

Umar Shaikh, M. Pharmacy, Fresher

📍hyderabad ✉umarshaikh10866@gmail.com ☎+917020301607 🌐https://www.linkedin.com/in/shaikh-umar-757816213

SUMMARY

M. Pharmacy (Quality Assurance) postgraduate with strong knowledge in Clinical Research, Clinical Data Management, and Pharmacovigilance. Trained in ICH-GCP, GVP, ICH E2A-E2F, and ICSR processing, narrative writing, CRF/eCRF review, and clinical trial documentation. Eager to contribute to data integrity, regulatory compliance, and patient safety in entry-level clinical research roles.

PROJECT

Formulation and Evaluation of Microwave-Assisted Synthesis of Nanoparticles for Enhancement of Mesalamine Drug Solubility”

- **Methodology:** Developed Mesalamine nanoparticles using a microwave-assisted green synthesis technique with Guar Gum, followed by optimization of process parameters. Characterized the formulation through particle size analysis, FTIR, SEM, and dissolution studies to confirm solubility enhancement.
- **Conclusion:** The microwave-assisted technique successfully produced Mesalamine nanoparticles with significantly improved solubility and dissolution rate.
- The study highlights the effectiveness of microwave-assisted synthesis as a fast, eco-friendly method for nanoparticle formulation. This approach can be further explored for improving the solubility of other poorly water-soluble drugs.

EDUCATION

M. Pharmacy

MCE Society's Allana College of Pharmacy, Pune • 2022

B. Pharmacy

Shri Balaji Shikshak Prasarak Mandal's College of pharmacy (SBSPM), Ambajogai • 2018-2022

Intermediate

Dr Muhammad Iqbal junior college of Arts and science, Ambajogai. • 2018

CERTIFICATIONS

3 Months of Advanced Diploma in Clinical Research, Clinical Data Management, Pharmacovigilance, Medical Writing, and Regulatory Affairs • CliniWings - Clinical Research Training Institute • Nov 2025

PUBLICATIONS

Microwave Assisted Synthesis of Nanoparticles for Enhancement of Mesalamine Drug Solubility • Published in IJRAR, Volume 11, Issue 3, July 2024 📄 <https://ijrar.org/papers/IJRAR24B1304.pdf> Lancet Diabetes Endocrinol (2013); 12 (1); 208-306 •

SKILLS

Clinical Research: ICH-GCP Guidelines, Clinical Trial Phases (O-IV), Protocol & CSR, Ethics (IRB/IEC, Declaration of Helsinki, Belmont Report), Randomized Trial, Blinding, Biasness, Centralised/Decentralised Trials, IRT, CRA/CRC/Sponsor/Investigator, TMF/e-TMF, Informed Consent (ICF), CRF, CFR Regulations

Clinical Data Management: eCRF Design, Database Setup, Data Entry, Data Review, Edit Checks, UAT, Query & Discrepancy Management, SAE Reconciliation, Medical Coding, Clean File Declaration, Database Lock, 21 CFR 11

Pharmacovigilance / Drug safety: AE/ADR, SAE/SUSAR, MedWatch, Yellow Card, EudraVigilance, ICSR Case Processing, Narrative Writing, CIOMS, GVP, WHO-UMC & Naranjo Causality, Signal Detection, Aggregate Reports (DSUR, PSUR, PADER, PBRER), MedDRA, WHO-DDE

Medical Writing: Regulatory Writing (Protocols, CSRs, Safety Reports), Scientific Writing (Manuscripts, Posters, Abstracts), Medico-Marketing Content, Literature Search (PubMed, EMBASE, Scopus, Cochrane, Medline, Clinical Trials.gov)

Regulatory Affairs: DMF, Dossiers (IND, IMPD, NDA, ANDA, BLA, MAA), eCTD (Modules 1-5), Regulatory Submissions, Regulatory Compliance

Tools: Argus, Aris-G, Rave, MACRO, Oracle Clinical, LifeSphere, Veeva Vault