Jaimin Patel

PROCESS DEVELOPMENT SPECIALIST(BIOPHARMACEUTICAL DOWNSTREAM, API SYNTHESIS AND PHARMACEUTICAL EXCIPIENT DEVELOPMENT[LACTOSE MONOHYDRATE])

Profile

Proactive and results-driven professional with a strong background in new molecule API synthesis, multi-step organic synthesis, and custom compound synthesis. Proficient in downstream processing techniques and analytical methods, including particle size distribution analysis. Known for exceptional project management, experimental design, and problem-solving skills, consistently delivering above expectations. Proven ability to develop cost-effective and safe routes for Active Pharmaceutical Ingredients. Effective communicator with a track record of contributing to diverse projects in synthetic, oncological, and biotech fields, encompassing API and excipient development.

Employment History

Lactose India Ltd, Manager Process Development, Vadodara

APRIL 2023 — PRESENT

Ami Lifesciences Pvt. Ltd., Assistant Manager Process Development, Vadodara

MAY 2022 — MARCH 2023

Sterling Biotech Limited, Assistant Manager Process Development, Vadodara

NOVEMBER 2007 — APRIL 2022

Zydus Cadila, Cadila Healthcare Ltd., R&D Chemist, Vadodara

OCTOBER 2006 — NOVEMBER 2007

Genesis Organics Pvt. Ltd., Jr. Research Officer, Vadodara

SEPTEMBER 2005 — OCTOBER 2006

Education

Master of Business Administration (International Business), Sikkim Manipal University (Distance Learning), Manipal

2014

Master of Science in Organic Chemistry, Hemchandra Charya North Gujarat University, Patan

2005

Bachelor of Science in Industrial Chemistry (Vocational), Sardar Patel University, Vallabh Vidyanagar

2003

Competency Covers

- **Process Development**: Expert in cost-effective and safe development of API and Excipient manufacturing routes, ensuring scalability.
- **Technical Leadership and Process Transfer**: As the leader of the process development team, assume a pivotal role in transferring projects to production facilities. This role encompasses overseeing experimental design for process development studies.
- **Purification and Impurity Management**: Proficient in purification techniques and impurity characterization.
- **Analytical Expertise**: Experienced in using various analytical methods for impurity profiling and expert in particle size distribution interpretation, including sieve, air-jet, and laser diffraction methods.

Details

4, Vipul Vatika, Near Citizen Society, Atmajyoti Ashram Road
Vadodara, 390023
India
+919879936936
jim28982@yahoo.com

NATIONALITY

Indian

DATE / PLACE OF BIRTH

22/09/1982
Patan (North Gujarat)

Links

https://www.linkedin.com/in/jp28091982

Skills

Problem Solving Skills
Leadership and Teamwork
Technical Leadership
Purification Expertise
Impurity Profiling
Analytical Mastery
Particle Size Analysis
Data Handling
Innovative Thinking
Chromatography Skills
Regulatory Support
Technology Integration

Languages

English
Hindi
Gujarati

- **Innovative Problem Solver:** Proficient in identifying and independently resolving technical challenges, conceptualizing and implementing innovative process research ideas, and integrating cutting-edge technology to enhance processes.
- **Data Analysis**: Conduct literature surveys, data generation, and analysis.
- **IPR Compliance**: Skilled in creating non-infringing processes while meeting regulatory and safety standards.
- **Regulatory Support**: Provide documentation for CEP, DMF, and other regulatory filings.
- **Chromatography**: Well-versed in various chromatography techniques, including Normal Phase, Reverse Phase, Resin (Hydrophobic Interaction), and Preparative HPLC, from laboratory-scale to process-scale applications.

Current Responsibilities

- Leading the development of Lactose Monohydrate processes and the introduction of Lactose derivatives in collaboration with an experienced team.
- Developing a range of Lactose Monohydrate grades, including Milled, Sieved, Spray-dried, and Micronized variants, alongside different Lactose derivatives like Beta-Lactose, Lactulose, Lactitol.
- Collaborating closely with the Marketing team to interpret customer-specific requirements, particularly concerning particle size, to meet market demands.
- Implementing innovative and cost-effective approaches to enhance the processing of Lactose Monohydrate and Lactulose.
- Ensuring meticulous data monitoring and generation at every stage of Lactose Monohydrate and Lactulose manufacturing.
- Upholding stringent adherence to Good Laboratory Practices (GLP) and Good Documentation Practices (GDP) as per Good Manufacturing Practice (GMP) norms.
- Offering specialized technical support to address production challenges and operational issues.
- Compiling the requisite documentation for regulatory filings, including US Drug Master File (US-DMF) and Certificate of Suitability to the Monographs of the European Pharmacopoeia (CEP).
- Strategically planning and establishing new laboratory and pilot plant setups to facilitate daily experiments.
- Engaging with various internal teams, including Manufacturing, Engineering, Validation, Quality Assurance, Quality Control, Project Management, and Materials Management, and external stakeholders like clients, material/equipment vendors, and commercial partners.
- Demonstrating strong technical communication skills within the team, ensuring clarity and precision in interactions.

Publications

1. Synthetic Methods for Simvastatin – an Overview, ***J. Pharm. Appl. Chem., 5, No. 1, 23-43 (2019)***
2. Solvent-free synthesis for imidazole-1-yl-acetic acid hydrochloride: an intermediate for zoledronic acid, ***Asian Journal of Green Chemistry 3, 483-491 (2019)***