



Handbook of Pharmaceutical Salts : Properties, Selection, and Use

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An estimated half of all drug molecules used in medicine are administered as salts, and the formation and the selection of a suitable salt for a drug candidate is recognized as an essential step in the preclinical phase of modern drug development. Surprisingly, however, the scientific literature on this topic is rather limited and scattered throughout numerous journals and patents. The majority of medicinal chemists in pharmaceutical industry whose primary focus is the design and synthesis of novel compounds as future drug entities are organic chemists for whom salt formation is often a marginal activity restricted to the short-term objective of obtaining crystalline material. Because a comprehensive resource that addresses the preparation, selection, and use of pharmaceutically active salts has not been available, researchers may forego the opportunities for increased efficacy and improved drug delivery provided by selection of an optimal salt. To fill this gap in the pharmaceutical bibliography, we have gathered an international team of seventeen authors from academia and pharmaceutical industry who, in their contributions to this volume, present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts.

An introductory chapter presents a concise review of the various objectives in the pursuit of pharmaceutically active salts, followed by contributions that present the theoretical background of salt formation: dissociation and ionic equilibria, solubility and dissolution (Chapters 1 and 2), evaluation of solid-state properties (Chapter 3), and safety, biopharmaceutical, and pharmaceutical-technological aspects (Chapters 4 and 5). In Chapters 6, 7, and 8, the practice of salt formation in an industrial research-and-development environment is described, including salt-selection strategies, aspects of large-scale industrial salt production, and the significance of salt formation in industrial processing. Regulatory and patent issues are addressed in Chapters 9 and 10, and Chapter 11 provides practical examples of preparation of salts for the practitioners at the lab bench. The book concludes with a comprehensive annotated compilation of the individual salt-forming acids and bases with their relevant properties (Chapter 12), followed by an Appendix containing tables with the acids and bases sorted alphabetically and by pKa, supplemented with other useful facts and data.

The editors have taken care to address every conceivable aspect of the

preparation of pharmaceutical salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products. This book is destined to be an essential reference resource for students of medicinal and pharmaceutical chemistry, and an indispensable handbook for research-and-development chemists, analytical chemists, biologists, development pharmacists, regulatory and patent specialists, and medicinal scientists engaged in preclinical development of drugs. This comprehensive up-to-date guide and information source will be an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms.

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Editorial Review

Review

"...It should be in the library of every pharmaceutical company...It fills a vital gap in the literature..."

(Organic Process Research & Development Journal)

"...the editors have produced a rare commodity, a body of knowledge on an important area, summarized in single volume. In a nutshell, this long-overdue volume belongs on the personal shelf of every pharmaceutical scientist working with new chemical entities." *(Pharmaceutical Development and Technology, Vol. 8, No. 3)*

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