SUSHEN
Building Partner

Project Management Services

- Designing of the plant as per WHO-GMP/USFDA/UKMHRA
- Later Project Executed on Turnkey basis

Formulation Development Services

- Delivers a broad range of drug formulation development service in oral solid dosage form.
- Later Tech Transfer to the manufacturing site.

Pharmaceutical Project Management Services

Pharma Project. Turnkey Solutions.

Designing of the plant (as per WHO-GMP/USFDA/UK-MHRA)

- Site master planning
- Conceptualization & capacity balancing
- Equipment sizing & selection
- Architectural design services:
- Civil and structural works
- Heating ventilation and air conditioning (HVAC) engineering
- Mechanical and piping engineering
- Electrical engineering

Equipment and processing specifications

- Expertise in procurement, installation & qualification for required equipment & machineries
- Provide supply of complete production equipment as well as HVAC and Clean room panel system
- Preparations of these equipment and system qualifications protocol such as URS, DQ, IQ, OQ, PQ

Engineering Services

- Inception to Execution
- Commissioning of plant

Formulation and Development Services

Formulation. Tech Transfer.

Facilities

- 43,000 sq. ft. area & 38,000 sq. ft. of constructed area
- WHO-GMP certified, 21 CFR compliance, DSIR-Govt. of India approved R&D facility and in process for US FDA & UK MHRA approval
- Formulation Development set-up
- Facility includes UPLC/HPLC, GC, STIR, AAS etc
- Stability Chambers
- Total validation support
- Knowledge management sharing
- Pilot batch as well as scale-up facility

Strengthening Product Portfolio

- Design and Development for Solid Oral Dosage form - Tablet (IR, SR, MR, Mouth Dissolving, Sub Lingual, Chewable, Dispersible etc), Capsules and Pallets
- GMP manufacturing for samples for Clinical Trials
- Formulation Development with pilot BE batch and Tech Transfer to the manufacturing site.
- Development of specification and Method of Analysis (MOA)
- Separation and Purification of Impurities
- Method Development, Optimization and Validation
- Organizing BA/BE Studies
- Preparation of CTD / ANDA Dossiers
- Microbiology studies
- Endotoxin Testing
- Identification of microbes up to genus and species level

Validation and support activities

- Validation Master Plan (VMP)
- Qualification protocols like DQ, IQ, OQ, PQ
- Validation protocol for utility, systems, processes, cleaning, analytical methods with validation summary reports
- Actual qualification and validation support for equipment, systems and processes
- Training

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