

Namita Dalal

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EDUCATION

Duquesne University, Pittsburgh, PA, USA

2009-2015

Doctor of Philosophy, Pharmaceutical Sciences (Major: Pharmaceutics)

Dissertation project: Understanding the solid state, solubility and dissolution behavior of cefuroxime axetil diastereomers in interactive mixture formulations

- Use of several solid state characterization techniques to understand the solid state behavior of cefuroxime axetil diastereomers
- Formulation of interactive mixtures of cefuroxime axetil with carrier materials to improve dissolution rate
- Dissolution modeling using non-linear regression to understand drug release from interactive mixtures

Collaborative project: Determination of solid dispersion API:polymer miscibility

- Demonstrated the need for comprehensive characterization, using a suite of complementary analytical techniques in order to properly classify API:polymer behavior
- Characterized co-solidified solids using powder X-ray diffraction (PXRD), analysis of pair distribution function-transformed PXRD data, hot-stage polarized light microscopy, and differential scanning calorimetry (DSC)

Relevant Experience:

- Understanding of basic statistical analyses techniques and hypotheses testing
- Use of linear and multiple linear regression to understand significant/non-significant factors and interaction between factors on outcome variables
- Mathematical modeling of drug release from formulations and utilization of non-linear regression to understand drug dissolution
- Ability to develop pharmacokinetic models from plasma concentration data to explain drug disposition in the body
- Development of models to understand drug degradation

Institute of Chemical Technology, Mumbai

2005-2007

Master of Pharmaceutical Sciences

Thesis project: Studies on Carotenoids

- Extracted, purified and characterized a carotenoid pigment, capsanthin from *Capsicum annum*
- Developed a water-miscible paprika oleoresin formulation utilizing a surfactant and co-solvent system

Other research projects:

- Assisted in the formulation of an aloe vera based lotion
- Developed a simple and efficient method for extraction of a phytoconstituent, rhein from *Cassia angustifolia* (senna) leaves

Principal K.M. Kundnani College of Pharmacy, Mumbai

2001-2005

Bachelor of Pharmaceutical Sciences

WORK EXPERIENCE

Alpha MD LifeSciences, Mumbai

2016 July-2020 February

Head of Quality

- Responsible for creating presentations and training slides for pharmaceutical industry personnel on implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) in pharmaceutical manufacturing
- Developed and delivered a presentation on Process Validation and statistical procedures used in validation to the manufacturing and R&D staff of generic pharmaceutical company in India

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- Preparation of training modules in Good Manufacturing Practices (GMP) to be delivered to relevant industry personnel
- Data handling and statistical analysis of several clinical and observational studies in the areas of bariatric, trauma and orthopedic surgeries for various KOLs across India
- Developed a health economic model to assess the cost-effectiveness of an intervention to reduce Surgical Site Infections (SSI) across common surgical procedures in the areas of obstetrics/gynecology, orthopedics, cardiovascular, general and oncology for a multinational healthcare company in Mumbai, India
- Worked on and presented proposals for development of economic models mimicking disease progression in the areas of cardiovascular and bariatric surgery for multinational companies
- Worked on an IND submission of a drug for the treatment of opioid addiction and withdrawal to be submitted to USFDA for Phase I clinical trial
- Worked on validation of a questionnaire related to insomnia for a Mumbai-based pharmaceutical company
- Developed a statistical method to identify out-of-trend data for solid dosage form quality characteristics
- Involved in preparation of in-house Standard Operating Procedures (SOPs) for quality aspects of clinical trials and data handling and statistical analyses
- Carried out in-house audits for SOPs and various quality-related aspects of the company

Duquesne University, Pittsburgh, PA, USA

2009-2014

Graduate Teaching Assistant

- Taught pharmaceutical compounding practices to undergraduate pharmacy students
- Assisted in the teaching of the subject of Pharmaceutics to undergraduate pharmacy students and grading of papers for this subject
- Co-instructed a course on Process Analytical Technology (PAT) delivered to Food and Drug Administration (FDA) review staff on tableting equipment, tablet quality control and basic scientific principles related to tableting

Haffkine Institute, Mumbai

2004 May-July

Summer Intern

- In-Plant training in Production, Quality Control and Quality Assurance of liquid dosage forms as a part of the Bachelor of Pharmaceutical Sciences program

PEER-REVIEWED PUBLICATIONS

1. **Dalal, N.**, Buckner, I.S. and Wildfong, P.L.D. Experimental Determination and Theoretical Calculation of the Eutectic Composition of Cefuroxime Axetil Diastereomers. AAPS PharmSciTech, 2017 doi:10.1208/s12249-017-0739-8
2. Vasa, D.M., **Dalal, N.**, Katz, J.M., Roopwani, R., Nevrekar, A., Patel, H., Buckner, I.S. and Wildfong, P.L.D. Physical Characterization of Drug: Polymer Dispersion Behavior in Polyethylene Glycol 4000 Solid Dispersions Using a Suite of Complementary Analytical Techniques. Journal of Pharmaceutical Sciences, 2014, 103 (9): 2911-2923
3. Laddha, K.S., **Mehta, N.** A modified method for isolation of rhein from senna. Indian Journal of Pharmaceutical Sciences, 2009, 71 (2), 128-129
4. Laddha, K.S., **Mehta, N.** Solubilization of paprika oleoresin. Chemical Weekly, July 2008

POSTER AND PODIUM PRESENTATIONS

1. **Dalal N.** Quality by Design (QbD) in Pharmaceutical Product Development: Deciphering QbD Terminology. 2017 QbD in Pharma Development World Congress, Hyderabad, India

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2. Vasa, D.M., **Dalal, N.**, Nevrekar, A., Roopwani, R., Katz, J.M., Patel, H., Wildfong, P., Buckner, I.S. Persistent Amorphous PEG 4000 and Recrystallization Behavior in High Drug-Load API/PEG 4000 Solid Dispersions. 2013 AAPS Annual Meeting Poster
3. **Dalal N.**, Vasa, D.M., Roopwani, R., Nevrekar, A., Katz, J.M., Patel, H., Buckner, I.S. and Wildfong, P. Categorization of Drug Miscibility in API:PEG 4000 Solid Dispersions Using Thermal Analysis and Powder X-Ray Diffraction. 2013 AAPS Annual Meeting Poster
4. **Dalal N.**, Buckner, I.S. Solubility Studies on the Diastereomers of Cefuroxime Axetil. 2013 Duquesne University Symposium Poster
5. **Dalal N.**, Buckner I.S. Binary Solid-Liquid Phase Diagram of Diastereomers of Cefuroxime Axetil. 2012 AAPS Annual Meeting Poster
6. **Dalal, N.**, Buckner, I.S. Interactive Mixtures for Dissolution Rate Enhancement of Cefuroxime Axetil. 2012 American Institute of Chemical Engineers (AIChE) Annual Meeting Podium Presentation
7. **Dalal, N.**, Buckner, I.S. Effect of solid form of cefuroxime axetil on Solubility and Dissolution Behavior. 2011 Duquesne University Symposium Poster
8. Nevrekar, A., **Dalal, N.**, Buckner, I.S. Design of a protocol using heat capacity and isothermal calorimetric measurements for predicting physicochemical processed in multicomponent systems. 2011 Duquesne University Symposium poster
9. Buckner, I.S., **Dalal, N.**, Radaduen, T., Zhong, Z., Huang, H-S., Qiu, J., Kirsch, L.E. Excipient effects on the solid-state stability of gabapentin. 2010 AAPS Annual Meeting Poster

TRAININGS AND MEETINGS

1. Participated in a training on 'Application of Statistical tools in Pharmaceuticals & Biotech using Minitab 17' organized by QSutra in Mumbai, India
2. Participated in the 4th International 'QbD in Pharma Development World Congress) organized by SelectBio in Hyderabad, India

AWARDS AND HONORS

1. Award from the University of Mumbai and the Indian Pharmaceutical Association for scoring the highest percentage of marks in the Final year Bachelor of Pharmaceutical Sciences Examination, 2005
2. Award from Principal K.M. Kundnani College of Pharmacy for securing the highest percentage of marks in the Bachelor of Pharmaceutical Sciences Examination, 2003, 2004 and 2005

PROFESSIONAL MEMBERSHIPS

American association of Pharmaceutical Scientists (AAPS)	2009-Present
Phi Kappa Phi Honor Society	2010-2014