

# **CERTIFICATE OF ACCREDITATION**

# The ANSI National Accreditation Board

Hereby attests that

# Center for Laboratory Services and Research Food and Drugs Authority

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

(and satellite location as listed on scope)

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 <u>www.anab.org</u>.



R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 03 June 2024 Certificate Number: AT-1870



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

### Center for Laboratory Services and Research 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, 2024

Certificate Number: AT-1870

Chemical			
Specific Tests and/or Properties Measured	Specifica <mark>tion, Standard,</mark> Method, or <mark>Test Technique</mark>	Items, Materials or Product Tested	Key Equipment or Technology
Assay	Current USP-NF <621> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and Related Products	HPLC
Identification	Current USP-NF <621> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and Related Products	HPLC
Assay	Current USP-NF <857> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and Related Products	UV/VIS Spectrophotometer
Identification	Current USP-NF <857> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and Related Products	UV/VIS Spectrophotometer
рН	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



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#### Chemical



#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Loss on Drying (LOD)	Current USP-NF <731> and Pharmacopeial Monographs, Current European and British Pharmacopeia	Pharmaceutical and Related Products	Gravimetric Ovens
Water content determination	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
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)
Chemical testing for Cosme	tic/Household Chemical Subst	ances	
Identification	British Pharmacopeia	Cosmetic and Household Chemical Substances	FTIR-Spectrophotometer
Assay	British Pharmacopeia Ghana Standards Monographs	Cosmetic and Household Chemical Substances	Automatic Titrator Burette
рН	Ghana Standard Monographs Current USP-NF <791> and British Pharmacopeia	Cosmetic and Household Chemical Substances	pH Meter
Loss on drying (LOD)	Ghana Standard Monographs Current USP-NF <731> and British Pharmacopeia	Cosmetic and Household Chemical Substances	Gravimetric Oven



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#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Assay	Current USP-NF British Pharmacopeia Ghana Standards Monographs	Cosmetic and Household Chemical Substances	UV-VIS Spectrophotometer
Identification	Current USP-NF British Pharmacopeia Ghana Standards Monographs	Cosme <mark>tic a</mark> nd Household Chemical Substances	UV-VIS Spectrophotometer

#### Microbiological

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 Pharmac opeial Monographs, Current European and British Pharmac opeia	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 • E. coli • Salmonella • S. aureus • P. aeruginosa	Current USP-NF <62> and Pharmac opeial Monographs, Current European and British Pharmac opeia	Pharmaceutical and related products, cosmetics	Detection
Limit Test for Bacteria Endotoxin (BET)	Current USP-NF <85> and Pharmacopeial Monographs	Sterile Pharmaceutical and Medical Devices products	Gel clot
Semi-quantitative test for Bacteria Endotoxin (BET)	Current USP-NF <85> and Pharmacopeial Monographs	Sterile Pharmaceutical and Medical Devices products	Gel clot
Aerobic microbial count	ISO 4833-1 and 2:2013	Food and animal feeding stuffs	Colony count
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 Staphylococcus aureus count	ISO 6888-2:1999	Food and animal feeding stuffs	Colony count



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#### Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
β-glucuronidase positive <i>E</i> . <i>coli</i> count	ISO 16649-2:2001	Food and animal feeding stuffs	Colony count
Clostridium perfringens 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 Salmonella spp.	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 9 <mark>308:20</mark> 14	Water	Membrane Filtration
<i>Clostridium perfringens</i> enumeration and detection	ISO 1 <mark>4189:20</mark> 13	Water	Membrane Filtration
<i>Pseudomonas aeruginosa</i> enumeration and detection	ISO 1 <mark>6266:2006</mark>	Water	Membrane Filtration
Aerobic Plate Count (Enumeration)	ISO 18593:2018	Food Industry Environmental Samples	Colony Count
Enumeration of Presumptive Bacillus cereus	GS ISO 7832:2005	Food and Animal Feeding Stuffs	Colony Count
Detection of Vibrio spp	ISO 21872-1:2017	Food and Animal Feeding Stuffs and Environmental Samples in Food Production and Food Handling	Colony Count

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





#### Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Pr <mark>o</mark> duct Tested	Key Equipment or Technology
Determination of thickness	ISO 4074:2015 Annex F	Medical device-Latex Male	Dimensional
Determination of busting volume and pressure	ISO 4074:2015 Annex H	Medical device-Latex Male	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
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	Gravimetric
Condom Sampling	ISO 2859-1:1999 WHO - Male Latex Condom Guidelines, 2010	Medical device-Latex Male Condom	Sampling Technique

### Satellite Location Center for Laboratory Services and Research Food and Drugs Authority

P.O.Box CT 2783, Cantonments – Accra, Ghana Digital Address: GA-107-5451

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## TESTING

#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
pH	USP-NF <791> ; Ghana Standards	Food products	pH Meter
Loss on Drying (LOD)	AOAC	Food products	Gravimetric Oven





#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Acid Insoluble Ash (AIA)	AOAC	Food products	Furnace
Total Ash Content	AOAC	Food products	Furnace
Identification of Sudan dyes	In-house	Pa <mark>lm o</mark> ils/spices	HPLC

Note:

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



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