Srinath Palakurthi, Ph.D.

Srinath Palakurthi, Ph.D. is a Professor of Pharmaceutical Sciences at the Texas A&M University, a tier-1 research institution in Unites States. He has over 20 years of academic research experience in formulation development and pharmacokinetics. Dr. Palakurthi's current research focuses on developing novel nanoparticle-based drug as well as gene delivery systems for targeted therapy of cancer. He is also developing biorelevant in vitro drug release testing (IVRT) methods for topical ocular products, a project supported by Food and Drug Administration (FDA). His research has been funded by National Institutes of Health (NIH), Department of Defense (DOD), FDA and private research foundations.

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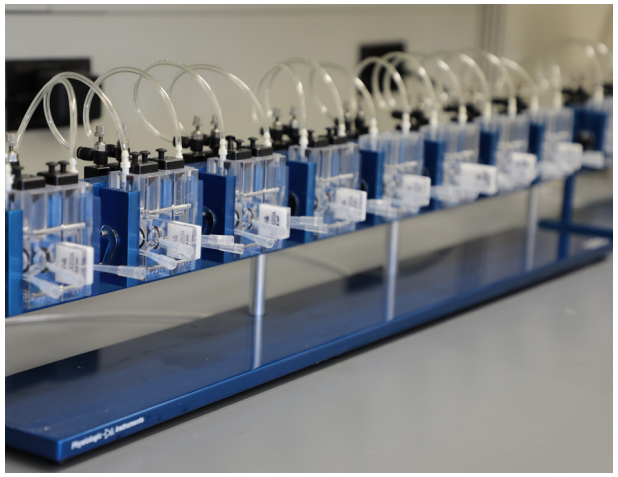
GENERICS DEVELOPMENT RESEARCH LABORATORY (GDRL)



PREFORMULATION & EARLY PHASE DEVELOPMENT

Undesirable physicochemical properties of a drug substance pose a major challenge in developing a drug product and designing innovative solutions to overcome these challenges is a strength of our laboratory. With expertise in characterizing a drug substance's physicochemical properties, we will guide you in selection of suitable excipients and facilitate development of an optimal oral, topical and parenteral formulations. We also conduct preformulation studies and provide early phase formulation design and development data.

PREFORMULATION:

We have expertise in conducting relevant preformulation studies including

- Solubility
- Partition coefficient
- Stability
- Permeability across Caco-2 cell monolayers
- Pharmacokinetics (PK)
- In vitro metabolism

FORMULATION DEVELOPMENT:

TABLETS:

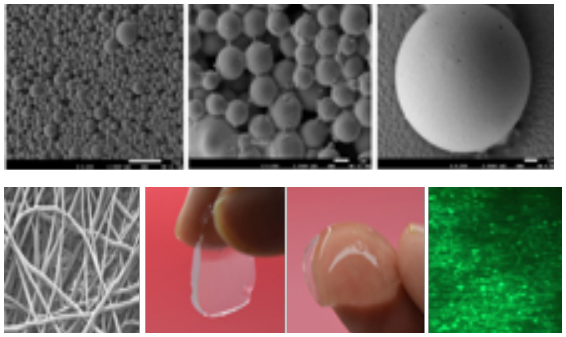
- Tablet blend characterization
- Quick-dissolve oral dosage forms
- Gastro retentive (Hydrodynamically balanced system, HBS) tablets

TOPICAL/TRANSDERMAL SYSTEMS:

- Formulation development of Topical gels, creams and ointments
- Development of transdermal patches
- Oral: Enteric coated microparticles/granules
- Parenteral: Polymer Depot formulations

NANOPARTICLE/MICROPARTICLES:

- (Liposomes, PLGA nanoparticles, nanoemulsions)
- Nanoparticle preparation and characterization
- Cellular uptake and intracellular trafficking
- Pharmacokinetics in xenograft models



GENERIC OPHTHALMIC PRODUCTS

Dr. Palakurthi's research group is working to develop generic formulations for topical ophthalmic products that are available in the market. He developed a formulation that is chemically equivalent to Durezol®, a medication used for the treatment of postoperative inflammation and pain in the eye. Following detailed comparative characterization of the product properties, a novel method to test the drug release from chemically equivalent formulations was developed. Currently there is no specific method to differentiate the drug release from the topical ophthalmic products that are prepared under different manufacturing conditions. For the first time his research group developed a method and demonstrated that drug release from the prepared chemically equivalent formulation is similar to that of the marketed product. The study was funded by Food and Drug Administration (FDA) from 2014-2017.

TOPICAL FORMULATION DEVELOPMENT

- Emulsions
- Suspensions
- Gels
- Ointments

SUSTAINED RELEASE FORMULATIONS

- Microneedles
- Soft contact lenses

ANALYTICAL/PRE-CLINICAL SUPPORT:

1. Drug-excipient compatibility studies for oral and topical dosage forms

- The API and excipients compatibility studies
- 1H-NMR
- Fourier transform infrared spectroscopy (FTIR)
- X-ray diffraction (XRD) analysis
- Differential scanning calorimetry (DSC)

2. Analytical Method Development & Validation

- Shimadzu UPLC
- LC-MS (Shimadzu UPLC connected to Adveon MS)

3. IVRT Method Development & Validation

- USP-II apparatus
- Diffusion Chamber (Ussing chamber)
- Franz Diffusion cell
- Microdialysis as IVRT method
- USP 4 apparatus

4. In vitro permeability testing (IVPT)

- aco-2/MDCK permeability assay
- Parallel artificial membrane permeability assay (PAMPA)
- Corneal permeability
- Skin permeability
- Permeability across nasal mucosa
- Intestinal permeability

PHARMACOKINETICS & BIOEQUIVALENCY STUDIES

1. In vivo Pharmacokinetics in rats and mice

- Single/multiple oral administration with sampling from jugular vein catheter
- Development and validation of analytical method (LC-MS) from serum
- In vivo drug stability
- PK parameters using WinNonlin software (t1/2, Vd, Cmax, Tmax, AUC0-∞, Cl, F)

2. In vitro-metabolism

- Screening using liver S9 fraction, microsomes
- Identification of the principal enzyme and metabolites of the CYP 450 pathway.
- Enzyme kinetics (km and Vmax).
- CYP 450 isozymes induction & inhibition assays

BIOEQUIVALENCY TESTING:

- Bioequivalency testing of oral and topical products in small animals (rats and rabbits)
- Bioequivalency testing of oral products in large animals (pigs and horses)