



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

National Drug Authority – Uganda
National Drug Quality Control Laboratory
Mulago, Kampala, Uganda

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: 23 March 2027

Certificate Number: AT-2137



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

National Drug Authority – Uganda

National Drug Quality Control Laboratory, Mulago, Kampala, Uganda

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TESTING

Valid to: **March 23, 2027**

Certificate Number: **AT-2137**

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Dimensional tests: Length, Width, thickness	NDA/DLS/STP-D/005 based on ISO 4074 and WHO Specifications	Male Latex Condoms	Mitutoyo Thickness gauges, Steel Ruler
Burst Volume and Pressure	NDA/DLS/STP-D/001 based on ISO 4074 and WHO Specifications	Male Latex Condoms	Enersol Air Inflation system DOKA Air burst testing machine
Freedom from holes / Detection of holes	NDA/DLS/STP-D/002 based on ISO 4074 and WHO Specifications	Male Latex Condoms	Enersol Electric Leak Tester
Critical and Non-Critical Defects	NDA/DLS/STP-D/002 based on ISO 4074 and WHO Specifications	Male Latex Condoms	Visual inspection
Package Integrity	NDA/DLS/STP-D/003 based on ISO 4074 and WHO Specifications	Male Latex Condoms	DOKA vacuum chamber and seal package tester
Lubricant test	NDA/DLS/STP-D/004 based on ISO 4074 and WHO Specifications	Male Latex Condoms	Analytical balance
Dimensions tests: Length, Width, thickness	NDA/DLS/STP-D/007 based on ASTM D3578	Medical Examination Gloves	Mitutoyo Thickness gauges, Steel Ruler
Water tightness/ Freedom from holes	NDA/DLS/STP-D/006 based on ASTM D3578, ISO 11193-1 and ASTM D5151	Medical Examination Gloves	Enersol Visual Leak tester
Dimensions tests: Length, Width, thickness	NDA/DLS/STP-D/008 based on ASTM D3577	Surgical Gloves	Mitutoyo Thickness gages, Steel Ruler
Water tightness/ Freedom from Holes	NDA/DLS/STP-D/006 based on ASTM D3577, ISO 10282 and ASTM D5151	Surgical gloves	Enersol Visual Leak tester

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Testing for Auto-disable feature of syringes or Re-use prevention feature for RUP Syringes Packaging, Labeling	NDA/DLS/STP-D/021 based on ISO 7886	Hypodermic Syringes	Dynamometer (Instron-5943)
Needle Point, Bond between the Hub and Needle Tube, Needle tube freedom from defects, Cleanliness of the needle tube, Packaging, Labeling	NDA/DLS/STP-D/013 based on ISO 7864 NDA/DLS/STP-D/012 based on ISO 7864	Hypodermic Needles	Dynamometer (Instron-5943), Stereo Microscope, Stainless Steel Ruler
Tensile Strength of Sutures, Length of Sutures, Diameter of Sutures, Needle Attachment of Sutures Packaging, Labeling	NDA/DLS/STP-D/014 based on US 1958	Surgical Sutures (Absorbable/Non-absorbable)	Dynamometer (Instron-5943), Stainless Steel Ruler

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography	British Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia	Pharmaceutical Products	HPLC, GC, UPLC, HPTLC
Dissolution	British Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia	Pharmaceutical Products	HPLC, UV/Vis Spectrophotometer Dissolution testers and analytical balances
Spectrophotometry	British Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia	Pharmaceutical Products	UV/Vis Spectrophotometer and FTIR Spectrophotometer

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2137



Jason Stine, Vice President

