

Formulations and Drug Delivery Systems Division

Overview:

IIIM pharmaceutical development team is experienced in formulation development of both small molecules and macromolecules into a diversity of formulation presentations. Preclinical formulation development for developing, manufacturing for preclinical pharmacology and GLP toxicology studies. Formulation expertise includes development of a wide variety of dosage forms appropriate for clinical trials and commercialisation. In support of these activities, we conduct formulation feasibility studies, scale-up studies and stability studies.

Mission and goals

- We undertake formulation development challenges of biopharmaceuticals and to successfully overcome them.
- Explore and learn about unique challenges in the formulation development of drugs from natural products.
- Bioanalytical methods used in the physiochemical characterization and preformulation studies.
- Design and conduct stability studies.
- Chemical modification techniques useful in the development of biopharmaceutical drug products.
- Innovative Formulation Development Solutions Novel drug delivery systems like nanoparticles, nanogels, microemulsions, liposomes, dendrimers etc.
- Regulatory issues of formulation development, drug product characterization, and manufacturing of biopharmaceuticals.

Competencies:

Preformulation studies

- Physico-chemical characterization of drug substance
- Solubility and partitioning studies
- Polymorphism studies
- Powder X-ray diffraction
- Particle size analysis
- Qualitative and quantitative thermal analysis
- Excipient compatibility studies
- Rheological studies
- Packaging compatibility and extractability studies
novel delivery drug technologies

Formulation Services

- Formula and process optimization through DOE
- Tablets, capsules, liquids, suspensions and semi-solids
- Modified and controlled release tablets and capsules
- Evaluation of packaging presentations based on formulation requirements
- Bottle, blister, sachet and tube packaging
- Clinical supply and placebo manufacture
- Review of batch documentation by Quality Assurance team

Analytical Research Support

- Process development support and release testing
- Dissolution studies (ICH guidelines)
- Accelerated Stability studies (ICH guidelines)
 - Validated environmental chambers
 - 25°C/60%RH, 30°C/65%RH
 - 40°C/75%RH, 25°C/40%RH
 - 40°C/25%RH, 5°C, photostability

Facilities

State of art cGMP compliant pilot plant for formulation and development of natural products in various dosage forms like tablets, capsules liquid orals commissioning work is underway.

People

Dr. Shashank Kumar Singh

Dr. Shashi Bhushan

Area of Research: Formulation Development and Novel Drug Delivery Systems.