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**Veterinary Drugs Directorate (VDD)**

**Health Products and Food Branch (HPFB)**

**CERTIFIED PRODUCT INFORMATION DOCUMENT (CPID)**

|  |  |
| --- | --- |
| **SUMMARY OF PRODUCT INFORMATION** | |
| **Proprietary (brand) name of drug product** |  |
| **Non-proprietary (proper or common name) name of drug product** |  |
| **Non-proprietary or Common Name of drug substance (medicinal ingredient)** |  |
| **Manufacturer name (fabricator)** |  |
| **Manufacturer name (sponsor)** |  |
| **Dosage Form(s)** |  |
| **Strength(s)** |  |
| **Drug Identification Number (DIN) (if applicable)** |  |
| **Route of administration** |  |
| **Submission Type** (*for generics,* *see Appendix 1)* |  |
| **ADMINISTRATIVE SUMMARY** | |
| **Dossier ID number** |  |
| **Control Number (DSTS number)** |  |
| **Sponsor’s date of preparation or revision** |  |
| **Revision number (for sponsor use)** |  |

# S DRUG SUBSTANCE (NAME, MANUFACTURER)

Note: Include the information on the drug substance in the open part of the Master File (MF) in the appropriate sections.

## S.1 General Information

### S.1.2 Structure

1. **Structural formula, including relative and absolute stereochemistry (include a chemical structure):**
2. **Molecular formula:**
3. **Molecular mass:**

### S.1.3 General Properties

1. **Physical form (for example, polymorphic form, solvate, hydrate):**
2. **Solubilities and Dose/Solubility Volume over the physiological pH range (1.2-6.8):**
3. **pKa:**

## S.2 Manufacture (name, manufacturer)

### S.2.1 Manufacturer(s) (name, manufacturer)

* 1. **Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing of the drug substance:**

| **Name and Address** | **Responsibility**  (for example, manufacturing, packaging, labelling and testing) | **MF # or**  **CEP #** |
| --- | --- | --- |
|  |  |  |

### S.2.2 Description of Manufacturing Process and process controls (name, manufacturer)

1. **Flow diagram showing reactants, solvents and reagents:**
2. **Name and address of sites manufacturing the drug substance starting material(s) and/or intermediates *(if not available, reference to Master File and delete the table below)*:**

|  |  |  |
| --- | --- | --- |
| **Name and chemical structure of drug substance starting material/intermediate:** | **Manufacturer** | **Manufacturing site address** |
|  |  |  |

### S.3.2 Impurities

**Potential impurities not routinely controlled in the drug substance:**

## S.4 Control of the Drug Substance

### S.4.1 Specification (name, manufacturer)

1. **Specification for the drug substance:**

| **Standard Claimed [for example, House, United States Pharmacopeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur.)]** | |  |
| --- | --- | --- |
| **Specification Reference Number and/or Version** | |  |
| **Test** | **Acceptance Criteria** | **Analytical Procedure**  **(Type/Source/Version)** |
|  |  |  |
|  |  |  |

## S.6 Container Closure System (name, manufacturer)

1. **Description of the container closure system(s) including materials of construction for the storage and shipment of the drug substance:**

## S.7 Stability (name, manufacturer)

### S.7.1 Stability Summary and Conclusions

1. **Proposed storage conditions and re-test period (or shelf-life, as appropriate):**

| **Container Closure System** | **Storage Conditions** | **Re-test (or shelf-life) Period** |
| --- | --- | --- |
|  |  |  |

### S.7.2 Post-approval Stability Protocol and Stability Commitment (name, manufacturer)

1. **Stability protocol for commitment batches:**

| **Protocol Parameter** | **Description** |
| --- | --- |
| **Storage conditions (including tolerances)** |  |
| **Testing frequency** |  |
| **Number of batches and batch sizes** |  |
| **Container closure system(s)** |  |
| **Tests and acceptance criteria** |  |
| **Other** |  |

1. **Stability protocol for continuing (i.e., ongoing) batches:**

| **Protocol Parameter** | **Description** |
| --- | --- |
| **Storage conditions (including tolerances)** |  |
| **Testing frequency** |  |
| **Number of batches and batch sizes** |  |
| **Container closure system(s)** |  |
| **Tests and acceptance criteria** |  |
| **Other** |  |

# P DRUG PRODUCT (NAME, DOSAGE FORM)

## P.1 Description and Composition of the Drug Product

1. **Composition of the drug product:**
2. **Composition, that is (i.e.), list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any):**

| **Component and Quality Standard (and Grade, if applicable)** | **Function** | **Strength (label claim)** | | | |
| --- | --- | --- | --- | --- | --- |
| *(e.g. mg, mg/mL)* | | *(e.g. mg, mg/mL)* | |
| **Quantity per unit** | **% (w/v, w/w)** | **Quantity per unit** | **% (w/v, w/w)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Total |  |  |  |  |  |

1. **Composition of all *components that are mixtures* (e.g., colourants, coatings, capsule shells, imprinting inks):**
2. **Description of accompanying reconstitution diluent(s), if applicable:**
3. **Description of container/closure system used for the accompanying reconstitution diluent, if applicable:**
4. **Description of accompanying dosing devices, if applicable:**

## P.3 Manufacture (name, dosage form)

### P.3.1 Manufacturer(s) (name, dosage form)

1. **Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing:**

| **Name and Address** | **Responsibility**  (e.g., manufacturing, packaging, labelling and testing) | **MF #** |
| --- | --- | --- |
|  |  |  |

### P.3.2 Batch Formula (name, dosage form)

**List of all components of the drug product to be used in the manufacturing process, and their amounts on a per batch basis (including overages, if any):**

| **Strength (label claim)** |  | |
| --- | --- | --- |
| **Master Production Document**  **Reference # and/or Version #** |  |  |
| **Batch Size(s) (number of dosage units)** |  |  |
| **Component and Quality Standard**  **(and Grade, if applicable)** | **Quantity per batch** | **Quantity per batch** |
|  |  |  |
|  |  |  |
| Total |  |  |

### P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form)

1. **Flow diagram of the manufacturing process:**
2. **Narrative description of the manufacturing process, including equipment type and working capacity, process parameters, in-process testing with acceptance criteria:**

### P.3.4 Controls of Critical Steps and Intermediates (name, dosage form)

**Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:**

### P.3.5 Process Validation and/or Evaluation (name, dosage form)

**Summary of process validation information, including any commitments, for the critical steps in the manufacturing process (e.g., protocol number, parameters):**

| **Validation Protocol # / Report #** | **Description** | **Status** (Commitment / Completed**)** | **Filed with Submission Control No.** |
| --- | --- | --- | --- |
|  |  |  |  |

## P.5 Control of Drug Product (name, dosage form)

### P.5.1 Specification(s) (name, dosage form)

**Specification(s) for the drug product:**

| **Standard Claimed (for example, House, USP, BP)** | |  |
| --- | --- | --- |
| **Specification Reference Number and/or Version** | |  |
| **Test** | **Acceptance Criteria**  **(release and stability)** | **Analytical Procedure**  **(Type/Source/Version)** |
|  |  |  |
|  |  |  |

## P.7 Container Closure System (name, dosage form)

**Description of the container closure systems, including unit count or fill size, container size or volume:**

| **Strength** | **Unit Count or Fill Size** | **Container Size(s)** | **Description** |
| --- | --- | --- | --- |
|  |  |  |  |

## P.8 Stability (name, dosage form)

### P.8.1 Stability Summary and Conclusions (name, dosage form)

**Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable):**

| **Container Closure System** | **Storage Conditions (and In-use Storage Conditions, if applicable)** | **Shelf Life (and In-use Period, if applicable)** |
| --- | --- | --- |
|  |  |  |

### P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)

1. **Stability protocol for commitment batches:**

| **Protocol Parameter** | **Description** |
| --- | --- |
| **Storage conditions (including tolerances)** |  |
| **Testing frequency** |  |
| **Number of batches per strength and batch sizes** |  |
| **Container closure system(s)** |  |
| **Tests and acceptance criteria** |  |
| **Other** |  |

1. **Stability protocol for continuing (i.e., ongoing) batches:**

| **Protocol Parameter** | **Description** |
| --- | --- |
| **Storage conditions (including tolerances)** |  |
| **Testing frequency** |  |
| **Number of batches per strength and batch sizes** |  |
| **Container closure system(s)** |  |
| **Tests and acceptance criteria** |  |
| **Other** |  |

1. **Bracketing and matrixing design for commitment and/or continuing (i.e., ongoing) batches, if applicable:**

# APPENDIX

## Appendix 1: Additional information for generic drug products

|  |  |
| --- | --- |
| **CANADIAN REFERENCE PRODUCT INFORMATION** | |
| **Proprietary (brand) name** |  |
| **Drug Identification Number (DIN)** |  |
| **Proper or common name of drug substance (medicinal ingredient)** |  |
| **Market Authorization Holder’s Name** |  |
| **Dosage form(s) and strength(s)** |  |