



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

US Pharmacopeia-India (P) Ltd.

Plot no. D6 & D8, IKP Knowledge Park, Genome Valley
Shamirpet, Turkapally Village
Medchal District, Hyderabad 500 101
Telangana, India

has been assessed by ANAB and meets the requirements of international standard

ISO/IEC 17025:2017

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AT-1261

Certificate Number



ANAB Approval

Certificate Valid Through: 03/23/2021
Version No. 006 Issued: 01/14/2020



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 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, 2021**

Certificate Number: **AT-1261**

I. 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
Ordinary Impurities (TLC)	USP – 466	Reference Material/ External pharmaceutical and nutraceutical products	Thin-layer chromatography
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
Elemental Analysis (ICP)	USP - 730	Reference Material/ External pharmaceutical and nutraceutical products	ICP MS/ICP OES
Loss on Drying	USP – 731	Reference Material/ External pharmaceutical and nutraceutical products	Hot Air/Vacuum Oven

I. Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mass Spectrometry	USP – 736	Reference Material/ External pharmaceutical and nutraceutical products	Mass Spectrometry (MS)
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

II. 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

III. 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.



Vice President

