

**Drug Identification Number (DIN)**

**Submission Certification for Human and Disinfectant Drugs**

**Drug Product Name: .**

We certify that:

1. The information and data provided in support of this DIN submission is complete and accurate and, where summarized, correctly represents the information and material to which it refers.

2. The manufacturing site where the product is manufactured is in compliance with Canadian Good Manufacturing Practices (GMP) as required under Part C, Division 2 of the *Food and Drug Regulations*.

NOTE: This requirement does not apply to "antimicrobial agents" as defined in Part C, Division 1A of the *Food and Drug Regulations* but is applicable to higher risk disinfectant products such as contact lens disinfectants, chemosterilants and high level disinfectants used to sterilize invasive devices or devices used for circulation, reintroduction of a body fluid or for introduction in a body cavity as well as to antimicrobial drug products for use on the skin.

3. Stability data will support the labelled expiration date of the drug product. In addition a Continuing Stability Programme will be implemented for the drug product to ensure compliance with the approved shelf life specifications.

4. For injectables and ophthalmic preparations, the container will meet the appropriate requirements for containers in either the United States Pharmacopeia (USP), European Pharmacopeia (Ph. Eur.), or British Pharmacopoeia (BP).

5. The drug product does **not** contain any of the following ingredients:

a) phenacetin in combination with any salt or derivative of salicylic acid (C.01.036. (1) (a))

 b) oxyphenisatin (C.01.036. (1) (b) (i))

c) oxyphenisatin acetate (C.01.036. (1) (b) (ii))

 d) phenisatin (C.01.036. (1) (b) (iii))

e) strychnine or any of its salts (C.01.038. (a))

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 f) extracts or tinctures of (C.01.038. (b)):

i) *Strychnos nux vomica*

ii) *Strychnos Ignatii*

iii) a *Strychnos* species containing strychnine, other than those species mentioned in subparagraph i) and ii)

 g) Methapyrilene or any of its salts (C.01.038. (c))

h) Echimidine or any of its salts (C.01.038. (d))

 i) any of the following plant species or extracts or tinctures thereof (C.01.038. (e)):

i) *Symphytum asperum*

 ii) *Symphytum X uplandicum*

 iii) any other plant species containing echimidine

 j) chloroform (C.01.040 (a)) (C.01.036.(1))

 k) arsenic or any of its salts or derivatives (C.01.040 (b))

 l) methyl salicylate (as a medicinal ingredient in a drug for internal use) (C.01.040.1)

m) mercury or a salt or derivative thereof, unless the drug is one of the following
C.01.036. (1) c) (ii)):

A) an ophthalmic drug or other drug to be used in the area of the eye

B) a drug for nasal administration

C) a drug for otic administration

D) a drug for parenteral administration that is packaged in a multi-dose container

in which the mercury or the salt or derivative thereof is present as a preservative and the manufacturer or importer has submitted evidence to the Director demonstrating that the only satisfactory way to maintain the sterility or stability of the drug is to use that preservative.

1. The product does not contain any colouring agent, with the exception of those listed in Section C.01.040.2 of the *Food and Drug Regulations* (this does not apply to hard surface or instrument disinfectants).

7. If the product contains animal tissue or animal tissue was used as an intermediate during manufacturing, the required information has been submitted (Animal Tissues Form).

8. The product has been assessed to determine the applicability of bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence requirements. Where applicable, the data have been submitted. Excluded from this assessment are:

- injectable or prescription homeopathic preparations

- injectable or prescription traditional herbal medicines

- hard surface or instrument disinfectants

- injectable or prescription vitamin, mineral or vitamin/mineral preparations

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- nonprescription products subject to a standardized proprietary medicine monograph (SPMM)

- nonprescription products subject to a labelling standard where the standard specifies that a bioavailability assessment for the purpose of a DIN application is not required

- peritoneal dialysis

- hemodialysis

- contact lens solutions

- artificial tears

- eye washes

9. Signature of the responsible officer of the company certifying the accuracy of this document.

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Signature Date

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Name Position Title

Company