



# CERTIFICATE OF ACCREDITATION

## ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

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 17025:2017

while demonstrating technical competence in the field of

## TESTING

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

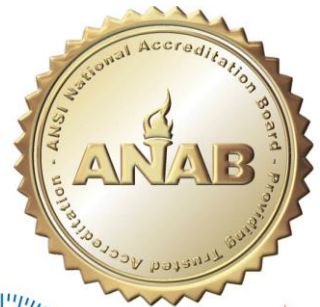
AT-1942

Certificate Number



ANAB Approval

Certificate Valid Through: 04/28/2021  
Version No. 006 Issued: 02/20/2020



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

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**TESTING**

Valid to: **April 28, 2021**

Certificate Number: **AT-1942**

**Chemical**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
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

## Chemical

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



Vice President