CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

US Pharmacopeia-India (P) Ltd.
Plot. D6 & D8, IKP Knowledge Park, Genome Valley
Shamirpet, Turkapally Village
Medchal (Malkajgiri) District, Hyderabad 500 101
Telangana, India

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.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 23 March 2023
Certificate Number: AT-1261

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

US Pharmacopeia – India (P) Ltd.

Plot. D6 & D8, IKP Knowledge Park, Genome Valley, Shamirpet, Turkapally Village,
Medchal (Malkajgiri) District, Hyderabad - 500 101
Telangana, India.
T. Lakshmana Murthy, Phone: +91-40-4448-8888, Direct Tel No.: +91-40-4448-8906

TESTING

Valid to: **March 23, 2023** Certificate Number: **AT-1261**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Spectroscopic Identification Tests (IR and UV)	USP – 197	Reference Material/ External pharmaceutical and nutraceutical products	Fourier-transform infrared spectroscopy (FTIR), Ultraviolet–Visible (UV)
Residue on Ignition	USP – 281	Reference Material/ External pharmaceutical and nutraceutical products	Muffle furnace
Organic Volatile Impurities / Residual Solvents Limits (GC)	USP – 467	Reference Material/ External pharmaceutical and nutraceutical products	Gas Chromatography
Titrimetry	USP – 541	Reference Material/ External pharmaceutical and nutraceutical products	Potentiometric Titrator
Chromatography (HPLC, GC, TLC)	USP – 621	Reference Material/ External pharmaceutical and nutraceutical products	High-performance liquid chromatography (HPLC), Gas Chromatography (GC), Thin-layer chromatography (TLC)
Dissolution	USP – 711	Reference Material/ External pharmaceutical and nutraceutical products	Dissolution Apparatus
Loss on Drying	USP – 731	Reference Material/ External pharmaceutical and nutraceutical products	Hot Air/Vacuum Oven
Mass Spectrometry	USP – 736	Reference Material/ External pharmaceutical and nutraceutical products	Mass Spectrometry (MS)

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Thermo Gravimetric Analysis	USP – 891	Reference Material/ External pharmaceutical and nutraceutical products	Thermo Gravimetric Analyzer
Water Determination	USP – 921	Reference Material/ External pharmaceutical and nutraceutical products	Karl Fischer Titration
Ion Chromatography	USP – 1065	Reference Material/ External pharmaceutical and nutraceutical products	Ion Chromatography

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Antibiotics—Microbial Assays	USP – 81	Reference Material/ External pharmaceutical and nutraceutical products	OMNICON Zone Reader/ Multi-mode readers Antibiotics—Microbial Assays
Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests	USP-61	Reference Material/ External pharmaceutical and nutraceutical products	Biosafety Cabinet (BSC) – Class II
Microbiological Examination of Non-sterile Products: Tests For Specified Microorganisms	USP-62	Reference Material/ External pharmaceutical and nutraceutical products	Biosafety Cabinet (BSC) – Class II
Bacterial Endotoxins Test	USP-85	Reference Material/ External pharmaceutical and nutraceutical products	Dry Heating Block

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatography (HPLC)	USP – 621	Reference Material/ External pharmaceutical and nutraceutical products	High-Performance Liquid Chromatography (HPLC)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1261.

R. Douglas Leonard Jr., VP, PILR SBU