



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: 05/27/2016-04/28/2017
Version No. 002 Issued: 05/27/2016



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).



ANSI-ASQ National Accreditation Board

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, 2017

Certificate Number: AT-1942

I. 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

Notes:

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



Vice President

