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Canada

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Ottawa, ON K1P 6L5
Canada

SCOPE OF ACCREDITATION

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

TORONTO LABORATORY - LABORATOIRE DE TORONTO
2301 Midland Ave.
Scarborough, ON
M1P 4R7

Accredited Laboratory No. 449
(Conforms with requirements of ISO/IEC 17025:2005)

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CLIENTS SERVED: Health Canada Inspectors

FIELDS OF TESTING: 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, Longueuil Laboratory, accredited laboratory no 450.

CHEMICALS AND CHEMICAL PRODUCTS

Pharmaceuticals and Cosmetics

(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 Chromatography: GC

Pharmacopeial Spectrophotometry: UV/Visible

Pharmacopeial Spectrophotometry: IR

Pharmacopeial Water Determination

Pharmacopeial Dissolution and Drug Release

Processing of samples that are suspected counterfeits or suspected unapproved according to SOP-0441, Health Canada

Notes:

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

EDQM: European Directorate for the Quality of Medicines & HealthCare

HPFB: Health Products and Food Branch

GC: Gas Chromatograph

LC: Liquid Chromatography

IR: Infrared

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: 07

SCC 1003-15/527

Partner File #0

Partner: