



# Rashid Khan (M. Pharm)

## Assistant Manager

### Professional Summary

Pharmaceutical professional with over **13+** years of progressive experience in Analytical Method Validation, Research & Development, and Quality Control across global regulatory markets. Skilled in developing and validating analytical methods, managing regulatory deficiency responses, and driving compliance with USFDA, EMA, ANVISA, ICH, and cGMP guidelines. Adept at troubleshooting analytical challenges, interpreting stability data, and preparing technical documentation to support regulatory submissions. Recognized as a Subject Matter Expert (SME) in validation, regulatory audit readiness, and cross-functional collaboration.

### Contact

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### Core Expertise

- Regulatory Submissions & Deficiency Responses
- Quality Management System (QMS) Implementation
- Stability Studies & Data Interpretation
- Instrument Qualification, Calibration & Troubleshooting
- Technical Documentation & Report Writing
- Team Leadership, Mentoring & Training Delivery
- Cross-Functional Collaboration (R&D, QA, RA, QC)
- Compliance: USFDA, EMA, ANVISA, ICH, cGMP
- Progress Reporting & PowerPoint Presentation of Validation Status to Management.

### Education

- M. Pharmacy (Pharmaceutical Chemistry) – Amaravati University, MH | 2012 | CGPA: 7.02 (75%)
- B. Pharmacy – Amaravati University, MH | 2010 | 60.3%

### Key Achievements

- Analytical Method Validation Leader** – Directed a team of 15 professionals, executing multiple validation projects monthly while ensuring compliance with international regulatory requirements.
- Method Development Specialist** – Independently developed 10+ robust, cost-efficient analytical methods for assay, dissolution, related substances, and residual solvent analysis.
- Regulatory Deficiency Expert** – Successfully resolved 7+ critical regulatory deficiencies within deadlines, enhancing audit readiness and product approvals.
- SME in Validation** – Applied AQbD principles, identified critical attributes, and resolved OOS/OOT issues, ensuring compliance with stringent quality standards.

### Professional Experience

**Aizant Drug Research Solutions Pvt Ltd., Hyderabad**  
**Assistant Manager – Analytical Method Validation (R&D/QC)**  
Oct 2023 – Present

- Lead planning, execution, and transfer of analytical methods across AR&D and QC teams, ensuring compliance with USFDA, EMA, ANVISA, and ICH guidelines.
- Designed validation protocols for assay, dissolution (Type I, II, III), related substances, water content, and excipient testing.
- Reviewed and approved analytical documents, including validation protocols, summary reports, and equivalency justifications.
- Conducted forced degradation and stress testing to establish method robustness and stability-indicating capability.
- Performed swab recovery and residue analysis to validate cleaning procedures in manufacturing.
- Oversaw lyophilized injection validations, ensuring accuracy in assay and impurity profiling.
- Monitored stability study programs, analyzing trends and reporting deviations proactively.
- Implemented QMS practices, managing investigations for OOS, deviations, incidents, and change controls.
- Acted as SME in audit preparations, supporting regulatory inspections with complete documentation.
- Delivered monthly management review presentations with validation updates, risks, and mitigation strategies.
- Coordinated with formulation and RA teams to align validation activities with product filing timelines.
- Mentored junior chemists, ensuring adherence to SOPs and Good Documentation Practices (GDP).

- Evaluated analytical instruments' qualification status and initiated re-qualification where necessary.
- Collaborated with procurement for vendor qualification of critical analytical consumables.

### **Alembic Pharmaceuticals Ltd., Hyderabad**

**May 2017 – Oct 2023 (6 Years)**

#### **Research Scientist – Analytical R&D**

- Led method development, validation, and transfer for solid oral dosage forms, injectables, and complex formulations, ensuring compliance with ICH and regulatory requirements.
- Executed stability studies, impurity profiling, and dissolution testing to establish product safety, efficacy, and shelf life.
- Conducted forced degradation and stress testing to define degradation pathways and support robust formulation development.
- Optimized HPLC, UPLC, GC, UV, FTIR, and wet chemistry techniques to achieve accurate, precise, and reproducible results.
- Prepared and reviewed analytical protocols, method validation reports, and technical documents for ANDA, DMF, and global regulatory submissions.
- Partnered with formulation and regulatory affairs teams to provide analytical support during development, scale-up, and commercialization.
- Investigated out-of-specification (OOS) and out-of-trend (OOT) results, implementing corrective and preventive actions (CAPA) to maintain data integrity.

### **MacLeod Pharmaceuticals, Mumbai**

**Nov 2014 – April 2017 (2.6 Years)**

#### **Getz Pharma Pvt Ltd., Mumbai**

**Apr 2012 – Nov 2014 (2.6 years)**

#### **Research Associate – Analytical R&D**

- Conducted method development, validation, and transfer for pharmaceutical formulations in compliance with ICH guidelines.
- Performed routine and stability analysis of raw materials, intermediates, and finished products using HPLC, GC, UV, FTIR, and dissolution apparatus.
- Designed and optimized analytical methods to ensure accuracy, precision, and reproducibility in results.
- Prepared standard operating procedures (SOPs), analytical protocols, and technical reports aligned with regulatory standards.
- Supported product development teams by providing analytical data for formulation design and stability studies.
- Monitored forced degradation and impurity profiling studies to establish product stability and shelf life.
- Collaborated with cross-functional teams for regulatory submissions (ANDA, DMF) by providing detailed analytical documentation.
- Ensured compliance with Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) in all laboratory activities.
- Troubleshoot analytical instruments and implemented preventive maintenance to minimize downtime.

### **Medley Pharmaceuticals Ltd., Daman & Diu**

**7 months (2011–2012)**

#### **M.Pharm Project Trainee – Analytical R&D**

- Conducted project work in analytical R&D with exposure to HPLC, UV/Vis, and dissolution testing.
- Assisted in method optimization for assay and related substances.
- Documented findings in technical reports to support ongoing development.
- Gained hands-on experience with Karl Fischer titration, UV spectrophotometry, and dissolution apparatus.
- Supported senior scientists in validation activities.

## **Technical Skills** —

- Instruments: HPLC (PDA, UV, RI, Fluorescence), UPLC, UV/Vis, Dissolution (Type I, II, III, Flow-Through Cell), Karl Fischer (KF), Coulometer
- Occasional Exposure: PSD (Malvern 3000), Agilent GC, IR Spectroscopy
- Documentation: Validation Protocols, Reports, Justification Reports, Equivalency Reports
- Expertise Areas: Data interpretation, stability trend analysis, troubleshooting analytical deviations

## **Personal Details** —

- Date of Birth: 31 May 1986
- Languages: English, Hindi, Marathi, Arabic, Telugu
- Address: Hyderabad, Telangana (Permanent Address: Amravati, Maharashtra)
- Notice Period: 3 Months (Negotiable)
- Passport: Yes | Visa: Available for India