



# CERTIFICATE OF ACCREDITATION

## ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

**National Drug Authority - Uganda**  
**National Drug Quality Control Laboratory**  
**Mulago, Kampala**

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 activities to which this accreditation applies

AT-2137

Certificate Number

  
ANAB Approval

Certificate Valid Through: 03/23/2021  
Version No. 003 Issued: 02/15/2019



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 April 2017).

**SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005**

**National Drug Authority – Uganda**

National Drug Quality Control Laboratory, Mulago, Kampala

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**TESTING**

Valid to: **March 23, 2021**

Certificate Number: **AT-2137**

**Mechanical**

<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>
Dimensional tests: Length, Width, thickness	SOP D-005 based on ISO 4074 and WHO 2010 Specifications	Male Latex Condoms	Mitutoyo Thickness gages, Steel Rule
Burst Volume and Pressure	SOP D-001 based on ISO 4074 and WHO 2010 Specifications	Male Latex Condoms	DOKA burst-volume testing machine
Freedom from holes / Detection of holes	SOP D-002 based on ISO 4074 and WHO 2010 Specifications	Male Latex Condoms	DOKA electronic leakage testing machine and Enersol Electric Leaks Tester
Critical and Non-Critical Defects	SOP D-002 based on ISO 4074 and WHO 2010 Specifications	Male Latex Condoms	Visual inspection
Package Integrity	SOP D-003 based on ISO 4074 and WHO 2010 Specifications	Male Latex Condoms	DOKA vacuum chamber and seal package tester
Lubricant test	SOP D-004 based on ISO 4074 and WHO 2010 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 gages, Steel Rule
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 Leaks tester
Dimensions tests: Length, Width, thickness	NDA/DLS/STP-D-008 based on ASTM D3577	Surgical Gloves	Mitutoyo Thickness gages, Steel Rule

**Mechanical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Water tightness/ Freedom from Holes	NDA/DLS/STP-D-006 based on ASTM D3577, ISO 10282 and ASTM D5151	Surgical gloves	Enersol Visual Leaks tester

**Chemical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography	Current USP-NF <621> and Pharmaceutical Monographs, current International, British and European Pharmacopoeia.	Pharmaceutical Products	HPLC
Dissolution	Current USP-NF <711> and Pharmaceutical Monographs, current International, British and European Pharmacopoeia.	Pharmaceutical Products	HPLC, UV/Vis Spectrophotometer Dissolution testers and analytical balances
Spectrophotometry	Current USP-NF <857> and Pharmaceutical Monographs, current International, British and European Pharmacopoeia.	Pharmaceutical Products	UV/Vis Spectrophotometer

Note:

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



Vice President