



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.

A handwritten signature in black ink, appearing to be 'J. Stine', is positioned above a horizontal line.

Jason Stine, Vice President

Expiry Date: 28 April 2025

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

Ximena Silva Araya 56-2-25755352
xsilva@ispch.cl www.ispch.cl

TESTING

Valid to: **April 28, 2025**

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
Identification and quantification by Chromatography	Current USP NF <621>, International Pharmacopeia method: 1.14.4, Manufacturer monographs (Internal SOP ME-422.00-179)	Pharmaceutical Products	HPLC
Identification and quantification by Spectrophotometry UV/VIS	Current USP-NF <851>, Current USP-NF <857>, International Pharmacopeia method: 1.6, Manufacturer monographs (Internal SOP ME-422.00-179)	Pharmaceutical and products subject to health control	UV/VIS Spectrophotometer
pH	Current USP NF <791>, International Pharmacopeia method: 1.13, Manufacturer monographs (Internal SOP ME-422.00-106)	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 (Internal SOP ME-422.00-125)	Pharmaceutical and products subject to health control	UV/VIS 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 (Internal Procedure ME-422.00-172)	Pharmaceutical and products subject to health control	UV/VIS Spectrophotometer, HPLC, Analytical balances

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification by Thin layer chromatography (TLC)	Current USP-NF <621>, International Pharmacopeia method: 1.14.1, Manufacturer monographs (Internal SOP ME-422.00-153)	Pharmaceutical and products subject to health control	Thin layer chromatography System
Identification by Infrared Spectroscopy	Current USP-NF <197>, International Pharmacopeia method: 1.7, Manufacturer monographs (Internal SOP ME-422.00-133)	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 (Internal SOP ME-422.02-004)	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 (Internal SOP ME-422.02-003)	Medical device hypodermic needles	Vernier calibrator & Precision pin Gauges
Friability	Current USP <1216>, Current European Pharmacopeia 2.9.7, International Pharmacopeia method "Supplementary information: Tablet friability", BP Appendix XVII G (Internal SOP ME-422.00-170)	Tablets	Friability Tester
Dimensions	Current USP <1217>, Current European Pharmacopeia Chapter 2.9.8, BP Appendix XVII H, Manufacturer monographs (Internal SOP ME-422.00-171)	Tablets	Hardness tester Micrometer Vernier calibrator

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Breaking Strength	Current USP <1217>, Current European Pharmacopeia Chapter 2.9.8, BP Appendix XVII H, International Pharmacopeia method Resistance to crushing of tablets (Internal SOP ME-422.00-171)	Tablets	Hardness tester

Note:

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



Jason Stine, Vice President

