

**Pharmaceutical Substances: Syntheses, Patents and Applications of the Most Relevant APIs**; by Axel Kleeman, Jürgen Engel, Bernhard Kutscher, Dietmar Reichert, 5th ed., Georg Thieme Verlag: Stuttgart, New York, 2009, XXXI, hardcover, 1800 pp., \$ 849/ 599 €, ISBN: 978-3-13-558405-8

*Pharmaceutical Substances (PS): Syntheses, Patents and Applications of the Most Relevant APIs* is the new completely revised and expanded fifth edition of *Pharmazeutische Wirkstoffe*, in English. *PS* was fully updated in August 2008 and contains a collection of about 1300 of the most relevant APIs, which are of interest to the pharmaceutical and chemical industry, academia and government agencies. *Pharmaceutical Substance PS5* is designed to be a complete reference guide to every pharmaceutical compound of significance and an essential, first point of reference to specialists in drug chemistry and anyone involved in the synthesis and use of pharmaceuticals. The purpose and objective of this book are to establish a link between International Non-proprietary Names (INNs), structures, syntheses and production processes, patent (and literature) scenarios, medical uses and trade names of important pharmaceuticals.

The description of each API in *PS5* includes the following components: Chemical structure; molecular formula; molecular weight; graphical representation of the synthetic route(s), including intermediates; nomenclature; INN and other generic names (e.g., BAN, DCF, USAN), trivial names, synonyms, chemical abstract name; trade names (for the six most important markets, France, Germany, Great Britain, Italy, Japan, USA) and the names of the companies that market the product; CAS registry number; anatomic therapeutic chemical (ATC) code number; medical application/therapeutic category; formulations, including pharmaceutical dosage forms; toxicological data; patent numbers, origin, holder application, priority and expiry dates; bibliographical information. The book includes in addition to the drug monographs and the alphabetical list of drug monographs four indexes: trade names; intermediates; enzymes, microorganisms, plants, animal tissue and substance classes.

165 new API monograph entries were added in *PS5* and the existing monographs were completely revised, taking into account the many changes that had taken place in the pharmaceutical market since *PS4* had been published. The focus in *PS5* is on the most important drugs in terms of volume and sales, excluding biopharmaceuticals. Due to the continued availability and updates of the electronic version, the authors decided not to include in the printed edition of *PS5* drugs that had been withdrawn from all the six markets to which they referred, as well as those drugs which have become much less commercially important or

are quite trivial and to highlight key intermediates in the electronic version only. It should be noted that the alphabetical list of monographs at the beginning of *PS5* lists all APIs covered in the electronic version, while those that have been included in the printed edition appear in bold letters. The authors should be praised for these selection measures. An exception is the decision not to include the withdrawn drugs (“wfm”), e.g., Rofecoxib (Vioxx), and Cerivastatin Sodium (Lipobay, Baycol). From this perspective, the authors’ idea that the printed edition of *PS5* should be used not only in combination (“a handy add-on”) with the electronic version, but also as a stand-alone resource for the occasional reader, is hardly justified. The special emphasis given to patents, trade names and synthetic schemes is maintained in *PS5*. Although *PS5* has a distinct chemical character, its pharmacological characteristics are pronounced. Unfortunately, *Pharmaceutical Substances PS5* has not been comprehensively updated with new chemical entities (NCEs). According to the *Annual Reports in Medicinal Chemistry* (Volumes 42 and 43, Academic Press), in 2006 and 2007, the numbers of New Molecular Entities (NMEs) introduced into the world market for the first time, were 21 and 19, respectively, excluding new biological entities (NBEs). *PS5* contains only 12 (57%) of the 2006 NMEs and 10 (53%) of the 2007 NMEs. In order to overcome this deficiency (which might have been due to the fact that the missing NMEs of 2006 and 2007 have not been considered sufficiently commercially interesting), this reviewer recommends that the authors use the chapters “From Market to Market” in the *Annual Reports in Medicinal Chemistry* as additional sources for introducing new APIs in future editions (printed and electronic) of *PS*. The treatment of stereochemistry in *PS5* has hardly been improved. For example, the characterization of the drug Thalidomide as a racemate is still missing.

According to the publisher, the electronic version of *PS5* is available as an online version and as an STN version (on a pay-per-use basis). It is updated twice annually and its structure and full text searchable. In contrast to the printed edition, the electronic version of *PS5* is aimed to be comprehensive, providing a ready access to more than 2400 APIs.

In conclusion, *Pharmaceutical Substances PS5* has maintained its high quality. It is an excellent, indispensable source of information and reference guide of drugs, which should be present in all libraries of pharmaceutical companies, departments of medicinal chemistry and institutes of pharmaceutical chemistry, colleges of pharmacy, patent attorneys, and government agencies (including regulatory and patent agencies) involved in the design, discovery, development, evaluation, marketing and patenting of drugs, world wide.

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