Drug Development and Industrial Pharmacy, 2010; 36(2): 127

informa
healthcare

Guest Editor's Comments

Coating of solid oral dosage forms is one of the oldest pharmaceutical processes still in existence today. One of the earliest references in the literature is about Rhazes (850–932 AD), who used the mucilage of psyllium seeds to coat pills with an offensive taste. Historical accounts also note coating of substrates to prevent accidental poisonings, where pills were hand-dipped in gold, silver, or other nondissolving materials. In the mid-1800s, sugar-coating processes from the candy industry were used in the manufacturing of pharmaceutical products. These coatings could improve the appearance of drug products, enhance the mechanical strength of the dosage form, and provide some protection against environmental conditions. The use of organic solvent-based polymer systems for a new coating process, called film coating, was introduced as a pharmaceutical process in the middle of the twentieth century. This process was used for coating both immediate- and modified-release products. Toxicity concerns associated with residual solvents in the coatings, coupled with explosive potential, costs, and environmental issues encouraged the use of aqueous-based polymer systems, a move facilitated by improvements in the drying efficiency of the processing equipment. Aqueous coating formulations for use with immediate-release products simply used 'solutions' of water-soluble polymers; however, formulations intended for modified-release applications required the introduction of aqueous polymeric dispersions. The film formation process from such aqueous-based dispersed systems was not fully understood and much research has been published over the years to address film coalescence and physical aging. In more recent years, the focus has been on continued improvements to coating equipment, the development of new coating materials, novel application methods including dry polymer powder deposition, and the use of polymer blends and multiple coating layers to achieve desired film performance. In addition to these areas, basic research to broaden our general understanding of film coating processes has continued.

The process of film coating is quite complex. In simplest terms, a liquid material is atomized with air and sprayed onto a solid substrate where the droplets spread on the surface of the substrate and the film forms upon subsequent solvent evaporation. In reality, variables in the coating formulation and the substrate as well as processing parameters can significantly impact film performance. Moreover, the underlying mechanisms of film formation and interactions between the surface of the substrate and the coating are still not well understood. These unresolved mysteries can have significant regulatory implications yet are often unappreciated by the scientific community.

This special theme edition of the journal aims to highlight film coating and some concerns associated with the application of polymeric films to solid dosage forms. Some of the leaders in the pharmaceutical coating field have contributed to this issue that consists of two review manuscripts and a number of research articles. One of the reviews addresses analytical techniques used to characterize coatings and coated products. These methods can be used by the pharmaceutical scientist to optimize product performance and investigate interactions between the coating and the solid surface. The second review article is focused on the modeling of coating processes to provide a better understanding of how processing parameters affect film formation. The scope of the contributed research articles for this issue is broad and covers subjects such as continuous processing, multiple coating layers, food effects on drug release, and various modified-release applications. By advancing our knowledge of coating processes and mechanisms of film formation, the cause of problems that arise during manufacturing, defects in the films, and changes in product performance upon storage may be quickly and accurately identified and resolved. Certainly, a better understanding of many of these issues is critical if quality by design (QbD) initiatives are to be effectively implemented for products that undergo film coating.

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ISSN 0363-9045 print/ISSN 1520-5762 online © Informa UK, Ltd.
DOI: 10.3109/03639040903499923