

JOB DESCRIPTION

ROLE: Sr.Executive - Formulation research and development

SALARY AND BENEFITS: Negotiable

REPORTS TO: Sr. Manager - Formulation and development

LOCATION: Vadodara

JOB TIMING: 12.00 am to 9.00 pm India time

PRIMARY RESPONSIBILITIES

- Literature search for development of new products with - Martindale, Merck index, Physician desk reference, Handbook of excipient & all electronic media (Internet search).
- Patent search for desired Formulation and Development with WIPO, USPTO, Patent lens, HMA, EMC, medicine.ie, BP, Patent storms, Google patents, Patent watch.
- To perform Preformulation Study for the development of new drug products and interpretation of DSC and HPLC data.
- Expertise on Dissolution profile matching (F1-Dissimilarity factor & F2-Similarity factor) through adopting different Formulation and Process strategies.
- Interpretation of Physicochemical data and application in formulation development.
- Innovator sample characterization.
- Checking in-process parameters during product development.
- Review of Bioequivalence Study Data available on Internet (reference product).
- Stability studies of new developed products as per ICH guidelines.
- Effective coordination with team by educating stringent means for routine product development activities.
- To give technical support to regulatory affairs department in solving product related queries.
- Co-Ordination of Development activities within R&D, ADL, Production & QA.
- Formulation and Development of Solid Oral Dosage Form: Modified Release Tablets & Immediate release Tablets and Capsules.
- To Conduct the Scale-up Batches.
- To Conduct the Pre-exhibit Batches.
- To Conduct the Validation Batches.

SECONDARY RESPONSIBILITIES

- Communication with third party for procurement of free samples of excipients and tooling development in line to RLD.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Development of various dosage forms for regulated, Semi regulated and ROW markets. Ex.: Uncoated, Coated Tablets, matrix controlled, Osmotic Controlled, monolithic and Push pull osmotic Bilayer tablet, Parental Products and Hard Gelatin Capsule for less regulated markets including ROW countries.
- Preparation of technology transfer documents.
- Good hand in reformulation of existing products to improve quality and cost reduction. Preparation of Product Development Report, Master formula card, sampling protocols & stability protocol.
- Facilitate technology transfer from lab to plant. Well versed with Quality by Design (QBD): Process analytical technology (PAT), Design Space (DS), Quality risk management.
- Good knowledge of Scale up Post Approval Changes (SUPAC) Guidelines.



INSTRUMENT/MACHINE SKILLS

- Experience in understanding instruments and machines like Silverson Homogeniser, Compression machine, Rapid mixer granulator, Fitz Patrik[®] Roll compacter, Fluidised bed drier & Fluidized bed processor, Multimill, Supermill, , Planetary Mixer, Vibrosifter, Auto Coater with PLC, Brookefield Viscometer, Ultrasonicator, UV Spectrophotometer, IR moisture analyser, Particle Size Analyzer (Malvern Zeta Sizer) & Soft gelatin encapsulation machine.

COMPUTER SKILLS

- Adobe series, MS-office and Working Knowledge of SAP.