

sorption of digoxin from all commercially available compressed tablets and their dissolution *in vitro*. The results also indicate the poor applicability of the USP (8) dissolution test in predicting the bioavailability of this particular brand of commercial digoxin tablets.

(1) E. J. Fraser, R. H. Leach, J. W. Poston, A. M. Bold, L. S. Culank, and A. B. Lipede, *J. Pharm. Pharmacol.*, **25**, 968(1973).

(2) B. F. Johnson, H. Greer, J. McCreerie, C. Bye, and A. Fowle, *Lancet*, **1**, 1473(1973).

(3) J. Lindenbaum, V. P. Butler, Jr., J. E. Murphy, and R. M. Cresswell, *ibid.*, **1**, 1215(1973).

(4) J. G. Wagner, M. Christensen, E. Sakmar, D. Blair, J. D. Yates, P. W. Willis, III, A. J. Sedman, and R. G. Stoll, *J. Amer. Med. Ass.*, **224**, 199(1973).

(5) P. F. Binnion, *Clin. Pharmacol. Ther.*, **16**, 807(1974).

(6) D. J. Greenblatt, D. W. Duhme, J. Koch-Weser, and T. W. Smith, *J. Amer. Med. Ass.*, **229**, 1774(1974).

(7) P. R. Klink, R. I. Poust, J. L. Colaizzi, and R. H. McDonald, Jr., *J. Pharm. Sci.*, **63**, 1231(1974).

(8) "Sixth Interim Revision Announcement Pharmacopeia of the United States," 18th rev., United States Pharmacopeial Convention, Rockville, Md., 1973, pp. 1, 2.

Pauli Ylitalo *

Institute of Biomedical Sciences
University of Tampere
Teiskont. 35
SF-33520 Tampere 52, Finland

Gunilla Wilén

Stig Lundell

Research Laboratory of Star Ltd.
Pinnink. 53
SF-33100 Tampere 10, Finland

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* To whom inquiries should be directed.

BOOKS

REVIEWS

Proceedings of the USP Conference on Radiation Sterilization, The United States Pharmacopeia, Inc., Rockville, MD 20852, 224 pp. 16 × 22 cm. Price \$10.00.

This volume consists of 15 papers devoted to an area of pharmaceutical and biomedical technology in which the United States has lagged behind several European nations, largely because of strict controls on testing of safety and efficacy imposed by federal agencies. Among the subjects considered in detail are instrumentation and experimental conditions employed in radiation sterilization, chemical dosimetry, the effects of ionizing radiations on microorganisms, and the evaluation of microbiological control systems for the determination of the efficacy of radiation sterilization.

Ionizing radiation offers an advantage over heat in the sterilization of thermally degradable materials. However, the high doses and dose rates required to effect sterilization, especially against radio-resistant bacteria, represent a problem because of the susceptibility of many materials to chemical and structural alterations as a result of their interactions with ionizing radiations. The treatment of bacteria-containing samples with UV light prior to high-energy irradiation provides a solution to this problem, at least in some cases, as bacteria preirradiated with UV light appear to require smaller doses of ionizing radiations to produce the same degree of sterilization observed in untreated bacterial samples. The cobalt-60 γ -ray source which, historically, was the first sterilization source employed on a wide scale is still preferred over other isotopic sources because of its high radiation flux, long-term stability, and relatively low cost and is favored over electronuclear sources such as the linear accelerator because of the high cost of the latter. It is suggested by several contributors to the volume that the cobalt-60 source is expected to maintain its preeminence for the foreseeable future. It is also suggested that the search for and evaluation of better dosimeters and microbiological standards will be a major area of endeavor for some time to come. The need

for improved microbiological controls is particularly acute because much of the testing of the efficacy of radiation sterilization has been carried out with bacteria which are unrepresentatively sensitive to radiation damage.

"Proceedings of the USP Conference on Radiation Sterilization" is a comprehensive, authoritative, and very readable account of a subject which is probably the major industrial application of ionizing radiations. Although it deals primarily with applications to biological test systems and surgical products, it is worthwhile reading for all pharmaceutical and biological scientists.

*Reviewed by Stephen G. Schulman
College of Pharmacy
University of Florida
Gainesville, FL 32610*

The United States Pharmacopeia, Nineteenth Revision. Prepared and Published by The United States Pharmacopeial Convention, Inc., Distributed by Mack Publishing Co., 20th & Northampton Sts., Easton, PA 18042, 1974. 1 + 824 pp. 21.5 × 28 cm. Price \$25.00.

This latest revision of the *United States Pharmacopeia* (USP XIX) continues its respected tradition by providing legally recognized standards for identity, strength, quality, and purity for nearly 1300 important and well-established drugs and their dosage forms in use in the United States. Additionally, about one-fourth of this volume is devoted to general chapters, reagent specifications, and tables.

Among other noticeable changes introduced in USP XIX and not found in its predecessor, USP XVIII, are the considerable revisions in the *General Notices and Requirements (General Notices)*. Of particular note are those relating to containers (e.g., definitions for single-unit, multiple-unit, and unit-dose), labeling (e.g., expiration date requirement), and the use of newer metric abbreviations.

Further changes are found in the many new features that characterize the revised format and style of USP XIX. A larger page size and two-column format were utilized to maximize the amount of textural content per page; USP XIX includes 1284 monographs in 570 pages in contrast to USP XVIII's 1103 monographs in 788 pages. The running heads now include an alphabetic keyword in boldface type designating the title of the first monograph or chapter on the left-hand page or the last monograph or chapter on the right-hand page.

The monographs themselves are divided into two sections: the first section contains monographs on drug substances and dosage forms and the second section contains monographs on articles known as pharmaceutical ingredients. The word order for the monograph titles of most organic compounds follows the USAN principle that the pharmacologically active portion appears first, e.g., Oxacillin Sodium rather than Sodium Oxacillin as used in USP XVIII. An additional chemical subtitle comprising the inverted name currently in the Indexes used by the Chemical Abstracts Service (CAS) of the American Chemical Society has been included in most monographs. As such they provide direct access to the literature as indexed in *Chemical Abstracts*. Also, for convenience, CAS registry numbers have been added to the chemical data section.

The format for the monographs has been modified to present the primarily informational sections first, followed by the specific compendial requirements that must be met by the article (the latter being introduced by a bold-face double-arrow symbol). These informational sections of most concern to the physician and pharmacist include category, dose information, sizes available, dispensing information, description, and solubility. The category and dose statement information that appeared in the drug monographs in USP XVIII has been moved and now appears instead in the dosage form monographs. The dose information itself has been expanded frequently to include a *Usual pediatric dose*. However, the *General Notices* cautions that the provision for this information is not to be construed as a recommendation or indication that the drug should be used in the pediatric patient but is intended to be only a guide to the physician after the prescribing decision has been made. The *General Notices* further recommends strongly that the package insert or full disclosure information about the drug be consulted. For the convenience of the physician who chooses to use body surface area as a basis for pediatric dose, a nomogram on the flyleaf opposite the inside back cover has been provided to simplify square meters of body surface calculations.

An entirely new section entitled *Dispensing information* has been added to individual dosage form monographs. This section, which consists of labeling suggestions, statements of advice that may be directed toward the patient, and notes that may be considered by the pharmacist, is intended for use in the prescription dispensing situation. According to the *General Notices*, the information is not complete, is intended to serve only as a basic reminder or general guide to the pharmacist and as a general reminder to the physician, and is not intended to limit or influence the professional judgment of the pharmacist in determining correct and proper patient information in accordance with the best interests of the patient or the particular circumstances involved.

Some specific revisions in the compendial requirements for articles include: a larger number of monographs with *in vitro* dissolution test requirements; extended content uniformity requirements for active drug substance in solid dosage forms (e.g., all 50-mg or smaller tablets); and expanded availability and use of reference standards.

The general chapters also have been divided into two sections: those pertaining to compendial requirements are grouped under the heading *General Tests and Assays* and those containing no standards, tests, assays, or other mandatory specifications for any compendial article are grouped together as *General Information, Processes, Techniques, and Apparatus*.

Of particular interest, a new chapter on *Automated Methods of Analysis* has been included in this latter section as has a new pharmacist-oriented chapter on *Stability Considerations in Dispensing Practice*. A new general test chapter entitled *Containers—Per-*

meation is introduced and describes a moisture permeation test capable of demonstrating whether a multiple-unit container is tight enough to protect its contents from evaporation and gain of moisture. And, in conjunction with this requirement, official standards are set to determine compliance with existing definitions for well-closed and tight containers.

Sections on reagent specifications, pertinent tables, and an index round out this current volume.

Purchasers of the bound volume of USP XIX are entitled to receive the *First Supplement* and also a copy of the current edition of the *USP Guide to Select Drugs*, at no additional charge. And since formal negotiations were completed in January 1975 whereby the USP Convention acquired the National Formulary and thereby assumed full responsibility for publishing all supplements to the newly published edition, NF XIV, this first supplement will actually be a combined supplement to both USP XIX and NF XIV. The supplement was published in April and became official simultaneously with the main volumes of both compendia on July 1.

The exact nature of future publication plans for the compendia is still yet to be determined, but to quote Dr. William M. Heller from his *Foreword* to USP XIX, "[the] historic consolidation of USP and NF brings together two significant traditions, with all the strengths of both now united and at the ready to fulfill still larger purposes which demand our efforts and energies."

Staff Review

Sprowls' American Pharmacy, 7th Edition. Edited by LEWIS W. DITTERT. Lippincott, Philadelphia, PA 19105, 1974. 511 pp. 18 × 26 cm. Price \$19.50.

For all those educators familiar with the series of editions of the "American Pharmacy" texts little can be said of the latest high quality revision in the 7th Edition. Although we now see a new Editor-in-Chief in Professor Lewis W. Dittert and a change in names of some of the chapter contributors from the previous 6th Edition, upon complete review, we see a finished product in keeping with the tradition of excellence brought to us by the previous contributors and the late Editors-in-Chief Rufus A. Lyman and Joseph B. Sprowls.

In the first five editions of this series, the attention was focused on compounding of medicinals primarily discussing specifics of the then official preparations. With the 6th Edition the attention was turned to the manufacturing of dosage forms at the industrial level. This appears to be the goal of the present 7th Edition as well. To this end, the goal is reached in a better than adequate format since the theory and practice given in this text are most appropriate to the industrial formulator. In no way should this detract from its use in preparing a dispensing pharmacist for a future role since some exposition is given for compounding on the extemporaneous level as well. Similarly, pharmaceutical heritage of the various dosage forms is given either as an historical overview in the first chapter or as an introduction to the chapters dealing with the particular groups of dosage forms.

This newest edition has had some changes of chapter headings compared to the previous one, but the new organization allows for integration of subject matter. As an example, the previous edition contained a separate chapter on "Galenicals" (reviewer's condensed title) which is now condensed and incorporated into the chapter on "Solutions Using Mixed Solvent Systems." As one might also expect, the topic of "Pills" is now relegated to a paragraph or two in the "History of Dosage Forms."

For those unfamiliar with this series, it may be said that the organization of subject matter is well suited to a syllabus in a modern course in pharmaceuticals or pharmaceutical technology. It begins with the historic development of pharmaceuticals to the present day standards. This is followed by a short review chapter on pharmaceutical measurements. The next three chapters (3, 4, and 5) logically introduce the student to solutions. The first of these chapters briefly discusses the solubility phenomenon with exten-