CERTIFIED PRODUCT INFORMATION DOCUMENT (SCHEDULE D DRUGS) (CPID (SCHEDULE D DRUGS)) IN THE CTD FORMAT

INTRODUCTION

Submission File#

NDS Approval Date and Control#

CPID Revision Date and Control#

Proprietary Name:

Non-proprietary name or common name of the drug substance:

Company Name:

Name of Canadian Distributor:

Therapeutic or Pharmacological Classification:

Dosage form(s):

Strength(s):

Route(s) of Administration:

Maximum Daily Dose:

New Active Substance (NAS)?

S DRUG SUBSTANCE (NAME, MANUFACTURER)

Manufacture (name, manufacturer)

Manufacturer(s) (name, manufacturer)

[Insert the completed Module 3.2.S.2.1.]

Description of Manufacturing Process and Process Controls (name, manufacturer)

[Insert the flow diagram(s) from the completed Module 3.2.S.2.2.]

Control of Materials (name, manufacturer)

[Insert the tabulated summary of the biological raw material(s) used, from the completed Module 3.2.S.2.3.]

[Insert the tabulated summary of prepared reagents from the completed Module 3.2.S.2.3.]

Controls of Critical Steps and Intermediates (name, manufacturer)

[Insert a summary of critical manufacturing steps, process controls performed, and acceptance criteria from the completed Module 3.2.S.2.4, under *Critical Steps*.]

[Insert a summary of the quality, control and storage conditions of intermediates isolated during the process from the completed Module 3.2.S.2.4, under *Intermediates*.]

Characterisation (name, manufacturer)

Elucidation of Structure and other Characteristics (name, manufacturer)

[Insert a summarized description of this information from the completed Module 3.2.S.3.1.]

Impurities (name, manufacturer)

[Insert the tabulated summary on actual impurity levels detected from the completed Module 3.2.S.3.2.]

Control of Drug Substance (name, manufacturer)

Specification (name, manufacturer)

[Insert the specification for the drug substance from the completed Module 3.2.S.4.1.]

[Insert the declared drug substance standard from the completed Module 3.2.S.4.1.]

Stability (name, manufacturer)

Stability Summary and Conclusions (name, manufacturer)

[Insert the proposed storage conditions, retest date or shelf-life, where relevant, from the completed Module 3.2.S.7.1.]

P DRUG PRODUCT (NAME, DOSAGE FORM)

Manufacture (name, dosage form)

Manufacturer(s) (name, dosage form)

[Insert the completed Module 3.2.P.3.1.]

Batch Formula (name, dosage form)

[Insert the tabulated summary on the batch formula from the completed Module 3.2.P.3.2.]

Description of Manufacturing Process and Process Controls (name, dosage form)

[Insert the process flow diagram from the completed Module 3.2.P.3.3.]

Controls of Critical Steps and Intermediates (name, dosage form)

[Insert a summary of critical manufacturing steps, process controls performed, and acceptance criteria from the completed Module 3.2.P.3.4, under *Critical Steps*.]

[Insert information on the quality and control of intermediates isolated during the process, from the completed Module 3.2.P.3.4, under *Intermediates*.]

Control of Excipients (name, dosage form)

Excipients of Human or Animal Origin (name, dosage form)

[Insert the tabulated summary of excipients of human or animal origin that are used from the completed Module 3.2.P.4.5.]

Control of Drug Product (name, dosage form)

Specification(s) (name, dosage form)

[Insert the specification(s) for the drug product from the completed Module 3.2.P.5.1.]

[Insert the declared drug product release standard from the completed Module 3.2.P.5.1.]

Container Closure System (name, dosage form)

[Insert a brief description of the container closure system for the drug product from the completed Module 3.2.P.7.]

Stability (name, dosage form)

Stability Summary and Conclusion (name, dosage form)

[Insert the proposed labelled storage conditions and retest date or shelf-life, including after reconstitution and in-use storage conditions (if applicable) from the completed Module 3.2.P.8.1.]

Post-approval Stability Protocol and Stability Commitment (name, dosage form)

[Insert the post-approval stability protocol and stability commitment from the completed Module 3.2.P.8.2.]

A APPENDICES

Facilities and Equipment (name, manufacturer)

[Insert information on all developmental or approved products manufactured or manipulated in the same areas as the applicant's product from the completed Module 3.2.A.1.]

Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)

[Insert the tabulated summary of the reduction factors for viral clearance from the completed Module 3.2.A.2 under *Viral Clearance Studies*.]

[Insert the calculation of estimated particles/ dose, where relevant from the completed Module 3.2.A.2, under *Viral Clearance Studies*.]