

TESTING AND CALIBRATION LABORATORY ACCREDITATION PROGRAM (LAP)

Scope of Accreditation

Accredited Laboratory No. 899

Legal Name of Accredited Laboratory: **Synfine Research Limited**

Location Name or Operating as (if applicable):

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SCC File Number:	151073
Accreditation Standard(s):	ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
Fields of Testing:	Chemical/Physical
Program Specialty Area:	Test Method Development and Evaluation and Non-routine Testing (TMDNRT)
Initial Accreditation:	2019-08-01
Most Recent Accreditation:	2021-04-09
Accreditation Valid to:	2023-08-01

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.

TEST METHOD DEVELOPMENT AND NON-ROUTINE TESTING.

Note: The laboratory accredited under this PSA have demonstrated that it meets ISO/IEC 17025 requirements for non-routine testing under the following product classification.

1. Description of Activities under TMDNRT:

Synfine Research Limited carries out the following tests/analysis on analytical reference standards in support of client requests by using validated methods or modifying/adapting and verifying existing methods. This includes identification and quantification of chemicals, pharmaceutical active ingredients, impurities, degradation products, metabolite, related substance, and related isotopic standards.

2. Description of Techniques under TMDNRT:

1. High Performance Liquid Chromatography (HPLC) Analysis
2. Mass Spectrometry (MS) Analysis
3. Nuclear Magnetic Resonance (NMR) Analysis
4. Karl Fischer Titration test
5. Specific Rotation Test
6. Anions and cations by Ion Chromatography (IC) analysis
7. Sample preparation extraction, separation, and general chemical tests

CHEMICALS and CHEMICAL PRODUCTS

Organic

SOP SF4014	High Performance Liquid Chromatography Purity Test
SOP SF4015	Water Determination by Karl Fischer Titration
SOP SF4029	Specific Rotation Testing by Polarimeter
SOP SF4030	NMR Spectroscopy Procedure
SOP SF4031	Mass Identification and Isotopic Purity Calculation by Mass Spectrometer
SOP SF4034	Ion Content Test by Ion Chromatography

Number of Scope Listings: 6
 Number of TMDNRT Techniques: 7
 SCC 899 / 151073

Notes:

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



RG-TMDNRT: SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing

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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