

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

National Agency for Food and Drug Administration and Control (NAFDAC) Central Drug Control Laboratory, Yaba, Lagos

8-10, Merret Road, Medical Compound Yaba, Lagos, Nigeria

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: 20 January 2025 Certificate Number: AT-1913







SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

National Agency for Food and Drug Administration and Control (NAFDAC) Central Drug Control Laboratory, Yaba, Lagos

8-10, Merret Road, Medical Compound, Yaba, Lagos, Nigeria

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TESTING

Valid to: January 20, 2025 Certificate Number: AT-1913

Chemistry

Version 009 Issued: November 3, 2023

| 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 | Pharmaceuticals and related products | HPLC |
| Spectrophotometry | Current USP-NF <1857> and Pharmaceutical Monographs | Pharmaceuticals and related products | UV/VIS Spectrophotometer |
| рН | Current USP-NF <791> and Pharmaceutical Monographs | Pharmaceuticals and related products | pH Meter |
| Dissolution | Current USP-NF <711> and Pharmaceutical Monographs | Pharmaceuticals and related products | Dissolution |
| Loss on Drying (LOD) | Current USP-NF <731> and Pharmaceutical Monographs | Pharmaceuticals and related products | Oven |
| Karl Fischer Water-content determination | Current USP-NF <921> and Pharmaceutical Monographs | Pharmaceuticals and related products | Karl Fischer Titrator |
| Uniformity of Dosage | Current USP-NF <905> and Pharmaceutical Monographs | Pharmaceuticals and related products | Spectrophotometer and HPLC |
| FTIR | Current USP-NF <197> and Pharmaceutical Monographs | Pharmaceuticals and related products | FTIR system |
| Melting Point | Current USP-NF <741> and Pharmaceutical Monographs | Pharmaceuticals and related products | Melting point apparatus |
| Titration | Current USP-NF <541> and Pharmaceutical Monographs | Pharmaceuticals and related products | Titrator |
| Friability | Current USP-NF <1216> and Pharmaceutical Monographs | Pharmaceuticals and related products | Friability Tester |
| Hardness Test | Current USP-NF <1217> and Pharmaceutical Monographs | Pharmaceuticals and related products | Hardness Tester |





Chemistry

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|---------------------------------------|--------------------------------|
| Disintegration | Current USP-NF <701> and Pharmaceutical Monographs | Pharmaceuticals and related products | Disintegration Tester |
| Optical Rotation | Current USP-NF <781>, Current BP and Pharmaceutical Monographs | Pharmaceuticals and related products | Polarimetry |

Microbiology

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|---|---------------------------------------|--|
| Sterility | Current USP-NF <71> and Pharmaceutical Monographs | Pharmaceuticals and related products | Membrane Filtration (Biosafety Cabinet) |
| Microbial Limit Test | Current USP-NF <61> <62> <1111> and Pharmaceutical Monographs | Pharmaceuticals and related products | Membrane Filtration (Biosafety Cabinet) |
| Bacterial Endotoxin (LAL) | Current USP-NF <85> and Pharmaceutical Monographs | Pharmaceuticals and related products | LAL machine and GEL- CLOT Method |

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1913.



