

## 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 laboratoires des produits de santé**

**Location Name or Operating as (if applicable):** HEALTH PRODUCTS LABORATORY AND MICROBIOLOGY LABORATORY LONGUEUIL – LABORATOIRES DES PRODUITS DE SANTÉ ET DE MICROBIOLOGIE DE LONGUEUIL

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<b>SCC File Number:</b>	15526
<b>Accreditation Standard(s):</b>	ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
<b>Fields of Testing:</b>	Biological Chemical/Physical
<b>Initial Accreditation:</b>	2002-06-17
<b>Most Recent Accreditation:</b>	2022-04-24
<b>Accreditation Valid to:</b>	2026-06-17

**SCC Group Accreditation:**

This laboratory is a part of a Group Accreditation with the following facilities 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 laboratoires des produits de santé, TORONTO LABORATORY - LABORATOIRE DE TORONTO, 2301 Midland Ave., Scarborough, ON, M1P 4R7, Accredited Laboratory No. 449

*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.*

## CHEMICALS AND CHEMICAL PRODUCTS

### **Pharmaceuticals and Cosmetics:**

#### **(Chemical)**

##### Activities

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.

##### Techniques

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

#### **(Microbiological)**

##### Activities

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.

##### 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

Number of Scope Listings: 14 techniques

### **Notes:**

This Scope is based on the following documents:

- European Directorate for the Quality of Medicines (EDQM) European Network of Official Medicines Control Laboratories (OMCL) PA/PH/OMCL (05) 48 DEF: Scope of accreditation of Official Medicines Laboratories
- *Canadian Food and Drugs Act*-Schedule B publications (e.g. United States Pharmacopeia, the



British Pharmacopoeia, and the European Pharmacopoeia)

**ISO/IEC 17025-2017:** General Requirements for the Competence of Testing and Calibration 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](http://www.scc.ca).

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Elias Rafoul  
Vice-President, Accreditation Services  
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