Kaushalendra Chaturvedi, Ph.D.

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PROFESSIONAL SUMMARY

- Ph.D. in Pharmaceutics and Drug Design.
- Over nine years of experience in pharmaceutical field with 2.5 years of industrial experience in solid form screening, crystallization, pre-formulation and formulation development.
- Solid knowledge of pre-formulation and materials science activities including form screening, salt/co-crystal screening, crystallization process development, solid state characterization, and solid-state methods for dissolution and solubility improvement.
- Experienced in characterization of API/excipient/dosage form physico-chemical properties impacting drug release and *in-vitro* and *in-vivo* of drug product performance. Experienced in formulation development and processing technology.
- Demonstrated leadership in planning, executing, and completing research for publications (21 completed, 3 in progress). Strong record of publication, presentation and communication skills.
- Reviewer for publication house and international scientific communities including Elsevier, Springer, Royal Society of Chemistry, Tylor and Francis, American Association of Pharmaceutical Scientists, DOVE publications, Material Science Research India, and NERDG.
- Co-advisor/committee member in Ph.D. doctoral dissertation work for a Ph.D. candidate.
- Awarded by Rho-Chi Society and Who's Who for extraordinary scholastic and leadership performance.
- Self-motivated, target-oriented, can work independently as well as collaborative, desired to work in flexible and dynamic environment.
- Ability to prioritize and schedule work to meet the demand.

EDUCATION

- ***Ph.D. in Pharmaceutical Sciences with specialization in Pharmaceutics*** GPA: 3.81/4.0
  Long Island University, Brooklyn, NY, USA Jan 2015-May 2019
- **Master of Science in Pharmaceutical Sciences with specialization in QAT** GPA: 3.85/4.0
  Pune University, Pune, India Sep 2009-Nov 2011
- **Bachelor of Pharmacy**, GPA: 3.75/4.0
  Pune University, Pune, India Jun 2005-May 2009

WORK EXPERIENCE

1. ***Senior Research Scientist***
   J-Star Research Inc, (A Member of the Porton Group) *Aug 2019- Present*

- **Successfully delivered 10 projects**.
- Worked on **more than 10 pharmaceutical molecules** involving therapeutic areas such as **anti-addiction**, Relapsed/Refractory Acute Leukemias, Antineoplastic, **Steatohepatitis**, Idiopathic Pulmonary Fibrosis, Primary Sclerosing Cholangitis, **Advanced Solid Tumor**, Small Cell Lung Cancer, Colorectal Cancer, and **Cardiovascular**.
- Salt and co-crystal form screening of drug candidates including hydrates, solvates and polymorphs.
- Key member of a team responsible **for setting-up formulation development laboratory** designed to provide a support in solving the scientific problems associated with formulations and supplying finished dosage forms for pre-clinical and clinical studies.
- **Evaluate crystal forms** for acceptability as drug substances as it relates to chemical manufacturing and formulation into pharmaceutical products.
- Performing solid state physical and chemical characterization of molecules of pharmaceutical relevance including solid-state characterization using X-ray powder diffraction, thermal analysis, spectroscopy and particle morphology characterization.
- Solving scientific problems using contemporary solid state experimental and computational techniques.
- Actively involved in multidisciplinary project teams to define and implement screening and characterization strategies according to project timelines.

2. Senior Research Scientist
Lachman Institute for Pharmaceutical Analysis Laboratory, LIU Sep 2016- May 2019

- Worked as a senior scientist on a **US-FDA funded project** entitled 'Statistically Based Pharmaceutical Quality Standards'
- Worked on projects and other activities conducted under good manufacturing practices **(GMP's)**.
- Developed, and validated protocol for novel fiber optic dissolution system for pharmaceutical drug testing.
- Designed and developed first ever idea proposed of "**New Prior Knowledge**" in pharmaceutical industry with National Institute of Pharmaceutical Technology and Education (**NIPTE**).
- Worked on multiple research projects focusing on solid state changes of drugs and its impact on physical, chemical and pharmacological properties.
- Sample analysis/ material characterization of samples from pharmaceutical companies, contract research and manufacturing organizations (**CRO's & CMO's**) and compounding pharmacies.
- Writing and reviewing current and new standard operating procedures (SOPs) associated with instruments and laboratory practices.

3. Research Assistant
Natoli Institute for Industrial Pharmacy, Research and Development, LIU May 2015-May 2019

- Worked with multi-national tablet tooling company "**Natoli Engineering**" on troubleshooting existing manufacturing process as well as development of new solid oral dosage forms.
- Conducted research in collaboration with **multi-national companies** on changes in the excipient functionality under different pharmaceutical manufacturing techniques.
- Worked in collaboration with pharmaceutical and excipient companies on pharmaceutical manufacturing process improvement.
- Trained industrial staff scientist and managers of pharmaceutical companies from **USA, Canada, Mexico, and Latin America** on different pharmaceutical unit operations including Granulation, Tableting, Fluidize Bed Drying, and Wurster Coating.
- Performed projects involving granulation, amorphous formulation development, hot melt extrusion, tablet coating and tableting.
- Conducted laboratory experiments and training sessions for PharmD students to trained them for **North American Pharmacist Licensure Examination** (NAPLEX).

4. Analytical Development-Intern
Ferring Pharmaceuticals Inc. New Jersey, USA May 2018-Aug 2018

- Assisted in designing and developing brand product for **ulcerative colitis targeted delivery**.
- Performed pre-formulation screening studies, designed and executed stability studies for microbead formulation.
- Surface characterization of beads inner and outer core using scanning electron microscopy (SEM), transmission and reflection microscopy.
- Characterization of drug in and coating on beads using thermal analysis i.e., DSC, TGA and DVS (Vapor sorption analyzer).
- Rheological characterization and stability of pectin solution used in formulations using Malvern Kinexus pro.
- Micro beads particle size analysis using Mastersizer 3000.

5. Scientific and Medical Writer
Crest Pre-media Solutions (A Springer Company), Pune, India Jan 2014- Dec 2014

- Reviewed and wrote updated **clinical trials** information and drug development programs information from the trial registry, clinical meetings, clinical conferences, publications from top medical journals and international conferences.
- **Training** new hires in tasks associated with the updating of existing clinical trial profiles and drug development profiles. Subject matter expert in clinical trial information writing and result writing.

6. Territory Manager
Medley Pharmaceuticals Pvt. Ltd, Mumbai, India Jan 2013- Dec 2013

- Developed effective strategies for identifying new markets to launch the new product in the market.

- Handled a team to promote the product and making a new market base for the same product.

AWARDS AND ACHIEVEMENT

- Included as **Reviewer Panel member** for Royal Society of Chemistry- Advances Journal (March 2021)
- Awarded as "**Reviewer of the Month**" By Material Science Research India (March 2021)
- Organized and managed virtual conference sponsored by J-Star Research, presented in the **USA, UK, India, China, Hongkong, and Singapore** (Year-2020 and 2021)
- Key member of the team responsible for establishing Drug Product Development group and **state of the art facility** at J-Star Research to support early formulation development, pre-clinical and clinical trial formulation development (Year-2019 to Present)
- Sr Research Analyst in **United States-Food and Drug Administration** sponsored project (Year 2016 to 2019)
- Received **funding** from Long Island University and Pfizer Pharmaceuticals on Project entitled "Modeling of Tablet Adhesion at Molecular Level by Thermal Analysis and Molecular Simulations" (Year-2018)
- Instructor in Tablet Formulation **workshops** organized for industrial scientist by Natoli Engineering and Long Island University (Year 2016-2019)
- **Rho Chi:** Outstanding Scholastic Achievement *National Award* by Beta Theta Chapter of Rho Chi Society (Year-2017)
- **Who's Who** Amongst Students in American Universities and Colleges *National Award* for admirable qualities, excellent scholastic record, participated in many worthwhile endeavors and exhibits promise of useful service to business and society (Year-2017)
- **Graduate Scholar Award** by Long Island University (Year-2015 and 2016)
- **Post Graduate Scholarship** *National Award* by All India Council for Technical Education, Ministry of Human Resource Development, Department of Higher Education (Government of India) (Year-2009 to 2011)

REVIEWER EXPERINCE

- Manuscript reviewed for *ChemComm* peer-reviewed scientific journal by Royal Society of Chemistry (CC-COM-01-2019-000397)
- Manuscript reviewed for *RSC Advances* peer-reviewed scientific journal by Royal Society of Chemistry (RA-ART-08-2018-006925)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-21-00144)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-20-00924)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-20-01156)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-21-00202)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-21-00450)
- Manuscript reviewed for *Polymer Bulletin* peer-reviewed scientific journal by Springer Science (POBU-D-21-00450)
- Manuscript reviewed for *Drug Testing and Analysis* peer-reviewed scientific journal by John Wiley & Sons (DTA-21-0124)
- Manuscript reviewed for *AAPS PharmSciTech* peer-reviewed scientific journal by Springer Science (AAPSPT-D-21-00292)
- Manuscript reviewed for *Pharmaceutical Development and Technology* peer-reviewed scientific journal by Tylor and Francis (PDT-2021-OR-0010)
- Manuscript reviewed for *Drug Delivery and Translational Research* peer-reviewed scientific journal by Springer Science (DDTR-D-21-00159)
- Manuscript reviewed for *European Journal of Pharmaceutical Sciences* peer-reviewed scientific journal by Elsevier (PHASCI-D-21-00575)
- Manuscript reviewed for *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy* peer-reviewed scientific journal by Dovepress (Title- Dissolution Profile Evaluation of Eight Brands of Metformin Hydrochloride Tablets Available in Jimma. Southwest Ethiopia)
- Manuscript reviewed for peer-reviewed scientific journal by *Material Science Research India* (Title- Antibacterial Properties of Scallop Shell Derived Calcium Hydroxide Powders)

- Manuscript reviewed for peer-reviewed scientific journal by *Material Science Research India* (Title- Bronsted Acid Catalyzed Synthesis of 2-(p-Tolyl)-2,3-Dihydro-1H-Perimidine and its Structural, FMO, Chemical and Thermochemical Study)
- Reviewed thirty-five posters from international conferences organized by *Americal Association of Pharmaceutical Scientists*
- Reviewed six posters from international conferences organized by *American Association of Pharmaceutical Scientists – Northeast Regional Discussion Group*

JUDGE/PANEL EXPERINCE

- Judge for Academic Research Award-Presentation Organized by American Association of Pharmaceutical Scientists – Northeast Regional Discussion Group (April 2021)
- Co-advisor for Doctoral candidate dissertation work
    - Student- Hatem Naseer, Long Island University
    - Research work entitled "Investigation and Prediction Of 3D Printed Dosage Forms Performance Using Thermal, Mechanical, And Rheological Analysis" Year 2019- Year 2021

RESEARCH ARTICLE PUBLICATIONS

1. Shah HS, **Chaturvedi K**, Dave RH, Morris KR. Molecular Insights into Warfarin Sodium 2-Propanol Solvate Solid Form Changes and Disproportionation Using a Low Volume Two-Stage Dissolution Approach. Molecular Pharmaceutics. 2021 Mar 9.

2. Rusha Sardhara, **Kaushalendra Chaturvedi**, Harsh S. Shah, Bhavani Prasad Vinjamuri, Antoine Al-Achi, Kenneth R. Morris, Rahul V. Haware. Predictive Performance Comparison of Computed Linear and Quadratic Multivariate Models for In-Situ UV Fiber Optics Tablet Dissolution Testing, European Journal of Pharmaceutical Sciences, March 2021.

3. Dangre, P.V., Dusad, P.P., Singh, A.D., **Chaturvedi K** et al. Fabrication of hesperidin self-micro-emulsifying nutraceutical delivery system embedded in sodium alginate beads to elicit gastric stability. Polym. Bull. (2021). https://doi.org/10.1007/s00289-020-03507-7

4. **Chaturvedi K**, Shah HS, Sardhara R, Nahar K, Dave RH, Morris KR. Protocol Development, Validation, and Troubleshooting of In-Situ Fiber Optic Bathless Dissolution System (FODS) for a Pharmaceutical Drug Testing. Journal of Pharmaceutical and Biomedical Analysis. (2020 Dec 7:113833).

5. Chalikwar, Shailesh S; Surana, Sanjay; Goyal, Sameer N; **Chaturvedi, Kaushalendra**; Dangre, Pankaj. Solid self-microemulsifying nutraceutical delivery system for hesperidin using quality by design: Assessment of biopharmaceutical attributes and shelf-life. Accepted to Journal of Microencapsulation. (2020)

6. Shah HS, **Chaturvedi K**, Dave R, Bates S, Haware RV, Morris KR. New Insights on Warfarin Sodium 2-Propanol Solvate Solid-State Changes Using Multivariate Approach. Crystal Growth & Design. (2020 Sep 24)

7. **Chaturvedi K**, Shah HS, Nahar K, Dave R, Morris KR. Contribution of Crystal Lattice Energy on the Dissolution Behavior of Eutectic Solid Dispersions. ACS omega. (2020) Apr 21;5(17):9690-701

8. Saddik J, **Chaturvedi K**, Dave R. Investigating the impact of manufacturing and formulation factors on the compatibility of acetaminophen tablets using Heckel and multivariate analysis. International Journal of Pharmaceutical Sciences and Research (IJPSR). (2020) (Accepted)

9. Shah, H. S., **Chaturvedi, K.**, Zeller, M., Bates, S., & Morris, K. (2019). A threefold superstructure of the anti-epileptic drug phenytoin sodium as a mixed methanol solvate hydrate. Acta Crystallographica Section C: Structural Chemistry, 75(9), 1213-1219

10. **Chaturvedi, K.K.,** (2019). Modeling of Adhesion in Tablet Compression at Molecular Level Using Thermal Analysis and Molecular Simulations (Doctoral dissertation, Long Island University, The Brooklyn Center)

11. Shah, H. S., **Chaturvedi, K.**, Hamad, M., Bates, S., Hussain, A., & Morris, K. (2019). New insights on solid- state changes in the levothyroxine sodium pentahydrate during dehydration and its relationship to chemical instability. AAPS PharmSciTech, 20(1), 39

12. **Chaturvedi, K.,** Gajera, B. Y., Xu, T., Shah, H., & Dave, R. H. (2018). Influence of processing methods on physico-mechanical properties of Ibuprofen/HPC-SSL formulation. Pharmaceutical development and technology, 23(10), 1108-1116

13. **Chaturvedi, K.** and R. Nanda (2010). "Hyphenated Gas Chromatography." International Journal of Pharmaceutical Sciences Review and Research 5(3): 18-27

14. Chitlange, S. S., **K. K. Chaturvedi,** et al. (2011). "UV Spectroscopic and Stability-Indicating TLC-Densitometric Method for Simultaneous Estimation of Salbutamol sulphate and Prednisolone in Pharmaceutical Dosage Form. Asian Journal of Research in Chemistry 4(5).

15. Chitlange, S. S., **K. K. Chaturvedi**, et al. (2011). "Development and validation of spectrophotometric and HPLC method for the simultaneous estimation of salbutamol sulphate and prednisolone in tablet dosage form. J Anal Bioanal Techniques 2(117): 2.

16. Chitlange, S. S., **K.K. Chaturvedi**, et al. (2011). "High-Performance Thin-Layer Chromatographic Estimation of Thiocolchicoside and Aceclofenac In Bulk and Pharmaceutical Dosage Forms. Inventi Rapid: Pharm Ana & Qual Assur.

17. Chitlange, S. S., **K.K. Chaturvedi**, et al. (2011). "Simultaneous Determination of Amoxicillin trihydrate and Ambroxol hydrochloride in solid dosage form by spectrophotometric and stability indicating RP-HPLC method. Asian Journal of Research in Chemistry 4(6): 1025-1030.

18. Chitlange, S. S., **K.K. Chaturvedi**, et al. (2011). "UV Spectrophotometric Estimation of Amoxicillin trihydrate and Ambroxol hydrochloride in Bulk and Combined Pharmaceutical Dosage Form. Inventi Impact: Pharm Ana & Qual Assur.

BOOK CHAPTER PUBLICATIONS

1. Dangre P, **Chaturvedi K,** Pofali P. Lipidic Nanoparticles: A Platform for Advancement in Drug Delivery Systems. In Molecular Chemistry and Biomolecular Engineering, September 2019 (pp. 191-213). Apple Academic Press, Canada (Hard ISBN: 9781771887922)

2. **Chaturvedi K,** Gajera B, Shah H. Challenges in Oral Delivery of Nutraceuticals: From Formulation Scale-up to Clinical Assessment. In Nutraceutical Delivery Systems-Promising Strategies for Overcoming Delivery Challenges, November 2021. Apple Academic Press, Canada (Hard ISBN: 9781774637166)

3. Vishal C. Gurumukhi, Sanjaykumar B. Bari, and **Kaushalendra Chaturvedi.** Solid Lipid Nanoparticles (SLNs): An Emerging Platform for Nutraceutical Delivery. In Nutraceutical Delivery Systems-Promising Strategies for Overcoming Delivery Challenges, November 2021. Apple Academic Press, Canada (Hard ISBN: 9781774637166)

4. **Chaturvedi K,** Gajera B, Shah H. Spay Drying. In Newer Solubilization Techniques for dissolution of Phytophenol. Apple Academic Press, Canada (under-review)

POSTER PRESENTATION

1. Shah HS, **Chaturvedi K**, Hamad M, Bates S, Hussain A, Morris KR. New Insights on Solid-State Changes in the Levothyroxine Sodium Pentahydrate during Dehydration and its Relationship to Chemical Instability. American Association of Pharmaceutical Scientists- Northeast Regional Discussion Group (NERDG) (Annual Conference-2019)

2. **Chaturvedi K,** Shah HS, Nahar K, Dave R, Morris KR. Contribution of Crystal Lattice Energy on the Dissolution Behavior of Eutectic Solid Dispersion. American Association of Pharmaceutical Scientists (Annual Conference-2018)

3. Nahar K, **Chaturvedi K**, Shah HS, Morris KR. Estimating Intrinsic Solubility of Metastable Form of Drugs Using Modified Nogami Method. American Association of Pharmaceutical Scientists (Annual Conference-2018)

4. **Chaturvedi K**, Shah HS, Nahar K, Dave R, Morris KR. Method development and validation scheme for In-Situ fiber optic probe/ bathless dissolution system for a pharmaceutical drug testing. National Institute of Pharmaceutical Technical Education, USA. (Annual Conference-2017)

5. Shah HS, **Chaturvedi K**, Nahar K, Dave R, Morris KR. Effect of operational changes and data analysis variables on dissolution testing using Symphony 7100/ Opt-diss 410. American Association of Pharmaceutical Scientists (Annual Conference-2017)

6. **Chaturvedi K**, Shah HS, Nahar K, Dave R, Morris KR. Method development and validation scheme for In-Situ fiber optic probe/ bathless dissolution system for a pharmaceutical drug testing. American Association of Pharmaceutical Scientists (Annual Conference-2017)

7. **Chaturvedi K**, Shah HS, Gajera B, Rathod V, Dave R. Effect of different grades of hydroxypropyl cellulose (HPC-SL and HPC-SSL) on physical and mechanical properties of Ibuprofen granules and tablets. American Association of Pharmaceutical Scientists (Annual Conference-2016)

MANUSCRIPT IN-PREPARATION

1. **Chaturvedi K**, Shah HS, Bates S, Morris KR, Dave R. Modeling of adhesion in tablet compression at molecular level using thermal analysis and molecular simulations- Part I. In-preparation. (2021)

2. **Chaturvedi K**, Shah HS, Bates S, Morris KR, Dave R. Modeling of adhesion in tablet compression at molecular level using thermal analysis and molecular simulations- Part II. In-preparation. (2021)

MEMBERSHIP AND VOLUNTEER

- American Chemical Society (ACS)
- American Association of Pharmaceutical Scientist (AAPS)
- International Society for Pharmaceutical Engineering (ISPE)
- American Association of Pharmaceutical Scientists – Northeast Regional Discussion Group (NERDG)
- Rho-Chi Society- Pharmaceutical Sciences (Rho-Chi)
- Institute of Scholars, India (InSc)

SKILLS

Materials Science and Product Development Skills:

- Crystal form screening, salt screening and crystallization process development
- Materials characterization of drug substances, excipients and finished drug products using Thermal Analysis, PXRD, SEM, Particle Size, Moisture Sorption, Thermal Microscopy, Reflection/Transmission Microscopy, and IR Spectroscopy.
- Developing and characterizing amorphous formulations using spray, freeze drying and thermal quench methods.
- Relating materials' physical properties and, their modification, to changes in melting point, solubility, glass forming ability and improved mechanical properties.
- Hands on using formulation equipment including but not limited to fluid bed processor, roller compactor, hi-coater, high shear mixer, hot melt extruder and single/multi-station rotary tablet press for formulating an oral solid dosage form from lab scale to manufacturing scale.

Molecular simulation and modeling:

Material Studio® expertise in studying crystal growth morphology, polymorph structures, molecular dynamics, adsorption studies relating molecular structure with physical properties and behavior.

Computer skills: Proficient in Material Studio (Biovia), Dynochem, Minitab 17, Microsoft Office, Empower, Chemstation, WinNonlin, and Simcyp.