

TO WHOM IT MAY CONCERN

This is to certify that **Pharmexpert Consultant LLP** has conducted a **detailed and comprehensive Qualified Person (QP) Audit** of the analytical testing facility of **Shiva Analyticals (India) Private Limited**, conducted on **21st to 22nd January 2026** at the following audited site:

Audited Site Address	Shiva Analyticals (India) Private Limited. Plot No: 24D(P) & 34D, KIADB Industrial Area, Hoskote, Bangalore – 562 114, Karnataka, India
-----------------------------	---

The audit was performed by our **EU QP** in accordance with applicable **EU GMP requirements**, including but not limited to **EudraLex Volume 4**, relevant **ICH Guidelines**, and current European Union regulatory expectations applicable to quality control and analytical laboratories supporting pharmaceutical, herbal, and medical device products intended for the EU market.

Scope of EU-QP Audit

The QP audit covered, but was not limited to, the following systems and activities:

1. Quality & Compliance

- Quality Management System (QMS)
- Compliance with EU GMP & EudraLex Volume 4
- Documentation practices & record control
- Data integrity compliance (ALCOA+ principles)

2. Personnel & Organization

- Qualification, training, and organizational structure

3. Facilities & Equipment

- Laboratory infrastructure, utilities, and environmental controls
- Equipment qualification, calibration, and maintenance

4. Analytical & Testing Systems

- Method development, validation, and verification
- Stability studies management
- Sample handling, storage, and traceability

5. Deviation & Risk Management

- Deviation, OOS/OOT, change control, and CAPA management

6. Supply Chain & Vendor Oversight

- Vendor qualification and material controls

7. Microbiological Controls

- Contamination prevention

Scope of Services Reviewed During EU-QP Audit

Pharmacopeial Testing

- Raw Materials
- Excipients
- Active Pharmaceutical Ingredients (APIs)
- Bulk Drugs
- Finished Pharmaceutical Products
- Medical Devices (analytical & safety testing)

Analytical Research & Development

- Analytical Method Development & Validation (ICH Q2)
- Stability-Indicating Method Development
- Impurity Profiling (LC-MS/MS & GC-MS/MS)
- Elemental Impurities (ICP-MS / ICP-OES / AAS)
- Dissolution Testing
- Extractables & Leachable (E&L) Studies
- Stability Studies as per ICH Q1 guidelines
- Cleaning Validation Studies

Specialized & Advanced Testing

- Nitrosamine and NDSRI evaluations using LC-MS and GC-MS
- Azido impurities testing in APIs and formulations
- Evaluation of elemental impurities using ICP-MS, ICP-OES, and AAS
- Evaluation of genotoxic impurities by LC-MS
- Residual Ethylene Oxide (ETO), Ethylene Glycol, and Ethylene Chlorohydrin analysis
- Residual Genotoxic Impurities in APIs and formulations
- Nitrogen and compressed air analysis under cGMP
- Evaluation of ETO residues in medical devices
- In-Vitro Performance & Bioequivalence Studies (NG/G-Tube & IVBE)

Chemical & Physical Testing

- Residual Solvents (ICH Q3C compliant)
- Physico-chemical properties
- pXRD, PSD, BET Surface Area
- Thermal Analysis (DSC/TGA)
- FTIR

Microbiological Testing

- Sterility testing
- Microbial Limit (Non-sterile) Testing
- Water Testing & Environmental Monitoring Support

Facility & Utility Qualification

- Cleanroom validation and qualification

Certification Statement

Based on the review of systems, controls, and documentation during the on-site assessment, and the compliance responses submitted to the Qualified Person (QP) audit observations, we confirm that Shiva Analyticals (India) Private Limited demonstrates compliance with EU GMP expectations for the audited scope of analytical testing services. This facility is therefore considered acceptable for the provision of analytical testing within this qualified scope. Ongoing adherence to EU GMP standards and periodic re-evaluation is expected. This confirmation does not substitute for inspections or approvals by competent regulatory authorities.

**Atul
Kulkarni**

Digitally signed
by Atul Kulkarni
Date: 2026.02.20
18:03:43 +05'30'

Name: Mr. Atul Kulkarni
Title: EU-QP



Digitally signed by
Priyanka
siddhpura
Date: 2026-02-21
11:40+05:30

Name: Ms. Priyanka Siddhpura
Title: Director, Operations