Krutika Harish Jain

AREAS OF INTEREST AND EXPERTISE

Solid- and Solution-state Chemistry and Characterization, Pre-formulation Studies, Formulation & Process Development, Physical Chemistry, Medical Device Design and Rapid Prototyping, Mathematical Modeling (Mass Transfer and Diffusion, Drug Release Kinetics, Crystallization and Pharmacokinetics)

TECHNICAL SKILLS

- **Dissolution Testing:** USP Apparatus I, II and IV, Side-by-side Diffusion Cell, Biphasic Dissolution Testing
- Analytical Techniques: HPLC, Spectroscopy (UV-Vis, IR, NMR, Fluorescence), Thermal/gravimetry analysis (TGA, DSC, DVS), X-ray Powder Diffraction Analysis, Polarimetry, Particle Analysis (Polarized Light Microscopy, Sieve Analysis, Dynamic Light Scattering, Nanoparticle Tracking Analysis), Surface Tensiometry, Static and Dynamic Contact Angle Goniometry, Viscometry, Water Activity Measurement, Uni- and Bi-axial Tensile Testing
- Rapid Prototyping: 3D Printing, Laser Cutting, Injection Molding, Hot Embossing
- Software: MATLAB, GastroPlus, AutoCAD, Creo, Python, R-Studio, Minitab, ImageJ

EDUCATION

Aug. 2017 - Present (Exp. graduation: Spring 2021)	Ph.D., Pharmaceutics University of Minnesota , Twin Cities, MN Advisor: Dr. Ronald A. Siegel	CGPA: 3.63/4.00
Aug. 2015 - July 2017	M.S., Pharmaceutics University of Minnesota , Twin Cities, MN Advisor: Dr. Ronald A. Siegel	CGPA: 3.63/4.00
July 2010 - May 2014	Bachelor of Pharmacy Manipal University , India	CGPA: 9.66/10.00 (Rank: 3/120)

RESEARCH EXPERIENCE

Biorelevant Dissolution Testing of BCS-II Drug Formulations

Aug. 2017 - Present

Graduate Student, Department of Pharmaceutics, University of Minnesota | Advisor: Dr. Ronald A. Siegel

- Collaborated with Dr. Hao Helen Hou at Genentech Inc. to test various enabling formulations of BCS-II compounds using an in-house constructed *artificial gut simulator* equipped with a hollow fiber-based absorption module. A 3 mL UV spectrometer cuvette was modified into a dissolution vessel in which the absorption module was suspended. The operating parameters were systematically optimized to simulate absorption at a physiological rate.
- Determined the effect of absorption on drug dissolution, liquid-liquid phase separation and crystallization kinetics. (manuscript submitted to JPharmSci)
- Developed a fluorescence spectroscopy-based method to measure drug concentration in amorphous and crystalline precipitate present in supersaturated solutions generated by the dissolution of amorphous solid dispersions in biorelevant media. The results were validated by PXRD. (manuscript under preparation)
- Demonstrated reduction in supersaturated solutions' crystallization propensity in the presence of an absorption module as well as reduction in drug absorption in the presence of crystallization and drug solution activity-reducing bile micelles and polymers.
- Developed a non-steady state mass transfer model convoluted with a dispersive kinetic model for modeling crystallization occurring simultaneously with drug absorption. (ongoing work)

Biodegradable Drug Delivery Implant to Prevent Surgical Adhesions

May 2018 - Present

Graduate Student, Department of Pharmaceutics, University of Minnesota | Advisor: Dr. Ronald A. Siegel

- Designed and 3D-printed a biodegradable osmotic mini-pump using poly(lactic acid-co-glycolic acid) (PLGA) polymer to deliver heparin, an anticoagulant, at a constant rate for 7 days. To ensure zero-order drug release, an 'oil piston' was introduced between a saturated osmotic agent solution and an unsaturated aqueous dextran blue (high solubility model drug similar to heparin) solution.
- Osmotic pumping principle, Poiseuille's and Laplace's laws were applied to guide the optimization of the microchannels and core and constant drug release was successfully demonstrated. (ongoing work)

Biodegradable, Liquid-filled, Spherical Capsules with Pre-Determined June 2015 - June 2017 Burst Times (Master's Thesis ♥)

Graduate Student, Department of Pharmaceutics, University of Minnesota | Advisor: Dr. Ronald A. Siegel

- Developed a novel preparation technique of a spherical, liquid-filled PLGA capsule that exploits the principle of osmosis to achieve a delayed-burst release of its load.
- Developed a novel "beach ball" inflation technique to conduct elastoplastic, necking and failure characterization of PLGA along with uniaxial and biaxial tensile testing.
- Demonstrated accurate prediction of capsule burst time *in vitro* by modelling the rate of water uptake by the capsule core as a function of capsule shell thickness, its radius, core osmotic pressure and the membrane tensile strength. *(manuscript under preparation)*

Fc-hGH Fusion Protein Dec. 2014 - March 2015

Graduate Research Assistant, Dept. of Pharm. Sci., Uni. of Southern California | Advisor: Dr. Wei-Chiang Shen

- Assisted Dr. Li Zhou to prepare a monomeric Fc fusion protein devoid of the hinge region to stabilize it against proteolysis. This was used as a carrier for human growth hormone to prolong its *in vivo* $t_{1/2}$.
- Work included PCR, restriction digestion, DNA purification, cloning, transfection, expression of the fusion protein, protein purification and gel-running assays.

Anti-biofilm Phytosomes

June 2012 - Aug. 2013

Undergraduate Research Assistant, Dept. of Microbiology, Manipal University | Advisor: Dr. Jesil Mathew

- Tested various organic solvent extracts of *Murraya koenegii* (known as curry leaves in Indian vernacular) and its phytosomes for antibiofilm activity.
- Biofilms of *B.subtilis* and *S.aureus* (Gram-positive), and *P.aeruginosa* and *E.coli* (Gram-negative) were cultured. Anti-biofilm activity screening of extracts was conducted by drop-collapse test, crystal violet and microbial adhesion to hydrocarbon assays.

WORK EXPERIENCE

Intern, Research and Early Development, Genentech, Inc., South SF, CA
Mentor: Dr. Dawen Kou, Small Molecule Analytical Chemistry and Quality Control

May 2019 - Aug. 2019

- Conducted dissolution testing of solid oral dosage forms using USP II and IV apparatus and generated *in vitro* dissolution profiles. Drug concentration in dissolution samples was determined by HPLC.
- Used GastroPlus to simulate absorption profiles based on dissolution data.
- Compared *in silico* simulation data with *in vivo* plasma concentration-time profiles to fine tune *in vitro* dissolution model and conditions to attain better correlation.

Intern, Formulation Development, ProMed Pharma, LLC., Plymouth, MN Sept. 2015 - Aug. 2016 Mentors: Dr. Matthew A. Petersen and Dr. James Arps

- Intravaginal Rings for Delivery of Anti-HIV macromolecules (in collaboration with Dr. Thomas Zydowsky at the Population Council, Inc., New York): Developed intravaginal rings with controlled porosity, loaded with a protein drug and a polysaccharide stabilizer, to overcome the shortcoming of limited drug release by monolithic rings. Mixing and injection molding parameters were established using a two-level factorial design to obtain optimum void fraction, open pore content and mechanical properties. (work presented at 2016 CRS meeting)
- Controlled Drug Delivery from Sinuplasty Balloons: Developed a novel dip-coating method and constructed an in-house device to coat tri-folded, nylon balloons with drug-loaded polyurethane to obtain uniform, visually smooth and mechanically resilient membranes of target masses that release drug in a sustained and reproducible manner.
- Breast Implants: Tested various silicone grades and developed a method to obtain low density breast implants by application of optimized conditions of vacuum and heat.
- · Assisted in tech transfer and scale-up of intravaginal rings and sinuplasty baloons manufacturing.
- Authored multiple internal technical documents and provided technical training in process development to R&D employees and interns.

POSTER PRESENTATIONS

Artificial Gut Simulator for Simultaneous Evaluation of Dissolution and Absorption of Supersaturating Drug Formulations

Krutika Harish Jain, Helen Hao Hou and Ronald A. Siegel Gordon Research Conference, Waterville Valley, NH, June 9-14, 2019

 Artificial Gut Simulator for Simultaneous Evaluation of Drug Dissolution and Absorption Krutika Harish Jain, Helen Hao Hou and Ronald A. Siegel PharmSci 360 Conference, Washington D.C., Nov 4-7, 2018

 Biodegradable Liquid-filled Spherical Capsules with Pre-Determined Burst Times Krutika Harish Jain and Ronald A. Siegel
 AAPS Annual Meeting and Exposition, San Diego, Nov 12-15, 2017

• Silicone Intravaginal Rings for Co-delivery of Macromolecular and Conventional Pharmaceuticals Matthew A. Petersen, Sasha Rios, Krutika Harish Jain and James Arps

CRS Annual Meeting and Exposition, Seattle, July 17-20, 2016

ACADEMIC SERVICES AND OUTREACH

• Reviewer Oct. 2020 - Present

Molecular Pharmaceutics, ACS Publications

• Mentor Jan. 2019 - Present

Supervised and mentored a graduate and an undergraduate student in planning and conducting collaborative and independent research work.

• Lab Safety Officer Oct. 2018 - Present

• Chair, Scientific Committee, 50th Annual PGSRM

Led the planning of the scientific sessions at a student-organized conference bringing together over 150 graduate and postdoc delegates from various universities.

• President, Students' Council, Manipal University

June 2013 - May 2014

AWARDS AND GRANTS

- Bighley Graduate Fellowship, 2018-2019
- Rowell Graduate Fellowship, 2018-2019
- Bighley Graduate Fellowship, 2017-2018
- GAP College of Pharmacy Grant, Jan. 2017 Present | University of Minnesota A bioresorbable osmotic pump for extended postsurgical intraperitoneal delivery of therapeutic agents Principal Investigator: Ronald A. Siegel, Sc.D.

Award: \$40,000

Role: My work on the design of osmotic implant was the basis of this grant. I provided preliminary data and wrote the grant with Dr. Siegel.

• S.K. Patil Scholarship for pursuing M.S. degree, 2014

TEACHING EXPERIENCE

Controlled Drug and Gene Delivery: Mechanisms and Models

Spring Semesters: 2018, 2019

Graduate Teaching Assistant | Course Coordinator: Prof. Ronald A. Siegel

 \bullet Conducted review sessions on the mathematical principles underlying the design of drug delivery systems and graded assignments and exams for a graduate-level class of 10 - 20 students.

Physical Pharmacy Fall Semesters: 2017, 2018

Graduate Teaching Assistant | Course Coordinator: Prof. Ronald A. Siegel

• Conducted review sessions on physical chemistry principles applicable to pharmaceutical dosage forms such as intermolecular forces, phase equilibria, colligative properties, solubility, partitioning, and pH-partition hypothesis. Graded assignments and exams for a graduate-level class of 15 - 20 students.

Drug Delivery I & II Fall 2016, Spring 2017

Graduate Teaching Assistant | Course Coordinators: Proffs. Changquan Calvin Sun & Raj Suryanarayanan

• Developed and delivered 1-2 hours' lectures on chemical kinetics, stability, buffer systems, rheology and physicochemical principles relevant to pharmaceutical dosage forms. Conducted after-class review sessions and graded assignments and exams for a Pharm. D. class of 150 students.