



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

Food and Drugs Authority

17th Indian Ocean Street, Nelson Mandela Avenue
South Legon Commercial Area, Shiashie, Legon-Accra, Ghana

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-1870

Certificate Number



ANAB Approval

Certificate Valid Through: 06/03/2020
Version No. 009 Issued: 07/18/2019



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

Food and Drugs Authority

17th Indian Ocean Street, Nelson Mandela Avenue
South Legon Commercial Area, Shiashie, Legon-Accra, Ghana

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TESTING

Valid to: **June 03, 2020**

Certificate Number: **AT-1870**

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 Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	HPLC
Spectrophotometry	Current USP-NF <857> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	UV/VIS Spectrophotometer
pH	Current USP-NF <791> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Potentiometric pH Meter
Dissolution	Current USP-NF <711> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Spectrophotometer HPLC Dissolution System
Loss on Drying (LOD)	Current USP-NF <731> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Gravimetric Ovens
Moisture Determination by Karl Fischer	Current USP-NF <921> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Karl Fischer Titrators
Uniformity of Dosage	Current USP-NF <905> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Spectrophotometer HPLC

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification	Current USP-NF <197> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	FTIR
Assay	Current USP-NF <541> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Automatic Titrator Burette
Optical Rotation	Current USP-NF <781> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Polarimetry
Identification	Current USP-NF <621> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products	Thin Layer Chromatography (TLC)

Microbiology

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Total aerobic microbial count	Current USP-NF <61> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products, cosmetics	Colony count
Total yeast and mold count	Current USP-NF <61> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products, cosmetics	Colony count
Sterility	Current USP-NF <71> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products, cosmetics	Direct Inoculation
Test for specific organisms <ul style="list-style-type: none"> • <i>E. coli</i> • <i>Salmonella</i> • <i>S. aureus</i> • <i>P. aeruginosa</i> 	Current USP-NF <62> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and related products, cosmetics	Detection
Aerobic microbial count	ISO 4833-1 and 2:2013	Food and animal feeding stuffs	Colony count

Microbiology

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Coliform count	ISO 4832:2006	Food and animal feeding stuffs	Colony count
Yeast and mold count	ISO 21527-1 and 2:2008	Food and animal feeding stuffs	Colony count
Coagulase-positive <i>Staphylococcus aureus</i> count	ISO 6888-2:1999	Food and animal feeding stuffs	Colony count
β -glucuronidase positive <i>E. coli</i> count	ISO 16649-2:2001	Food and animal feeding stuffs	Colony count
<i>Clostridium perfringens</i> count	ISO 7937:2004	Food and animal feeding stuffs	Colony count
Enterobacteriaceae enumeration and detection	ISO 21528-2:2004	Food and animal feeding stuffs	Colony count
Detection of <i>Salmonella spp.</i>	ISO 6579:2017	Food and animal feeding stuffs	Culture
Aerobic microbial count	ISO 6222: 1999	Water	Colony count
Coliform enumeration and detection	ISO 9308:2014	Water	Membrane Filtration
<i>E. coli</i> enumeration and detection	ISO 9308:2014	Water	Membrane Filtration
<i>Clostridium perfringens</i> enumeration and detection	ISO 14189:2013	Water	Membrane Filtration
<i>Pseudomonas aeruginosa</i> enumeration and detection	ISO 16266:2006	Water	Membrane Filtration

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Determination of length	ISO 4074:2015 Annex D	Medical device-Latex Male condom	Dimensional
Determination of width	ISO 4074:2015 Annex E	Medical device-Latex Male condom	Dimensional
Determination of thickness	ISO 4074:2015 Annex F	Medical device-Latex Male condom	Dimensional
Determination of busting volume and pressure	ISO 4074:2015 Annex H	Medical device-Latex Male condom	Accurate Inflation System
Testing for holes	ISO 4074:2015 Annex M	Medical device-Latex Male condom	Water Leakage Tester
Visible Defect	ISO 4074:2015 Annex M (M.2.3.4; M.3.3.5)	Medical device-Latex Male condom	Visual Inspection

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Testing for Package Seal Integrity	ISO 4074:2015 Annex N	Medical device-Latex Male condom	Vacuum Tester
Determination of total lubricant for condoms in individual container	ISO 4074:2015 Annex C	Medical device-Latex Male condom	Gravimetric
Condom Sampling	ISO 2859-1:1999 WHO - Male Latex Condom Guidelines, 2010	Medical device-Latex Male condom	Sampling Technique

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1870.



Vice President

