

WORKING DRAFT

Phase 1

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**GUIDANCE DOCUMENT**

Structured Product Labeling (SPL) -

Validation Rules for the Product Monograph

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Published by authority of the

Minister of Health

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| **Adopted Date** | ??? |
| **Effective Date** | ??? |

**Health Products and Food Branch**



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| Our mission is to help the people of Canada maintain and improve their health.  *Health Canada* | The Health Products and Food Branch (HPFB)’s mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:   * Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, * Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.   *Health Products and Food Branch* |

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***Également disponible en français sous le titre :*** *Ligne directrice: Monographie de produit*

**FOREWORD**

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance’s.

**DOCUMENT REVISION HISTORY**

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| --- | --- | --- | --- |
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|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Location of Change** | **Change Made** | **Effective Date** |
| 1 | Not Applicable | Initial Issuance of Guidance | ??? |
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# Introduction & General Information

This section will outline the intent of guidance document along with general information on the guidance document.

## Purpose

The purpose of this technical guidance document is to assist with the overall technical validation of the Product Monograph (PM) using as a Structured Product Labeling (SPL) document.

The guidance document is limited to the technical aspects of validating a PM, it is a companion to the business related PM Guidance document, it extends the HPFB Structured Product Labelling (SPL) – General Validation Rules for all Document Types document. Note the format and style if this document is very different from the HPFB Structured Product Labelling (SPL) – General Validation Rules for all Document Types as the focus is on business rules not on technical compliance.

This technical guidance document only contains specifics relating to the structured Product Monograph, that means all general rules are omitted and detailed in the general SPL validation documents.

## Order

The Business Guidance details the presentation and sequence of the information as well as the layout and formatting.

This guidance document presents the information based on the section ID and the order the element occurs in the associated schema. Several aspects of the information such as the Document and Author sections are not exposed to the user and the Product Data Element sections is embedded in the content of the document rather than exposed as a separate section.

## Scope

As outlined in the purpose information above, any aspect of the guidance that is common to all HPFB SPL documents is omitted from this document, this includes any structure, element, or attribute that is common.

As an example, in the Document Information section only 3 elements are described even though the Document Information section has 9 elements.

# General Validation

Outlined in this section are all PM specific aspects that apply to the overall document, aspects that are common to all HPFB SPL documents are omitted from this document.

* 1. For simplicity only, the English display name has been included in this document, the display names are detailed in the controlled vocabulary (CV) documentation.

1. Informational only (there is no validation aspect).
   1. Numbers (1) are used to detail technical conformance requirements; validation rules are detailed directly below the requirements and are organized using letters (a).
2. Informational only (there is no validation aspect).
   1. Only items that have specific Doctype validation are included.
3. Informational only (there is no validation aspect).
   1. Time values (such as effectiveTime@value, [effectiveTime.low@value](mailto:effectiveTime.low@value) and [effectiveTime.high@value](mailto:effectiveTime.high@value)) shall utilize only the date aspect (time and GMT offset based time values are not permitted). An example can be found in Appendix B – effectiveTime Details, outlined below is an overview of the intended use of time values:
4. DT Rule 12 identifies that the content is incorrectly formatted.
   1. For initial submissions the Date of Revision will be set to equal the Date of Initial Approval, this does not apply to Marketing effectiveTime elements.
5. DT Rule 8 identifies that the attribute value is incorrect or contextually incorrect.
   1. For all other submissions the Date of Revision will greater than the Date of Initial Approval, this does not apply to Marketing effectiveTime elements.
6. DT Rule 8 identifies that the attribute value is incorrect or contextually incorrect.
7. DT Rule 12 identifies that the content is incorrectly formatted.
   1. Terms (context=Term)

The usage of CV terms is restricted to specific term statuses depending on the context of the PM, these rules are outlined below, however they are validated at the element level:

* For initial draft (ie. Where Document Date of Initial Approval = Document Date of Revision and versionNumber.description = Draft) terms having a status of 1; 2; 3; 5 are permitted.
* For initial final (ie. Where Document Date of Initial Approval = Document Date of Revision and versionNumber.description = Final) terms having a status of 1; 5 are permitted.
* For revision draft (ie. Where Document Date of Initial Approval < Document Date of Revision and versionNumber.description = Draft) terms having a status of 1; 2; 3; 5; 7 are permitted.
* For revision final (ie. Where Document Date of Initial Approval < Document Date of Revision and versionNumber.description = Final) terms having a status of 1; 5 are permitted.
  + 1. The SPM term context validation works along the following concept: Term Status in (valid term status) where valid term status is defined as above.

1. Informational only (validation is performed at the element level).
   1. Doctype (context=Document)

The usage of CV terms is restricted to specific term statuses depending on the context of the document type, these rules are outlined below, however they are validated at the element level:

* The Doctype for the SPM is 1 (please refer to OID 2.16.840.1.113883.2.20.6.10), both document|1| and document|\*| are applicable.
  + 1. SPM doctype context validation works along the following concept: if the context is document the valid constructs are as above:

Informational only (validation is performed at

1. the element level).
   1. Template (context=Document)

The usage of CV terms is restricted to specific term statuses depending on the document template, outlined below is a table showing the relationship, however please refer to OID 2.16.840.1.113883.2.20.6.9 for the authoritative list):

| **Document Template** | **templateId@extension Value** |
| --- | --- |
| 2004 Standard Product Monograph | 1 |
| 2004 NOCC Product Monograph | 2 |
| 2004 Subsequent Entry Product Product Monograph | 3 |
| 2004 Schedule C Product Monograph | 4 |
| 2004 Schedule D Product Monograph | 5 |
| 2016 Standard Product Monograph | 6 |
| 2016 NOCC Product Monograph | 7 |
| 2016 Subsequent Entry Product Product Monograph | 8 |
| 2016 Schedule C Product Monograph | 9 |
| 2016 Schedule D Product Monograph | 10 |

This implies that document|1|\* or any of document|1|1 trough document|1|10 are applicable., note document|\*|1 is not a valid nomenclature.

* + 1. SPM template context validation works along the following concept: if the context is document the valid template ID’s and constructs are as above:

Informational only (validation

1. is performed at the element level).

# 

2. DT Rule 11 identifies that the Processing Instructions are not compliant to the IG.
   1. The location of the stylesheet is: <https://rawgit.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/SPM/current/hpfb-spl.xsl>
3. DT Rule 11 identifies that the Processing Instructions are not compliant to the IG.
4. DT Rule 11 identifies that the Processing Instructions are not compliant to the IG.
   1. <https://rawgit.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/SPM/current/hpfb-spl-core.css>
5. DT Rule 11 identifies that the Processing Instructions are not compliant to the IG.
6. DT Rule 11 identifies that the Processing Instructions are not compliant to the IG

# Validation

* 1. templateId@extension value shall be in accordance to OID 2.16.840.1.113883.2.20.6.9.

1. DT Rule 6 identifies that the (extension) attribute is empty.
2. DT Rule 7 identifies that label does not match the CV.
3. DT Rule 8 identifies that the (extension) attribute value is incorrect or contextually incorrect.
4. DT Rule 16 identifies that there is a notification flag for the content.
   1. is a title element.
5. DT Rule 2 identifies that the element has not been defined.
6. DT Rule 3 identifies that the element has been defined more than once.
   1. There is a versionNumber@description attribute, where the value is derived from OID: 2.16.840.1.113883.2.20.6.37.
7. SPL Rule 5 identifies that the (description) attribute has not been defined.
8. SPL Rule 7 identifies that displayName does not match the CV value.
9. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct.
10. DT Rule 16 identifies that there is a notification flag for the content.
    1. There is an effectiveTime element
11. DT Rule 2 identifies that the element has not been defined.
    1. There is an effectiveTime@value attribute that shall contain the Date of Revision (for the entire document, regardless of the change or reason for change)
12. SPL Rule 5 identifies that the (value) attribute has not been defined.
13. DT Rule 6 identifies that the (value) attribute is empty.
14. DT Rule 12 identifies that the content is incorrectly formatted.
    1. There is an effectiveTime.originalText element that shall contain the Date of Initial Approval (i.e., NDS or ANDS) the format for is year, month and day (yyyymmdd).
15. DT Rule 2 identifies that the element has not been defined.
16. DT Rule 3 identifies that the element has been defined more than once, this will trigger a schema validation error however schema errors are obscure.
17. DT Rule 5 identifies that the (originalText) element is empty.
    1. The [effectiveTime.originalText@description](mailto:effectiveTime.originalText@description) attribute shall contain “Date of Initial Approval “.
18. DT Rule 8 identifies that the (description) attribute value is incorrect.
    1. There will be a templateId element where the root attribute value is: 2.16.840.1.113883.2.20.6.11 and the value of the extension attribute derived from the OID. It captures the Marketing Category associated with the current version.
19. DT Rule 1 identifies that the OID value is incorrect.
20. DT Rule 5 identifies that the (extension) attribute has not been defined.
21. DT Rule 8 identifies that the (extension) attribute value is incorrect or contextually incorrect.
22. DT Rule 13 identifies that the (extension) attribute is not in the CV or is not contextually correct.
23. DT Rule 16 identifies that there is a notification flag for the content.

# Author Information

* 1. Undefined company ID’s are not allowed

1. DT Rule 8 identifies that the (extension) attribute value is incorrect (i.e. “Pending”).

# Product Data Elements Section

Outlined below are the specifics relating to the SPM Product Data (the section where the code@code is 48780-1 and the code@codeSystem is 2.16.840.1.113883.2.20.6.8), this excludes all overall document and labeling content information.

* 1. There is a section where the code@code is 48780-1 and the codeSystem is 2.16.840.1.113883.2.20.6.8 (i.e component.structuredBody.component[section/code/@code = “48780-1”].section)

1. DT Rule 15 identifies that required content is missing.
   1. The effectiveTime element shall contain a low element.
2. DT Rule 2 identifies that the element has not been defined.
   1. The effectiveTime.low@value attribute captures the Date of Initial Approval (for entire product section)
3. DT Rule 15 identifies that required content is missing.
4. DT Rule 8 identifies that the (extension) attribute value is incorrect or contextually incorrect, this includes verification against child elements.
   1. The effectiveTime element shall contain a high element.
5. DT Rule 2 identifies that the element has not been defined.
   1. The effectiveTime.high@value attribute captures the Date of Revision (for entire product section)
6. DT Rule 15 identifies that required content is missing.
7. DT Rule 8 identifies that the (extension) attribute value is incorrect or contextually incorrect, this includes verification against child elements.
   1. There are one or more subject elements
8. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is an manufacturedProduct.manufacturedProduct.name element.
9. SPL Rule 3 identifies that the element has not been defined.
10. SPL Rule 6 identifies that the name is empty.
    1. an marketingAct.effectiveTime element.
11. SPL Rule 3 identifies that the element has not been defined.
    1. For each subject element there may not be a marketingAct.effectiveTime.low element.
12. DT Rule 14 identifies that a disallowed element has been included.
    1. element there may be a marketingAct.effectiveTime.high element, that captures the date off the market (product and/or package).
13. Informational only (there is no validation of optional aspects).
    1. For each subject element there is an approval.code element that captures the i.e. the Regulatory Activity (e.g., A/NDS, A/SNDS, NC, Level III, Level IV) this version of the SPM is associated with.
14. DT Rule 15 identifies that required content is missing.
    1. For each subject element there is an approval.effectiveTime element.

SPL Rule 3 identifies that the

1. element has not been defined.
   1. subject element there is an approval.effectiveTime.low element that captures the Date of Initial Approval of the specific product.
2. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is an approval.effectiveTime.high element that captures the Date of Revision of the specific product.
3. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”13” that captures the Pharmaceutical Standard.
4. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”14” that captures the Scheduling Symbol.
5. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”15” that captures the Therapeutic Class.
6. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is an manufacturedProduct.manufacturedProduct.name element that captures the Brand Name.
7. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is one or more manufacturedProduct.manufacturedProduct.asEntityWithGeneric.genericMedicine.name elements that captures the Proper Name.
8. DT Rule 15 identifies that required content is missing.
   1. For each subject element there is a manufacturedProduct.manufacturedProduct.formCode element that captures the Dosage Form.
9. DT Rule 15 identifies that required content is missing.
   1. For each subject element there are one or more manufacturedProduct.consumedIn.substanceAdministration.routeCode elements that capture the Route of Administration.
10. DT Rule 15 identifies that required content is missing.
    1. The outer package description for a product shall detail the production quantity characteristic.
11. Informational only (currently this is not validated, however it is planned to introduce this in the future)

# Labeling Section Information Validation

Outlined below are the specifics relating to the PM Content Sections. Sections may contain sub sections as well as content unless specified in the section validation rules.

* 1. The Section Details are encoded in OID 2.16.840.1.113883.2.20.6.36 (structure-aspects), it is included in Appendix A as a reference, it details the code@code value, as well as the heading level and cardinality for each labeling section:

1. Verification that no additional sections are included is currently not validated, however it is planned to introduce this in the future.
2. DT Rule 9 identifies that the section is incorrect or contextually incorrect.
3. DT Rule 10 identifies that the section sequence is incorrect or contextually incorrect.
4. DT Rule 16 identifies that there is a notification flag for the content.
   1. Each section shall have an effectiveTime.low element that captures the Date of Initial Approval for the specific content section. Note this value changes if a link target is changed (changing the file content requires the reference to have a new effectiveTime).
5. DT Rule 15 identifies that required content is missing.
   1. section shall have an effectiveTime.high element that captures the Date of Revision for the specific content section.
6. DT Rule 15 identifies that required content is missing.
   1. Title Page Information, shall not contain any content other than nested content sections.
7. DT Rule 4 identifies that the section has content.
   1. Part I: Health Professional Information section, shall not contain any content other than nested content sections.
8. DT Rule 4 identifies that the section has content.
   1. Part II: Scientific Information section, shall not contain any content other than nested content sections.
9. DT Rule 4 identifies that the section has content.
   1. Part III: Consumer Information section, shall not contain any content other than nested content sections.

DT Rule 4 identifies that

1. the section has content.

Date of Initial Approval, may

* 1. not be modified after the initial submission

1. Informational only (currently this is not validated, however it is planned to introduce this in the future).
2. Each

Submission Control No section may one or more

* 1. Submission Control values that captures the Submission ID.

1. DT Rule 15 identifies that required content is missing.
   1. Title Page Warning Box section shall not have a Title.
2. DT Rule 4 identifies that the section has content.
   1. Serious Warnings and Precautions Box section shall not have a Title.
3. DT Rule 4 identifies that the section has content.

# 

This is convenience copy extract of the OID, the OID remains the authoritative source. Derived sections have been greyed out as they are not included in the content.

| **Code** | **Level** | **Card.** | **Title** | **Code@displayName (Language=ENG)** | **TemplateId Exception** |
| --- | --- | --- | --- | --- | --- |
| 10 | N/A | 1:1 | N/A | Title Page | None |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 50 | | H2 | 1:1 | F | | Document Information | | | None | | |
| 60 | | H2 | 1:1 | N/A | | Scheduling Symbol | | | None | | |
| 70 | | N/A | 1:n | F | | Brand Name | | | None | | |
| 80 | | N/A | 1:n | F | | Proper Name | | | None | | |
| 90 | | N/A | 1:n | F | | Dosage Form(s) | | | None | | |
| 100 | | N/A | 1:n | F | | Strength(s) | | | None | | |
| 110 | | H2 | 1:1 | N/A | | Pharmaceutical Standard | | | None | | |
| 70 | | H2 | 1:1 | N/A | | Therapeutic Classification | | | None | | |
| 530 | | N/A | 1:1 | N/A | | Title Page Box Warning | | | Only applicable to: 2, 7 | | |
| 80 | | H2 | 1:1 | F | | Sponsor Name | | | None | | |
| 90 | | H2 | 1:1 | F | | Sponsor Address | | | None | | |
| 500 | | H2 | 0:n | F | | Other Party Name | | | None | | |
| 510 | | H2 | 0:n | F | | Other Party Address | | | None | | |
| 170 | | H2 | 1:n | F | | Submission Control Number | | | None | | |
| 440 | | H2 | 0:1 | F | | Footnote | | | None | | |
| 540 | | H2 | 1:1 | F | | Title Page General Information | | | Only applicable to: 2, 7 | | |
| 520 | | H2 | 1:1 | F | | Table Of Contents | | | None | | |
| 20 | | H1 | 1:1 | F | | Part I: Health Professional Information | | | None | | |
| 180 | | H2 | 1:1 | F | | Summary Product Information | | | None | | |
| 550 | | H2 | 1:1 | F | | Description | | | Only applicable to: 4, 5, 9, 10 | | |
| 550-10 | | H3 | 1:1 | F | | Physical Characteristics | | | Only applicable to: 4, 9 | | |
| 550-20 | | H3 | 1:1 | F | | External Radiation | | | Only applicable to: 4, 9 | | |
| 190 | | H2 | 1:n | F | | Indications And Clinical Use | | | None | | |
| 190-10 | | H3 | 1:1 | F | | Patient Subsets | | | None | | |
| 190-10-10 | | H4 | 1:1 | F | | Geriatrics | | | None | | |
| 190-10-20 | | H4 | 1:1 | F | | Pediatrics | | | None | | |
| 580 | | H2 | 0:1 | F | | Serious Warnings and Precautions Box | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 200 | | H2 | 1:1 | F | | Contraindications | | | None | | |
| 210 | | H2 | 1:1 | F | | Warnings And Precautions | | | None | | |
| 580 | | H3 | 0:1 | F | | Serious Warnings and Precautions Box | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 210-10 | | H3 | 0:1 | F | | General | | | None | | |
| 210-240 | | H3 | 1:1 | F | | Contamination | | | Only applicable to: 1, 2, 3, 5, 6, 7, 8, 9, 10 | | |
| 210-250 | | H3 | 1:1 | F | | Local Skin Reactions at Vaccination Sites | | | Only applicable to: 4, 10 | | |
| 210-20 | | H3 | 0:1 | F | | Carcinogenesis And Mutagenesis | | | None | | |
| 210-30 | | H3 | 0:1 | F | | Cardiovascular | | | None | | |
| 210-240 | | H3 | 1:1 | F | | Contamination | | | Only applicable to: 4 | | |
| 210-40 | | H3 | 0:1 | F | | Dependence/Tolerance | | | None | | |
| 210-260 | | H3 | 0:1 | F | | Driving and Operating Machinery | | | Only applicable to: 8, 9, 10 | | |
| 210-50 | | H3 | 0:1 | F | | Ear/Nose/Throat | | | None | | |
| 210-60 | | H3 | 0:1 | F | | Endocrine And Metabolism | | | None | | |
| 210-70 | | H3 | 0:1 | F | | Gastrointestinal | | | None | | |
| 210-80 | | H3 | 0:1 | F | | Genitourinary | | | None | | |
| 210-90 | | H3 | 0:1 | F | | Hematologic | | | None | | |
| 210-100 | | H3 | 0:1 | F | | Hepatic/Biliary/Pancreatic | | | None | | |
| 210-60 | | H3 | 0:1 | F | | Immune | | | None | | |
| 210-230 | | H3 | 0:n | M | | Warnings and Precautions - Misc. | | | None | | |
| 210-70 | | H3 | 0:1 | F | | Neurologic | | | None | | |
| 210-80 | | H3 | 0:1 | F | | Ophthalmologic | | | None | | |
| 210-90 | | H3 | 0:1 | F | | Peri-Operative Considerations | | | None | | |
| 210-150 | | H3 | 0:1 | F | | Psychiatric | | | None | | |
| 210-160 | | H3 | 0:1 | F | | Renal | | | None | | |
| 210-170 | | H3 | 0:1 | F | | Respiratory | | | None | | |
| 210-180 | | H3 | 0:1 | F | | Sensitivity/Resistance | | | None | | |
| 210-190 | | H3 | 0:1 | F | | Sexual Function/Reproduction | | | Not applicable to: 6, 7, 8, 9, 10 | | |
| 210-200 | | H3 | 0:1 | F | | Skin | | | None | | |
| 210-270 | | H3 | 0:1 | F | | Sexual Health | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 210-270-10 | | H4 | 0:1 | F | | Reproduction | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 210-270-20 | | H4 | 0:1 | F | | Function | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 210-270-30 | | H4 | 0:1 | F | | Fertility | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 210-210 | | H3 | 0:1 | F | | Special Populations | | | None | | |
| 210-210-10 | | H4 | 0:1 | F | | Pregnant Women | | | None | | |
| 210-210-20 | | H4 | 0:1 | F | | Nursing Women | | | None | | |
| 210-210-30 | | H4 | 0:1 | F | | Pediatrics | | | None | | |
| 210-210-40 | | H4 | 0:1 | F | | Geriatrics | | | None | | |
| 210-210-60 | | H4 | 0:n | M | | Special Populations - Misc. | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 210-220 | | H4 | 1:1 | F | | Monitoring And Laboratory Tests | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 220 | | H2 | 1:1 | F | | Adverse Reactions | | | None | | |
| 650 | | H3 | 0:1 | F | | Serious Adverse Reactions Box | | | None | | |
| 220-80 | | H3 | 0:1 | F | | General | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 220-10 | | H3 | 0:1 | F | | Adverse Drug Reaction (ADR) Overview | | | None | | |
| 220-20 | | H3 | 0:1 | F | | Clinical Trial Adverse Drug Reactions | | | None | | |
| 220-30 | | H3 | 0:1 | F | | Less Common Clinical Trial Adverse Drug Reactions | | | None | | |
| 220-90 | | H3 | 0:1 | F | | Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and other Quantitative Data | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 220-40 | | H3 | 0:1 | F | | Abnormal Hematologic And Clinical Chemistry Findings | | | None | | |
| 220-100 | | H3 | 0:1 | F | | Clinical Trial Adverse Reactions (Pediatrics) | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 220-50 | | H3 | 0:1 | F | | Post-Market Adverse Drug Reactions | | | None | | |
| 230 | | H2 | 1:1 | F | | Drug Interactions | | | None | | |
| 660 | | H3 | 0:1 | F | | Serious Drug Interactions Box | | | None | | |
| 230-80 | | H3 | 1:1 | F | | Overview | | | None | | |
| 230-10 | | H3 | 0:1 | F | | Drug-Drug Interactions | | | None | | |
| 230-20 | | H3 | 0:1 | F | | Drug-Food Interactions | | | None | | |
| 230-30 | | H3 | 0:1 | F | | Drug-Herb Interactions | | | None | | |
| 230-40 | | H3 | 0:1 | F | | Drug-Laboratory Test Interactions | | | None | | |
| 230-50 | | H3 | 0:1 | F | | Drug-Lifestyle Interactions | | | None | | |
| 240 | | H2 | 1:1 | F | | Dosage And Administration | | | None | | |
| 240-10 | | H3 | 1:1 | F | | Dosing Considerations | | | None | | |
| 240-60 | | H3 | 1:1 | F | | Dosage | | | Only applicable to: 4, 9 | | |
| 240-70 | | H3 | 1:1 | F | | Image Acquisition and Interpretation | | | Only applicable to: 4, 9 | | |
| 240-80 | | H3 | 1:1 | F | | Instructions for Preparation and Use | | | Only applicable to: 4, 9 | | |
| 240-90 | | H3 | 1:1 | F | | Directions for Quality Control | | | Only applicable to: 4, 9 | | |
| 240-20 | | H3 | 1:1 | F | | Recommended Dose And Dosage Adjustment | | | None | | |
| 240-30 | | H3 | 1:1 | F | | Missed Dose | | | None | | |
| 240-40 | | H3 | 0:1 | F | | Administration | | | None | | |
| 240-50 | | H3 | 0:1 | F | | Reconstitution | | | None | | |
| 240-50-10 | | H4 | 0:1 | F | | Oral Solutions | | | None | | |
| 240-50-20 | | H4 | 0:1 | F | | Parenteral Products | | | None | | |
| 250 | | H2 | 1:1 | F | | Overdosage | | | None | | |
| 260 | | H2 | 1:1 | F | | Action And Clinical Pharmacology | | | None | | |
| 260-10 | | H3 | 1:1 | F | | Mechanism Of Action | | | None | | |
| 260-20 | | H3 | 1:1 | F | | Pharmacodynamics | | | None | | |
| 260-30 | | H3 | 1:1 | F | | Pharmacokinetics | | | None | | |
| 260-30-10 | | H4 | 0:n | F | | Absorption | | | None | | |
| 260-30-20 | | H4 | 0:n | F | | Distribution | | | None | | |
| 260-30-30 | | H4 | 0:n | F | | Metabolism | | | None | | |
| 260-30-40 | | H4 | 0:n | F | | Excretion | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50 | | H4 | 0:n | F | | Special Populations And Conditions | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-10 | | H5 | 0:n | F | | Pediatrics | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-20 | | H5 | 0:n | F | | Geriatrics | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-30 | | H5 | 0:n | F | | Gender | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-40 | | H5 | 0:n | F | | Race | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-50 | | H5 | 0:n | F | | Hepatic Insufficiency | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-60 | | H5 | 0:n | F | | Renal Insufficiency | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-50-70 | | H5 | 0:n | F | | Genetic Polymorphism | | | Only applicable to:  1, 2, 3, 4, 5 | | |
| 260-30-70 | | H4 | 0:n | F | | Elimination | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 260-40 | | H3 | 1:1 | F | | Duration of Effect | | | Only applicable to: 5 | | |
| 560 | | H2 | 1:1 | F | | Radiation Dosimetry | | | Only applicable to: 4, 9 | | |
| 270 | | H2 | 1:1 | F | | Storage And Stability | | | None | | |
| 280 | | H2 | 0:1 | F | | Special Handling Instructions | | | None | | |
| 290 | | H2 | 1:1 | F | | Dosage Forms, Composition And Packaging | | | None | | |
| 30 | | H1 | 1:1 | F | | Part II: Scientific Information | | | None | | |
| 300 | | H2 | 1:1 | F | | Pharmaceutical Information | | | None | | |
| 300-10 | | H3 | 1:n | F | | Drug Substance | | | None | | |
| 300-10-10 | | H4 | 1:n | F | | Proper Name | | | None | | |
| 300-10-20 | | H4 | 1:1 | F | | Chemical Name | | | None | | |
| 300-10-30 | | H4 | 1:1 | F | | Molecular Formula And Molecular Mass | | | None | | |
| 300-10-40 | | H4 | 1:1 | F | | Structural formula, including relative and absolute stereochemistry | | | None | | |
| 300-10-50 | | H4 | 1:1 | F | | Physicochemical Properties | | | None | | |
| 300-20 | | H2 | 1:1 | F | | Product Characteristics | | | Only applicable to: 4, 5, 9, 10 | | |
| 300-30 | | H3 | 1:1 | F | | Viral Inactivation | | | Only applicable to: 5, 10 | | |
| 310 | | H2 | 1:1 | F | | Clinical Trials | | | None | | |
| 310-10 | | H3 | 0:1 | F | | Efficacy and Safety Studies | | | None | | |
| 310-10-10 | | H4 | 0:1 | F | | Study Demographics And Trial Design | | | None | | |
| 310-10-20 | | H4 | 0:1 | F | | Study Results | | | None | | |
| 310-20 | | H3 | 0:1 | F | | Pivotal Comparative Bioavailability Studies | | | None | | |
| 320 | | H2 | 1:1 | F | | Detailed Pharmacology | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 330 | | H2 | 0:1 | F | | Microbiology | | | None | | |
| 340 | | H2 | 0:1 | F | | Toxicology | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 350 | | H2 | 0:1 | F | | References | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 590 | | H2 | 0:1 | F | | Non-clinical Toxicology | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 600 | | H2 | 0:1 | F | | Supporting Product Monographs | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 40 | | H1 | 1:n | F | | Part III: Consumer Information | | | None | | |
| 480 | | N/A | 1:1 | F | | General | | | None | | |
| 490 | | H2 | 1:1 | F | | Opening Disclaimer | | | None | | |
| 360 | | H2 | 1:1 | F | | About This Medication | | | None | | |
| 360-10 | | H3 | 1:1 | F | | What The Medication Is Used For | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-20 | | H3 | 1:1 | F | | What It Does | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-30 | | H3 | 1:1 | F | | When It Should Not Be Used | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-40 | | H3 | 1:1 | F | | What The Medicinal Ingredient Is | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-50 | | H3 | 1:1 | F | | What The Important Nonmedicinal Ingredients Are | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-60 | | H3 | 1:1 | F | | What Dosage Forms It Comes In | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 360-70 | | H3 | 1:1 | F | | What is <Brand name> used for? | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 360-80 | | H3 | 1:1 | F | | How does <Brand name> work? | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 360-90 | | H3 | 1:1 | F | | What are the ingredients in <Brand name>? | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 360-100 | | H3 | 1:1 | F | | <Brand name> comes in the following dosage forms: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 360-110 | | H3 | 1:1 | F | | Do not use <Brand name> if: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 370 | | H2 | 1:1 | F | | Warnings And Precautions | | | None | | |
| 370-10 | | H3 | 0:1 | F | | To help avoid side effects and ensure proper use, talk to your healthcare professional before you take <Brand name> | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 370-20 | | H3 | 0:1 | F | | Other warnings you should know about: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 380 | | H2 | 1:1 | F | | Interactions With This Medication | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 610 | | H2 | 1:1 | F | | Interactions | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 610-10 | | H3 | 0:1 | F | | Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 610-20 | | H3 | 0:1 | F | | The following may interact with <Brand name>: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 390 | | H2 | 1:1 | F | | Proper Use Of This Medication | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 390-10 | | H3 | 1:1 | F | | Usual Dose | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 390-20 | | H3 | 1:1 | F | | Overdose | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 390-30 | | H3 | 1:1 | F | | Missed Dose | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 620 | | H2 | 1:1 | F | | Proper Use | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 620-10 | | H3 | 1:1 | F | | How to take <Brand name>: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 620-20 | | H3 | 1:1 | F | | Usual dose | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 620-30 | | H3 | 1:1 | F | | Overdose | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 620-40 | | H3 | 1:1 | F | | Missed dose | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 400 | | H2 | 1:1 | F | | Side Effects And What To Do About Them | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 410 | | H2 | 1:1 | F | | How To Store It | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 420 | | H2 | 1:1 | F | | Reporting Suspected Side Effects | | | Only applicable to: 1, 2, 3, 4, 5 | | |
| 630 | | H2 | 1:1 | F | | Side Effects | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 630-10 | | H3 | 1:1 | F | | What are possible side effects from using <Brand name>? | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 640 | | H2 | 1:1 | F | | Storage | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 430 | | H2 | 1:1 | F | | More Information | | | None | | |
| 430-10 | | H3 | 1:1 | F | | If you want more information about <Brand name>: | | | Only applicable to: 6, 7, 8, 9, 10 | | |
| 470 | | N/A | 1:1 | N/A | | Part 3 Revision Date | | | None | | |
| 48780-1 | | N/A | 1:1 | F | | SPL Product Data Elements Section | | | None | | |

# Appendix B – effectiveTime and Marketing Activity Details

The following table illustrates events and the element and or attribute that shall be used to identify the changes (red underline has been used to identify changes):

| **SPM Components** | **NDS Approved Products 1,2,3 on 2013-01-01** | **SNDS#1 Added Products 4,5 on 2014-01-01** | **SNDS#2 Modified Products 2,3 on 2015-01-01** | **Level III Change to correct Typos in Part III on 2016-01-01** | **SNDS#3 Removed Products 1,4 on 2017-02-01** |
| --- | --- | --- | --- | --- | --- |
| **SPM v1 Dates** | **SPM v2 Dates** | **SPM v3 Dates** | **SPM v4 Dates** | **SPM v5 Dates** |
| **Document** |  |  |  |  |  |
| * Date of Initial Approval   document/effectiveTime/originalText | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Date of Revision   document/effectiveTime@value | 20130101 | 20140101 | 20150101 | 20160101 | 20170201 |
| * Submission Type   extension value with name-eng in ()  templateId extension="???" root="2.16.840.1.113883.2.20.6.11" where ??? is the term from the CV. | 308 (NDS) | 314 (SNDS) | 314 (SNDS) | 306 (Level III Changes) | 314 (SNDS) |
| **Product Root** |  |  |  |  |  |
| * Date of Initial Approval   component/section[@code = ‘48780-1’]/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Date of Revision   component/section[@code = ‘48780-1’]/effectiveTime/high@value | 20130101 | 20140101 | 20150101 | 20150101 | 20170201 |
| **Product #1** |  |  |  |  |  |
| * Marketing Effective Time Low   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low@value |  |  |  |  |  |
| * Marketing Effective Time High   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high@value |  |  |  |  | 20170201 |
| * Marketing Activity   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/code | 308 (NDS) | 308 (NDS) | 308 (NDS) | 308 (NDS) | 314 (SNDS) |
| * Approval Effective Time Low   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Approval Effective Time High   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/effectiveTime/high@value | 20130101 | 20130101 | 20130101 | 20130101 | 20170201 |
| **Product #2** |  |  |  |  |  |
| * Marketing Effective Time Low   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low@value |  |  |  |  |  |
| * Marketing Effective Time High   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high@value |  |  |  |  |  |
| * Marketing Activity   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/code | 308 (NDS) | 308 (NDS) | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) |
| * Approval Effective Time Low   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Approval Effective Time High   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/effectiveTime/high@value | 20130101 | 20130101 | 20150101 | 20150101 | 20150101 |
| **Product #3** |  |  |  |  |  |
| * Marketing Effective Time Low   (See above for subject[3]) |  |  |  |  |  |
| * Marketing Effective Time High   (See above for subject[3]) |  |  |  |  |  |
| * Marketing Activity   (See above for subject[3]) | 308 (NDS) | 308 (NDS) | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) |
| * Approval Effective Time Low   (See above for subject[3]) | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Approval Effective Time High   (See above for subject[3]) | 20130101 | 20130101 | 20150101 | 20150101 | 20150101 |
| **Product #4** |  |  |  |  |  |
| * Marketing Effective Time Low   (See above for subject[4]) |  |  |  |  |  |
| * Marketing Effective Time High   (See above for subject[4]) |  |  |  |  | 20170601 |
| * Marketing Activity   (See above for subject[4]) |  | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) |
| * Approval Effective Time Low   (See above for subject[4]) |  | 20140101 | 20140101 | 20140101 | 20140101 |
| * Approval Effective Time High   (See above for subject[4]) |  | 20140101 | 20140101 | 20140101 | 20170201 |
| **Product #5** |  |  |  |  |  |
| * Marketing Effective Time Low   (See above for subject[5]) |  |  |  |  |  |
| * Marketing Effective Time High   (See above for subject[5]) |  |  |  |  |  |
| * Marketing Activity   (See above for subject[5]) |  | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) |
| * Approval Effective Time Low   (See above for subject[5]) |  | 20140101 | 20140101 | 20140101 | 20140101 |
| * Approval Effective Time High   (See above for subject[5]) |  | 20140101 | 20140101 | 20140101 | 20140101 |
| **Title Page**   * EffectiveTime   component/section[@code = ‘10’]/ /effectiveTime@value | 20130101 | 20140101 | 20150101 | 20160101 | 20170201 |
| **Part I**   * EffectiveTime   A nested section under component/section[@code = ‘20]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20150101 | 20170201  (Assuming content changes due to revised products) |
| **Part II**   * EffectiveTime   A nested section under component/section[@code = ‘30]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20150101 | 20170201  (Assuming content changes due to revised products) |
| **Part III**   * EffectiveTime   A nested section under component/section[@code = ‘40]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20160101 | 20170201  (Assuming content changes due to revised products) |