method should be equally applicable to all other specific ion electrodes.

(1) M. S. Frant and J. W. Ross, Jr., *Science*, **154,** 1553(1966).
(2) L. Singer and W. D. Armstrong, *Anal. Chem.*, **40,** 613(1968).
(3) M. W. Sun, *J. Amer. Ind. Hyg. Ass.*, **30,** 133(1969).
(4) M. S. Frant, *Plating*, **54,** 702(1967).
(5) B. A. Raby and W. E. Sunderland, *Anal. Chem.*, **39,** 1304 (1967).
(6) N. Shane and D. Miele, *J. Pharm. Sci.*, **57,** 1260(1968).
(7) J. J. Lingane, *Anal. Chem.*, **39,** 881(1967).
(8) K. Strinivasan and G. A. Rechnitz, *ibid.*, **40,** 509(1968).

LAWRENCE T. SENNELLO
RONALD J. GORSKI
Analytical Research Department
Abbott Laboratories
North Chicago, IL 60064

Received May 8, 1970.
Accepted for publication June 25, 1970.

# *BOOKS*

## REVIEWS

***Editor's Note:*** *While it is not usual Journal practice to run more than one review on a particular book, "The Theory and Practice of Industrial Pharmacy" appeared to warrant a broader approach as it is an initial attempt to produce a textbook in the area of industrial pharmacy. For this reason, we are providing the opinions of two reviewers in the book reviews which follow.*

**The Theory and Practice of Industrial Pharmacy.** Vol. 1. Edited by LEON LACHMAN, HERBERT A. LIEBERMAN, and JOSEPH L. KANIG. Lea & Febiger, Philadelphia, PA 19106, 1970. xii + 811 pp. 15.5 × 23 cm. Price $24.50.

In their preface, the editors state that a good textbook on industrial pharmacy has been sorely needed. This is indeed the case and this book represents the first modern comprehensive treatment of industrial pharmacy to be published in the English language.

The book has three coeditors and thirty-eight contributors. As a result some chapters are truly outstanding and others are distinctly disappointing.

The book is written in four sections. These sections deal with the principles of pharmaceutical processing, dosage forms, quality control, and industrial pharmaceutical law and structures of pharmaceutical companies.

The first third of the book deals with principles of pharmaceutical processing and is written from a unit operations standpoint. Unit operations which are of particular importance in pharmaceutical processing are covered in separate chapters and include drying, mixing, milling, dispersion, clarification and filtration, compaction and compression, heat transfer, and fluid flow. Other specialized pharmaceutical processes treated are sterilization and tablet coating. One of the most outstanding chapters in the entire book appears to be very much out of place in the pharmaceutical processing or unit operations section and that is the chapter on biopharmaceutics. This chapter which was contributed by Professor Gibaldi is perhaps the most outstanding single chapter on the subject of biopharmaceutics to have been written to this date.

Section two treats on an individual chapter basis all of the various major classes of pharmaceutical dosage forms, including tablets, capsules, liquids, emulsions, semisolids, suspensions, suppositories, sterile products, aerosols, and sustained-release products. This section is entitled in the table of contents, "Dosage Forms: Design and Evaluation." Unfortunately dosage form design principles and drug product evaluation are either inadequately treated or are virtually missing from many of the chapters in this section. For example, in the chapter on capsules, no mention is made of the importance of availability studies or methods of characterizing *in vitro* availability. In most of the chapters in this section mechanical methods of manufacture are stressed. In the approximate 40% of the book dealing with dosage forms the chapter on sustained-action dosage forms by Eriksen, the chapter on sterile products by Avis, and the chapter on aerosols by Sciarra are outstanding in organization and content. The chapter on pilot plant scale-up techniques by Michelson is also well done, but seems strangely out of place, not to have been located in part one of the book dealing with pharmaceutical processing.

The nearly 100 pages of the book dealing with quality control contain two chapters coauthored by Dr. Lachman, one dealing with kinetic principles of stability testing and the other with quality assurance. These are very well written and represent a significant textbook compilation on these subjects to the literature.

In the design, organization, and writing of their book the editors have overlooked one important aspect of industrial pharmacy today. That aspect is the role of preformulation research and the application of physical-chemical principles in a systematic manner for the rational design of pharmaceutical drug products and dosage forms. It is obvious from the examination of the table of contents that the authors were at some loss as to the location of the section on biopharmaceutics. This excellent chapter together with a section on preformulation, its implications in drug product design, and the components of a total preformulation system would have provided a very good foundation for the dosage form section of the book. Unfortunately the preformulation concept is not treated by the book, making the foundation for the following dosage form section inadequate, and accentuating the lack of total information on basic principles of dosage form design and evaluation.

Even though this book contains some obvious omissions, quite often is incomplete on the subjects of dosage form design principles and evaluation, and is questionably organized in two instances, the book does represent a creditable and laudable effort to cover a broad and very difficult area. This book is recommended as a textbook for any advanced pharmaceutics or manufacturing graduate course. The book warrants consideration for elective undergraduate manufacturing pharmacy courses. It is doubtful that the book will find wide-scale acceptance as an undergraduate text based on the specialized subjects treated and the nature of the material being covered. The book should, however, have a prominent place on the shelf of every pharmacy school and pharmaceutical laboratory library. It will also undoubtedly be a valuable contribution to the working bookshelf of many industrial and development pharmacists.

*Reviewed by* Gilbert S. Banker
*School of Pharmacy and Pharmacal Sciences*
*Purdue University*
*Lafayette, IN 47907* ■

**The Theory and Practice of Industrial Pharmacy.** Vol. 1. Edited by LEON LACHMAN, HERBERT A. LIEBERMAN, and JOSEPH L. KANIG. Lea & Febiger, Philadelphia, PA 19106, 1970. xii + 811 pp. 15.5 × 23 cm. Price $24.50.

The preparation of this first attempt at a text on industrial pharmacy was undoubtedly difficult. The very scope of the subject must have given rise to many hard decisions finally arrived at with much hesitation, breadth *versus* depth alone being one of the most weighty of these.

All in all, the book is an excellent beginning and the editors are congratulated in obtaining the consistently good help of so many competent contributors.

But there are serious omissions in a text that by its title claims exposition of both theory and practice, and there are inclusions that seem a bit unnecessary here, however necessary and important as ancillary materials that have been very properly treated in other works.

As to the latter, it seems that for the most part the chapters on heat transfer, momentum transfer, and fluid flow have been well treated elsewhere and need not have been included here, however well done. In actual practice an engineering department would or should function competently in these areas.

It is interesting to note that the technological details of dosage form development in the various areas are never tied in with control and production in the sense that in a well-run outfit development should issue detailed specifications for the finished job and assume the responsibility for the accuracy of these regardless of the degree of control and production involvement during the planning stages of new drug design. The chapter on pilot plant scale-up techniques is well done technically, but needs the finishing touch of stress on the responsibilities to be assumed and by whom. This is the important connecting link between development and production and is an extremely important administrative factor in the pursuit of industrial pharmacy. Interestingly, it is often disregarded in practice as it is disregarded in this text.

Little if any reference is made to the construction and control of labeling information, to include both label and package circular, yet these are grave responsibilities that come much earlier in the scheme of things than the mechanical control of finished labeling.

In the chapter on quality assurance, reference is made to a zero-defect concept. It is unfortunate that this widely used term is repeated here since it is a physical and psychologic anomaly. Yet the notion, as developed by Sinotte and others, is a most interesting approach to quality control because it deals with the fallibilities of the human which, after all is said and done, constitute the fundamental need for control. But the term "zero defect" should be replaced with one of greater semantic digestibility. Personnel may and should be qualified not only by training, experience, and the like, but also by their emotional attitudes toward the job after training and motivational incentives have been applied. The applicable paragraph on page 715 could and should be greatly expanded by competent psychological treatment. It is not too difficult to calculate a standard deviation, but a human can ruin its importance.

The control of bulk raw material is well spiced with general statements such as "adequate systems," "appropriate records," and our old friend "careful handling." A few pages later these are followed by a quite satisfactory handling of statistical quality control for the purposes of this text, but in neither case nor in any other area of this volume is much attention given to how samples are taken, and where and when, and by whom. It is one thing to give a blessing to Military Standards sampling plans, but quite another to show how these are not complete and practical answers to the requirements of practice. The reader should like to know who trains the sampler or his supervisor and how this is done and what responsibilities reside in these operators. Often no one else sees what they do, or how they do it.

Automated sampling and assay procedures have already solved many problems in quality control, as this reviewer prophesized many years ago, and as this volume gives adequate description, but we need more definitive treatment of hand sampling and bench assay operation in a text on industrial pharmacy too, it would seem. The day is somewhat in the future when relatively small pharmaceutical operations will have disappeared. These need specific and truly applicable help in these areas of quality control far more than their more sophisticated counterparts.

This reviewer is impelled once again to point out that it seems almost axiomatic that authors in this field must use terms such as, "carefully," "adequate," "absolutely correct," "proper," "suitable," "reasonable," and the like. This volume has far too many such terms. As a text it needs none of them, or at the most, few. But it does need definitive statements in these applicable areas.

In no place was there found any statement as to the organizational responsibilities and authorities of the director of quality control. This matter has been so avoided or mishandled in the industry generally that a careful discussion of it would seem to be in order. The statement in the last paragraph on page 748 is good, but it is altogether too general for a text without more detailed support.

The matter of patents is well discussed and is quite informative to those of little experience in the field, which is as it should be. It would have been most helpful however, if some discussion of the manner in which ideas are developed in the group research that pertains today, and the difficulty of assigning the proper credit to individuals who participate in invention. These are the very facts of life to directors of development, or should be. Patents protect and provide incentive, but they are not the research "thing" itself. The "thing" itself is the heart and soul of industrial pharmacy.

But this is an excellent "first try" in the elaboration of a text that has been long sorely needed. Careful revision will make it into a most valuable resource. Such revision will surely follow its use as a text, a use which is recommended.

*Reviewed by* Sereck H. Fox
*Professor of Industrial Pharmacy*
*Wayne State University*
*Detroit, MI 48202* ■

---

**European Pharmacopoeia.** Vol. 1. Published under the direction of the Council of Europe (Partial Agreement) in accordance with the Convention on the Elaboration of a European Pharmacopoeia. Maisonneuve S. A., 57-Sainte-Ruffine, France, 1969. i + 401 pp. 15.5 × 24.5 cm. (*English and French versions available*)

The publication of the *European Pharmacopoeia* represents a significant step toward greater cooperation across national boundaries in the field of public health. The European Pharmacopoeia Commission was established by a Convention signed in September 1964 by the following countries: Belgium, France, Federal Republic of Germany, Italy, Luxembourg, the Netherlands, Switzerland, and the United Kingdom.

For the past five years, some hundred scientists, representing these eight countries, have been preparing this compilation. Application of the standards established in this volume must be made before January 1, 1972, with this volume gradually replacing the traditional national pharmacopoeias.

This volume contains general methods of analysis as well as 51 monographs on specific basic medicinal substances. A second volume of this compendium containing biological substances such as hormones, vaccine serum, and antibiotics is scheduled for publication next year.

*Staff Review* ■

---

**Pharmacology and Patient Care.** By Solomon Garb, Betty Jean Crim, and Garf Thomas. Springer, 200 Park Ave. So., New York, NY 10003, 1970. x + 597 pp. 14 × 21.5 cm. Price $8.95 (hard cover), $6.75 (soft).

This, the third edition of *Pharmacology and Patient Care*, is somewhat broader than the first two editions. Garf Thomas, Chief Hospital Pharmacist, University of Missouri Medicial Center, has been added as a coauthor, in an attempt to give this book, originally published as a textbook for nurses, a more interdisciplinary, paramedical approach.

This edition contains several new chapters, with all the chapters from the preceding editions being updated. Of particular interest are the chapters on "Drug Interaction and Incompatibilities" and "Pharmaceuticals and Society."

*Staff Review* ■