



TESTING AND CALIBRATION LABORATORY ACCREDITATION PROGRAM (LAP)

Scope of Accreditation

Accredited Laboratory No. 450

Legal Name of Accredited Laboratory: Health Canada Health Products Laboratory Program - Santé Canada - Programme de laboratoire des produits de santé

HEALTH PRODUCTS LABORATORY AND MICROBIOLOGY LABORATORY
LONGUEUIL – LABORATOIRES DES PRODUITS DE SANTÉ ET DE MICROBIOLOGIE À LONGUEUIL

Location Name or Operating as (if applicable): Longueuil, QC

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SCC File Number:	15526
Accreditation Standard(s):	ISO/IEC 17025:2017
Fields of Testing:	Biological, Chemical /Physical
Initial Accreditation:	2002-06-17
Most Recent Accreditation:	2020-06-03
Accreditation Valid to:	2022-06-17

SCC Group Accreditation:



This laboratory is a part of a Group Accreditation with the following facility in accordance with SCC's policy on Group Accreditation documented in the Accreditation Services Accreditation Program Overview.

- 15527 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

CHEMICALS AND CHEMICAL PRODUCTS

Pharmaceuticals and Cosmetics

(Chemical)

Assay, identity, purity, impurities, related compounds, screening and confirmation of substances of interest and physical-chemical tests of pharmaceutical products, active pharmaceutical ingredients, natural health products, cannabis products, plant materials, suspected counterfeits, suspected unapproved products and miscellaneous samples as necessary for the enforcement of the Food and Drugs Act, the Controlled Drugs and Substances Act, the Cannabis Act and the Regulations associated with these Acts.

Physical and chemical analyses, using the following techniques:

Liquid Chromatography (LC)
Gas Chromatography (GC)
Inductively Coupled Plasma - Tandem Mass Spectrometry (ICP-MS/MS)
UV/Visible Spectrophotometry
Infrared Spectrophotometry
Water Determination
Dissolution and Drug Release
Particulate Matter

(Microbiological)

Microbiological tests of pharmaceutical products, active pharmaceutical ingredients, natural health products, cannabis products, plant materials, suspected counterfeits, suspected unapproved products and miscellaneous samples as necessary for the enforcement of the Food and Drugs Act, the Controlled Drugs and Substances Act, the Cannabis Act, and the Regulations associated with these Acts.

Microbiological analysis, using the following tests/techniques:

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



Notes /Remarque:

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

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

Scope is based on the following documents:

- 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
- Canadian Food and Drugs Act-Schedule B publications (e.g. US Pharmacopeia, British Pharmacopoeia, and European Pharmacopoeia)

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, Health Products Laboratory Toronto, accredited laboratory no 449.

ISO/IEC 17025-2017: General Requirements for the Competence of Testing and Calibration Laboratories

OMCL: Official Medicines Control Laboratories

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC). The original version is available in the Directory of Accredited Laboratories on the SCC website at www.scc.ca.

Elias Rafoul
Vice President, Accreditation Services
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