



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

**Food and Drugs Authority
17th South Legon Commercial Area, Shiashie
Legon-Accra, Ghana**

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the fields of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of calibrations and/or tests to which this accreditation applies.

AT-1870

Certificate Number



ANAB Approval

Certificate Valid: 07/12/2018-06/03/2020
Version No. 006 Issued: 07/12/2018



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

Food and Drugs Authority

17th Indian Ocean Street, Nelson Mandela Avenue,
South Legon Commercial Area, Shiashie, Legon-Accra, Ghana
Eric Karikari Boateng Phone: + 2332-4438-5086
www.fdaghana.gov.gh Eric.Boateng@fdaghana.gov.gh

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 6579:2002	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

Medical Devices

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

Medical Devices

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	FDA LSD/MED/SOP-09 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

