

Book Review

Handbook of Pharmaceutical Granulation Technology, Second Edition. D. M. Parikh, Taylor and Francis, Boca Raton, Florida, 2005, Hardback, 656 pages, ISBN: 0824726472

Granulation is one of the oldest and most widely used technologies in pharmaceutical manufacturing. Although its origins are humble, it has in recent years developed into a sophisticated science providing unique advantages in the production of solid dosage forms. As the technology continues to expand, it is imperative that scientists, engineers, and students in the field be made aware of the new developments and current issues concerning pharmaceutical granulation. This is precisely the aim of the *Handbook of Pharmaceutical Granulation Technology, Second Edition* as it updates and expands the contents of the *First Edition* to include recent technological advances as well as changes in the regulatory climate.

The book begins with a detailed discussion on the theory of granulation from an engineering perspective which is a marked expansion on the granulation theory presented in the *First Edition*. The chapter is mathematically rigorous, providing an in-depth explanation of the major theoretical aspects of granulation technology. Chapters Three and Four are similar to the *First Edition* detailing drug and excipient characterization methods as well as the types, efficiencies, and processing parameters for commonly used binders and solvents. Chapters Six through Eleven address the core granulation technologies, i.e., spray drying, roller compaction, high-shear granulation, low-shear granulation, batch fluid bed granulation, single-pot processing, and extrusion spheronization. Each of these chapters has been expanded to include the latest findings, new works, and the best practices that have transpired since the *First Edition*. Chapters Twelve through Fourteen are new additions to the book dealing with the latest processing and formulation developments;

namely effervescent granulation, melt granulation/pelletization, and rapid release granulation. These technologies are gaining increased attention as of late for their unique processing capabilities and granulate properties. The latest developments in granulation as a continuous process are presented in Chapter Fifteen. Chapter Sixteen is a new chapter that deals with scale-up of granulation processes that, much like the updates to the previous chapters, indicates a recent movement toward understanding and manipulating granulation processes from an engineering perspective. This chapter focuses on general engineering approaches to scale-up, key granulation rate process affecting scale-up, and provides suggestions for the scale-up of fluid bed and high-shear granulators. Chapters Seventeen through Nineteen offer similar discussions to the previous edition of granulation sizing and characterization, as well as how granule properties affect drug bioavailability. Chapter Twenty is a new addition to the book concerning the FDA's Process Analytical Technology and its methodology for reducing variability and ensuring final product quality via monitoring and control strategies for key variables of a manufacturing process. Chapter Twenty-one is another new chapter that provides substantial detail regarding granulation process modeling and the reasons for modeling, specifically how models are applied to granulation systems and the resulting benefits that can be obtained. This chapter again illustrates how the application of engineering principles can improve the design, performance, and output of a granulation process. The final chapter, similar to the *First Edition*, focuses on regulatory issues in granulation with updated discussion of GMP, ICH, and ISO standards; FDA guidelines for scale-up and postapproval changes; as well as various aspects of process validation.

The *Handbook of Pharmaceutical Granulation Technology, Second Edition* provides a complete discussion of all relevant aspects of granulation technology from the

underlying theory to process technology and regulatory issues. The breadth and depth of the topics covered in this text make it an indispensable resource for scientists, engineers, and students involved in pharmaceutical granulation. The *Second Edition* picks up where the *First Edition* left off documenting the refinement and expansion of pharmaceutical granulation

technology as it has evolved from its rudimentary origins into a sophisticated science.

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