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Research Interests

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Highlights

- Preformulation
- Solubilization techniques
- Salt screening and selection
- Novel drug delivery systems
- Sterile product development
- Quality by Design (QbD) approach
- Design of experiments (DOE)

Preformulation

- Physicochemical characterization of NCEs
  - Physical characteristics including thermal properties
  - Solid state and solution stability evaluation
  - pH solubility and stability
  - Stress studies – light, temperature, oxygen
  - Hygroscopicity – dynamic vapor sorption
  - Developability evaluation
  - Recommendation for suitable dosage forms

Preclinical Product Development

- Peroral/parenteral formulation for preclinical Pharmacology, PK, and Tox Studies
  - Ability to develop with limited quantities of the active with limited information than structure and chemical formula
  - Predictions of pKa, Log P values to support formulation development process
  - Injectable product development is challenging

Solubilization Strategies

- Decision-tree based approach
  - pH adjustment and *in situ* salt formation for actives with ionizable groups
  - Co-solvent systems
  - Surfactant based systems
  - Combination of co-solvent and surfactants
  - Complexation – e.g., cyclodextrin based systems
  - Particle engineering
  - Nanoparticulate systems

Salt Selection

- To increase or decrease stability
- Improved stability
- Improved solid-state properties
- Improved PK profile
- Intellectual property
- Critical to identify the salt form that can be developed into a drug product (developability studies)
- Early in the drug development process

In Situ Salt Screening

- Selecting the right version (parent or salt) of a molecule for clinical product development is critical
- Screening method without the need to synthesize a salt, avoiding synthesis of in-soluble salts
- Screen several counter-ions
- Solubility Product (K_{sp}) used to estimate salt solubility

Bioadhesive Rapidly Disintegrating Tablets

- Two contradictory concepts
- Design of experiments (DOE) for optimization of formulation
- *In vitro* method for evaluation of bioadhesive characteristics

Design of Experiments

- Screening design to identify variables to study
- Experiments based on a design
- Fitting the data to a model
- Predictions using the model within the design space
- Ability to hit the bull's eye

Nanosuspension

- Poorly soluble drugs when other solubilization approaches can not be used
- Milling or High Pressure Homogenization
- Stabilization of particles
  - Prevent aggregation/agglomeration
- Solubility vs Pharmacokinetics relationship

Liposomes

- Biocompatible carriers
- Encapsulation of hydrophobic and hydrophilic drugs
- Protect molecules from inactivation
- Targeting capability
- Flexibility in design
- Achieve longer circulation times
- Minimize systemic toxicity

Liposomes

- Improve physical stability of dispersions
  - Optimize lipid composition
  - Optimize drug loading
  - Optimize process parameters
- Drug release/leakage method
- Purification from free drug

Advantages of Drug Targeting

- Alteration in pharmacokinetics and biodistribution
- Restriction of drug at the tissue of interest
- Controlled drug delivery

- Increase in treatment efficacy
- Decrease in Drug toxicity
- Reduction of the drug dose

Targeting

- Passive targeting by
  - PEGylation
  - Particle size
  - EPR effect
- Active targeting by coupling with
  - small peptides
  - immunoglobulins

Stability of Liposomes

- Lyophilization to improve stability
  - Optimization of formulation
  - Optimization of process
  - Thermal evaluation of pre-lyophilized solution for Tg’
  - Thermal evaluation of lipid films for Tm

Microbubbles

- Ultrasound contrast agents used in radiology for imaging organs and tissues accessible to ultrasound
- Can undergo cavitation under ultrasound
- Development of ultrasound active liposomes
- *In vitro* evaluation

Parenteral Product Development

- Injectables/ophthalmics
  - Filter selection
  - Drug/excipient compatibility
  - Material compatibility
  - Sterilization method evaluation
  - Stability evaluation
  - Ad-mix compatibility

Quality by Design

- Regulatory expectation
- Formulation & process risk identification
- Evaluation of risks through studies
- Risk mitigation and control strategies

Glass Delamination

- Several recalls due to glass particles in product
- Identify risks per USP<1660>
- Accelerated studies per USP to identify potential issues

Extractables & Leachables

- Finished product primary components
  - Controlled extraction studies
  - Testing samples on stability program
- Processing equipment
  - Process simulation studies

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