

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

National Control Laboratory (NCL) Directorate General of Drug Administration (DGDA)

IPH Campus, Mohakhali, Dhaka-1212, Bangladesh

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: 18 October 2024 Certificate Number: AT-2627

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

National Control Laboratory (NCL) Directorate General of Drug Administration (DGDA)

IPH Campus, Mohakhali, Dhaka-1212, Bangladesh

Dr. Md. Harun-Or-Rashid www.dgda.gov.bd

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TESTING

Valid to: October 18, 2024

Certificate Number: **AT-2627**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography HPLC	British Pharmacopeia <2.2.29>, United States Pharmacopeia <621>, and Pharmaceutical monographs	Pharmaceutical and related products	HPLC
Loss on Drying	British Pharmacopeia <2.2.32>, United States Pharmacopeia <731> and Pharmaceutical monographs	Pharmaceutical and related products	Oven, Analytical Balance,
Dissolution	British Pharmacopeia <2.9.3>, United States Pharmacopeia <711> and Pharmaceutical monographs	Pharmaceutical and related products	Dissolution Tester Spectrophotometer HPLC
UV-VIS- Spectrophotometry	British Pharmacopeia <2.2.25>, United States Pharmacopeia <857> and Pharmaceutical monographs	Pharmaceutical and related products	UV-VIS Spectrophotometer
рН	British Pharmacopeia <2.2.4>, United States Pharmacopeia <791> and Pharmaceutical monographs	Pharmaceutical and related products	pH Meter
KF Water Determination (KFT)	British Pharmacopeia <2.5.12>, United States Pharmacopeia <921> and Pharmaceutical monographs	Pharmaceutical and related products	Karl Fischer Titrator, Analytical Balance
Uniformity of Dosage Units & Weight Variation	British Pharmacopeia < 2.9.40>, United States Pharmacopeia <905> and Pharmaceutical monographs	Pharmaceutical and related products	UV Spectrophotometer, HPLC, Analytical Balance





Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Disintegration	British Pharmacopeia <2.9.1>, United States Pharmacopeia <701> and Pharmaceutical monographs	Pharmaceutical and related products	Disintegration Tester
TLC- Identification	British Pharmacopeia <2.2.27>, United States Pharmacopeia <201> and Pharmaceutical monographs	Pharmaceutical and related products	TLC Chamber
FTIR- Identification	British Pharmacopeia <2.2.24>, United States Pharmacopeia <197> and Pharmaceutical monographs	Pharmaceutical and related products.	FTIR
Gas Chromatography	British Pharmacopeia < 2.2.28>, United States Pharmacopeia <621> and Pharmaceutical monographs	Pharmaceutical and related products.	Gas Chromatography
Titrimetry	British Pharmacopeia < Appendix VI B>, United States Pharmacopeia <541> and Pharmaceutical monographs	Pharmaceutical and related products.	Titrimetry

Dimensional

Differisional			
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Resistance to Crushing / Hardness	British Pharmacopeia < Appendix V-A 584>, United States Pharmacopeia <1217>	Pharmaceutical and related products.	Hardness Tester
Diameter	As per NCL SOP: NC-CD-EQP-036	Pharmaceutical and related products.	Hardness Tester
Thickness	As per NCL SOP: NC-CD-EQP-036	Pharmaceutical and related products.	Hardness Tester
Friability – Loss of Mass	British Pharmacopeia < Appendix V-A 581>, United States Pharmacopeia <1216>	Pharmaceutical and related products.	Friability Tester

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2627.



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