

Sonali Badak, M. Pharmacy (QAT), 2018

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 - Preferred Job Locations: Pune & everywhere in India.
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PROFILE SUMMARY

I'm a Postgraduate in Pharmacy with demonstrated theoretical knowledge along with 3 months of certification courses in **Clinical Research, Clinical Data Management, Pharmacovigilance, Medical Writing, and Regulatory Affairs**. Now, I'm looking for an opportunity in your organization where I can contribute to growing myself and the organization.

BASIC SKILLS

- **Clinical Research** – Drug discovery and development process, Animal research, Clinical research phases 0, 1, 2, 3, & 4; ICH, GCP, & Ethics, Dossiers (INDA, NDA, ANDA, & BLA), CTD modules, Clinical study designs – experimental & observations (RCT, n-RCT, prospective, retrospective, cross-sections, case study, case-series & case controls), Placebo, Biasness, Centralized & De-centralized trials, Responsibilities of CRA, CRC, Investigator & Sponsor.
 - **Clinical Data Management** – CDM overview, Aims & objectives, Study start-up phase (CRF & Database designing), Study conduct phase (data collection, CRF tracking, data entry, data validation, discrepancy management, medical coding, & SAE reconciliation), Study close-out phase (declaring clean file & database lock), 21 CFR 11 & CDM databases (Rave, Macro & Oracle clinical).
 - **Pharmacovigilance** – PV overview, Responsibilities, definitions (AE, ADR, SAE, SUSAR, abuse, misuse, off-label use, medication error), Sulfanilamide tragedy, Thalidomide tragedy, 21 CFR 312 & 314, GVP, ICH E2A-F, CIOMS, ICSR processing, Causality assessment scales – WHO UMC, Naranjo, De-challenge & Re-challenge, Reporting systems, PVPI, Aggregate reports (DSUR, PSUR, PADER & PBRER, MedDRA, WHO COSTAT, & ART).
 - **Medical Writing** – MW overview, Responsibilities, Regulatory writings (protocols, reports, & safety aggregate reports), scientific writings (Manuscripts, abstracts, & posters), Medico-marketing writings (product monographs, brochures, leaflets, news blogs, & websites) & Academic writings (medical books, thesis & chapters).
 - **Regulatory Affairs** – RA, overview, responsibilities, Dossiers (INDA, NDA, MAA, ANDA, & BLA), CTD modules 1, 2, 3, 4, and 5 & Regulatory bodies.
 - **Pharmacology** – Basic knowledge of medical conditions including Diabetes, Cancer, Asthma, COPD, Hypertension, COVID-19, Malaria etc.,
 - Good at using MS Office
 - Good written and verbal communication
 - Flexible and punctual to timelines
 - EndNote software
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EDUCATIONAL BACKGROUND

- **M. Pharmacy (QAT)** – Savitribai Phule Pune University, 2016 – 2018, 7.5 CGPA
 - **B. Pharmacy** – Savitribai Phule Pune University, 2013 – 2016, 67.67 %
 - **D. Pharmacy** – Rajgad Dnyanpeeth's College of Pharmacy Bhor, Pune, 2011-2013, 76%
 - **Intermediate** – Shree Chhatrapati Shivaji Junior College Bhor, Pune, 2009 - 2011, 68%.
 - **SSC** – Raja Raghunathrao Vidyalaya Bhor, Pune, 2009, 82.30%
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ACADEMIC PROJECTS

- **Title:** "Development and validation of Analytical method for simultaneous Estimation of Ketoconazole and Salicylic Acid in bulk and Pharmaceutical dosage form."
- **Aim/Objective:** To devise simple, precise, rapid and economical method for the estimation of ketoconazole and salicylic acid in buik drug and the lotion formulation.
- **Methods:** Simultaneous Estimation Method and Absorbance Ratio Method.
- **Conclusions:** Two new, simple, sensitive and economical UV Spectrophotometric methods were developed for the simultaneous analysis of ketoconazole and salicylic acid in bulk and in pharmaceutical formulations .

ACHIEVEMENTS & PUBLICATIONS

- **GPAT (2016):** 1804 AIR
 - **Publication 1:** Analysis of Tolnaftate – Review; Current Pharma Research ISSN:2230 – 7842 CPR 8(2),2018,58-65.
 - **Publication 2:** Development and Validation of Analytical Method for Simultaneous Estimation of Ketoconazole and Salicylic Acid in Bulk and Dosage Form; Current Pharma Research ISSN:2230-7842,CPR 8(4),2018,2531-2548.
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WORK EXPERIENCE

Position: Assistant Professor

Organization : Siddhi College of Pharmacy

Duration: Currently working

Roles and Responsibility: Teaching a requisite number of classes, providing guidance and supervision to graduate students, participated in departmental meetings and providing academic support to professor and other faculty members.

- **Position:** Hospital Pharmacist
- **Hospital:** Talera Hospital, Pune.
- **Duration:** Feb 2021 to Sep 2022

- **Roles and Responsibility:** Dispensing the medicines and Maintaining the Medicines stock and records
- **Position:** Assistant Professor
- **Organization:** M.M. College of Pharmacy, Thergaon, Pune.
- **Duration:** July 2022 to Dec 2022
- **Roles and Responsibility:** Teaching a requisite number of classes, providing guidance and supervision to graduate students, participated in departmental meetings and providing academic support to professor and other faculty members.
- **Position:** Assistant Professor
- **Organization:** R. Ds. College of Pharmacy, Bhor, Pune.
- **Duration:** June 2018 to Apr 2019
- **Roles and Responsibility:** Teaching a requisite number of classes, providing guidance and supervision to graduate students, participated in departmental meetings and providing academic support to professor and other faculty members.

CERTIFICATION COURSE

- **3 months of an advanced certification course on the basic concepts and workflow in Clinical Research, Clinical Data Management, Pharmacovigilance, Medical Writing and Regulatory Affairs".**
- **Institute's Name:** CliniWings- Clinical Research Training Institute
- **Duration:** Nov 2023 to Feb 2024

INTERESTED AREAS TO WORK

- Clinical Research
- Clinical Data Management
- Pharmacovigilance
- Medical Writing
- Regulatory Affairs

STRENGTHS

- Adaptable
- Flexible
- Honest
- Self-motivative
- Optimistic

