



# CERTIFICATE OF ACCREDITATION

## The ANSI National Accreditation Board

Hereby attests that

**Instituto de Salud Pública de Chile /  
Agencia Nacional de Medicamentos**  
Laboratorio Nacional de Control-Marathon 1000  
Ñuñoa, Santiago, Chile

Fulfills the requirements of

**ISO/IEC 17025:2017**

In the field of

**TESTING**

This certificate is valid only when accompanied by a current scope of accreditation document.  
The current scope of accreditation can be verified at [www.anab.org](http://www.anab.org).

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 28 April 2023

Certificate Number: AT-1942



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.  
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory  
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

## SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

### Instituto de Salud Pública de Chile / Agencia Nacional de Medicamentos

Laboratorio Nacional de Control-Marathon 1000, Ñuñoa, Santiago, Chile

Luz Maria Hederra Duplaquet 56-2-25755384  
lhederra@ispch.cl [www.ispch.cl](http://www.ispch.cl)

### TESTING

Valid to: **April 28, 2023**

Certificate Number: **AT-1942**

#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography	Current USP NF <621>; International Pharmacopeia method: 1.14.4; Manufacturer monographs	Pharmaceutical Products	HPLC
Spectrophotometry UV/VIS	Current USP-NF <851>; Current USP-NF <857>; International Pharmacopeia method: 1.6; Manufacturer monographs	Pharmaceutical and products subject to health control	UV/VIS Spectrophotometer
pH	Current USP NF <791>; International Pharmacopeia method: 1.13; Manufacturer monographs	Pharmaceutical and products subject to health control	pH Meter
Dissolution	Current USP-NF <711>; International Pharmacopeia method: 5.5; Dissolution for solid oral dosage forms Manufacturer monographs	Pharmaceutical and products subject to health control	Spectrophotometer, HPLC, Dissolution System
Uniformity of Dosage Units	Current USP-NF <905>; International Pharmacopeia method: 5.1; Content uniformity for unit dose preparations Manufacturer monographs	Pharmaceutical and products subject to health control	Spectrophotometer, HPLC, Analytical balances
Identity by thin layer chromatography (TLC)	Current USP-NF < 621>; International Pharmacopeia method: 1.14.1; Manufacturer monographs	Pharmaceutical and products subject to health control	Thin layer chromatography System

**Chemical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identity by Infrared Spectroscopy	Current USP-NF <197>; International Pharmacopeia method; 1.7; Manufacturer monographs	Pharmaceutical and products subject to health control	Fourier transform infrared spectrophotometer FTIR (ATR/IR)

**Mechanical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Dead space	Technical protocols summary of Good Laboratory Practice applied to quality control syringes, PAHO/WHO, Ed. 2015 NCh 2504/1. Of 2004	Medical device conventional and self-deactivating syringes	Analytical Balance
Dimensions (length, inner diameter and outer)	Technical protocols summary of Good Laboratory Practice applied to quality control syringes, PAHO/WHO, Ed. 2015 NCh 2503 Of 2004	Medical device hypodermic needles	Vernier calibrator & Precision pin Gauges

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1942.



R. Douglas Leonard Jr., VP, PILR SBU