

# Dana E. Moseson

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## EDUCATION

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| <b>Ph.D. Candidate in Industrial and Physical Pharmacy</b><br>Purdue University, West Lafayette, IN<br>NSF Graduate Research Fellow<br><i>Advisor:</i> Lynne S. Taylor, Ph.D.<br><i>Committee:</i> Zoltan K. Nagy, Ph.D. (Chemical Engineering), Qi (Tony) Zhou, Ph.D. (IPPH), Stephen R. Byrn, Ph.D. (IPPH)<br><i>Project Title:</i> Origin and Significance of Residual Crystallinity in Hot Melt Extruded Amorphous Solid Dispersions | Expected May 2021<br>GPA 4.0/4.0 |
| <b>B.S. in Life Science</b><br>Pennsylvania State University, University Park, PA  | May 2005<br>GPA 3.6/4.0          |

## RESEARCH EXPERIENCE

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| <b>Graduate Research Assistant</b><br>Purdue University, West Lafayette, IN<br>Conduct a self-directed research program focused on amorphous solid dispersion (ASD) formulations and hot melt extrusion (HME) manufacturing processes; mentored several undergraduate students. Project goals include: <ul style="list-style-type: none"><li>• Provide a process design strategy to eliminate or minimize residual crystallinity in HME ASDs, while simultaneously avoiding thermal degradation.</li><li>• Elucidate the critical attributes of residual crystals which influence the non-sink dissolution performance and physical stability of HME ASDs.</li><li>• Apply innovative analytical techniques to image and characterize crystals found in HME ASDs to understand the effects of processing conditions on residual crystals and elucidate critical mechanistic factors influencing drug crystallization in the solid and solution states.</li><li>• Probe the mechanism and kinetics of crystal dissolution in polymer melts.</li></ul> | May 2016 – present  |
| <b>Undergraduate Research Assistant</b><br>Purdue University, West Lafayette, IN<br>Conducted experiments concerning the decay and stability of 1-dimensional waves.   | Jan 2002 – May 2003 |

## JOURNAL PUBLICATIONS

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### **Peer Reviewed/Accepted:**

1. **Moseson, D.E.**, A.S. Parker, S.P. Beaudoin, & L.S. Taylor. Amorphous solid dispersions containing residual crystallinity: Influence of seed properties and polymer adsorption on dissolution performance. *European Journal of Pharmaceutical Sciences*, 146, 2020. DOI: 10.1016/j.ejps.2020.105276
2. Elkhabaz, A., **D.E. Moseson**, J. Brouwers, P. Augustijns, & L.S. Taylor. Interplay of supersaturation and solubilization: Lack of correlation between concentration-based supersaturation measurements and membrane transport rates in simulated and aspirated human fluids. *Molecular Pharmaceutics*, *Accepted*, 2019. DOI: 10.1021/acs.molpharmaceut.9b00956
3. **Moseson, D.E.**, A.S. Parker, C.J. Gilpin, A.A. Stewart, S.P. Beaudoin, & L.S. Taylor. Dissolution of Indomethacin Crystals into a Polymer Melt: Role of Diffusion and Fragmentation. *Crystal Growth & Design*, 19, 3315-3328, 2019. DOI: 10.1021/acs.cgd.9b00200
4. **Moseson, D.E.**, N.A. Mugheirbi, A.A. Stewart, & L.S. Taylor. Nanometer-Scale Residual Crystals in a Hot Melt Extruded Amorphous Solid Dispersion: Characterization by Transmission Electron Microscopy. *Crystal Growth & Design*, 18, 7633-7640, 2018. DOI: 10.1021/acs.cgd.8b01435
5. **Moseson, D.E.**, & L.S. Taylor. The application of temperature-composition phase diagrams for hot melt extrusion processing of amorphous solid dispersions to prevent residual crystallinity. *International Journal of Pharmaceutics*, 553, 454-466, 2018. DOI: 10.1016/j.ijpharm.2018.10.055
6. Moseson, A.J., **D.E. Moseson**, & M.W. Barsoum. High Volume Limestone Alkali-Activated Cement Developed by Design of Experiment. *Cement & Concrete Composites*, 34, 328-336, 2012. DOI: 10.1016/j.cemconcomp.2011.11.004
7. Segur, H., D. Henderson, J. Carter, J. Hammack, C.-M. Li, **D. Pheiff**, & K. Socha. Stabilizing the Benjamin-Feir Instability. *Journal of Fluid Mechanics*, 539, 229-271, 2005. DOI: 10.1017/S002211200500563X

### **In Preparation/Under Review:**

8. Saboo, S., **Moseson, D.E.**, U.S. Kestur, & L.S. Taylor. Patterns of drug release as a function of drug loading from amorphous solid dispersions: A comparison of five different polymers, 2020. Submitted
9. **Moseson, D.E.**, M.A. Jordan, D.D. Shah, I.D. Corum, & L.S. Taylor. Application and Limitations of Thermogravimetric Analysis to Delineate the Hot Melt Extrusion Chemical Stability Processing Window, 2020. In Preparation
10. **Moseson, D.E.**, A. Eren, K.J. Altman, I.D. Corum, Z.K. Nagy, & L.S. Taylor. Impact of Particle-Level Attributes on Amorphization Rate During Hot Melt Extrusion Processing of Amorphous Solid Dispersions, 2020. In Preparation
11. **Moseson, D.E.**, I.D. Corum, A. Lust, K.J. Altman, A. Eren, Z.K. Nagy, & L.S. Taylor. Amorphous Solid Dispersions Containing Residual Crystallinity: Competition Between Dissolution and Matrix Crystallization, 2020. In Preparation
12. Ueda, K., **Moseson, D.E.**, Pathak, V., & L.S. Taylor. Effect of polymer species on maximum free drug concentration in aqueous phase revealed by quantitative nuclear magnetic resonance technique: A consideration on polymer chemical structure, molecular weight, and dose concentration of drug and polymer, 2020. In Preparation
13. Elkhabaz, A., **D.E. Moseson**, & L.S. Taylor. Influence of simulated and aspirated human fluids on crystallization kinetics from supersaturated solutions. In Preparation, 2020. In Preparation

## JOURNAL PUBLICATIONS (continued)

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14. Chen, Y-C, **Moseson, D.E.**, Y. Li, & L.S. Taylor, K. Park, & Y. Yeo. Development In Preparation of hot-melt extruded drug/polymer matrix for sustained delivery of meloxicam, 2020.
15. Saboo, S., **Moseson, D.E.**, Bapat, P., U.S. Kestur, & L.S. Taylor. Impact of Surfactant Level on Congruent Release Behavior from Amorphous Solid Dispersions, 2020. In Preparation

## FELLOWSHIPS AND AWARDS

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|  |                     |
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| IPEC Foundation Graduate Student Award (\$1500)  | November 2019       |
| Gordon Research Conference Top 25 Poster Award   | June 2019           |
| College of Pharmacy Travel Award (\$1000)  | February 2019       |
| National Science Foundation Graduate Research Fellowship (NSF GRFP), \$34,000/yr stipend for 3 years | June 2018 – present |
| Purdue Graduate School Summer Research Grant Award (\$3300)  | Summer 2017         |

## TEACHING EXPERIENCE

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### Graduate Teaching Assistant

Purdue University, West Lafayette, IN

Principles of Pharmacokinetics

Fall 2016

Drug Discovery & Development II

Spring 2017

Provided logistical support to instructors; mentored and tutored students; hosted office hours; graded homework, exams, and presentations.

## RESEARCH MENTORSHIP EXPERIENCE

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### Research Mentor/Supervisor, Purdue University, West Lafayette, IN

Undergraduate Students

Kevin J. Altman

Fall 2018 – present

Isaac D. Corum

Summer 2019 – present

Madison A. Jordan

Summer 2019

Visiting Researchers

Benedito Roberto de Alvarenga, Jr. (Federal University of São Carlos, Brazil)

January 2020 – present

## VOLUNTEERING AND SERVICE

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| Abstract reviewer, American Association of Pharmaceutical Scientists (AAPS) annual meeting | 2020       |
| Judge, Virtual Purdue Undergraduate Research Conference                                    | April 2020 |
| Abstract reviewer, AAPS annual meeting   | 2019       |

## INDUSTRY EXPERIENCE

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### **Emerson Resources, Inc.**, Norristown, PA

*Quality Systems Coordinator*

Dec 2012 – Aug 2016

Spearheaded projects to bring company (30-50 employees) into cGMP compliance. Provided QA oversight of GMP manufacturing operations.

- Executed quality management systems (QMS) improvements through SOP revision, training, internal audits, and trending.
- Developed and implemented environmental monitoring, supplier qualification, and risk management programs.
- Reviewed and approved manufacturing and packaging batch records.
- Released Phase I/II clinical trial materials and excipients.

*Senior Formulation Scientist*

Dec 2011 – Dec 2012

*Formulation Scientist & Analytical Chemist*

Aug 2006 – Dec 2011

Coordinated the technical strategy for 25+ NCE and generic drug projects, coordinating with all stakeholders, including clients, development, manufacturing, QA, and QC. Developed quality systems for the analytical laboratory.

- Developed solid, liquid, and semi-solid formulations to meet client-defined objectives, with emphasis on feasibility, robustness, simplicity, and manufacturability; delivered 80+ GMP Phase I/II clinical batches for 20+ clients.
- Supervised and trained laboratory technicians in development and manufacturing operations; mentored interns.
- Co-invented and patented several innovations.
- Authored and executed IQ/OQ/PQ protocols.
- Developed and coordinated the cold chain program.
- Authored and reviewed GMP documentation (SOPs, batch records).
- Represented the company in a sworn deposition regarding intellectual property for a client.

### **Reckitt Benckiser, Inc.**, Montvale, NJ

*Product Development Scientist, Lavatory Care*

June 2005 – Aug 2006

Formulated cleaning products to enhance performance, profitability, and claims.

### **Pfizer, Inc.**, Groton, CT

*Intern, Analytical Research and Development*

May 2004 – Aug 2004

Developed a robust analytical method to characterize crystallinity of a high-profile Phase III spray-dried dispersion (SDD) product.

### **McNeil Consumer and Specialty Pharmaceuticals**

Fort Washington, PA, *Co-op*, Research and Development

June 2003 – Jan 2004

Partnered with principal scientist to formulate a sustained release dosage form using a novel coating technology.

## TECHNICAL SKILLS

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### Product Development:

- Solid dose formulation and process development (e.g. tablets, capsules, powders, multi-particulates), including amorphous solid dispersions, techniques for solubility enhancement, modified and controlled release, granulation, tablet compaction optimization, and specialty coating applications
- Liquid, semi-solid, and specialty formulations, including oral solutions and suspensions, suppositories, lozenges, ODTs, and mini-tabs
- Scale-up and technology transfer, IQ/OQ/PQ, Design of Experiments (DOE)
- Theoretical and experiential knowledge of the full range of excipients
- Controlled substances management
- Equipment/manufacturing processes: hot melt extrusion, wet and dry granulation, fluid bed coating, blending, tableting, encapsulation, perforated pan coating
- Microscopy, analytical testing, and solid state characterization: SEM, TEM, PLM, XRPD, DSC, TGA, dissolution, UV-Vis, HPLC, Micro-CT
- Color matching by CIELAB color space

### Quality Assurance:

- Quality management systems administration (SOPs, change control, CAPA, stability program, deviations and investigations, OOS/OOT, risk management, data integrity)
- Internal audits, training, quality agreements, supplier qualification
- Batch release, batch record and GMP document review

### Technical Writing:

- Journal publications, batch records, SOPs, technical reports, document editing

### Project Management:

- Client relations, design and planning, resource allocation, procurement

## ADDITIONAL TRAINING

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| Lyo101: Lyophilization Formulation and Process Development<br>(LyoHUB at Purdue University) | July 2017   |
| Making Medicines: The Process of Drug Development (Eli Lilly online course)                 | May 2017    |
| Mixture Design of Experiments (StatEase)  | August 2007 |

## ORAL PRESENTATIONS

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1. **Moseson, D.E.** and L.S. Taylor. Insights into Crystal Dissolution and Crystal Growth using Transmission Electron Microscopy. *Center for Pharmaceutical Development (CPD) Meeting* (West Lafayette, IN, May 2019).
2. **Moseson, D.E.** and L.S. Taylor. Hot Melt Extrusion Process Design of Amorphous Solid Dispersions Based on Phase Diagrams. *Purdue University Industrial and Physical Pharmacy Departmental Seminar* (West Lafayette, IN, February 2018).
3. **Pheiff, D.** and D. Henderson. Damping and Stability of Deep-Water Wavetrains. *5th Annual Nebraska Conference for Undergraduate Women in Mathematics* (Lincoln, NE, February 2003).

## POSTER PRESENTATIONS

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1. Corum, I.D., **Moseson, D.E.**, A. Lust, & L.S. Taylor. Competition of dissolution and matrix crystallization in amorphous solid dispersions containing residual crystals. *Virtual Purdue Undergraduate Research Conference* (Purdue University, West Lafayette, IN, April 2020).
2. **Moseson, D.E.**, Corum, I.D, A.S. Parker, S.P. Beaudoin, & L.S. Taylor. Dissolution outcomes of amorphous solid dispersions containing residual crystals. *College of Pharmacy Graduate Students Research Symposium* (Purdue University, West Lafayette, IN, November 2019).
3. **Moseson, D.E.** & L.S. Taylor. Crystal Seed Growth Poisoning by Polymeric Additives in Non-Sink Dissolution of Amorphous Solid Dispersions Containing Residual Crystallinity. *2019 AAPS PharmSci 360 Annual Meeting* (San Antonio, TX, November 2019).
4. **Moseson, D.E.**, K.J. Altman, & L.S. Taylor. Influence of Drug Particle Size on Hot Melt Extrusion Processing and Product Characteristics of Bicalutamide-PVPVA Amorphous Solid Dispersions. *2019 AAPS PharmSci 360 Annual Meeting* (San Antonio, TX, November 2019).
5. **Moseson, D.E.**, A.S. Parker, C.J. Gilpin, A.A. Stewart, S.P. Beaudoin, & L.S. Taylor. Dissolution of Indomethacin Crystals into a Polymer Melt: Role of Diffusion and Fragmentation. *2019 AAPS PharmSci 360 Annual Meeting* (San Antonio, TX, November 2019).
6. **Moseson, D.E.**, Corum, I.D, A.S. Parker, S.P. Beaudoin, & L.S. Taylor. Dissolution outcomes of amorphous solid dispersions containing residual crystals. *Center for Pharmaceutical Processing Research (CPPR) Meeting* (University of Minnesota, Minneapolis, MN, October 2019).
7. Corum, I.D, **D.E. Moseson**, & L.S. Taylor. Impact of Residual Crystallinity on Dissolution Performance of Amorphous Solid Dispersions. *Purdue Summer Research Symposium* (Purdue University, West Lafayette, IN, July 2019).
8. Jordan, M.A, **D.E. Moseson**, & L.S. Taylor. Investigation of Thermogravimetric Analysis Methods to Characterize Thermal Degradation of Amorphous Drug and Polymer Systems. *LSAMP Summer Research Symposium* (Purdue University, West Lafayette, IN, July 2019).
9. **Moseson, D.E.**, N.A. Mugheirbi, A.S. Parker, C.J. Gilpin, A.A. Stewart, S.P. Beaudoin, & L.S. Taylor. Microstructural Progression of Crystal Dissolution into Polymer Melts under Quiescent and Dynamic Conditions. *2019 Gordon Research Conference on Preclinical Form and Formulation for Drug Discovery* (Waterville Valley, NH, June 2019). \*Top 25 GRC poster award winner
10. Elkhazab, A, **D.E. Moseson**, S. Sarkar, G.J. Simpson, P. Augustijns, & L.S. Taylor. Characterization of the Phase Behavior of Supersaturated Solutions in Biorelevant Media and Aspirated Human Fluids. *2019 Gordon Research Conference on Preclinical Form and Formulation for Drug Discovery* (Waterville Valley, NH, June 2019). \*Top 4 GRS poster award winner, top 25 GRC poster award winner
11. **Moseson, D.E.**, N.A. Mugheirbi, A.S. Parker, C.J. Gilpin, A.A. Stewart, S.P. Beaudoin, & L.S. Taylor. Microstructural Progression of Crystal Dissolution into Polymer Melts under Quiescent and Dynamic Conditions. *Center for Pharmaceutical Processing Research (CPPR) Meeting* (University of Connecticut, Storrs, CT, May 2019).

## POSTER PRESENTATIONS

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12. **Moseson, D.E.**, N.A. Mugheirbi, A.S. Parker, C.J. Gilpin, A.A. Stewart, S.P. Beaudoin, & L.S. Taylor. Microstructural Progression of Crystal Dissolution into Polymer Melts under Quiescent and Dynamic Conditions. *2019 Garnet E. Peck Symposium* (Purdue University, West Lafayette, IN, May 2019).
13. Altman, K.J., **D.E. Moseson**, & L.S. Taylor. The effect of drug particle size, temperature, and residence time on hot melt extrusion processing of amorphous solid dispersions. *Purdue Undergraduate Research Conference* (Purdue University, West Lafayette, IN, April 2019).
14. **Moseson, D.E.** & L.S. Taylor. The application of temperature-composition phase diagrams for hot melt extrusion processing of amorphous solid dispersions to prevent residual crystallinity. *College of Pharmacy Graduate Students Research Symposium* (Purdue University, West Lafayette, IN, November 2018).
15. **Moseson, D.E.** & L.S. Taylor. Exploiting Melting Point Depression for Hot Melt Extrusion Processing of Amorphous Solid Dispersions. *Center for Pharmaceutical Processing Research (CPPR) Meeting* (Purdue University, West Lafayette, IN, October 2018).
16. **Moseson, D.E.** & L.S. Taylor. Hot Melt Extrusion Processing Regimes Based on Temperature-Composition Phase Diagrams. *2018 Garnet E. Peck Symposium* (Purdue University, West Lafayette, IN, March 2018).
17. **Moseson, D.**, N. Kirkland, & S.P. Levine. Comparison of Talc and PlasACRYL T20 in Wurster Coating with Eudragit RS30D. *2011 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition* (Washington DC, October 2011).
18. **Moseson, D.**, N. Kirkland, & S.P. Levine. GMS as Effective Anti-Agglomeration Agent in Drug Layering of MCC Spheres. *2011 AAPS Annual Meeting and Exposition* (Washington DC, October 2011).
19. **Moseson, D.**, N. Kirkland, & S.P. Levine. GMS as Effective Anti-Agglomeration Agent in Drug Layering of MCC Spheres. *2011 Controlled Release Society Annual Meeting and Exposition* (National Harbor, MD, 2011).
20. **Moseson, D.** & S.P. Levine. Evaluation of Various Drug-Layering Substrates for Extended Release Tablets. *2010 AAPS Annual Meeting and Exposition* (New Orleans, LA, 2010).
21. **Moseson, D.**, R. Mulcrone, S.P. Levine, N. Kirkland, & T. Smith. Optimization of Aqueous Shellac Coating Formulations Using Design of Experiments. *2009 AAPS Annual Meeting and Exposition* (Los Angeles, CA, 2009).
22. **Moseson, D.**, R. Mulcrone, S.P. Levine, N. Kirkland, & T. Smith. Aqueous Shellac Coatings with Effective Taste Masking and Stable Release Properties. *2008 AAPS Annual Meeting and Exposition* (Atlanta, GA, 2008).
23. **Moseson, D.**, J. Isaac, & S.P. Levine. Evaluation of Processing and Physical Properties of Effervescent Tablets with Water Soluble Lubricants Using Design of Experiments. *2008 AAPS Annual Meeting and Exposition* (Atlanta, GA, 2008).
24. **Pheiff, D.**, S.P. Levine, & C.A. Signorino. Comparing Moisture Vapor Barrier Properties of Pigmented Films Using Lakes and Dyes and as Applied Out of Various Solvent Systems. *2007 AAPS Annual Meeting and Exposition* (San Diego, CA, 2007).
25. **Pheiff, D.**, S.P. Levine, N. Kirkland, & C.A. Signorino. Color Variation of Lakes and Dyes in Tablet Coating with Various Solvent Systems. *2007 AAPS Annual Meeting and Exposition* (San Diego, CA, 2007).
26. **Pheiff, D.**, S.P. Levine, N. Kirkland, & C.A. Signorino. Adhesive Properties in Tablet Coating by Variation of Colorants and Solvent Systems. *2007 AAPS Annual Meeting and Exposition* (San Diego, CA, 2007).

## POSTER PRESENTATIONS

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27. **Pheiff, D.**, R. Joseph, & H. Clarke. Phase Separation, Crystallization, & Characterization of CP-529,414 Spray Dried Dispersions (SDDs). (Pfizer, Groton, CT, August 2004).

## PATENTS

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1. Lu, R.Z. & **D. Moseson**. Dispensing device for toilet bowl. Patent number US 8,966,674 B2 (2015).
2. Bowe, C.M., J.C. Carter, **D.E. Moseson**, & S.P. Levine. Controlled-release solid dosage forms of mesalamine. Application number US2015/0056275 A1 (2015).
3. Arora, N., R.Z. Lu, & **D. Moseson**. Method for production of dispensing devices. Patent number US 8,858,879 B2 (2014).
4. Paborji, M., R.V. Tuohy, S.P. Levine, **D.E. Moseson**, & N. Kirkland. Pharmaceutical Formulations of Pilocarpine. Application number US2014/0105976 A1 (2014).
5. Arora, N., C.B. King, R.Z. Lu, T. Nguyen, **D. Pheiff** [sic], & S. Wu. Process for manufacturing improved dispensing devices. Patent number US 8,685,304 B2 (2014).
6. Arora, N., C.B. King, R.Z. Lu, T. Nguyen, **D. Moseson**, & S. Wu. Dispensing devices. Patent number US 8,615,820 B2 (2013).
7. Mayes, B.A., A.M. Moussa, R. Gasparac-Knezic, A.J. Stewart, R.V. Tuohy III, & **D.E. Moseson**. Pharmaceutical Compositions of 2'-C-Methyl-Guanosine, 5'-[2[(3-Hydroxy-2,2-Dimethyl-1-Oxopropyl)Thio]Ethyl N-(Phenylmethyl)Phosphoramidate]. Application number US2013/0217644 A1 (2013).
8. Cheung, T.W., R.Z. Lu, **D. Moseson**, & S. Wu. Solid treatment blocks for sanitary appliances. Patent number US 8,367,595 B2 (2013).
9. King, C.B., R. Koontz, R.Z. Lu, T. Nguyen, **D. Moseson**, & S. Wu. Lavatory dispensing devices. Application number US2010/0146687 A1 (2010).
10. King, C. & **D. Pheiff**. Hanger for a lavatory dispensing device. Patent number US D555,758 S (2007).
11. King, C., N. Arora, & **D. Pheiff**. Cageless lavatory dispensing device. Patent number US D548,304 S (2007).