Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Exchange

Background

In 2017, the U.S. Food and Drug Administration (FDA or Agency) published a Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Elements and Controlled Terminology document as part of Federal Register Notice (FRN)[https://www.regulations.gov/docket/FDA-2017-N-2166]. That document proposed structured data standards for a set of electronic common technical document (eCTD) Module 3 content. There was a large volume of comments received from the industry in response to the FRN with overall support for structuring Module 3 content and detail comments on the data elements and controlled terminologies. The comments and feedback were incorporated into the structured data elements and controlled terminology. This document is a follow-up of the previous FRN document. While the previous document focused on introducing the structuring and standardization of some parts of eCTD Module 3 and solicited feedback from the industry, this document is focused on representation of those published PQ/CMC structured data elements in the new healthcare data exchange standard from Health Level 7 (HL7) called Fast Health Interoperability Resources (FHIR). FDA is now seeking feedback and comments on how the PQ/CMC data elements are represented in HL7 FHIR. The FDA team has worked collaboratively with the members of various HL7 work groups, including the Biomedical Research and Regulation (BR&R) Workgroup. The BR&R workgroup includes participants from teams working on the FHIR representation of related requirements from the European Medicines Agency (EMA) and Health Canada. FDA is specifically seeking comments on the mapping of the PQ/CMC data elements to the various FHIR Resources. This is not a technical specification or an implementation guide. The actual implementation Guide (IG) will be a separate document and will be published after the HL7 FHIR R5 is officially published. This PQ/CMC information would be submitted in the Common Technical Document (CTD) as defined by the International Council for Harmonisation's (ICH) CTD[1].

Several of the HL7 FHIR Resources related to medicinal products and substances represent the concepts described by the International Organization of Standardization for the Identification of Medicinal Products (ISO IDMP) standards. Many Docket comments to the 2017 PQ/CMC Federal Register Notice emphasized the importance of IDMP conformance [ref]. The IDMP suite of standards are a result of a need to standardize the definition of medicinal product and substance information to facilitate the unique identification and exchange of such information in regulatory submissions. PQ/CMC team has worked actively with EMA representatives in aligning the PQ/CMC and IDMP representations in FHIR resources, where relevant; but note that there are many IDMP code lists left to regional terminologies.

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

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

provided here have been developed for purposes of review of information in Module 3 of the eCTD. For the most current information on the PQ/CMC effort, please go to FDA's Data Standards page, https://www.fda.gov/industry/fda-resources-data-standards.

This document provides a draft design of FHIR profiles that contain the data elements and terminologies associated with PQ/CMC topics and aligned with data elements that are typically included in Module 3 of the electronic Common Technical Document (eCTD)[2] regulatory submissions. It is not intended to be comprehensive in covering all eCTD product quality information, only those concepts that were considered amenable to structuring and would bring value to the quality review process. The existing HL7 v3 eStability data standard has been withdrawn from HL7 and the scope and content of eStability is now covered under PQ/CMC as FHIR representation. The submission of structured data in a standardized format should 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).

Review of these elements and definitions should be conducted by personnel in pharmaceutical companies who will be able to determine if the element definitions and controlled terminologies are understandable and meaningful. Since this document is providing the additional representation and mapping of the PQ/CMC data elements to HL7 FHIR, personnel from the information technology department of the pharmaceutical companies are encouraged to review and provide feedback on the FHIR representation and mapping. A basic understanding of FHIR would aid in the review.

Understanding HL7 FHIR

HL7 FHIR is a standard for exchanging healthcare information electronically. It is an extensive Health IT standard whose communities range from hospital care to regulatory processes. FHIR is a set of modular components called Resources. They document the basic data exchange format and data model behind its exchange. Resources define the component data elements, constraints, and relationships. FHIR supports a mechanism called profiles to constrain and/or extend a resource definition and bind to it a specific vocabulary for a specific use case. PQ/CMC has leveraged twelve FHIR resources and at present designed six PQ/CMC foundational FHIR profiles: Drug Substance, Drug Product, Batch Formula, Quality Specification, Batch Analysis, and Stability. These six profiles are presented in this document.

- The FHIR mapping presented in this document is bound to a pre-R5 ballot draft of HL7 FHIR. All the Medication Definition resources that are used by PQ/CMC were balloted in this release (R5). As with any balloting in a Standards Development Organization (SDO), it is anticipated that once all the FHIR R5 ballot comments are reconciled some parts of the mapping presented in this document will change.
- Information about FHIR and specifically the FHIR R5 release can be found at

[2] Electronic Common Technical Document v3.2.2

https://build.fhir.org/branches/master/.

- Specific examples explaining some of the Medication Definition resources are explained here https://build.fhir.org/medication-definition-module.html.

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.

#	High Level PQ/CMC Domain Mapping	HL7 FHIR Resource Name
1	Drug Product definition	MedicinalProductDefinition
2	Substance definition	SubstanceDefinition
3	Ingredient definition	Ingredient
4	Drug Product packaging definition	PackagedProductDefinition
5	Stability Study	ResearchStudy
6	Instance of Substance	Substance
7	Instance of Product, Batch	Medication
8	Product and Substance testing results	Observation
9	Stability Reports, Testing reports	DiagnosticReport
10	Specification	PlanDefinition
11	Batch Formula	ActivityDefinition
12	Drug manufacturers, API manufacturers, Testers, Suppliers	Organization

Figure 1: High Level PQ/CMC domains mapped to FHIR Resources

These twelve (12) FHIR Resources have been arranged together to support the PQ/CMC domains in scope of Phase 1. The first four FHIR resources from the above list (MedicinalProductDefinition, SubstanceDefinition, Ingredient and PackagedProductDefinition) have their origins in the IDMP concepts in support of ISO IDMP 11615 and 11238 standards. PQ/CMC project has leveraged these resources where relevant and extended them to support PQ/CMC requirements.

Additional profiles will describe these main profiles as compositions following the FHIR designation of a bundle as type document. The compositions will align with the eCTD sections. The compositions will themselves be a profile. In FHIR, a profile can be based on other profiles by applying further constraints to another profile. In this manner, the conceptual entity can be presented in FHIR logically and then be broken into smaller files that will correspond to the requirements of the eCTD sections.

Figure 2 below shows how the 12 FHIR Resources are related to each other through references.

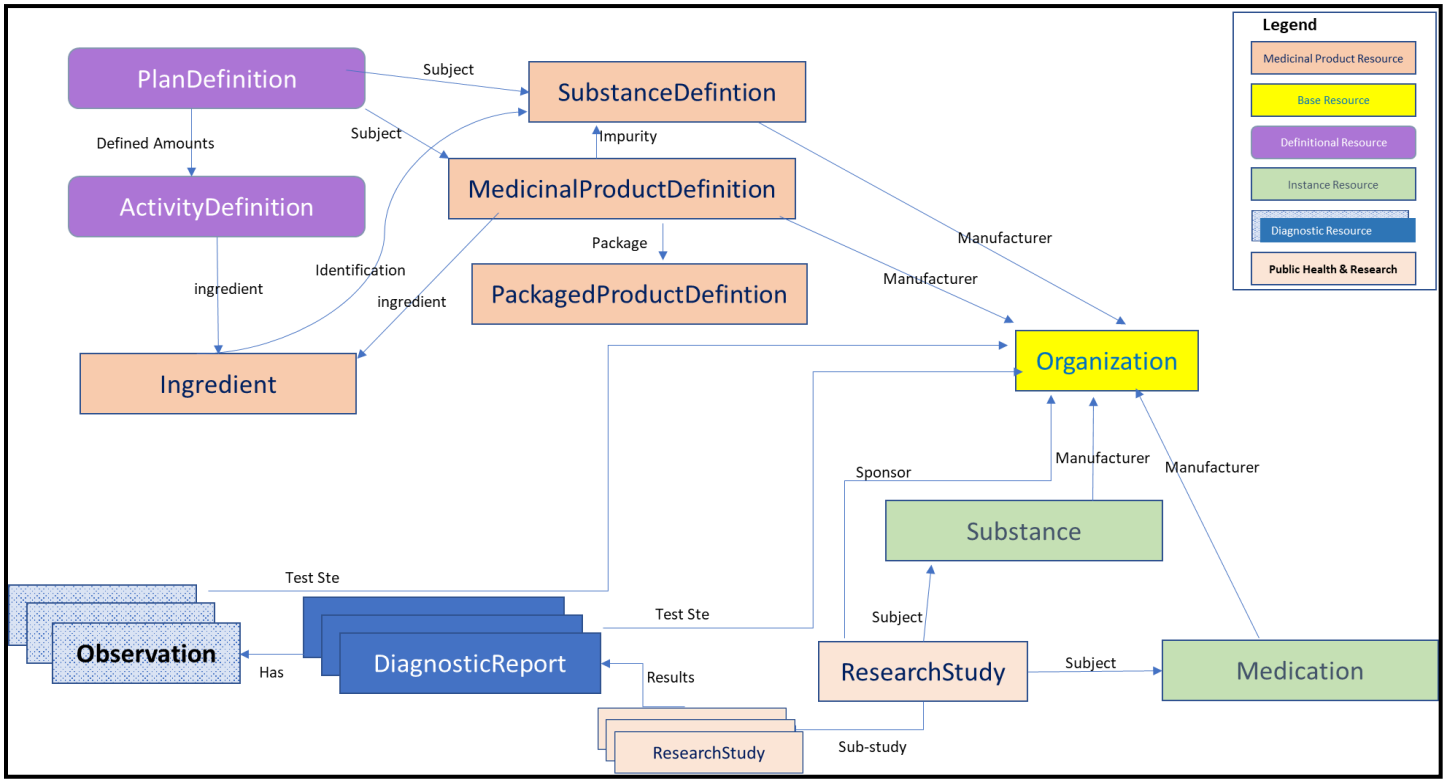

Figure 2: Collection of FHIR Resources in scope of Phase 1 PQ/CMC

This draft document is organized into the following eight sections:

Section 1: Drug Substance Data Elements, beginning on page [7];
Section 2: Drug Product Data Elements, beginning on page [17];
Section 3: Batch Formula Data Elements, beginning on page [30];
Section 4: Quality Specification Data Elements, beginning on page [34];
Section 5: Batch Analysis Data Elements, beginning on page [43];
Section 6: Stability Data Elements, beginning on page [59];
Section 7: PQ/CMC Controlled Terminology, beginning on page [66];
Section 8: Glossary, beginning on page [97].

Each data element section contains two tables: the first identifies and describes the PQ/CMC data elements, the second provides the mapping of each data element to the appropriate FHIR resource element.

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.

HL7 FHIR Mapping

The FHIR Mapping tables show the PQ/CMC Data Elements paired with the FHIR resource element it's mapped to. The FHIR Mapping tables show the FHIR resources as a tree structure and has following columns:

- **PQ/CMC Data Element Name**: Denotes the name of the PQ/CMC element. If the element name is Italicized, the element is not in the Data Elements and FHIR Mapping table and is either required by the FHIR resource or added to give context to the Data Elements. Contextual additions are typically textual, references to other resources for identification of the information or grouping articles.
- **FHIR Resource Element Name**: The name of the FHIR element in the resource. The FHIR element is prefixed by an icon that denotes the underlying type of the content. The icons are described below. The names are hyperlinked to the FHIR specification for additional information about the FHIR construct.
- **FHIR Data Type:** The type of the element hyperlinked to the definition of the type on the HL7 FHIR website.

Key to the Icons in the FHIR Mapping Tables in each section

Symbol	Meaning
	The base element for a resource.
	An element that is part of the resource and has elements within it defined in the same resource or profile.
	An element which can have one of several different types.
	An element of a data type which describes an element that has a value attribute/property. These are also known as primitive types and their names start with a lower-case letter.
	An element of a data type which describes an element that has other elements. These are known as complex types. All complex type names defined in this specification start with an upper-case letter.
	An element that contains a reference to another resource. Since there are no REST endpoints for the PQ/CMC implementation, references are contained resources within the XML file.
	This element has the same content as another element defined within this resource or profile.
	Introduction of a set of slices. Refer to the FHIR website for explanation of slice and slicing.
	A complex extension - one with nested extensions.
	An extension that has a value and no nested extensions.

Section 1: Drug Substance Data Elements and FHIR Mapping

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	

#	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..*	
9	**Molecular**	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	Numeric	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Weight	atoms. [Source: Merriam Webster]			
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	
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"	Graphic	0..*	BR: Multiple graphics are typically seen more often in Biologics. Some techniques produce

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		Example: This is the representation of the instrumental output for the molecule -- CH3OH			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 components intended for transfusion (must be labeled consistent with the requirements in 21 CFR 606.121 (container label) and 606.122

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					(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.
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.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
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	
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	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
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 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.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
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..*	
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.

FHIR Mapping

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Drug Substance	SubstanceDefinition	DomainResource
UNII	identifier	Identifier UNII codes
Impurity Classification (only used when SubstanceDefinition is a reference)	classification	CodeableConcept Binding: PQ/CMC Impurity Classification Terminology
Quality Standard	grade	CodeableConcept Binding: PQ/CMC Quality Benchmark Terminology
Drug Substance Component Manufacturer Name **Drug Substance Component Manufacturer Address**	manufacturer	Reference (Organization)
Drug Substance Component Supplier Name **Drug Substance Component Supplier Address**	supplier	Reference (Organization)
Substance Characterization Technique	technique	CodeableConcept Binding: Nomenclature|| Characterization
Molecular Weight	molecularWeight	
	amount	
	structure	BackboneElement
	representation	BackboneElement
Drug Substance Impurity Method Type	type	CodeableConcept Text only
Structural Representation **Impurity Chemical Structure Data File** **Impurity Analytical Instrument Data File**	representation	String
Structural RepresentationType **Analytical Instrument Data File Type**	format	CodeableConcept Binding (Chemical Structure Data File Type): PQ/CMC Chemical Structure Data File Type Terminology
Substance Structure Graphic **Analysis Graphic** **Analytical Instrument Data File** **Impurity Structure Graphic**	document	Reference (DocumentReference) Note: The file content is stored in the data element as Base64.

Impurity Analysis Graphic		
	code	BackboneElement
CAS Number **INN** **USAN** **IUPAC Name** **ISBT 128**	code	CodeableConcept Text only
	name	BackboneElement
Substance Name **Drug Substance Impurity Name** **Polymorphic Form Identification** **Substance Component Name** **Product Component Name**	name	string
A link between this substance and another, with details of the relationship	relationship	BackboneElement
A pointer to another substance, as a resource or just a representational code	substanceDefinition[x]	
(Impurity Classification)	substanceDefinitionReference	Reference (SubstanceDefinition)
Code (SubstanceDefinition Type) Note: IG code system	type	CodeableConcept Binding: IG codes
	sourceMaterial	BackboneElement
Source Type	type	CodeableConcept Binding: PQ/CMC Source Type Terminology
Source Organism	genus	CodeableConcept Text only
Source Organism	species	CodeableConcept Text only
Source Organism Part	part	CodeableConcept Text only
Source Organism Country of Origin	countryOfOrigin	CodeableConcept Binding: Geopolitical Entities, Names, and Codes Terminology

END OF SECTION 1

Section 2: Drug Product Data Elements and FHIR Mapping

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: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071683.htm] 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: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071638.htm]	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	Code	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		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.			
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 terminology, then propose this new dosage form during sponsor meetings with FDA.	Code	1	
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

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					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] Note: Strength can also be referred to as potency in biologics and other products. This information may be captured on the label.	Number	0..1	
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

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
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 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	
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

#	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.
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

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
					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 Standard**	The established benchmark to which the component complies. [Source: SME Defined] Examples: USP/NF, EP, Company Standard	Code	1..*	
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	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
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..*	
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	Text	0..1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		structure when there are many possible systematic, generic, proprietary or trivial names. [Source: Adapted from CAS.org] Example: CAS [103-90-2]			
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.

FHIR Mapping

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Drug Product	MedicinalProductDefinition	DomainResource
	identifier	Identifier
Drug Product Description	description	Markdown
Dosage Form	combinedPharmaceuticalDoseForm	CodeableConcept Binding: SPL Pharmaceutical Dosage Form Terminology
Reference to Product Component	ingredient	CodeableReference (Ingredient)
Reference to ProductImpurity	impurity	Reference (SubstanceDefinition)
	name	BackboneElement
Product Proprietary Name WHERE MedicinalProductDefinition.Name.type = "proprietary" **Product Non-proprietary Name** WHERE MedicinalProductDefinition.Name.type = "non-proprietary"	productName	String
	type	CodeableConcept Binding: IG codes
	crossReference	BackboneElement
Co-Packaged cross reference	product	CodeableReference (MedicinalProductDefinition)
	package	BackboneElement
Reference to PackagedProductDefinition	package	Reference (PackagedProductDefinition)
	administrableProduct	BackboneElement
Route of Administration	route	CodeableConcept Binding: SPL Pharmaceutical Dosage Form Terminology
Product Component	Ingredient	DomainResource

Reference Link	identifier	Identifier
Drug Product Component Function Category	role	CodeableConcept Binding: PQ/CMC Drug Product Component Function Category Terminology
Drug Product Component Function	function	CodeableConcept Binding: PQ/CMC Excipient Function Terminology
Component Group	group	CodeableConcept Binding: IG codes
Drug Product Component Additional Information	description	Markdown
	substance	BackboneElement
Reference to Ingredient Substance Definition	code	CodeableReference (SubstanceDefinition)
	strength	BackboneElement
	extension:pqStrengthType	
Strength Type (for API)	value[x]	string
	extension:pqContentPercent	
Content (%) Note: same as %w/w	value[x]	Decimal
	extension:pqStrenghtOperator	
Strength Operator Note: For use with presentationQuantity	code	CodeableConcept Binding: PQ/CMC Strength Operator Terminology
	presentation[x]	

StrengthNumericNumerator **Strength NumericNumerator UOM** **StrengthNumericDenominator** **StrengthNumericDenominatorUOM**	presentationRatio	Ratio
Strength (expressed with the Strength Operator)	presentationQuantity	Quantity
Strength Textual	presentationText	String
Ingredient Substance Definition	SubstanceDefinition	DomainResource
	identifier	Identifier
Quality Standard	grade	CodeableConcept Binding: PQ/CMC Quality Benchmark Terminology
	code	BackboneElement
UNII	code	CodeableConcept Binding: UNII codes
	name	BackboneElement
Product Component Name	name	string
	type	CodeableConcept Binding: IG codes
Product Impurity Substance Definition	SubstanceDefinition	DomainResource
	identifier	Identifier

Impurity Classification	classification	CodeableConcept Binding: Process Related Product Related Contaminants Binding: PQ/CMC Impurity Classification Terminology
	code	BackboneElement
UNII	code	CodeableConcept Binding: UNII codes
	structure	BackboneElement
	representation	BackboneElement
Drug Substance Impurity Method Type	type	CodeableConcept Text only
Impurity Chemical Structure Data File **Impurity Analytical Instrument Data File**	representation	String
Impurity Structure Graphic **Impurity Analysis Graphic**	document	Reference (DocumentReference) Note: The file content is stored in the data element as Base64.
	name	BackboneElement
Drug Product Impurity Name	name	String
Drug Product Impurity Method Type	type	CodeableConcept Binding: IG codes
Package PackagedProductDefinition	PackagedProductDefinition	DomainResource
	identifier	Identifier
Container Closure System Description	description	Markdown

Co-Packaged Indicator	copackagedIndicator	Boolean
	package	BackboneElement
Expiration Time (If known)	shelfLifeStorage	ProductShelfLife
	property	BackboneElement
Container Type	type	CodeableConcept Binding: PQ/CMC Container Type Terminology
	property	BackboneElement
Closure Type	type	CodeableConcept Binding: PQ/CMC Closure Type Terminology
	containedItem	BackboneElement
	amount[x]	
	amountQuantity	Quantity

END OF SECTION 2

Section 3: Batch Formula Data Elements and FHIR Mapping

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..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
9	**Product Proprietary Name**	See details of this element in Drug Product section 2			
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			

FHIR Mapping

The Batch Formula FHIR mapping contains a reference to the Ingredient resource. It is subject to change after ballot reconciliation on the Ingredient resource.

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Batch Formula	PlanDefinition	MetadataResource
	title	String
(required)	status	code FHIR codes
	subject[x]	
	subjectCanonical	Canonical (MedicinalProductDefinition)
Batch Formula Additional Information	description	markdown
	goal	BackboneElement
	target	BackboneElement
	detail[x]	
Quantity **Quantity UOM**	detailQuantity	Quantity
	action	BackboneElement

	definition[x]	
	definitionCanonical	Canonical (ActivityDefinition)
Referenced Activity Definition	ActivityDefinition	MetadataResource
Reference Link	identifier	Identifier
Component Additional Information	description	markdown
	product[x]	
	productReference	Reference (Ingredient)
Batch Formula Ingredient	Ingredient	DomainResource
Reference Link	identifier	Identifier
Additional Information	description	markdown
	substance	BackboneElement
	extension:pqQuantityPerrcent	
Quantity Percent	value[x]	Decimal
	extension:pqOveragePercent	
Overage Percent	value[x]	Decimal
	extension:pqOverageJustification	
Overage Justification	value[x]	string
Reference to Ingredient Substance Definition	code	CodeableReference (SubstanceDefinition)
	strength	BackboneElement
	concentration[x]	

Component Quantity Per Batch	concentrationQuantity	Quantity
Ingredient Substance Definition	SubstanceDefinition	DomainResource
Reference Link	identifier	Identifier
	code	BackboneElement
UNII	code	CodeableConcept Binding: UNII codes
	name	BackboneElement
Product Component Name	name	string

END OF SECTION 3

Section 4: Quality Specification Data Elements and FHIR Mapping

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	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
6	**Specification Status**	The current FDA regulatory status of the specification. [Source: SME Defined] Examples: Approved, Not Approved, Reported in a CBE or AR. 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	Code	1	
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	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
13	**Reference to Procedure**	A sponsor/applicant provided alphanumeric code that identifies the procedure. [Source: SME Defined]. Example: HP1234-2008 Note: This could also be a transferred lab method.	Text	1	
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	

#	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..*	

FHIR Mapping

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Quality Specification	PlanDefinition	MetadataResource
	extension:pqSpecificationStatus	
Specification Status	code	CodeableConcept Binding: PQ/CMC Specification Status Terminology
	extension:pqSpecificationType	
Specification Type	code	CodeableConcept Binding: PQ/CMC Specification Type Terminology
	identifier	Identifier
Specification Version	version	string
Specification Title	title	string
Subtitle (optional)	subtitle	string
FHIR PublicationStatus (Required)	status	code draft | active | retired | unknown
	subject[x]	
	subjectCanonical	canonical (MedicinalProductDefinition | SubstanceDefinition |)
Specification Status Date	date	dateTime
	goal	BackboneElement
Acceptance Criteria Usage	category	CodeableConcept Binding: PQ/CMC Test Usage Terminology
Original Text	description	CodeableConcept Text only
	documentation	RelatedArtifact

	type	code Fixed: documentation
Acceptance Criteria Additional Information	display	string
	target	BackboneElement
	detail[x]	
Acceptance Criteria (Numeric)	detailQuantity	Quantity
	extension:pqInterpretationCode	
	valueCodeableConcept	CodeableConcept Binding: PQ/CMC Interpretation Code (numeric) Terminology
Acceptance Criteria (Numeric range**)**	detailRange	Range
	extension:pqInterpretationCode	
	valueCodeableConcept	CodeableConcept Binding: PQ/CMC Interpretation Code (numeric) Terminology
Acceptance Criteria (Text)	detailCodeableConcept	CodeableConcept Binding: PQ/CMC Interpretation Code (text) Terminology
	action	BackboneElement
	extension:pqTestMethodOrigin	
Test Method Origin	code	CodeableConcept Binding: PQ/CMC Test Method Origin Terminology
	extension:pqRRT	
Test Order **Stage Order**	value[x]	Decimal
	extension:pqTestOrder	

Relative Retention Time	value[x]	string
Test Name **Stage Name**	title	string
Test Additional Information	description	string
Test Category **Analytical Procedure (**as Text)	code	CodeableConcept
Reference to Acceptance Criteria	goalId	id
Alternate Test or Prior Stage	relatedAction	BackboneElement
	targetId	id
	relationship	code concurrent | after ActionRelationshipType (Required)
Required for alternate tests	selectionBehavior	code exactly-one
	dynamicValue	BackboneElement
Reference to Procedure	path	string
Stage	action	see action
QS type is Drug Product		
Drug Product	MedicinalProductDefinition	DomainResource
Dosage Form	combinedPharmaceuticalDoseForm	CodeableConcept Binding: SPL Pharmaceutical Dosage Form Terminology
	name	BackboneElement
Product Proprietary Name WHERE MedicinalProductDefinition.Name.type = "proprietary" **Product Non-proprietary Name** WHERE MedicinalProductDefinition.Name.type = "non-proprietary"	productName	String
	type	CodeableConcept

		Binding: IG codes
Product Component	Ingredient	DomainResource
Reference Link	identifier	Identifier
	substance	BackboneElement
Reference to Ingredient Substance Definition	code	CodeableReference (CodeableConcept)
	CodeableReference	Element
UNII	concept	CodeableConcept Binding: UNII codes
	strength	BackboneElement
Strength Textual	presentationText	string
QS type is Drug Substance		
Drug Substance	SubstanceDefinition	DomainResource
UNII	identifier	Identifier UNII codes Note: Small molecule
	code	BackboneElement
ISBT 128	code	CodeableConcept Text only Note: Not small molecule
	name	BackboneElement
Substance Name	name	string
QS type is Drug Excipient		
Reference to Drug Substance	SubstanceDefinition	DomainResource
UNII	identifier	Identifier UNII codes
Drug Substance Component Manufacturer Name **Drug Substance Component Manufacturer Address**	manufacturer	Reference (Organization)

Drug Substance Component Supplier Name **Drug Substance Component Supplier Address**	supplier	Reference (Organization)
	code	BackboneElement
ISBT 128	code	CodeableConcept Text only
	name	BackboneElement
Product Component Name	name	string
	sourceMaterial	BackboneElement
Source Type	type	CodeableConcept Binding: PQ/CMC Source Type Terminology
Source Organism	genus	CodeableConcept Text only
Source Organism	species	CodeableConcept Text only
Source Organism Part	part	CodeableConcept Text only
Source Organism Country of Origin	countryOfOrigin	CodeableConcept Binding: Geopolitical Entities, Names, and Codes Terminology

END OF SECTION 4

Section 5: Batch Analysis Data Elements and FHIR Mapping

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	Code	1	This classification applies to ALL substances.

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		being proposed by the sponsor/applicant for a drug substance. [Source: SME Defined]			* For an original MF/application, Retest Date Classification is "Proposed". * 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**	A unique identifier assigned to the establishment (facility) which manufactures, prepares, propagates,	Text	1..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
	Identifier	compounds or processes drugs. [Source: Adapted from FDA Drug Establishment Current Registration Site]			
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.	Text	1	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		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]			
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	Text	0..*	

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR)/Comments
		batch manufactured using a new Active Pharmaceutical 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			

#	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			

FHIR Mapping

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Batch Analysis	DiagnosticReport	DomainResource
Specification and Specification Version	pqQualitySpecification	Extension
	identifier	Identifier
DiagnosticReportStatus (Required)	status	Code Binding: FHIR
Name/Code for this diagnostic report (Required)	code	CodeableConcept Binding: FHIR IG
	subject	Reference(Medication | Substance)
Batch Analysis Release Date	effective[x]	
	effectiveDateTime	dateTime

Test Site	performer	Reference(Organization)
Result	result	Reference(Observation)
Test Site Organization	Organization	DomainResource
Testing Site Unique Identifier	identifier	Identifier
Testing Site Unique Identifier Type	type	CodeableConcept
Testing Site Name	name	String
Testing Site Address	address	Address
Result Observation	Observation	DomainResource
Stage	identifier	Identifier Note: Fixed "Single Stage" for non-staged test
	status	code Binding: FHIR codes
Test Category	category	CodeableConcept
Test Name **RRT**	code	CodeableConcept Text only
	effective[x]	
Test Date	effectiveDateTime	dateTime
Reference **(Testing Site Unique Identifier)**	performer	Reference (Organization)
	value[x]	
Result **Result Unit of Measure**	valueQuantity	Quantity
Result	valueString	string
	dataAbsentReason	CodeableConcept Binding: FHIR codes
Conformance to Criteria	interpretation	CodeableConcept

		Binding: Conformance to Criteria Terminology
Additional Information	note	Annotation
Analytical Procedure	method	CodeableConcept Text only
	referenceRange	BackboneElement Note: Corresponds to Acceptance Criteria in Quality Specification
	low	SimpleQuantity
Interpretation Code	extension:pqInterpCode	
	value[x]	CodeableConcept Binding: Interpretation Code (numeric) Terminology
	high	SimpleQuantity
Interpretation Code	extension:pqInterpCode	
	value[x]	CodeableConcept Binding: Interpretation Code (numeric) Terminology
Original Text	text	string Note: For non-numeric tests, the Original Text is the only required element for referenceRange.
	hasMember	Reference (Observation) Note: The Stage Sequence Order is implied from the hasMember element. The reference is to the next stage.
	component	BackboneElement
	extension:pqReplicate	
Replicate Number	value[x]	Integer
Test Name RRT	code	CodeableConcept Text Only
	value[x]	

Result **Result Unit of Measure**	valueQuantity	Quantity
Result	valueString	string
	dataAbsentReason	CodeableConcept Binding: FHIR codes
Conformance to Criteria	interpretation	CodeableConcept Binding: Conformance to Criteria Terminology
	referenceRange	see referenceRange
Reference *(*Medication*)*	Medication	DomainResource
Product Proprietary Name **Product Non-proprietary Name**	identifier	Identifier
Organization responsible for manufacturing the item	sponsor	Reference(Organization)
Dosage Form	doseForm	CodeableConcept Binding: SPL Pharmaceutical Dosage Form Terminology
Active or inactive ingredient	ingredient	-
UNII	item	CodeableReference Binding: UNII codes
Active ingredient indicator	isActive	boolean
Quantity of ingredient present	strength[x]	
	strengthRatio	Ratio
Details about packaged medications	batch	BackboneElement
	manufacturingBatch	Extension: URL = http://hl7.org/fhir/StructureDefinition/medication-manufacturingBatch
	extension:manufacturingDate	Extension
	url	uri

Manufacturing Date	value[x]	dateTime
	extension:manufacturingDateClassification	Extension
	url	uri
Manufacturing Date Description	value[x]	CodeableConcept Text only
Extension	extension:assignedManufacturer	Extension
	url	uri
Manufacturing Site	value[x]	Reference(Organization)
	extension:expirationDateClassification	Extension
	url	uri
Expiration Date Classification	value[x]	CodeableConcept Binding: Expiration Date Classification Terminology
	extension:batchUtilization	Extension
	url	uri
Batch Utilization	value[x]	CodeableConcept Binding: PQ/CMC Batch Utilization Terminology
	extension:batchQuantity	Extension
	url	uri
Batch Size **Batch Size Unit**	value[x]	Quantity
	extension:additionalInformation	Extension
	url	uri
Additional Information	value[x]	string

	extension:container	Extension
	extension:lotNumber	Extension
	url	uri
Container Lot Number	value[x]	string
	extension:type	Extension
	url	uri
Container Type	value[x]	CodeableConcept Binding: PQ/CMC Container Type Terminology
	extension:quantity	Extension
	url	uri
Container Fill **Container Fill Unit** **Container Size** **Container Size Unit**	value[x]	Ratio
	extension:closureSystemDescription	Extension
	url	uri
Container Closure System Description	value[x]	string
	extension:closureType	Extension
	url	uri
Closure Type	value[x]	CodeableConcept Binding: PQ/CMC Closure Type Terminology
Batch or Lot Number (Bulk Batch ID)	lotNumber	string
Expiration Date	expirationDate	dateTime
Reference *(Substance)*	Substance	DomainResource

	manufacturingBatch	Extension: URL = http://hl7.org/fhir/StructureDefinition/medication-manufacturingBatch
	extension:manufacturingDate	Extension
	url	uri
Manufacturing Date	value[x]	dateTime
	extension:manufacturingDateClassification	Extension
	url	uri
Manufacturing Date Description	value[x]	CodeableConcept Text only
	extension:assignedManufacturer	Extension
	url	uri
Manufacturing Site	value[x]	Reference (Organization)
	extension:expirationDateClassification	Extension
	url	uri
Retest Date Classification	value[x]	CodeableConcept Binding: Expiration Date Classification
	extension:batchUtilization	Extension
	url	uri
Batch Utilization	value[x]	CodeableConcept Binding: PQ/CMC Batch Utilization Terminology

	extension:batchQuantity	Extension
	url	uri
Batch Size **Batch Size Unit**	value[x]	Quantity
	extension:additionalInformation	Extension
	url	uri
Additional Information	value[x]	string
	extension:container	Extension
	extension:type	Extension
	url	uri
Container Type	value[x]	CodeableConcept Binding: PQ/CMC Container Type Terminology
	extension:quantity	Extension
	url	uri
Container Fill **Container Fill Unit** **Container Size** **Container Size Unit**	value[x]	Ratio
	extension:closureSystemDescription	Extension
	url	uri
Container Closure System Description	value[x]	string
	extension:closureType	Extension
	url	uri
Closure Type	value[x]	CodeableConcept Binding: PQ/CMC Closure Type

		Terminology
Batch or Lot Number (Bulk Batch ID)	identifier	Identifier
	instance	boolean Fixed:"true"
	status	code active | inactive
UNII **Company Code** **CAS Number** **Substance Name**	code	CodeableReference Binding: UNII codes; Others optional Note: Substance Name text
Retest Date	expiry	dateTime

END OF SECTION 5

Section 6: Stability Data Elements and FHIR Mapping

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 specific elements from the referenced profiles are identified in the FHIR Mapping table.

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. A single file with the main study and all sub-studies can be entered within the contained FHIR element in the same file. Consideration of the file size must be noted. Anticipate the final data load. FHIR files are bound to the same maximum limit (100 MB) for the eCTD. A single sub-study can be submitted as a single file. The main study information is entered as a contained resource within the file. Complex study designs can be exchanged by using the part-of element in Research study to link research studies. A study can link to many studies. The relationship is one directional. The main study is not part-of any other study. The Sub-study always points to the prior condition of the sample. The main study has no condition.

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, this FHIR Profile invokes the FHIR Research Study Resource twice to support that requirement. The last column of the table below indicates the support requirements for the two levels. “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]	Text	0..1	Both

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study
		Example: 00001 - Testing methotrexate as a pill tablet under the storage conditions of 25 deg C/65% RH.			
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 Coated Extended Release Tablets (Product 54321) per the NDA post approval stability commitments.	Text	1	Study
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**	A placeholder for providing comments about the stability study. [Source: SME Defined]	Text	0..1	Both

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study
	Comment				
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
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

#	PQ/CMC Data Element Name	Data Element Name Definition	Data Type	Cardinality	Business Rule (BR) / Comments / Study

FHIR Mapping

PQ/CMC Data Element Name	FHIR Resource Element Name	FHIR Data Type
Stability Study	ResearchStudy	DomainResource
Study Identifier	identifier	Identifier
Study Identifier (optional)	version	string
Study Name	title	string
	protocol	Reference (PlanDefinition)
	Identifier	
	extension:pqProtocolVersion	
Protocol Version	value[x]	string
Protocol Identifier	value	string
Study Reason	primaryPurposeType	CodeableConcept Binding: PQ/CMC Application Type Terminology
Study Design	description	markdown
Reason Stopped	whyStopped	CodeableConcept Text only
	objective	BackboneElement
Study Purpose	description	markdown
Stability Sub-study	ResearchStudy	DomainResource
Sub-study Identifier	identifier	Identifier
Sub-study Identifier (optional)	version	string
Sub-study Name	title	string
Reference to main study or associated study	part of	Reference (ResearchStudy)
	status	Code

PublicationStatus (Required)		draft | active | retired | unknown
Storage Conditions Temp/RH Container Orientation	condition	CodeableConcept Binding: PQ/CMC Storage Conditions Terminology Binding: PQ/CMC Container Orientation Terminology
Sub-study Start Date	period	Period
Sub-study Storage Condition Comment	note	Annotation
Reason Stopped	whyStopped	CodeableConcept Text only
	objective	BackboneElement
Link to stability study results	result	Reference (DiagnosticReport)
Stability Study Results	DiagnosticReport	DomainResource
	pqPullInterval	Extension
Interval	value[x]	quantity
Interval Description Code	code	Code Binding: Binding: PQ/CMC Time Point Description Terminology
	pqQualitySpecification	Extension
	Identifier	Identifier
Quality Specification	value	string
Quality Specification Version	version	string
DiagnosticReportStatus (Required)	status	Code Binding: FHIR
Name/Code for this diagnostic report (Required)	code	CodeableConcept Binding: FHIR IG
	subject	Reference (Medication | Substance)
Test Site	performer	Reference (Organization)

Result	result	Reference (Observation)
NOTE: Test Site Organization, Result Reference (Observation), Reference (Medication) Reference (Substance) are the same as those defined in the Batch Analysis profile in Section 5.		

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 -- http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070336.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
		inverted	C133999	closure down orientation
		valve-up	C133914	dispenser (valve) pointing upwards for inhalers

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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).
		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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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 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]

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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]
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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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
		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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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]
		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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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.
		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 ^{o}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 ^{o}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 ^{o}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 ^{o}C	C133935	Storage at 5 degrees Celsius plus or minus 3 degrees Celsius.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		-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
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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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.
		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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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.
		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]

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		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 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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
		CFN	C134005	Central File Number
		Unknown	C17998	Unknown
30	**Interval Description Code**	Delayed Testing	C96151	Sample is not tested immediately.
		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		

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.

#	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.
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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				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 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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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 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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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.
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

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
				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.
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.

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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.
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).

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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>)
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**	Carrier	C176645	Agents designed to interact with, and enhance the properties, of active pharmaceutical ingredients (APIs). Carrier excipients promote various

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Function			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 Function**	Cryoprotectant	C53306	Agent added to prevent cell damage during freeze-drying. (Adapted from Medicinescomplete)
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)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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)
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)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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.
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)

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
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 Function**	Osmotic agent	C176657	Material used to provide osmotic pressure differential in osmotic pump-based drug product delivery systems.
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**	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).

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Function			
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.
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**	Surfactant	C42739	Substances used to enhance stability by reducing surface tension (e.g., anionic surfactant; cationic surfactant; nonionic surfactant).

#	PQ/CMC Data Element Name	Valid Values	NCIt Concept Codes	Valid Value Meaning
	Function			
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)
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

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
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
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

#	PQ/CMC Data Element Name	Valid values	Display Value	NCIt Concept Code
58	Unit of Measure	pg	Picogram	C64551
59	Unit of Measure	pmol	Picomole	C65045
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
MF	Master Files

Acronym	Description
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

Appendix A: Examples 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 DOCUMENT