| **ID#** | **Rule Name** | **Rule Description** | **Severity** | **Old Rule ID#** | **What has changed** |
| --- | --- | --- | --- | --- | --- |
| **1** | **General** | | |  |  |
|  | XML file | XML files must be well formed and valid against the schema. | Error | 1.01 | Revised wording for clarity |
|  | Image file type | Referenced image files must be JPEG with the .jpeg extension. | Error | 1.02 | Revised wording for clarity |
|  | File location | All referenced image files must exist in the same folder as the XML file. | Error | 1.03 & 1.05 | Revised wording for clarity and incorporated old rule 1.03 |
|  | XML file name | XML files must be named with the (Globally Unique Identifiers) GUID from the <document> <ID> root attribute. | Error | 1.04 | Revised wording for clarity |
|  | GUID | Values for <setID> root attribute and <id> root attribute must not be empty, be unique and be a GUID.  GUIDs must follow the canonical structure, content and formatting rules: displayed in five groups separated by hyphens, in the form 8-4-4-4-12 for a total of 36 characters (32 alphanumeric characters and four hyphens) and permitted characters only include a-f,0-9,-  Note: Rule does not apply to <representedOrganization> root attribute and <assignedOrganization> root attribute. | Error | 1.08 | Revised wording for clarity  Number changed |
|  | Date format | Date values associated with <effectiveTime> must be provided in the format YYYYMMDD. | Error | 1.06 | Revised wording for clarity |
|  | Controlled vocabulary | Coded values and display names must be equal to the associated CV. | Error | 1.10 | Revised wording for clarity  Number changed |
|  | Controlled vocabulary | Coded values must include a valid codeSystem attribute or root attribute and must be present only in allowable context as outlined in Appendix 1. | Error | 1.11 | Revised wording for clarity  Number changed  Increased severity |
|  | Display name | displayName attributes must be equal to the language-specific CV display name.  This does not apply to:   * <representedOrganization> <Id> root attribute 2.16.840.1.113883.2.20.6.31. * <assignedOrganization> <Id> root attribute 2.16.840.1.113883.2.20.6.31. | Error | 1.12 | Revised wording for clarity  Number changed |
|  | Identifier extensions | <id> extension attributes must not contain spaces. | Error | 1.13 | Revised wording for clarity  Number changed |
|  | Empty elements | <text>, <title>, <caption> and <content> must not be empty between opening and closing tags. | Error | 1.14 | Revised wording for clarity  Number changed |
|  | Characteristics | <characteristics> must not have a classCode attribute. | Error | 1.15 | Revised wording for clarity  Number changed |
|  | Content in major section headings | Major section headings listed below must not be immediately followed by <text> or <paragraph>:   * Code = “0TP” (TITLE PAGE) * Code = “pi00” (PART I: HEALTH PROFESSIONAL INFORMATION) * Code = “pii00” (PART II: SCIENTIFIC INFORMATION) * Code = “pim00” (PATIENT MEDICATION INFORMATION) | Error | 1.07 | Revised wording for clarity  Number changed |
|  | Non-applicable data elements and attributes | The following elements and attributes must not be used:   * <performance> * <actDefinition> * <product> * <manufacturedMaterialKind> * <confidentialityCode> | Error | 1.09 & 1.16 | Revised wording for clarity  Incorporated old rule 1.09  Number changed |
|  | Comments | No comments (i.e. “<!-- -->”) are allowed. | Error | 2.05 | Revised wording for clarity  Number changed |
| **2** | **XML Prolog** | | |  |  |
|  | XML version | <?xml> version attribute must be equal to “1.0”. The encoding attribute must equal “UTF-8”. | Error | 2.01 | Revised wording for clarity |
|  | Stylesheet | <?xml-stylesheet> href attribute must be equal to “https://raw.githubusercontent.com/HealthCanada/HPFB/master/product-monograph/style-sheet/spl\_canada.xsl”. | Error | 2.02 | Revised wording for clarity |
|  | Processing instructions | Only <?xml> and <?xml-stylesheet> XML declarations are allowed. | Error | 2.04 | Revised wording for clarity  Number changed |
| **3** | **Document** | | |  |  |
|  | Schema location | <document> xmlns attribute must be equal to “urn:hl7-org:v3”.  <document> xsi:schemaLocation attribute must be equal to “<https://raw.githubusercontent.com/HealthCanada/HPFB/master/product-monograph/schema/SPL.xsd>”. | Error | 2.03 | Revised wording for clarity  Number changed |
|  | Document identifier | <document> <id> root attribute must not be empty, be unique and be a GUID. | Error | 3.01 | Revised wording for clarity  Number changed |
|  | Document Type | Values for <document> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.10. Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 3.02 | Revised wording for clarity  Number changed |
|  | Language | Values for <languageCode> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.29. Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 3.04 | Revised wording for clarity |
|  | setId | <setId> root attribute must not be empty, be unique and be a GUID. | Error | 3.05 | Revised wording for clarity |
|  | Version number | <versionNumber> value attribute must be an integer greater than zero. | Error | 3.06 | Revised wording for clarity |
| **4** | **Organization (Market Authorization Holder / Importer or Distributor)** | | |  |  |
|  | Company | Values for <representedOrganization> and <assignedOrganization> must be taken from CV root 2.16.840.1.113883.2.20.6.31. Specifically:   * The <id> extension attribute value must be equal to a CV Code. * The <name> must be equal to the language-specific CV display name for that Code. | Error | 4.01 | Revised wording for clarity |
|  | Country | Values for <country> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.17. Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 4.05 | Revised wording for clarity  Number changed |
|  | Market Authorization Holder | <representedOrganization> […] <addr> must not be empty for:   * <streetAddressLine> * <city> * <state> * <postalCode> * <country> | Error | 4.03 | Revised wording for clarity |
|  | Distributor or importer | <representedOrganization> with <country> code attribute not equal to “CAN” must contain <assignedOrganization> <contactParty> information. | Error | 4.04 | Revised wording for clarity  Increased severity  Split rule across several rules |
|  | Canadian distributor or importer | <assignedOrganization> […] <country> code attribute must be equal to “CAN”. | Error | 4.04 & 4.05 | Revised wording for clarity  Incorporated part of old rule 4.04 |
|  | Distributor or importer address | <assignedOrganization> […] <addr> must not be empty for:   * <streetAddressLine> * <city> * <state> * <postalCode> * <country> | Error | 4.04 | Revised wording for clarity  Increased severity  Incorporated part of old rule 4.04 |
|  | Postal code format | <postalCode> must contain alphanumeric characters.  Canadian postal codes must be in “A1A 1A1” format with a single white space separating the third and fourth characters. | Warning | 4.06 | Revised wording for clarity  Increased severity  Number changed |
|  | Contact information | There must be three <telecom> elements with value attributes starting with the following:   * “tel:+” * “mailto:” * “http:” or “https:” | Warning | 4.07 | Revised wording for clarity  Incorporated old rules 4.07, 4.08 and 4.10  Increased severity |
|  | email address | <telecom> value attribute for “mailto:” must be in local-part@domain format. | Warning | 4.09 | Revised wording for clarity  Increased severity |
| **5** | **Manufactured Product** | | |  |  |
|  | Drug Identification Number (DIN) | <manufacturedProduct> <code> is required. The code attribute value must be an 8-digit number that may contain leading zeros. | Warning | 6.01 | Revised wording for clarity  Number changed |
|  | Brand name | <manufacturedProduct> <name> must not be empty. | Warning | 6.02 | Revised wording for clarity  Number changed |
|  | Dosage form | Values for <formCode> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.3. Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 6.03 | Revised wording for clarity  Number changed |
|  | Non-proprietary name | A <genericMedicine> <name> is required. | Warning | 6.04 | Revised wording for clarity  Number changed |
|  | Ingredient name | Values for <ingredientSubstance> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.14.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 6.11 | Revised wording for clarity  Number changed |
|  | Ingredient name | <ingredientSubstance> <name> must equal the <ingredientSubstance> <code> displayName attribute. | Error | 6.13 | Revised wording for clarity  Number changed |
|  | Ingredient code | Within a <manufacturedProduct> the <ingredientSubstance> <code> code attribute must only be used once. | Error | 6.12 | Revised wording for clarity  Number changed |
|  | Ingredient role | Values for <ingredient> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.39. Specifically:   * The classCode attribute must be equal to the language-specific CV display name. | Error | 6.06 | Revised wording for clarity  Number changed |
|  | Active ingredient strength | If <ingredient> classCode attribute equals “ACTIB”, “ACTIM” or “ACTIR” then <quantity> <numerator> and <quantity> <denominator> must not be empty. | Error | 6.07 | Revised wording for clarity  Number changed |
|  | Ingredient strength | The value attribute and unit attribute must not be empty for <quantity> <numerator> and <quantity> <denominator>. | Error | 6.08 | Revised wording for clarity  Number changed |
|  | Ingredient strength | Values for <quantity> <numerator> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.15.  Specifically:   * The unit attribute must be equal to the CV code. | Error | 6.09 | Revised wording for clarity  Split into two  Number changed |
|  | Ingredient strength | Values for <quantity> <denominator> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.15.  Specifically:   * The unit attribute must be equal to the CV code. | Error | 6.09 | Revised wording for clarity  Part of old rule 6.09  Number changed |
|  | Quantity | Within a <manufacturedProduct> all <quantity> <denominator> value attributes and unit attributes must be the same. | Error | 6.10 | Revised wording for clarity  Number changed |
|  | Active ingredient strength range | When <quantity> <numerator> is expressed as a range:   * <ingredient> classCode attribute must equal “ACTIB”, “ACTIM” or “ACTIR”. * <numerator> xsi:type attribute must equal “URG\_PQ”. * <numerator> <low> unit attribute must equal the <numerator> <high> unit attribute. * <denominator> value attribute and the <denominator> unit attribute must equal “1”. | Error | 6.14 | Revised wording for clarity  Number changed |
| **6** | **Packaging Status (single formulation)** | | |  |  |
|  | Packaging | Each <manufacturedProduct> must contain <asContent>. | Error | 7.01 | Revised wording for clarity  Number changed |
|  | Package identifier | <containerPackagedProduct> <code> code attribute must not be empty. | Information | 7.08 | Revised wording for clarity  Number changed |
|  | Package  description quantity | Each <manufacturedProduct> <asContent> <quantity> must contain <numerator> value attribute and <denominator> value attribute. | Error | 7.02 | Revised wording for clarity  Number changed |
|  | Package  description | <quantity> <numerator> value attribute must be greater than zero and unit attribute must not be empty. | Error | 7.03 | Revised wording for clarity  Split rule into two  Number changed |
|  | Package  description units | <quantity> <numerator> unit attribute must be a code from CV codeSystem 2.16.840.1.113883.2.20.6.15. | Error | 7.03 | Revised wording for clarity  Part of old rule 7.03  Number changed |
|  | Inner package description | The outermost occurrence of the <asContent> <quantity> <numerator> unit attribute must equal the <ingredient> <quantity> <denominator> unit attribute. | Error | 7.05 | Revised wording for clarity  Increased severity  Number changed |
|  | Package description hierarchy | If any <asContent> contains a nested <asContent> then the upper <quantity> <denominator> unit attribute must equal the lower <asContent> <quantity> <numerator> unit attribute.  Note that the unit attribute may be empty, representing “1”. | Warning | 7.04 | Revised wording for clarity  Number changed |
|  | Inner package description | Outermost occurrence of <asContent> <quantity> <denominator> value attribute must be equal to 1.  Outermost occurrence <asContent> <quantity> <denominator> unit attribute, if present, must be equal to 1. | Error | 7.06 | Revised wording for clarity  Number changed |
|  | Package type | Values for <formCode> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.32.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 7.07 | Revised wording for clarity  Number changed |
|  | Packaging type | Any <containerPackagedProduct> <formCode> code attribute may only appear once in a given packaging hierarchy. E.g. a box may not contain a box. | Error | 7.09 | Revised wording for clarity  Number changed |
| **7** | **Packaging Status (multiple formulations)** | |  |  |  |
|  | Product part | If <formCode> code attribute is equal to “C43197” then at least one <part> must be provided. | Error | 8.02 | Revised wording for clarity  Number changed |
|  | Overall package description | If a <manufacturedProduct> contains <part> then the <manufacturedProduct> <asContent> <quantity> <numerator> must have a unit attribute and value attribute equal to 1. | Error | 8.01 | Revised wording for clarity  Number changed |
|  | Overall package description | If a <manufacturedProduct> contains <part> then:  <manufacturedProduct> must contain <part> <quantity> <numerator> value attribute  <manufacturedProduct> must contain <part> <quantity> <denominator> value attribute | Error | 8.03 | Revised wording for clarity  Number changed |
|  | Total product quantity | <part><quantity><numerator> unit attribute must equal <part><partProduct><asContent> <quantity><numerator> unit attribute. | Error | 8.04 | Revised wording for clarity  Number changed |
|  | As content data element | If <part> does not contain <asContent> (i.e. no internal part-specific packaging is described) then <part><quantity><numerator> unit attribute must equal “1”. | Error | 8.05 | Revised wording for clarity  Number changed |
|  | Package identifier | <part> […] <containerPackagedProduct> <code> code attribute must not be empty. | Information | 8.06 | Revised wording for clarity  Number changed |
| **8** | **Package Availabile** | | |  |  |
|  | Package available | The innermost occurrence <asContent> must have one <marketingAct> <code>. | Error | New | Wording accommodates change from regulatory status of packaging to package available. |
|  | Package available | Values for <marketingAct> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.11.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 9.02 | Revised wording to accommodate change from regulatory status of packaging to package available.  Number changed |
| **9** | **Product Status** | | |  |  |
|  | Regulatory activity type | Values for <approval> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.37.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 10.02 | Revised wording for clarity  Number changed |
|  | Regulatory activity type | <manufacturedProduct> must have one <approval> <code>. | Error | 10.01 | Revised wording for clarity  Number changed |
|  | Territorial authority | <approval> […] <territory> <code> code attribute must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.17 and be equal to “CAN”.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 10.03 | Revised wording for clarity  Number changed |
|  | Control Number | <approval> <id> must not be empty. The <id> extension attribute must be a 6-digit number. | Warning | 10.04 | Revised wording for clarity  Number changed |
| **10** | **Product Characteristics** | | |  |  |
|  | Product characteristics | Value for <characteristic> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.23.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 12.01 | Revised wording for clarity  Number changed |
|  | Characteristic types | Value for <characteristic> <value> must be taken from CV codeSystem as listed below.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. * Product Type: 2.16.840.1.113883.2.20.6.53 * Colour: 2.16.840.1.113883.2.20.6.24 * Shape: 2.16.840.1.113883.2.20.6.25 * Score: 2.16.840.1.113883.2.20.6.4 * Flavour: 2.16.840.1.113883.2.20.6.26 * Pharmaceutical Standard: 2.16.840.1.113883.2.20.6.5 * Schedule: 2.16.840.1.113883.2.20.6.2 * Therapeutic Class: 2.16.840.1.113883.2.20.6.6 | Error | 12.02 | Revised wording for clarity  Number changed |
|  | Characteristic value type | <characteristic> <code> code attribute value must correspond with the <characteristic> <value> xsi:type attribute value using the table below.   |  |  | | --- | --- | | <code> code attribute | <value> xsi:type attribute | | “1” (PRODUCT TYPE) | “CV” | | “2” (COLOUR) | “CV” | | “3” (SHAPE) | “CV” | | “4” (SIZE) | "PQ” | | “5” (SCORE) | “CV” | | “6” (IMPRINT) | “ST” | | “7” (FLAVOUR) | “CV” | | “9” (PHARMACEUTICAL STANDARD) | “CV” | | “10” (SCHEDULE)\_ | “CV” | | “11” (THERAPEUTIC CLASS) | “CV” | | Error | 12.03 & 12.04 | Revised wording for clarity  Incorporated old rules 12.03 & 12.04  Number changed |
|  | Numeric value types | When <characteristic> <value> xsi:type is ”PQ” (SIZE) the value attribute must be an integer greater than zero and the <characteristic> <value> unit attribute must not be empty. | Error | 12.05 | Revised wording for clarity  Number changed |
| **11** | **Route of Administration** | | |  |  |
|  | Route of Administration | Value for <substanceAdministration> <routeCode> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.7.  Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 13.01 | Revised wording for clarity  Number changed |
| **12** | **Narrative Content** | | |  |  |
|  | Product Monograph template | Values for <section> <code> must be taken from CV codeSystem 2.16.840.1.113883.2.20.6.60 or 2.16.840.1.113883.2.20.6.63. Specifically:   * The code attribute value must be equal to a CV Code. * The displayName attribute must be equal to the language-specific CV display name for that Code. | Error | 5.05 | Revised wording for clarity  Number changed |
|  | Sections | The following major section headings must be provided:   * Code = “0TP” (TITLE PAGE) * Code = “pi00” (PART I: HEALTH PROFESSIONAL INFORMATION) * Code = “pii00” (PART II: SCIENTIFIC INFORMATION) * Code = “1RMLC” (RECENT MAJOR LABEL CHANGES) | Error | 5.01 | Revised wording for clarity  Number changed |
|  | Sections | The following major section headings should be provided:   * Code = “pim00” (PATIENT MEDICATION INFORMATION) * Code = ”0NOC” (NOTICE OF COMPLIANCE WITH CONDITIONS) * Code = “0BBD” (BIOSIMILAR BIOLOGIC DRUG) applies only to 2.16.840.1.113883.2.20.6.63 | Warning | 5.02 | Revised wording for clarity  Number changed |
|  | Section headings | <section> displayName attribute must equal the <title>.  This rule does not apply to:   * Where <code> equals “UA” * Where <code> equals “pmi##” when “##” is greater than “01” | Error | 5.07 | Revised wording for clarity  Increased severity  Number changed |
|  | Id root | <section> <id> root attribute must not contain extensions or other data elements. | Error | 5.03 | Revised wording for clarity  Number changed |
|  | Id root | <id> root attribute must not be empty, be unique and be a GUID. | Error | 5.04 | Revised wording for clarity  Number changed |
|  | Section effective time | <section> must have an <effectiveTime> with the format YYYYMMDD. | Error | 5.06 | Revised wording for clarity  Number changed |
|  | Section headings | <section> ID attribute must not be empty. | Warning |  | New |
|  | Narrative text | Narrative text must be enclosed under <paragraph>, <list>, or <table> elements. Text must not be enclosed directly within the <text> element. | Error | 14.02 | Revised wording for clarity  Number changed |
| **13** | **Cross-references** | | |  |  |
|  | Internal cross-references | If <linkHtml> href attribute value begins with ‘#’ then it must reference one of the following.   * <section> ID attribute * <paragraph> ID attribute * <table> ID attribute * <list> ID attribute * <content> ID attribute * <renderMultiMedia> ID attribute * <id> root attribute | Error | 14.01 | Revised wording for clarity  Split rule into two  Number changed |
|  | External cross-references | If <linkHtml> href attribute value does not begin with ‘#’ then it must be a properly formatted web reference. | Error | 14.01 | Revised wording for clarity  Part of old rule 14.01  Number changed |
| **14** | **Title Page** | | |  |  |
|  | Approval date structure | <section> <code> code attribute value equal to “0tp1.3” must exist even if <paragraph> is empty. | Error |  | New |
|  | Textual date format | <section> <text> must have a single <paragraph> in “YYYY-MM-DD” (e.g. “2020-03-25”) format when <section> <code> code attribute value is one of the following:   * “0tp1.3” (“Date of Initial Approval:”) or * “0tp1.4” (“Date of Revision:”) | Warning | 16.01 | Revised wording for clarity  Increased severity  Number changed |
|  | ~~Date of Initial Approval / Date of Last Revision~~ | ~~If <section> <code> code attribute is equal to “0tp1.3” or “0tp1.4” then it must contain <effectiveTime> value attribute in YYYYMMDD format.~~ | ~~Warning~~ | ~~3.03~~ | Deleted. |
|  | Control number structure | <section> <code> code attribute value equal to “0tp1.5” must exist even if <paragraph> is empty. | Error |  | New |
|  | Control number | If <section> <code> code attribute value equals “0tp1.5” then it must have a single <paragraph> with a 6-digit number. | Warning | 16.02 | Revised wording for clarity  Increased severity  Number changed |
| **15** | **Images** | | |  |  |
|  | Image description | <observationMedia> <text> must not be empty. | Error | 15.01 | Revised wording for clarity  Increased severity |
|  | Image data type | <observationMedia> <value> xsi:type attribute must be equal to “ED”. | Error | 15.02 | Revised wording for clarity |
|  | Image media type | <observationMedia> <value> mediaType must be equal to “image/jpeg”. | Error | 15.03 | Revised wording for clarity |
|  | Reference file name | <reference> value attribute must match the file name of a provided image and may not include directory path information. | Error | 15.04 | Revised wording for clarity |
|  | Image size | The size of the image file must not exceed 1 MB. | Information | 15.05 | Revised wording for clarity |
|  | Unused images | <observationMedia> must have an associated <renderMultiMedia> referencedObject attribute. | Error | 15.06 | Revised wording for clarity |
|  | Invalid reference | <renderMultiMedia> referencedObject attribute must match an <observationMedia> ID attribute. | Error | 15.07 | Revised wording for clarity |

Appendix 1- Valid codeSystem attributess or root attribute in allowable contexts

|  |  |  |
| --- | --- | --- |
| **CodeSystem OID** | **CodeSystem Name** | **Valid XML contexts** |
| 2.16.840.1.113883.2.20.6.2 | SCHEDULE | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.3 | DOSAGE FORMS | <formCode> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.4 | SCORE | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.5 | PHARMACEUTICAL STANDARD | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.6 | THERAPEUTIC CLASS | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.7 | ROUTE OF ADMINISTRATION | <substanceAdministration> <routeCode> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.10 | DOCUMENT TYPE | <document> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.11 | PACKAGE AVAILABLE | <marketingAct> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.14 | INGREDIENT IDENTIFIER | <ingredientSubstance> <code> codeSystem attribute  <activeMoiety> <code> codeSystem attribute  <definingSubstance> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.15  Note : This OID is used for validation but does not appear in the XML | UNITS OF MEASURE | <quantity> <numerator> unit attribute  <quantity> <denominator> unit attribute |
| 2.16.840.1.113883.2.20.6.17 | COUNTRY CODE | <country> codeSystem attribute  <approval> […] <territory> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.23 | PRODUCT CHARACTERISTICS | <characteristic> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.24 | COLOUR | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.25 | SHAPE | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.26 | FLAVOUR | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.29 | LANGUAGE CODE | <languageCode> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.31 | COMPANY IDENTIFIER | <representedOrganization> <id> root attribute  <assignedOrganization> <id> root attribute |
| 2.16.840.1.113883.2.20.6.32 | PACKAGE TYPE | <formCode> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.37 | REGULATORY ACTIVITY | <approval> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.39  Note : This OID is used for validation but does not appear in the XML | INGREDIENT ROLE | <ingredient> classCode attribute |
| 2.16.840.1.113883.2.20.6.53 | PRODUCT TYPE | <characteristic> <value> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.60 | 2016 PRODUCT MONOGRAPH TEMPLATE - STANDARD | <section> <code> codeSystem attribute |
| 2.16.840.1.113883.2.20.6.63 | MASTER TEMPLATE - 2020 | <section> <code> codeSystem attribute |