Health Canada Santé Canada

Sponsor Attestation
S(A)NDS for Generic Drugs - Product Monograph Updates to be in line with the CRP

Brand (Proprietary) Name of Drug Product	
Drug Substance / Medicinal Ingredient	
Manufacturer / Sponsor	
Dosage Form(s) and Strength(s)	
Canadian Reference Product (CRP)[ab]	

Reason for Submission	◯ Product Monograph (PM) update based on CRP's PM; control number: ____ ◯ Product Monograph update based on another labelling reference's PM; control number ____ Please specify the product used as a reference: ____ Please specify the reason the CRP's PM was not used: ____
Was this filed in response to an advisement letter	◯ Yes - Response to Advisement letter dated: ____ (YYYY/MM/DD) as per CRP PM update; control number ____ ◯ No
Confirm that the following **required** documents are **provided**:	☐ The Labels and Packages Certification Form ☐ Annotated PM against the **most recent CRP PM** dated: ____ (YYYY/MM/DD) - Note: Please complete Table 1 with the differences between your proposed PM and the CRP PM ☐ Annotated PM against **most recently approved PM for this generic product** dated: ____ (YYYY/MM/DD) - Note: Please complete Table 2 with the differences between your proposed PM and your currently approved PM.

[a] CRP refers to the reference product listed on the NOC of the original ANDS

[b] If you are filing a generic SNDS, please confirm that the original NDS was a generic approved prior to the ANDS regulations (i.e. pre-1996) and indicate the reference product used for the approval of that generic NDS

Canada

	Notes: - The annotated PMs, using a track changes feature or highlighting and strike-throughs, should clearly identify all additions, deletions and replacement of information between the proposed generic PM and the comparator PMs identified above, and be provided as two separate documents. - All differences must be listed in the Document Compare Tables 1 and 2 and must have a justification (for example, update as per the reference product, section not approved for this dosage form, level 3 change, etc.)
Description of PM updates (please check all that apply)	☐ There are **no differences** between our proposed PM and the CRP PM other than the product brand name and product specific sections that have been previously approved (for example, comparative bioavailability summary table(s), pharmaceutical information, storage and stability, non-medicinal ingredients, references). ☐ There are **some differences** between our proposed PM and the CRP PM, which **have been** previously approved (for example, a difference in market authorized dosage forms, dosing and administration, strengths and/or indications). ☐ The CRP has been discontinued and this is a first-time update against another reference product. ☐ The CRP has been discontinued and another reference product has been used for PM updates at least once previously, and this is a subsequent update against that other reference product. ☐ The PM is being migrated to a new format for the first time to match the CRP's PM. ☐ The PM combines multiple previously approved generic PMs into one PM, to match the CRP's PM. ☐ Other :

Attestation

We attest that the proposed revisions to the Product Monograph for _____ submitted by _____ contain only the changes outlined in this attestation.

We attest that the proposed revisions to the Product Monograph contain only updates to be in line with the CRP or reference product identified above.

We attest that the proposed revisions to the Product Monograph contain all required safety updates.

Name

Signature

Title

Date

Company

Document Compare 1:
Summary of differences between proposed PM and most recent Canadian Reference Product (CRP) PM:

CRP name: | **CRP PM Date:** | **CRP control number:**

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information		
Indications and Clinical Use		
Contraindications		
Warnings and Precautions		
Adverse Reactions		
Drug Interactions (Precautions)		
Dosage and Administration		
Overdosage		
Action and Clinical Pharmacology		
Storage and Stability		
Dosage Forms, Composition and Packaging (availability)		
Part II: Scientific Information		
Pharmaceutical Information		

Clinical Trials		
Detailed Pharmacology		
Toxicology		
References		
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**		

Document Compare 2:
Summary of Differences between proposed PM and most recently approved PM:

Most recently approved PM date: | **Most recently approved PM control number:**

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information		
Indications and Clinical Use		
Contraindications		
Warnings and Precautions		
Adverse Reactions		
Drug Interactions (Precautions)		
Dosage and Administration		

Overdosage		
Action and Clinical Pharmacology		
Storage and Stability		
Dosage Forms, Composition and Packaging (Availability)		
Part II: Scientific Information		
Pharmaceutical Information		
Clinical Trials		
Detailed Pharmacology		
Toxicology		
References		
Part III: Consumer Information (Patient Information Sheet) **Patient Medication Information**		

Appendix. Examples of document compare tables. These pages should not be included in the submission.

Please note the **examples** provided below are not all inclusive, it is recognized that these tables will vary by submission

Document Compare 1:
Summary of differences between proposed Product Monograph (PM) and most recent Canadian Reference Product (CRP) PM:

CRP name: **CRP PM date:** **CRP control number:**

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information	Non-medicinal ingredients (NMIs)	First inclusion or changes to the NMIs
Indications and Clinical Use	Not all indications present, dosage forms and/or strengths are included	Indications, dosage and strengths are not all approved for this product
Contraindications	No Differences	
Warnings and Precautions	No Differences	
Adverse Reactions	No Differences	
Drug Interactions (Precautions)	No Differences	
Dosage and Administration	No Differences	
Overdosage	No Differences	
Action and Clinical Pharmacology	No Differences	
Storage and Stability	Differences in storage conditions	Product specific
Dosage Forms, Composition and Packaging (availability)	Composition and packaging differences	Product specific
Part II: Scientific Information		
Pharmaceutical Information	Differences in chemical name	Product specific
Clinical Trials	Comparative Bioavailability Studies	Product Specific
Detailed Pharmacology	No Differences	
Toxicology	No Differences	
References	Updated CRP References	Product Specific
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**	Different non medicinal ingredients, dosage forms and storage conditions	Product Specific

Document Compare 2:
Summary of Differences between proposed PM and most recently approved PM:

Most recently approved PM date: **Most recently approved PM control number:**

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information	No Changes	
Indications and Clinical Use	No Changes	
Contraindications	Updates to Contraindications (brief summary to be included) That is (i.e.) Contraindicated in breastfeeding or nursing women	Changes are made to match the CRP
Warnings and Precautions	Updates to Warnings and Precautions (brief summary to be included) i.e., Additional Warning added for hypertension	Changes are made to match the CRP
Adverse Reactions	Updates to Adverse Reactions (brief summary to be included) i.e., Additional Adverse Reaction added to include rash	Changes are made to match the CRP
Drug Interactions (Precautions)	Updates to Drug Interactions (brief summary to be included) i.e., New Drug Interaction with metformin	Changes are made to match the CRP
Dosage and Administration	No Changes	
Overdosage	No Changes	
Action and Clinical Pharmacology	No Changes	
Storage and Stability	No Changes	
Dosage Forms, Composition and Packaging (Availability)	No Changes	
Part II: Scientific Information		
Pharmaceutical Information	No Changes	
Clinical Trials	No Changes	
Detailed Pharmacology	No Changes	
Toxicology	No Changes	
References	Updated the CRP Reference	Product Specific
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**	Changed “about this medication”, “warnings and precautions”, “interactions with this medication”, “proper use of this medication”, reporting suspected side effects” sections and revision date	Changes are made to match the CRP