Background

As part of an effort intended to support future electronic acquisition and use of submitted information, a project was undertaken to identify and prioritize pharmaceutical quality/chemistry, manufacturing and controls (PQ/CMC) information that would benefit from a structured submission approach. This information would be submitted in the Common Technical Document as defined by the International Council for Harmonisation's (ICH) Common Technical Document (CTD).[1] The goals of this project were (a) to identify types of PQ/CMC information that are available in applications, information that is important to evaluate an application, information categories and elements that are common across the various application types, and (b) to provide recommendations for standardization of the categories and data types necessary for application review. This initiative will align, where comparable elements exist, with substance and product identifiers described by the International Organization of Standardization for the Identification of Medicinal Products (ISO IDMP) standards.

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

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

This document provides draft data elements and terminologies associated with PQ/CMC subject areas and scoped to some of what is currently submitted in Module 3 of the electronic Common Technical Document (eCTD)[2] submission, but is not intended to be comprehensive in covering all eCTD product quality information. Currently, there are limited (e.g., HL7 eStability message) existing data standards and terminologies for PQ/CMC data. To address this issue, FDA has developed limited structured data elements and supporting terminologies for PQ/CMC and has recently engaged in discussions with standard-setting bodies to codify these data elements into a data exchange specification for the submission of PQ/CMC data. 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.

This draft document has three sections:

Section 1: PQ/CMC Data Elements

The tables in this section are the PQ/CMC data elements for which FDA is soliciting industry input and feedback. The PQ/CMC data elements are grouped by logical CMC domain categories such as Specification, Batch Information, Batch Analysis, etc. There are a total of

[2] Electronic Common Technical Document Specification V3.2.2

15 PQ/CMC tables. Some of the data elements in these tables have a controlled terminology (coded value set) which is documented in Section 2. The columns in the data element tables are as follows:

- **Data Element Name**: Denotes the name of the PQ/CMC element.
- **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. 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, etc.
- **Controlled Terminology/Vocabulary:** Refers to the associated terminology table in Section 2 of this document. When a data element has a pre-defined controlled terminology or a controlled list of permissible/valid values, the text in the column is "See Controlled Terminology Table in Section 2."

Some of the data elements occur in multiple tables but are only defined once. Subsequent occurrences of the data element refer to the initial occurrence. For example, in the Batch Analysis Table (Table 5), row 2, the data element is "Specification Version" and has a reference note stating "Same element as defined in Specification table, row 3." The reference to the initial definition is added to provide context. Currently, FDA is not seeking comment on data element conformance (e.g., mandatory/optional) and cardinality (e.g., one or more of each element). These will be addressed in a future implementation guide.

As an aid to evaluating the terms, the table headers often contain a definition for the domain category or concept (e.g., Specification) and also a reference to the sections in eCTD Module 3 where the pertinent PQ/CMC data resides. Typically, the elements in these tables are part of any general submission. Every submission will be tempered by factors such as: novelty of the drug, dosage, route of administration, known or suspected risks, etc.

1. Specification – Due to minor differences in the definition of Specification in CDER, CBER and CVM regulations we are including all three below:
CDER & CBER - (314.3) Specification means the quality standard (i.e. , tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.

CVM - (514.8 (iv)) Specification means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drugs including, for example, drug substances, Type A medicated articles, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug. For the purpose of this definition, the term "acceptance criteria" means numerical limits, ranges, or other criteria for the tests described.

CBER & CDER - (600.3 (kk)) Specification, as used in 601.12 of this chapter, means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.

eCTD Mapping: 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

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
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	Not Applicable
2	**Specification Type**	A classification of specification related to the kind of the entity it is referencing. [Source: SME Defined]	Code	See Controlled Terminology Table in

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Examples: Drug product, drug substance, etc.		Section 2
3	**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, etc.	Text	Not Applicable
4	**Specification Version Date**	The date when the sponsor assigned a date to a specific version. [Source: SME Defined]	Date	Not Applicable
5	**Specification Status**	The current FDA regulatory status of the specification. [Source: SME Defined] Examples: Approved, Not Approved, etc.	Code	See Controlled Terminology Table in Section 2
6	**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).	Date	Not Applicable
7	**Additional Information**	Placeholder for providing any comments that are relevant to the specification. [Source: SME Defined] Examples: replaces method ABC, using the XYZ facility, etc.	Text	Not Applicable

2. Test – A determination of a physical, chemical or biological property. [Source: SME Defined]

eCTD Mapping: 3.2.S.4.1, 3.2.P.5.1

Stage - A set of discrete sequential steps performed on a given test. [Source: SME Defined]
Note: Level and Tier could be synonyms for Stage. A Test can have many stages.

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Test Name**	The textual description of a procedure or analytical method. [Source: SME Defined]	Text	Not Applicable
2	**Test Usage**	A coded value specifying the time point during the manufacturing process of a substance or product when a particular analytical procedure or measurement is being performed. [Source: SME Defined]	Code	See Controlled Terminology Table in Section 2
3	**Test Method Origin**	A coded value specifying the source of the method. [Source: SME Defined] Example: Compendial	Code	See Controlled Terminology Table in Section 2
4	**Test Category**	A high level grouping of product quality attributes. [Source: SME Defined] Examples: Appearance, Content Uniformity, Dissolution, etc.	Code	See Controlled Terminology Table in Section 2
5	**Analytical Procedure**	A technique used to determine the nature of a characteristic. [Source: SME Defined] Examples: HPLC, Capillary Electrophoresis, etc.	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Note: ICH Glossary - Q2a - The analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each analytical test. This may include but is not limited to: the sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc.		
6	**Reference to Procedure**	A sponsor provided alphanumeric code that describes the procedure. [Source: SME Defined] Example: HP1234-2008 Note: This could also be a transferred lab method.	Text	Not Applicable
7	**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. It is used as an alias for the name of the unidentified impurities. [Source: Adapted from USP] Example: 1:23 (a ratio)	Numeric	Not Applicable
8	**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	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
9	**Stage Sequence Order**	The order of the stages in regular succession. [Source: SME Defined] Examples: 1, 2, 3, etc.	Numeric	Not Applicable

3. Acceptance Criteria – Numerical limits, ranges, or other criteria for the tests described. [Source: 21 CFR 314.3, 514.3 and 600.3]

eCTD Mapping: 3.2.S.4.1, 3.2.P.5.1

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Value**	A text or numeric value of the result of the test. [Source: SME Defined]	Text	Not Applicable
2	**Value 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: mg, L, etc.	Code	See Controlled Terminology Table in Section 2
3	**Literal 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	Not Applicable
4	**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	See Controlled Terminology Table in Section 2
5	**Additional Information**	A textual field to provide any additional information about the	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		acceptance criteria. [Source: SME Defined] Example: value changed from 4% to 5% on 01/01/2010		

4. Batch or Lot Information – Information associated with a specific quantity (or a subset of a quantity) of a drug or other material that is intended to have uniform character and quality, within specified acceptance criteria, and is produced according to a single manufacturing order during the same cycle of manufacture. [Source: Adapted from 21 CFR 210.3(b)(2). Nasal Spray 2002]
NOTE: For FDA CMC, the terms Batch and Lot may be considered synonymous.
NOTE: For Biologics, the reference quantity is typically referred to as a Lot as per biologics regulations (21 CFR 600.3(x)).

eCTD Mapping: 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

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
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	Not Applicable
2	**Batch or Lot Number (Packaged Batch ID)**	Same as above (For packaged Batch Lot)	Text	Not Applicable
3	**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	Not Applicable
4	**Manufacturing Site Unique**	A unique identifier assigned to the establishment (facility) which	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
	Identifier	manufactures, prepares, propagates, compounds or processes drugs. [Source: Adapted from FDA Drug Establishment Current Registration Site]		
5	**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	See Controlled Terminology Table in Section 2
6	**Manufacturing Date**	The date associated with manufacturing a batch. [Source: SME Defined] Note: See Manufacturing Date Description element.	Date	Not Applicable
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.	Text	Not Applicable
8	**Testing Site Name**	The name of the establishment (facility) which tests the raw materials, intermediates, drug substance, drug product, packaging components, etc. [Source: SME Defined]	Text	Not Applicable
9	**Testing Site Unique Identifier**	A unique identifier assigned to the establishment (facility) which performs the testing. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
10	**Testing Site Unique identifier Type**	A value that identifies the source of the unique identifier. [Source: SME Defined] Examples: DUNS, FEI, etc.	Code	See Controlled Terminology Table in Section 2
11	**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	Not Applicable
12	**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] Examples: L, Kg, etc.	Code	See Controlled Terminology Table in Section 2
13	**Expiration Date**	The date placed on the container label of a drug product (and/or drug substance) designating the time prior to which a batch of the product is expected to remain within the approved specification if stored under defined conditions, and after which it must not be used. [Source: Adapted from Q1A(R2)]	Date	Not Applicable
14	**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	Not Applicable
15	**Container Closure System**	Any textual comments that describe the sum of container closure system (CCS) components that together contain and protect the	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
	Description	dosage form or drug substance. [Source: Adapted from Q1A(R2)-ICH Glossary] Example: White opaque, round 50 mL High Density Polyethylene (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 product. A packaging system is equivalent to a container closure system. [Source: Adapted from Q1A(R2)-ICH Glossary]		
16	**Container Type**	The kind of container that drug substances and finished dosage forms are held, which could include both the immediate (or primary) and secondary containers [Source: Adapted from NCI Thesaurus C43164] Examples: Box, bottle, carton, canister, etc.	Code	See Controlled Terminology Table in Section 2
17	**Closure Type**	The kind of closures used for the container in which the drug substances and finished dosage forms are stored. [Source: SME Defined] Examples: Child-resistant, Metal; Press-on, Composite, etc.	Code	See Controlled Terminology Table in Section 2

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
18	**Container Size**	The volume or physical proportions or dimension of the container. [Source: SME Defined] Example: 250 Note: may not apply to all container types, for example – single dose	Text	Not Applicable
19	**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, etc.	Text	See Controlled Terminology Table in Section 2
20	**Container Fill**	Amount or volume of the drug product in the container. [Source: SME Defined]. Examples: 100 tablets; 10 mL, 1 patch, 1 sachet, etc. Note: the examples include both the Container Fill and the Container Fill Unit	Text	Not Applicable
21	**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, etc.	Text	See Controlled Terminology Table in Section 2
22	**Batch Utilization**	A categorization of the batch that identifies its usage. [Source: SME Defined] Examples: commercial, development, etc.	Code	See Controlled Terminology Table in Section 2
23	**Drug Substance Lot Number**	Lot number of the drug substance used in manufacturing a drug	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		product batch. [Source: SME Defined]		
24	**Additional Information**	A placeholder for providing any comments relevant to the Batch. [Source: SME Defined] Examples: first batch manufactured at a new facility; first batch manufactured using a new Active Pharmaceutical Ingredient (API) source, new process, new container closure, etc.	Text	Not Applicable

5. Batch Analysis Drug Substance or Drug Product – The results associated with analyzing or evaluating the quality of a drug substance or a drug product batch based on the release specification. [Source: SME Defined]

eCTD Mapping: 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

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Batch or Lot Number** [Same element as defined in Batch or Lot Information Table - row 1]	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	Not Applicable
2	**Specification Version** [Same element as defined in Specification Table - row 3]	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, etc.	Text	Not Applicable
3	**Test Date**	The date when a particular test was performed. [Source: SME Defined]	Date	Not Applicable
4	**Test Category** [Same element as defined in Test Table - row 4]	A high level grouping of product quality attributes. [Source: SME Defined] Examples: Appearance, Content Uniformity, Dissolution, etc.	Code	See Controlled Terminology Table in Section 2
5	**Results**	The outcome of a test performed on a batch. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Examples: 98% for Assay; 7.1 for pH, etc.		
6	**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	See Controlled Terminology Table in Section 2
7	**Testing Site Name** [Same element as defined in Batch or Lot Information Table - row 8]	The name of the establishment (facility) which tests the raw materials, intermediates, drug substance, drug product, packaging components, etc. [Source: SME Defined]	Text	Not Applicable
8	**Drug Substance Product Indicator**	A value indicating whether this batch analysis is for a drug substance or a drug product. [Source: SME Defined]	Text	See Controlled Terminology Table in Section 2
9	**Drug Substance Lot Number** [Same element as defined in Batch or Lot Information Table - row 23]	Lot number of the drug substance used in manufacturing a drug product batch. [Source: SME Defined]	Text	Not Applicable
10	**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 analysis.	Date	Not Applicable

6. Stability Study – An execution of a structured plan of a formal investigation to continually evaluate the physical, chemical, biological, microbiological, biochemical, and immunochemical attributes of a drug substance or a drug product as a function of time. [Source: SME Defined]
Note: This is intended to capture the results of the study as executed by the details defined by the protocol.

eCTD Mapping: 3.2.S.7.3; 3.2.P.8.3; Also used with Annual Report 1.13

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Study Name**	A non-unique textual identifier given to the drug stability study by the sponsoring organization. [Source: SME Defined] Example: 00001 - Testing methotrexate as a tablet under the storage conditions of 25 ˚C/65% Relative Humidity (RH).	Text	Not Applicable
2	**Study Design**	A textual description providing the details of the study plan which includes tests, time points, storage conditions, method, etc. [Source: SME Defined]	Text	Not Applicable
3	**Storage Conditions**	The temperature and the relative humidity under which the study was performed. [Source: SME Defined] Examples: 25 ± 2 ^{0}C /60% ± 5% RH ; 5 ± 3 ^{0}C , etc.	Code	See Controlled Terminology Table in Section 2
4	**Protocol Identifier**	An alphanumeric identifier assigned to a protocol by the sponsoring organization. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
5	**Study Identifier**	An alphanumeric identifier assigned to a study by the sponsoring organization. [Source: SME Defined] Example: Study Number- 565758	Text	Not Applicable
6	**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, etc. Note: simulating the periods of use could cover, for example – inhaler left in the car, removing the drug from refrigerator and putting it back in, etc.	Code	See Controlled Terminology Table in Section 2
7	**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, etc.	Code	See Controlled Terminology Table in Section 2
8	**Study Purpose**	A textual description intended to provide a high level objective and rationale for the study. [Source: SME Defined]	Text	Not Applicable

7. Nomenclature & Structure of Drug Substance – The description of how a substance is named and graphically rendered. [Source: SME Defined]

eCTD Mapping: 3.2.S.1.1; 3.2.S.1.2

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Chemical Name**	A commonly used name or a systematic name assigned to the chemical or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N-(4-hydroxyphenyl)-; 4-hydroxyacetanilide	Text	Not Applicable
2	**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	Not Applicable
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. [Source: International Nonproprietary Names]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Example: Paracetamol Note: International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients.		
4	**USAN**	A unique nonproprietary name assigned to drugs and biologics by the United States Adopted Names Council [Source: SME Defined] Example: acetaminophen	Text	Not Applicable
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	Not Applicable
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: Substance Registration System – Unique identifier] Example: 362O9ITL9D Note: If a UNII does not exist, please go to Substance Registration System – Unique identifier	Text	Not Applicable
7	**Company Code**	An internal identifier assigned by the sponsor to this drug substance. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
8	**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"	Graphic	Not Applicable
9	**Chemical Structure Data File**	A machine readable representation of the structure of the chemical. [Source: SME Defined] Examples: SDF, MOLFILE, InChi file (small molecule), PDB, mmCIF (large molecules), etc.	Text	Not Applicable
10	**Chemical Structure Data File Type**	A format name or abbreviation that identifies a file structure. [Source: SME Defined] Examples: SMILES, MOLFILE, etc.	Code	See Controlled Terminology Table in Section 2

8. Drug Substance Characterization – The structural and functional characterization of a drug substance using orthogonal analytical techniques. [Source: SME Defined]

eCTD Mapping: 3.2.S.3.1

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Chemical Name** [Same element as defined in Nomenclature Table 7 - row 1]	A commonly used name or a systematic name assigned to the chemical or compound. [Source: SME Defined] Examples: acetaminophen; acetamide, N-(4-hydroxyphenyl)-; 4 – hydroxyacetanilide	Text	Not Applicable
2	**USAN** [Same element as defined in Nomenclature Table 7- row 4]	United States Adopted Names (USAN) A unique nonproprietary name assigned to drugs and biologics by the United States Adopted Names Council). [Source: SME Defined] Example: acetaminophen	Text	Not Applicable
3	**UNII** [Same element as defined in Nomenclature Table 7- row 6]	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: Substance Registration System – Unique identifier] Example: 362O9ITL9D Note: If a UNII does not exist, please go to Substance Registration System – Unique identifier	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
4	**Drug Substance Method Type**	The technique used to elucidate the structure or characterization of the drug substance. [Source: SME Defined]	Text	Not Applicable
5	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram, etc. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	Not Applicable
6	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/ Binary	Not Applicable
7	**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), etc.	Text	Not Applicable

9. Description and Composition of Drug Product – The description of the drug product and the identification and amount of the components in a unit of a drug product. [Source: SME Defined]

eCTD Mapping: 3.2.P.1

Diluent - A diluent is a discrete, usually multicomponent part of a drug product. It can be thought of as part of a kit (the kit being the formal drug product), the pieces of which need to be combined in some manner for use. In some cases, it may be an independent drug product with other uses. Simplest example might be a vial of water (diluent) packaged with a vial of dry powder that are mixed to form an injectable solution.
Note: If a Product has a Diluent, then we need to know all the components of the Diluent.

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Product Proprietary Name**	The exclusive name of a drug substance or drug product owned by a company under trademark law regardless of registration status with the Patent and Trademark Office (PTO). [Source: FDA Data Standards Manual Proprietary Name]	Text	Not Applicable
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: FDA Data Standards Manual – Use of Drug Names Policy]	Text	Not Applicable
3	**Dosage Form**	The form in which active and/or inert ingredient(s) are physically presented. [Source: NCI EVS - C42636]	Code	See Controlled Terminology Table in

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Examples: tablet, capsule, solution, cream, etc. 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.		Section 2
4	**Strength**	The content of an active 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.	Number	Not Applicable
5	**Strength Unit of Measure**	The labeled unit of measure for the content of an active ingredient, expressed quantitatively per dosage unit. [Source: Adapted for NCI EVS C117055] Examples: mg, g, mL, etc.	Code	See Controlled Terminology Table in Section 2
6	**Overage Percent**	Overage is an amount of a drug substance in excess of the label claim. [Source: Guidance for Industry - ucm389069.pdf] Note: Overage is different from overfill. Overfill is excess volume intended to meet the label claim. [Source: SME Defined] Note: If overage is present, provide the rationale in the "Overage	Numeric Percent	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Justification" data element.		
7	**Overage Justification**	The rationale for use of excess material in the drug product or drug substance. [Source: SME Defined]	Text	Not Applicable
8	**Drug Product Description**	A textual narrative describing the drug product or products. [Source: SME Defined] Examples: dosage form, container closure system, purpose, etc.	Text	Not Applicable
9	**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	Not Applicable
10	**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: Substance Registration System – Unique Identifier] Note: If a UNII does not exist, please go to Substance Registration System – Unique Identifier	Text	Not Applicable
11	**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]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Example: CAS [103-90-2]		
12	**Drug Product Component Function**	A classification of components identifying its purpose/role in the drug product. [Source: SME Defined] Examples: Filler, Surfactant, etc.	Text	Not Applicable
13	**Amount per unit**	Specifies the quantity of the component per unit dose of the drug product consistent with the label claim. [Source: SME Defined] Examples: mg, g, Kg, mL, etc. Note: Kg value is only applicable for veterinary applications.	Code	See Controlled Terminology Table in Section 2
14	**Content (%)**	The percentage of the component in the drug product. [Source: SME Defined]	Numerical Percent	Not Applicable
15	**Quality Benchmark**	The established standard to which the component complies. [Source: SME Defined] Examples: United States Pharmacopeia/National Formulary (USP/NF); European Pharmacopoeia (EP), etc.	Code	See Controlled Terminology Table in Section 2
16	**Drug Product Component Additional Information**	A placeholder for providing any comments relevant to the component. [Source: SME Defined] Examples: removed during process, adjusted for loss on drying, etc.	Text	Not Applicable
17	**Diluent Description**	A narrative or text that provides the name, purpose, function, etc. of the diluent. [Source: SME Defined] Examples: sodium chloride solution, water for injection (WFI)	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Note: Diluent ONLY applies when it is part of the marketed drug product.		
18	**Diluent Volume**	Specifies the amount or measurement of the diluent to be used for reconstituting the drug product. [Source: SME Defined]	Numeric	Not Applicable
19	**Diluent Unit of Measure**	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds. [Source: NCI EVS C25709] Examples: mL, L, etc. Note: Only volume related units.	Code	See Controlled Terminology Table in Section 2
20	**Diluent Container Closure Type**	The kind of container/closure used in which the diluent is stored. [Source: SME Defined] Example: vial	Code	See Controlled Terminology Table in Section 2 for Closure Type Data Element
21	**Diluent Component Name**	Any ingredient intended for use in the manufacture of a diluent of a drug product, including those that may not appear in such drug product. [Source: 21 CFR 210.3(b)(3)); UCM070582.pdf]	Text	Not Applicable
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: Substance Registration System-Unique Identifier] Note: If a UNII does not exist, please go to Substance Registration	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		System-Unique Identifier		
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	Not Applicable
24	**Diluent Component Function**	A classification of components identifying its purpose/role in the diluent for the drug product. [Source: SME Defined] Examples: vehicle, solvent, etc.	Text	Not Applicable
25	**Amount Per Unit**	Specifies the quantity of the diluent in the container (vial, ampule, etc.). [Source: SME Defined]	Code	See Controlled Terminology Table in Section 2
26	**Content (%)**	The percentage of the components comprising the diluent, i.e., the materials in the diluent formulation. [Source: SME Defined]	Numerical Percent	Not Applicable
27	**Quality Benchmark**	The established standard to which the component complies. [Source: SME Defined] Examples: United States Pharmacopeia/National Formulary (USP/NF);	Code	See Controlled Terminology Table in Section 2

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		European Pharmacopoeia (EP), etc.		
28	**Diluent Component Additional Information**	A placeholder for providing any comments relevant to the diluent component. [Source: SME Defined]	Text	Not Applicable
29	**Diluent Component Supplier Name**	The full name of the establishment (facilities) that was the vendor for the component. [Source: SME Defined] Note: It may be different from the manufacturer of the component. Note: The words supplier and vendor are seen here as synonyms.	Text	Not Applicable
30	**Diluent Component Supplier Address**	The complete street address for the vendor of the component, including street name, city, state, zip, country, etc. [Source: SME Defined]	Text	Not Applicable
31	**Diluent Component Manufacturer Name**	The name of the establishment (facilities) that created, made, produced or fabricated the component. [Source: SME Defined] Note: If the manufacturer is different from the supplier, provide the manufacturer name.	Text	Not Applicable
32	**Diluent Component Manufacturer address**	The complete street address for the manufacturer of the component, including street name, city, state, zip, country, etc. [Source: SME Defined	Text	Not Applicable

10. Batch Formula –The list and quantity of drug product components for a set scale of a manufactured product. [Source: SME Defined]

eCTD Mapping: 3.2.P.3.2

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Amount**	The quantity of the drug product presented in a specific batch size. [Source: SME Defined] Example: 1000	Numeric	Not Applicable
2	**Amount 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] Example: Kg	Code	See Controlled Terminology Table in Section 2
3	**Batch Formula Additional Information**	A placeholder for providing any comments relevant to the batch formula. [Source: SME Defined] Examples: magnesium stearate, animal source	Text	Not Applicable
4	**Product Component Name** [Same element as defined in Description and Composition of Drug Product Composition Table-row 8]	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	Not Applicable
5	**Component Amount Per Batch**	Specifies the quantity of the component per batch size of the drug	Numeric	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		product. [Source: SME Defined]		
6	**Quality Benchmark**	The established standard to which the component complies. [Source: SME Defined] Examples: : United States Pharmacopeia/National Formulary (USP/NF); European Pharmacopoeia (EP), etc.	Code	See Controlled Terminology Table in Section 2
7	**Component Additional Information**	A placeholder for providing any comments relevant to the component. [Source: SME Defined] Examples: removed during process, adjusted for loss on drying, etc.	Text	Not Applicable

11. Drug Substance – Control of Materials – The evidence of the identity, composition and origin of the raw materials and the drug substance. [Source: SME Defined]

eCTD Mapping: 3.2.S.2.3

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Specification Version** [Same element as defined in Specification Table - row 3]	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, etc.	Text	Not Applicable
2	**Specification Version Date** [Same element as defined in Specification Table - row 4]	The date when the sponsor assigned a date to a specific version. [Source: SME Defined]	Date	Not Applicable
3	**Specification Status** [Same element as defined in Specification Table - row 5]	The current FDA regulatory status of the specification. [Source: SME Defined] Examples: Approved, Not Approved, etc.	Code	See Controlled Terminology Table in Section 2
4	**Specification Status Date** [Same element as defined in Specification Table - row 6]	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).	Date	Not Applicable
5	**Substance Component Name**	Any raw material intended for use in the manufacture of a drug substance. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
6	**Quality Benchmark**	The established standard to which the component complies. [Source: SME Defined]	Code	See Controlled Terminology Table in Section 2
7	**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: Substance Registration System-Unique Identifier] Note: If a UNII does not exist, please go to : Substance Registration System-Unique Identifier	Text	Not Applicable
8	**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	Not Applicable
9	**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	See Controlled Terminology Table in Section 2
10	**Diluent Component Supplier Name**	The full name of the establishment (facilities) that was the vendor for the component. [Source: SME Defined]	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		Note: It may be different from the manufacturer of the component. Note: The words supplier and vendor are seen here as synonyms.		
11	**Diluent Component Supplier Address**	The complete street address for the vendor of the component, including street name, city, state, zip, country, etc. [Source: SME Defined]	Text	Not Applicable
12	**Diluent Component Manufacturer Name**	The name of the establishment (facilities) that created, made, produced or fabricated the component. [Source: SME Defined] Note: If the manufacturer is different from the supplier, provide the manufacturer name.	Text	Not Applicable
13	**Diluent Component Manufacturer address**	The complete street address for the manufacturer of the component, including street name, city, state, zip, country, etc. [Source: SME Defined	Text	Not Applicable
14	**Source Organism**	The name, genus or genus and species of the organism from which the material is derived. [Source: SME Defined] Examples: human, Homo *Sapiens*, chicken, poultry, dog or canine, cow or bovine, *Rattus* or rat, etc.	Text	Not Applicable
15	**Source Organism Subsource**	A sub-part 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.	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
16	**Source Organism Country of Origin**	The name of the country where the organism was reared. [Source: SME Defined]	Code	See Controlled Terminology Table in Section 2

12. Drug Product – Control of Excipient – The evidence of the identity, composition and origin of the raw materials. [Source: SME Defined]

eCTD Mapping: 3.2.P.4.1

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Specification Version** [Same element as defined in Specification Table - row 3]	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, etc.	Text	Not Applicable
2	**Specification Version Date** [Same element as defined in Specification Table - row 4]	The date when the sponsor assigned a date to a specific version. [Source: SME Defined]	Date	Not Applicable
3	**Specification Status** [See Specification Table - row 5]	The current FDA regulatory status of the specification. [Source: SME Defined] Examples: Approved, Not Approved, etc.	Code	See Controlled Terminology Table in Section 2
4	**Specification Status Date** [Same element as defined in Specification Table - row 6]	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).	Date	Not Applicable
5	**Drug Product Component Name** [Same element as defined in	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
	Description and Composition of Drug Product - row 8]	[Source: (21 CFR 210.3(b)(3)) PAC-ATLS 1998]		
6	**Quality Benchmark**	The origin of the quality specification to which the component complies. [Source: SME Defined] Examples: United States Pharmacopeia/National Formulary (USP/NF); European Pharmacopoeia (EP), etc.	Code	See Controlled Terminology Table in Section 2
7	**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: Substance Registration System-Unique Identifier] Note: If a UNII does not exist, please go to Substance Registration System-Unique Identifier	Text	Not Applicable
8	**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	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
9	**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	See Controlled Terminology Table in Section 2
10	**Drug Excipient Component Supplier Name**	The full name of the establishment (facilities) that was the vendor for the component. [Source: SME Defined] Note: It may be different from the manufacturer of the component. Note: The words supplier and vendor are seen here as synonyms.	Text	Not Applicable
11	**Drug Excipient Component Supplier Address**	The complete street address for the vendor of the component, including street name, city, state, zip, country, etc. [Source: SME Defined]	Text	Not Applicable
12	**Drug Excipient Component Manufacturer**	The name of the establishment (facilities) that created, made, produced or fabricated the component. [Source: SME Defined] Note: If the manufacturer is different from the supplier, provide the manufacturer name.	Text	Not Applicable
13	**Drug Excipient Component Manufacturer Address**	The complete street address for the manufacturer of the component, including street name, city, state, zip, country, etc. [Source: SME Defined	Text	Not Applicable
14	**Source Organism**	The name, genus or genus and species of the organism from which the material is derived. [Source: SME Defined] Examples: human, Homo *Sapiens*, chicken, poultry, dog or canine,	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		cow or bovine, *Rattus* or rat, etc.		
15	**Source Organism Subsource**	A sub-part 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.	Text	Not Applicable
16	**Source Organism Country of Origin**	The name of the country where the organism was reared. [Source: SME Defined]	Code	See Controlled Terminology Table in Section 2
17	**Test Category** [Same element as defined in Test Table - row 4]	A high level grouping of product quality attributes. [Source: SME Defined] Examples: Appearance, Content Uniformity, Dissolution, etc.	Code	See Controlled Terminology Table in Section 2
18	**Analytical Procedure** [Same element as defined in Test Table - row 5]	A technique used to determine the nature of a characteristic. [Source: SME Defined] Example: HPLC, Capillary Electrophoresis, etc. ICH Q2A - The analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each analytical test. This may include but is not limited to: the sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc.	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
19	**Reference to Procedure** [Same element as defined in Test Table - row 6]	A sponsor provided alphanumeric code that describes the procedure. [Source: SME Defined] Note: This could also be a transferred lab method.	Text	Not Applicable

13. Drug Substance Impurities – Content in a drug substance that is unintentionally present and is generally found in reasonably low levels. [Source: SME Defined]

eCTD Mapping: 3.2.S.3.2

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Drug Substance Impurity Name**	Any component of the drug substance which is not the chemical entity defined as the drug substance. [Source: ICH Q6A]	Text	Not Applicable
2	**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: Substance Registration System –Unique Identifier] Note: If a UNII does not exist, please go to Substance Registration System –Unique Identifier	Text	Not Applicable
3	**Impurity Classification**	A categorization of impurities based on its source. [Source: SME Defined] Examples: Organic, Inorganic, etc.	Code	See Controlled Terminology Table in Section 2
4	**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, etc.	Text/ Binary	Not Applicable
5	**Impurity Structure Graphic**	A pictorial representation of the structure of the impurity. [Source: SME Defined]	Graphic	Not Applicable

6	**Drug Substance Impurity Method Type**	The technique used to elucidate the structure or characterization of the impurity. [Source: SME Defined]	Text	Not Applicable
7	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram, etc. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	Not Applicable
8	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/ Binary	Not Applicable
9	**Analytical Instrument Data File Type**	A format name or abbreviation that identifies a file structure. [Source: SME Defined] Examples: JCAMP, AnIML, etc.	Text	Not Applicable

14. Drug Product Impurities – Any component of the drug product which is not the chemical entity defined as the drug substance or an excipient in the drug product. This includes process-related impurities and contaminants, product-related impurities including degradation products. [Source: Adapted from ICH Q6A and ICH Q6B]

eCTD Mapping: 3.2.P.5.5

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**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]	Text	Not Applicable
2	**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: Substance Registration System-Unique Identifier] Note: If a UNII does not exist, please go to Substance Registration System-Unique Identifier	Text	Not Applicable
3	**Impurity Classification**	A categorization of impurities based on its source. [Source: SME Defined] Examples: Organic, Inorganic, etc.	Code	See Controlled Terminology Table in Appendix B
4	**Chemical Structure Data File**	A machine readable representation of the structure of the chemical. [Source: SME Defined] Examples: SDF, MOLFILE, InChi file, etc.	Text/ Binary	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
5	**Impurity Structure Graphic**	A pictorial representation of the structure of the impurity. [Source: SME Defined]	Graphic	Not Applicable
6	**Drug Product Impurity Method Type**	The technique used to elucidate the structure or characterize the impurity. [Source: SME Defined]	Text	Not Applicable
7	**Analysis Graphic**	The pictorial representation of the data. [Source: SME Defined] Examples: spectrum, chromatogram, etc. Note: Refer to the "Acceptable File Formats for use in eCTD"	Graphic	Not Applicable
8	**Analytical Instrument Data File**	The transport format for data exchange. [Source: SME Defined]	Text/Binary	Not Applicable
9	**Analytical Instrument Data File Type**	A value that identifies the file format. [Source: SME Defined] Examples: JCAMP, AnIML, etc.	Text	Not Applicable

15. Analytical Methods Validation – Validation of an analytical procedure is to demonstrate that the analytical procedure is suitable for its intended purpose. The objective of the analytical procedure governs the validation characteristics evaluated, such as: accuracy, precision, specificity, detection limit, quantitation limit, linearity and range. [Source: Adapted from ICH Q2]

eCTD Mapping: 3.2.S.4.3, 3.2.P.4.3, 3.2.P.5.3

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
1	**Compendial Method Verification Indicator**	An indicator that demonstrates whether the compendial method is suitable for its intended use. [Source: SME Defined] Examples: Yes, No	Code	See Controlled Terminology Table in Section 2
2	**Validation Title**	The textual identification for the validation. [Source: SME Defined] Example: HPLC method validation for assay and impurity.	Text	Not Applicable
3	**Test Name** [Same element as defined in Test Table - row 1]	The textual description of a procedure or an analysis measure. [Source: SME Defined] Examples: Assay by HPLC, moisture by Karl Fischer, analysis for impurities, etc. Note: as defined by the sponsor.	Text	Not Applicable
4	**Report Number**	The unique identifier assigned to the validation report by the sponsor. [Source: SME Defined] Note: This is typically the document control number on the report.	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
5	**Report Date**	The date of the validation report as identified by the sponsor. [Source: SME Defined]	Date	Not Applicable
6	**Validation Parameter**	The validation criteria used for method validation. [Source: SME Defined] Examples: Specificity, Linearity, etc.	Code	See Controlled Terminology Table in Section 2
7	**Test Usage** [Same element as defined in Test Table - row 2]	A coded value specifying the time point during the manufacturing process of a substance or product when this particular procedure or measurement is being performed. [Source: SME Defined] Examples: Release, Stability, etc.	Code	See Controlled Terminology Table in Section 2
8	**Test Method Origin** [Same element as defined in Test Table - row 3]	A coded value specifying the source of the method. [Source: SME Defined] Example: Compendial	Code	See Controlled Terminology Table in Section 2
9	**Test Category** [Same element as defined in Test Table - row 4]	A high level grouping of product quality attributes. [Source: SME Defined] Examples: Appearance, Content Uniformity, Dissolution, etc.	Code	See Controlled Terminology Table in Section 2
10	**Analytical Procedure** [Same element as defined in Test Table - row 5]	A technique used to determine the nature of a characteristic. [Source: SME Defined] Examples: HPLC, Capillary Electrophoresis, etc. Note: ICH Q2A - The analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each analytical test. This may include but is not limited to: the sample, the reference standard and the	Text	Not Applicable

#	Data Element Name	Data Element Name Definition	Data type	Controlled Terminology/ Vocabulary
		reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc.		
11	**Reference to Procedure** [Same element as defined in Test Table - row 6]	A sponsor provided alphanumeric code that describes the procedure. [Source: SME Defined] Example: HP1234-2008 Note: This could also be a transferred lab method.	Text	Not Applicable
12	**Validation Acceptance Criteria**	The numerical limits, ranges, or descriptive text associated with a validation parameter. [Source: SME Defined]	Text	Not Applicable
13	**Batch or Lot Number** [Same element as defined in Batch Information Table - row 1]	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 the batch or lot of drug product or other material can be determined. [Source: Adapted reference: 21 CFR 210.3 Definitions (4/1/2014)]	Text	Not Applicable
14	**Reference Material Standard**	A reference standard, or reference material, is a substance prepared for use as the standard in an assay, identification, or purity test. [Source: ICH Q6A]	Text	Not Applicable
15	**Validation Results**	The numeric or descriptive outcome of validation activities. [Source: SME Defined]	Text	Not Applicable
16	**Additional Information**	A textual field to provide any additional information about the validation activities. [Source: SME Defined]	Text	Not Applicable

END OF SECTION 1

Section 2

A: PQ/CMC Controlled Terminology

The table in Section 2A contains the controlled terminology/vocabulary defined by the 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. The last column "Table Name" provides a reference back to the PQ/CMC Data element table names in Section 1. Note that for all the Units-related data elements, the SPL Units of Measure (UoM) list, which is a subset of the Unified Code for Units of Measure (UCUM) values, found at the FDA Standards webpage will be used. All the unit-related data elements are presented in row 26 of the controlled terminology table. Values that are missing at present will be included from the UCUM list.

- **Data Element Name:** Denotes the name of the PQ/CMC element.
- **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.
- **Source:** The source of the valid value and/or the value meaning. SME Defined means that this was identified/developed by the FDA PQ/CMC SMEs who are CMC reviewers from CDER, CVM and CBER.
- **Data Element Table Reference:** Provides the reference to the PQ/CMC Data Element table in Section 1.

FDA PQ/CMC Controlled Terminology

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
1	**Batch Utilization**	Commercial	A product batch intended for marketing.	SME Defined	**Batch Lot Information**
		Development	Batches produced during the characterization and process definition for the desired product.	SME Defined	
		Clinical	Batches produced for use in clinical trials.	SME Defined	
		Validation	Batches 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]	SME Defined	
		Bioequivalence	Batch produced and used for the purposes of determining bioequivalence of the product.	SME Defined	
2	**Chemical Structure Data**	Experimental	Chemical structure derived from an investigative process using instrumentation.	SME Defined	**Nomenclature & Structure of**

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
	File Origin	Calculated	Algorithmically generated.	SME Defined	**Drug Substance**
3	**Chemical Structure Data File Type**	SMILES	Simplified Molecular Input Line Entry System	Not Applicable	**Nomenclature & Structure of Drug Substance**
		SDF	Structure Data File	Not Applicable	
		MOLFILE	MDL Molfile	Not Applicable	
		InChi File (small molecule)	IUPAC Chemical Identifier	Not Applicable	
		PDB	Protein Data Bank	Not Applicable	
		mmCIF (large molecules)	macromolecular Crystallographic Information Framework	Not Applicable	
4	**Closure Type**	See information in next column and download the file	HL7 eStability Closure Type values	eStability value list (stability.xls)	**Batch Lot Information**
5	**Compendial Method Verification Indicator**	Yes	Yes	SME Defined	**Analytical Methods Validation**
		No	No	SME Defined	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
6	**Conformance to Criteria**	Conforms	The result complies with the acceptance criteria for the given test	SME Defined	**Batch Analysis of Drug Substance or Drug Product**
		Does not conform	The result does not comply with the acceptance criteria for the given test	SME Defined	
7	**Container Orientation**	Horizontal	parallel to the surface	SME Defined	**Stability Study**
		Upright	closure-up orientation	SME Defined	
		Inverted	closure down orientation	SME Defined	
		valve-up	dispenser (valve) pointing upwards for inhalers	SME Defined	
		valve-down	dispenser (valve) pointing downwards for inhalers	SME Defined	
8	**Container Type**	See information in next column	FDA Data Standards –Package Type	SPL Value list	**Batch Lot Information**
9	**Dosage Form**	See information in next column	FDA Data Standards-Dosage Form	SPL Value list	**Description & Composition of Drug**

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
					Product
10	**Drug Substance Product Indicator**	Substance	Use ISO IDMP Standard definitions	Not Applicable	**Batch Analysis of Drug Substance or Drug Product**
		Product	Use ISO IDMP Standard definitions	Not Applicable	
11	**Impurity Classification**	Organic Impurities (process- and product-related)	Materials that are degradation products or residuals and are generated during a manufacturing process or storage.	Adapted from ICH Q3A(R2)	**Drug Substance Impurities; Drug Product Impurities**
		Inorganic Impurities	Materials based on metallic elements and are generated during a manufacturing process.	SME Defined	
		Residual Solvents	Inorganic or organic liquids used or generated during the manufacturing process.	Adapted from ICH Q3A(R2)	
12	**Interpretation Code (text)**	Passed	Acceptable per specification	SME Defined	**Acceptance Criteria**
		Failed	Not acceptable per specification	SME Defined	
		NA	Not Applicable	SME Defined	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
13	**Interpretation Code (numeric)**	NMT (not more than)	The value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to”.	SME Defined/ eStability message values	
		NLT (not less than)	The value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to”.	SME Defined/ eStability message values	
		MT (more than)	The value should not be smaller than the given value excluding the given value, which is equivalent to “greater than”.	SME Defined/ eStability message values	
		LT (less than)	The value should not be greater than the given value excluding the given value, which is equivalent to “less than”.	SME Defined/ eStability message values	
		NA	Not Applicable	SME Defined/ eStability message values	
14	**Manufacturing Site Unique identifier Type**	DUNS	Data Universal Number System	Not Applicable	
		FEI	Facility Establishment Identifiers	Not Applicable	
		CFN	Central File Number	Not Applicable	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
		Unknown	Unknown	Not Applicable	
15	**Quality Benchmark**	USP-NF	United States Pharmacopeia-National Formulary	Not Applicable	**Description & Composition of Drug Product; Batch Formula; Drug Substance-Control of Materials; Drug Product-Control of Excipients**
		EP	European Pharmacopoeia	Not Applicable	
		JP	Japanese Pharmacopoeia	Not Applicable	
		Company Standard	A proprietary standard internal to the organization.	SME Defined	
16	**Source Organism country of origin**	See information in next column and download the file	Geopolitical Entity, Names, and Codes (GENC)	Value list (NCIt-GENC_Terminology.xlsx)	**Drug Substance-Control of Materials; Drug Product-**

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
					Control of Excipients
17	**Source Type**	Chemical	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]	NCI EVS	**Drug Substance-Control of Materials; Drug Product-Control of Excipients**
		Animal	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]	NCI EVS	
		Microbial	A microscopic organism. [Source: Adapted from NCI EVS C14329]	NCI EVS/SME Defined	
		Plant	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]	NCI EVS	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
		Insect	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]	NCI EVS	
		Human	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]	NCI EVS	
		Animal-derived indirectly	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	SME Defined	
18	**Specification Status**	Approved	A specification that has met the requirements for approval	SME Defined	**Specification**
		Tentatively Approved	A specification that met the requirements for approval but the application could not be	SME	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
			approved for reasons such as patents and exclusivity.	Defined	
		Not Approved	A specification that has not yet been approved.	SME Defined	
		Reported in a CBE or AR	The specification may be used without prior approval, and was submitted in a changes being effected (CBE) supplement or an annual report (AR).	SME Defined	
19	**Specification Type**	Drug Product	The specification which is applied to the drug product.	SME Defined	**Specification**
		Drug Substance	The specification which is applied to the drug substance.	SME Defined	
		Raw Materials /Excipients/Intermediates/Reagents	The specification which is applied to the raw materials, excipients, intermediates or reagents.	SME Defined	
20	**Storage conditions**	25 ± 2 ^{o}C /60% ± 5% RH	Not Applicable	ICH/WHO	**Stability Study**
		30 ± 2 ^{o}C /65% ± 5% RH	Not Applicable	ICH/WHO	
		40 ± 2 ^{o}C /75% ± 5% RH	Not Applicable	ICH/WHO	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
		5 ± 3 °C	Not Applicable	ICH/WHO	
		-20 ± 5°C	Not Applicable	ICH/WHO	
		Proprietary	Not Applicable	SME Defined	
		30 ± 2 °C /75% ± 5% RH	Not Applicable	WHO	
		25 ± 2 °C /40% ± 5% RH	Not Applicable	WHO	
		30 °C ± 2 °C/35% RH ± 5% RH	Note: for semi-permeable containers	WHO	
		40 °C ± 2 °C/not more than (NMT) 25% RH	Note: for semi-permeable containers	WHO	
21	**Study Type**	Standard	A single set of environmental conditions. Example: 25 degree C, 60% RH, etc.	SME Defined	**Stability Study**
		Cycled-Simple	A set of two alternating environmental conditions. Example: freeze-thaw cycled study.	SME Defined	
		Complex	Multiple phases with different set of environmental conditions. Examples: typically for inhalers, nebulizers; transportation studies, etc.	SME Defined	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
		Photostability	Studies that evaluate the light sensitivity and stability of drugs. [Refer to ICH Q1B] One time study	SME Defined	
22	**Test Category**	See Section 2B Table	See Section 2B Table	SME Defined	**Test**
23	**Test Method Origin**	CFR	Method defined in the Code of Federal Regulation (CFR)	SME Defined	**Test**
		Proprietary	Method defined by the sponsor (not recognized in CFR or any compendium)	SME Defined	
		Compendial	Method defined in any recognized compendium (e.g., USP, PharmEU, JP, etc.).	SME Defined	
24	**Test Usage**	Release	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, etc.	SME Defined	**Test**
		Stability	For determination of maintained performance parameters on storage over time, of a material, drug or a drug substance.	SME Defined	
		Release and Stability	For determination at release and on stability when test and acceptance criteria are the	SME Defined	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
			same in both cases.		
25	**Testing Site Unique Identifier**	DUNS	Data Universal Number System	Not Applicable	**Batch Lot Information**
		FEI	Facility Establishment Identifiers	Not Applicable	
		CFN	Central File Number	Not Applicable	
		Unknown	Unknown	Not Applicable	
26	**Unit of Measure: Value Unit; Batch Size Unit; Container Size Unit; Container Fill Unit; Strength Unit of Measure; Amount Per Unit; Diluent Unit of Measure; Amount UOM;**	See information in next column	FDA Data Standards-Unit of Measure	SPL Value list	**Acceptance Criteria; Batch Lot Information; Description & Composition of Drug Product; Batch Formula**

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
	Amount Per Unit				
27	**Validation Parameter**	Specificity	Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present. Typically these might include impurities, degradants, matrix, etc.	ICH Q2(R1)	**Analytical Methods Validation**
		Linearity	The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.	ICH Q2(R1)	
		Range	The range of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity.	ICH Q2(R1)	
		Accuracy	The accuracy of an analytical procedure expresses the closeness of agreement	ICH Q2(R1)	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
			between the value which is accepted either as a conventional true value or an accepted reference value and the value found.		
		Precision	The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: repeatability, intermediate precision and reproducibility.	ICH Q2(R1)	
		Detection Limit	The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.	ICH Q2(R1)	
		Robustness	The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.	ICH Q2(R1)	
		System Suitability	The tests are based on the concept that the	ICH Q2(R1)	

#	Data Element Name	Valid Value	Valid Value Meaning	Source	Data Element Table Reference
			equipment, electronics, analytical operations, and samples to be analyzed constitute an integral system that can be evaluated as such. System suitability test parameters to be established for a particular procedure depend on the type of procedure being validated.		
		Quantitation Limit	The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy.	ICH Q2(R1)	

B: Test Category Values – Controlled Vocabulary (DRAFT List)

This is the list of test categories allowable values for the Test Category data element in the Test Table. The value meanings for these values have not been defined since they are commonly used and understood in the PQ/CMC domain and very often exist in the USP.

#	Test Category Values
1	Assay (chiral purity, preservative content, Anti-Oxidant Concentration, Chelate Concentration, isomeric ratio)
2	Container Closure Integrity Testing
3	Content Uniformity
4	Deliverable Volume/Fill Volume
5	Description/Appearance
6	Disintegration
7	Dissolution
8	Heavy Metals/Elemental Impurities
9	Homogeneity Test
10	Identification
11	Impurities/Degradation Products/Related Substances
12	Loss on Drying
13	Microbial Limits
14	Particle Size Distribution
15	Physicochemical Properties (below are the 16 sub-categories)

15a	Bulk Density
15b	Clarity of Solution
15c	Color of Solution
15d	Conductivity
15e	Crystallinity
15f	Friability
15g	Hardness
15h	Melting Point
15i	Odor
15j	Optical Rotation
15k	pH
15l	Solubility
15m	Specific Gravity
15n	Tablet Properties (Weight, length, thickness, diameter, color, shape)
15o	Tap Density
15p	Viscosity/Rheological Properties
16	Plume Geometry
17	Polymorphic forms
18	Potency
19	Pyrogenicity/Endotoxin

20	Reconstitution Time
21	Redispersibility
22	Residual Solvent
23	Residue on Ignition
24	Spray Pattern
25	Sterility
26	Sub-visible particulates
27	Syringe Functionality
28	Total Organic Carbon
29	Uniformity of Dosage Units
30	Water content

END OF SECTION 2

Section 3: 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

Acronym	Description
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
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

Acronym	Description
IUPAC	International Union of Pure and Applied Chemistry
JINAD	Generic Investigational New Animal Drugs
MF	Master Files
NADA	New Animal Drug Application
NDA	New Drug Application
NCI EVS	National Cancer Institute – Enterprise Vocabulary Service
PQ/CMC	Pharmaceutical Quality/Chemistry, Manufacturing & Controls
SME	Subject Matter Expert
SPL	Structured Product Labeling
UNII	Unique Ingredient Identifier
USAN	United States Adopted Name

Acronym	Description
WHO	World Health Organization

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