



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

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

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1942

Certificate Number


ANAB Approval

Certificate Valid: 05/03/2018-04/28/2019
Version No. 004 Issued: 05/03/2018



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 17025:2005

Instituto de Salud Pública de Chile / Agencia Nacional de Medicamentos

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

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TESTING

Valid to: April 28, 2019

Certificate Number: AT-1942

Chemistry

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

Chemistry

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)

Dimensional


Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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 Gauges Millimeter ruler

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

Note:

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



Vice President

