



How to Develop Robust Solid Oral Dosage Forms: From Conception to Post-Approval

By Bhavishya Mittal

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How to Develop Robust Solid Oral Dosage Forms from Conception to Post-Approval uses a practical and hands-on approach to cover the development process of solid oral dosage forms in one single source. The book details all of the necessary steps from formulation through the post-approval phase and contains industry case studies, real world advice, and troubleshooting tips.

By merging the latest scientific information with practical instructions, this book provides pharmaceutical scientists in formulation research and development with a concrete look at the key aspects in the development of solid oral dosage forms.

- Focuses on important topics, such as robustness, bioavailability, formulation design, continuous processing, stability tests, modified release dosage forms, international guidelines, process scale-up, and much more
- Part of the *Expertise in Pharmaceutical Process Technology* series edited by Michael Levin
- Discusses common, real-world problems and offers both theoretical and practical solutions to these everyday issues

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Editorial Review

About the Author

Bhavishya Mittal is a Staff Fellow at the Office of Pharmaceutical Quality at the US Food and Drug Administration (FDA) in Silver Spring, MD. Previously, Bhavi was employed as a Senior Scientist in the Formulation Sciences department at Takeda Pharmaceuticals International Company based in Cambridge, MA. Bhavi has a PhD in Materials Engineering from the Pennsylvania State University and a BS in Chemical Engineering from Regional Engineering College, Jalandhar (India). Bhavi has 13 years of industrial experience in formulation and process development of various solid oral dosages of small therapeutic molecules (oncology, inflammation, and CNS indications) aimed for NDA and ANDA filings. He is the co-chair of the Formulation and Drug Delivery (FDD) working group at MassBio. He is the author/co-author of 1 patent, 10 peer-reviewed manuscripts, and numerous conference papers and posters published/presented in various international journals and conferences. He is an active member of various international professional societies such as AAPS and ISPE. His research interests include formulation design, process engineering, scale-up and tech-transfer, and computational modeling of pharmaceutical unit operations for solid oral dosage manufacturing.

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