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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 insoluble 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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