Numeric Numerator UOM**	**Product Ingredient Amount Numeric Denominator**	**Product Ingredient Amount Numeric Denominator UOM**	**Product Ingredient Content Percent**
Ingredient 1	200	mg	1	unit	39.84
Ingredient 2	48	mg	1	unit	9.56
Ingredient 3	227	mg	1	unit	45.22
Ingredient 4	1	mg	1	unit	0.2
Ingredient 5	25	mg	1	unit	4.98
Ingredient 6	1	mg	1	unit	0.2

Product Parts			
Product Part Type	Layer	Coating	Coating
Product Part Identifier	1	Coat1	Coat2
Product Part Release Profile	IR	DR	Not Applicable
Product Part Release Mechanism	*NULL*	*NULL*	*NULL*
Tablet Product Part Function Description	delivers API	*NULL*	*NULL*
Coating Product Part Purpose	*NULL*	Delayed Release	Taste-masking
Product Part Color Description	white	blue	yellow
Product Part Total Weight Numeric Numerator	450	26	26
Product Part Total Weight Numeric Numerator UOM	mg	mg	mg
Product Part Total Weight Numeric Denominator	1	1	1
Product Part Total Weight Numeric Denominator UOM	unit	unit	unit
Product Part Content Percent	39.47	31.58	28.95

Product Part Ingredients			
Product Part Identifier: 1			
Product Part Ingredient Name	Ingredient 1	Ingredient 2	Ingredient 3
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	12345XYZ	67890ABC	889PXY
Product Part Ingredient Function Category	Active Ingredient	Inactive Ingredient	Active Ingredient
Product Part Ingredient Function	*NULL*	binder	*NULL*
Product Part Ingredient Physical Location	Active core/granulate	Active core/granulate	Active core/granulate
Product Part Ingredient Amount Numeric Numerator	200	23	227
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	layer	layer	layer
Product Part Ingredient Content Percent	44,44	5.11	50.44
Product Part Identifier: Coat1			
Product Part Ingredient Name	Ingredient 5	Ingredient 6	
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	
Product Part Ingredient UNII	00234PPX	978XYZ	
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	
Product Part Ingredient Function	release modifying agen	coloring agent	
Product Part Ingredient Physical Location	*NULL*	*NULL*	
Product Part Ingredient Amount Numeric Numerator	25	1	
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	
Product Part Ingredient Amount Numeric Denominator	1	1	
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	
Product Part Ingredient Amount Textual	coating	coating	
Product Part Ingredient Content Percent	96.15	3.85	
Product Part Identifier: Coat2			
Product Part Ingredient Name	Ingredient 2	Ingredient 4	
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	
Product Part Ingredient UNII	111UVWX	345STUV	
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	
Product Part Ingredient Function	film coating agent	coloring agent	
Product Part Ingredient Physical Location	*NULL*	*NULL*	
Product Part Ingredient Amount Numeric Numerator	25	1	
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	
Product Part Ingredient Amount Numeric Denominator	1	1	
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	
Product Part Ingredient Amount Textual	coating	coating	
Product Part Ingredient Content Percent	96.15	3.85	

4. Coated tablet containing one bead type; each bead has two coatings

Drug Product: a 1 layer coated tablet filled with 1 distinct bead type; the bead has two distinct coatings	
Dosage Form	Tablet
Overall Release Profile	IR
Overall Release Mechanism	*NULL*
Coating Indicator	Yes
Schematic	
Drug Product Tablet Layer Count	1
Drug Product Tablet Bead Type Count	1
Drug Product Total Weight Type	Mass
Drug Product Total Weight Numeric Numerator	510
Drug Product Total Weight Numeric Numerator UOM	mg
Drug Product Total Weight Numeric Denominator	1
Drug Product Total Weight Numeric Denominator UOM	unit



Product Composition per unit dose					
Product Part Ingredient Name	**Product Ingredient Amount Numeric Numerator**	**Product Ingredient Amount Numeric Numerator UOM**	**Product Ingredient Amount Numeric Denominator**	**Product Ingredient Amount Numeric Denominator UOM**	**Product Ingredient Content Percent**
Ingredient 1	125	mg	1	unit	31.25
Ingredient 2	50	mg	1	unit	12.5
Ingredient 3	95	mg	1	unit	23.75
Ingredient 4	15	mg	1	unit	3.75
Ingredient 5	85	mg	1	unit	21.25
Ingredient 6	30	mg	1	unit	7.5

Product Parts			*Tablet coating*	*Bead coatings*	
Product Part Type	Bead	Layer	Coating	Coating	Coating
Product Part Identifier	B1	Tablet Core	Coat1	Coat2	Coat3
Product Part Identifier Reference	*NULL*	*NULL*	*NULL*	B1	B1
Coating Product Part Purpose	*NULL*	*NULL*	taste masking	seal or non functional	irritant suppression
Tablet Product Part Function Description	*NULL*	contains the beads	*NULL*	*NULL*	*NULL*
Product Part Release Profile	IR	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Product Part Release Mechanism	*NULL*	*NULL*	*NULL*	*NULL*	*NULL*
Product Part Color Description	yellow	green	green	white	yellow
Product Part Total Weight Numeric Numerator	170	175	55	65	45
Product Part Total Weight Numeric Numerator UOM	mg	mg	mg	mg	mg
Product Part Total Weight Numeric Denominator	1	1	1	1	1
Product Part Total Weight Numeric Denominator UOM	unit	unit	unit	unit	unit
Product Part Content Percent	33.33	34.31	10.78	12.75	8.82

Product Part Ingredients			
Product Part Identifier: B1			
Product Part Ingredient Name	Ingredient 1	Ingredient 3	Ingredient 4
Product Part Ingredient Name Type	Systematic Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	773ABC	1234XXX	776TTY
Product Part Ingredient Function Category	Active Ingredient	Inactive Ingredient	Inactive Ingredient
Product Part Ingredient Function	*NULL*	stabilizer	filler
Product Part Ingredient Physical Location	Active core/granulate	intragranular	intragranular
Product Part Ingredient Amount Numeric Numerator	125	30	15
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	bead	bead	bead
Product Part Ingredient Content Percent	73.53	17.65	8.82
Product Part Identifier: Tablet Core			
Product Part Ingredient Name	Ingredient 2	Ingredient 3	Ingredient 5
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	333ABC	1234XXX	776TCCXY
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	Inactive Ingredient
Product Part Ingredient Function	filler	filler	stabilizer
Product Part Ingredient Physical Location	intragranular	intragranular	intragranular
Product Part Ingredient Amount Numeric Numerator	50	65	60
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	tablet	tablet	tablet
Product Part Ingredient Content Percent	28.57	37.14	34.29
Product Part Identifier: Coat1			
Product Part Ingredient Name	Ingredient 6	Ingredient 5	
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	
Product Part Ingredient UNII	9008GHI	776TCCXY	
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	
Product Part Ingredient Function	film coating agent	coloring agent	
Product Part Ingredient Physical Location	*NULL*	*NULL*	
Product Part Ingredient Amount Numeric Numerator	30	25	
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	
Product Part Ingredient Amount Numeric Denominator	1	1	
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	
Product Part Ingredient Amount Textual	coating	coating	
Product Part Ingredient Content Percent	54.55	45.45	

Product Part Identifier: Coat2			
Product Part Ingredient Name	Ingredient 6	Ingredient 5	Ingredient 8
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	9008GHI	776TCCXY	4646ZZZ
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient	Inactive Ingredient
Product Part Ingredient Function	film coating agent	stabilizer	dispersing agent
Product Part Ingredient Physical Location	*NULL*	*NULL*	*NULL*
Product Part Ingredient Amount Numeric Numerator	30	25	10
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U	arb'U
Product Part Ingredient Amount Textual	coating	coating	coating
Product Part Ingredient Content Percent	46.15	38.46	15.38

Product Part Identifier: Coat3		
Product Part Ingredient Name	Ingredient 6	Ingredient 7
Product Part Ingredient Name Type	GSRS Accepted Name	GSRS Accepted Name
Product Part Ingredient UNII	776TCCXY	4646ZZZ
Product Part Ingredient Function Category	Inactive Ingredient	Inactive Ingredient
Product Part Ingredient Function	film coating agent	dispersing agent
Product Part Ingredient Physical Location	*NULL*	*NULL*
Product Part Ingredient Amount Numeric Numerator	30	15
Product Part Ingredient Amount Numeric Numerator UOM	mg	mg
Product Part Ingredient Amount Numeric Denominator	1	1
Product Part Ingredient Amount Numeric Denominator UOM	arb'U	arb'U
Product Part Ingredient Amount Textual	coating	coating
Product Part Ingredient Content Percent	66.67	33.33

END OF APPENDIX B

END OF CHAPTER 2

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