



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: 04/27/2017-04/28/2019
Version No. 003 Issued: 04/27/2017



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 January 2009).

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

Chemical

Items, Materials or Products Tested	Specific Tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Pharmaceutical Products	Chromatography	- Current USP NF <621> - International Pharmacopeia method: 1.14.4 - Manufacturer monographs	HPLC
Pharmaceutical and products subject to health control	Spectrophotometry UV/VIS	- Current USP-NF <851>; <857> - International Pharmacopeia method: 1.6 - Manufacturer monographs	UV/VIS Spectrophotometer
Pharmaceutical and products subject to health control	pH	- Current USP NF <791> - International Pharmacopeia method: 1.13 - Manufacturer monographs	pH Meter
Pharmaceutical and products subject to health control	Dissolution	- Current USP-NF <711> - International Pharmacopeia method: 5.5 Dissolution for solid oral dosage forms - Manufacturer monographs	Spectrophotometer, HPLC, Dissolution System
Pharmaceutical and products subject to health control	Uniformity of Dosage Units	- Current USP-NF <905> - International Pharmacopeia method: 5.1 Content uniformity for unit dose preparations - Manufacturer monographs	Spectrophotometer, HPLC, Analytical balances
Pharmaceutical and products subject to health control	Identity by thin layer chromatography (TLC)	- Current USP-NF < 621> - International Pharmacopeia method: 1.14.1 - Manufacturer monographs	Thin layer chromatography system
Pharmaceutical and products subject to health control	Identity by Infrared Spectroscopy	- Current USP NF <197> - International Pharmacopeia method: 1.7 - Manufacturer monographs	Fourier transform infrared spectrophotometer FTIR (ATR/IR)

Dimensional

Items, Materials or Products Tested	Specific Tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Medical device hypodermic needles	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	Vernier calibrator Precision gauges Millimeter ruler

Mechanical

Items, Materials or Products Tested	Specific Tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Medical device conventional and self-deactivating syringes	Dead space	Technical protocols summary of Good Laboratory Practice applied to quality control syringes, PAHO/WHO, Ed. 2015 NCh 2504/1. Of 2004	Analytical Balance

Notes:

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



 Vice President