

# 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 <a href="https://www.anab.org">www.anab.org</a>.

Jason Stine, Vice President

Expiry Date: 23 March 2025 Certificate Number: AT-1261









### **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.

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#### **TESTING**

Valid to: March 23, 2025 Certificate Number: AT-1261

#### Chemical

Version 009 Issued: February 16, 2024

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 Pr <mark>o</mark> duct 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
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	No.	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		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.

Jason Stine, Vice President

Version 009 Issued: February 16, 2024

