

TIRUPATI MUNDKAR

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 LinkedIn

 Portfolio Site

PROFESSIONAL SUMMARY

M.Pharm (Pharmaceutics) professional with hands-on bioanalytical research experience at **Teva Pharmaceuticals**. Proficient in ICH guidelines, GCP compliance, and CTD/eCTD dossier preparation. Adept at technical documentation and method validation for global regulatory submissions. Seeking roles in Regulatory Affairs or Medical Writing.

EDUCATION

Savitribai Phule Pune University (SPPU), Pune	2022–2024
Master of Pharmacy (Pharmaceutics)	71.36%
SRTMUN University, Latur	2018–2022
Bachelor of Pharmacy	83.08%

PROFESSIONAL EXPERIENCE

Analytical Researcher – Teva Pharmaceuticals	Sept 2024 – Present
• Execute bioanalytical method development and validation in adherence to USFDA and EMA regulatory standards.	
• Author and review study documentation to ensure "submission-ready" quality for global markets.	
• Streamline sample logistics and collaborate with cross-functional teams to expedite regulatory filing timelines.	
M.Pharm Project Intern – Anish Pharmaceuticals	Jan 2024 – Jun 2024
• Optimized the formulation of extended-release Potassium Chloride pellets using Fluid Bed Processing.	
• Managed batch documentation and data compilation within a GMP-certified manufacturing environment.	
• Conducted rigorous sampling and stability testing to validate formulation efficacy.	

PROJECTS

Virtual Regulatory Strategy & Dossier Design	2024
• Simulated the structuring of Module 3 (Quality) and Module 5 (Clinical Study Reports) for eCTD submissions.	
• Developed a mock clinical trial protocol applying ICH-E6 (GCP) principles to assess regulatory feasibility.	

TECHNICAL SKILLS

Regulatory Affairs: CTD/eCTD Compilation, Global Regulatory Submissions, USFDA & EMA Guidelines
Compliance & Quality: ICH-GCP, Good Manufacturing Practices (GMP), GLP Standards
Bioanalytical Skills: Method Development, Validation, Sample Logistics, Study Report Writing
Tools & Documentation: MS Office (Excel, Word, PPT), Technical Writing, Data Compilation

ACHIEVEMENTS

- Qualified GPAT 2022 with an All India Rank (AIR) of 3870.
- Qualified NIPER 2022 with an All India Rank (AIR) of 714.
- Recipient of the AICTE PG Scholarship for academic excellence during M.Pharm.
- Proficiency in English, Hindi, and Marathi.