DISHA SHARMA

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PROFESSIONAL SUMMARY

Experienced and results-driven Research Associate with over **10+ years of proven success** in **analytical method development**, **validation**, and **regulatory documentation** across a wide range of **pharmaceutical dosage forms**, including **injectables**, **active pharmaceutical ingredients (APIs)**, and **formulations**. Demonstrated expertise in implementing **ICH Q2(R1) guidelines**, **cGMP/GLP compliance**, and executing **analytical procedures** aligned with **regulatory requirements** (USFDA, EMA, ANVISA, PMDA). Skilled in advanced **chromatographic techniques** (HPLC, GC), **instrument calibration**, and **method transfer** for both **R&D and quality control environments**. Proficient in **stability studies**, **OOS/OOT investigations**, and **regulatory data generation** for global submissions. Recognized for optimizing laboratory workflows, enhancing data integrity, and contributing to successful **regulatory audits and inspections**.

TECHNICAL SKILLS

- **Instruments:** HPLC (Agilent, Waters), GC (PerkinElmer, Agilent, Shimadzu), UV-Vis, FTIR, Potentiometer, Refractometer.
- **Software:** Empower 3, OpenLab, LabSolutions, LIMS, eLN.
- **Expertise:** Method Development, Validation, Transfer, Wet Chemistry, Stability Studies.
- **Compliance:** ICH Guidelines, FDA cGMP, 21 CFR Part 11, GLP, OOS/OOT/CAPA Documentation

PROFESSIONAL EXPERIENCE

Sr. Research Associate | Jun 2023 – Present at Macleods Pharmaceuticals Ltd. – Andheri, Mumbai

- Conduct routine/non-routine **analytical testing** of raw materials, intermediates, and finished products.
- Provide **analytical support** and implement **new analytical methods and technologies** in collaboration with cross-functional R&D and QA teams.
- Develop and validate methods using **HPLC, GC**, and **compendial techniques** per **ICH Q2(R1)** and **GMP** guidelines.
- Prepare and execute **Method Transfer Sheets (MTS)**, **Standard Operating Procedures (SOPs)**, **Standard Testing Procedures (STPs)**, **Method Development Reports (MDRs)**, and product **Specifications** as per approved protocols.

- Responsible for analysis and documentation of **new drug substances** and **drug products**, including **raw materials**, **intermediates**, and **in-process samples**.
- Ensure routine **instrument calibration** and maintenance of **HPLC, GC, UV-Vis, FTIR, KF Titrator, and Potentiometer** per calibration schedules.
- Perform **method transfer**, **wet analysis**, and documentation of **drug substances and products**..
- Manage **test data and documentation** using **Empower**, **LabSolutions**, **OpenLab**, **LIMS**, and **eLN** platforms.
- Support **OOS/OOT investigations**, implement **CAPA**, and ensure **ALCOA+ data integrity** principles are followed.
- Contribute to **stability studies**, **trend analysis**, and provide support during **regulatory inspections** (USFDA, WHO-GMP, MHRA).

Senior Executive (Sr. Research Scientist) | Jun 2017 – Dec 2022 at Sun Pharmaceuticals Industries Ltd. – Gurgaon

- Perform testing and reporting of routine samples and new product formats using **HPLC, GC, UV** in a **cGMP-regulated** environment.
- Execute **analytical method development**, **method verification**, and **validation** for raw materials, API, and finished products.
- Transfer analytical methods and implement new technologies with support and training for troubleshooting.
- Proficient in **chromatography techniques (HPLC/GC)** and software including **Empower**, compliant with **21 CFR Part 11**.
- Prepare and execute **Method Transfer Sheets (MTS), SOPs, STPs, MDRs, and Specifications** as per approved protocols.
- Responsible for **OOS investigation** and **CAPA** implementation in compliance with **FDA cGMP** guidelines.
- Conduct **stability studies** and **laboratory testing** on new drug products; prepare related analytical documentation.
- Perform routine and scheduled **instrument calibration** and maintenance (HPLC, GC, UV, FTIR, KF, etc.).
- Generate and compile analytical data for **regulatory submissions** (US, EU, Japan, China) for **pilot and bio batches**.
- Ensure 100% compliance with safety, quality, and regulatory standards, adhering to **Good Documentation Practices (GDP)**.
- Skilled in **eLN, LIMS**, and electronic data management systems for laboratory workflows.
- Independently handled multiple QC and business programs with minimal supervision.
- Solid understanding of **ICH Q2 guidelines** for method development, validation, and transfer activities.

Quality Control Executive | Jan 2014 – Jun 2017 at Bakson Drugs & Pharmaceuticals Ltd. – Parwanoo, Himachal Pradesh

- Performed **Quality Control analysis** on **APIs, tablets, liquids, cosmetics**, and **homeopathic formulations**.
- Operated and maintained analytical instruments: **GC, UV-Vis, FTIR, pH meter, viscometer**, and **Karl Fischer titrator**.
- Documented and reviewed **calibration records** and executed testing protocols as per **GLP guidelines**.
- Conducted **stability studies** in accordance with **ICH guidelines** for product shelf-life and degradation profiling.

EDUCATION

Shobhit University, Meerut, U.P | 2013 – 2015 M.Sc. in Analytical Chemistry

C.S.J.M. University, Kanpur, U.P | 2009 – 2012 B.Sc. in Biotech, Chemistry, Botany

CERTIFICATIONS & APPROVALS

Approved Analytical Quality Chemist – Drug and Licensing Authority, Baddi, Himachal Pradesh