



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

**Medicine Quality Control Directorate (MQCD) of
the Ethiopian Food and Drug Authority (EFDA)**

**Kirkos Sub-City, Kebele 02/03, House Number 03,
African Avenue (Bole road) Street, PO Box 5681
Addis, Ababa, Ethiopia**

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.

Jason Stine, Vice President

Expiry Date: 04 June 2025

Certificate Number: AT-2680



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

Medicine Quality Control Directorate (MQCD) of the Ethiopian Food and Drug Authority (EFDA)

Kirkos Sub-City, Kebele 02/03, House Number 03, African Avenue (Bole road) Street
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TESTING

Valid to: **June 4, 2025**

Certificate Number: **AT-2680**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography HPLC	Current USP-NF<621> and other pharmacopeial monographs	Pharmaceutical and related products	HPLC
Spectrophotometry	Current USP-NF<851> and other pharmacopeial monographs	Pharmaceutical and related products	UV/VIS Spectrophotometer
pH	Current USP-NF<791> and pharmacopeial monographs	Pharmaceutical and related products	pH Meter
Dissolution	Current USP-NF<711> and other pharmacopeial monographs	Pharmaceutical and related products	Spectrophotometer, HPLC, Dissolution System, Analytical Balances
LOD	Current USP-NF<731> and pharmacopeial monographs	Pharmaceutical and related products	Ovens, Analytical Balances
KF	Current USP-NF<921> and pharmacopeial monographs	Pharmaceutical and related products	Titration, Analytical Balances
Uniformity of Dosage Units	Current USP-NF<905> and pharmacopeial monographs	Pharmaceutical and related products	Spectrophotometer, HPLC, Analytical Balances
Conductivity	Current USP-NF<645> & other pharmacopeial monographs	Water	Conductivity Meter

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Infrared Spectroscopy	Current USP-NF<854>&other pharmacopeial monographs	Pharmaceutical Andrelatedproducts	FTIR
Titration	Current USP-NF<541>&other pharmacopeial monographs	Pharmaceutical Andrelatedproducts	Burette
Polarimetry (optical rotation)	Current USP-NF<781>&other pharmacopeial monographs	Pharmaceutical Andrelatedproducts	Polarimeter

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Freedom from holes	ISO 4074:2014;2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Electric hole tester and water leak tester
Inflation test (Burst volume and Burst pressure)	ISO 4074:2014; 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Inflation tester, Accurate Inflation tester
Lubricant quantity	ISO 4074:2014; 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Analytical balance
Dimension test	ISO 4074:2014; 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Caliper Ruler, Mandrill,
Package seal integrity test	ISO 4074:2014; 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Package seal integrity tester
Freedom from holes (Water tightness test)	ASTM D3578; D3577:2021	Medical Rubber Examination and Surgical Gloves	Water Leak Tester
Physical properties	ISO 11193:2020; ISO 10282; ISO 37:2014	Single-use Sterile Rubber Surgical and Examination Gloves	Tensile Tester, Die Cutter
Dimensional test	ISO 11193; ISO 10282:2014; ASTM D3767; ASTM D3577; ASTM D3578:2020	Single-use Sterile Rubber Surgical and Examination Gloves	Ruler, Mandrill

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Powder residue	ISO 21172:2006; ASTM D6124:2020	Single-use Sterile Rubber Surgical and Examination Gloves	Analytical Balance, Reciprocal or Rotator Mechanical Shaker

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2680.



Jason Stine, Vice President

