

Job Description for FR&D NDDS/Complex Injectables

Experience :2 -10 Years

Qualification:M.Pharma

Location: R&D Centre (Karakapatla)

- I) Literature review for product development for US/ EU/ ROW market especially complex injectable 's like Liposomes, Nanoparticle suspension, Microspheres, Suspension's, Emulsion's, Lyophilized products, Peptide Injectable's, Drug delivery systems.
- II) Assist in Product development activities for Complex injectable's including:
 - Execution of Lab trials with required documentation.
 - Stock maintenance with follow-up for procurement of packaging material, Excipients, API, etc.
 - Lab equipment calibration and maintenance in co-ordination with QA/Engineering team.
 - Preparation of study protocols including stability, photo, thermal, scale up study protocol with report as per ICH guidelines.
 - Perform stability studies, Photo stability study and Thermal cycling study on development trial batches.
 - Preparation of Product Development Report.
 - Support for the technology transfer of manufacturing procedure from R&D to manufacturing plant with required documentation.
 - Application of QBD during product development with required documentation.
 - Compilation of analytical results and conclusion's for stability trend.
 - Characterization of formulation & API for particle size, zeta potential, XRD, Polymorph, solubility, TEM, SEM, etc. at In-house and out sourced laboratories.
 - Support for the filter validation studies.
 - Evaluation of API and Excipients for various markets.
 - Preparation of In-process, finished product release and finished product stability specifications as per ICH guidelines.
 - RLD/ Innovator procurement and analysis
- III) Support with the innovative ideas for the development of new platform technologies.
- IV) Development of lyophilisation cycle.
- V) Test license, Import license application and record maintenance.
- VI) Procurement of Raw material, Packaging material, Consumables and Equipment's.