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SCOPE OF ACCREDITATION

Health Canada Health Products Laboratory Program - Santé Canada - Programme de laboratoire des produits de santé

**LONGUEUIL LABORATORY - LABORATOIRE DE LONGUEUIL
1001, rue Saint-Laurent ouest
Longueuil, QC
J4K 1C7**

Accredited Laboratory No. 450
(Conforms with requirements of ISO/IEC 17025:2005)

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CLIENTS SERVED: Health Canada Inspectors

FIELDS OF TESTING: Biological, Chemical/Physical

SCOPE ISSUED ON: 2018-06-21

ACCREDITATION 2022-06-17
VALID TO:

Remarque: La présente portée d'accréditation existe également en français, sous la forme d'un document distinct.

Note: This scope of accreditation is also available in French as a separately issued document.

Scope based on the following document: European Directorate for the Quality of Medicines (EDQM) European Network of Official Medicines Control Laboratories PA/PH/OMCL (05) 48 DEF: Scope of accreditation of Official Medicines Laboratories

This laboratory is a party to a SCC Group Accreditation with the following facility in accordance with SCC Accreditation Program Overview section F.5. Group Accreditation;
Health Canada, Health Products Laboratory Program, Toronto Laboratory, accredited laboratory no 449.

CHEMICALS AND CHEMICAL PRODUCTS

Pharmaceuticals
(Chemical)

(Assay, identity, impurity tests and physical-chemical tests of finished products, to specific monographs of Schedule B publications (e.g. US Pharmacopeia, British Pharmacopoeia, and European Pharmacopoeia) and Fabricator Standards, carried out as part of the enforcement of the Food and Drugs Act. Pharmaceutical Products: Parenteral, Tablet, Capsule, Solution, Suspension, Aerosol, Powder, Suppository, Veterinary Premix, Bulk Intermediates, Other)

Physical and chemical analyses, using the following techniques:

Pharmacopeial Chromatography: LC
Pharmacopeial Spectrophotometry: UV/Visible
Pharmacopeial Spectrophotometry: IR
Pharmacopeial Water Determination
Pharmacopeial Dissolution and Drug Release
Pharmacopeial Particulate Matter
Processing of samples that are suspected counterfeits or suspected unapproved according to SOP-0441, Health Canada
Analysis of arsenic, cadmium, mercury, and lead in health products by ICP-MS/MS according to SOP-0576, Health Canada

(Microbiological)

(Microbiological tests of finished products, to specific monographs of Schedule B publications (e.g. US Pharmacopeia, British Pharmacopoeia, and European Pharmacopoeia) and Fabricator Standards, carried out as part of the enforcement of the Food and Drugs Act. Pharmaceutical Products: Parenteral, Tablet, Capsule, Solution, Suspension, Aerosol, Powder, Suppository, Veterinary Premix, Bulk Intermediates, Other)

Microbiological analysis, using the following tests/techniques:

Pharmacopeial Bacterial Endotoxins Test by Gel-clot Method
Pharmacopeial Bacterial Endotoxins Test by Photometric method
Pharmacopeial Tests for Total Viable Aerobic Count and for Specified Micro-organisms
Pharmacopeial Sterility Test by Membrane Filtration and Direct Inoculation
Pharmacopeial Antibiotic Microbial Assays by Cylinder Plate Method
Pharmacopeial Antibiotic Microbial Assays by Turbidimetry

Notes:

ISO/IEC 17025-2005: General Requirements for the Competence of Testing and Calibration Laboratories

EDQM: European Directorate for the Quality of Medicines

ICP-MS/ MS: Inductively Coupled Plasma - Tandem Mass Spectrometry

IR: Infrared

LC: Liquid Chromatography

OMCL: European Network of Official Medicines Control Laboratories

US: United-States

UV: Ultraviolet

Elias Rafoul, Vice President
Accreditation Services

Date: 2018-06-21

Number of Scope Listings: 14

SCC 1003-15/526

Partner File #0

Partner: