Technical Report No. 5

Sterile Pharmaceutical Packaging: Compatibility and Stability

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FOREWORD

THIS IS THE FIFTH IN A SERIES OF TECHNICAL REPORTS.[1-4] This Technical Report was prepared by Dr. Y. John Wang and Dr. Yie W. Chien under the auspices of the PDA Research Committee. It provides a comprehensive review of sterile pharmaceutical packaging systems with regard to product–package interactions, stability and compatibility.

In the selection of pharmaceutical packaging systems one must be aware of the potential physicochemical interactions with the product. These interactions are discussed in detail from both a practical application and a theoretical point of view.

R. M. Enzinger, Ph.D.
Chairman
Research Committee

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[1] "Validation of Steam Sterilization Cycles," Parenteral Drug Association Inc., Technical Monograph No. 1.
[2] "Validation of Aseptic Filling for Solution Drug Products," Parenteral Drug Association Inc., Technical Monograph No. 2.
[3] "Validation of dry Heat Processes Used for Sterilization & Depyrogenation," Parenteral Drug Association Inc., Technical Report No. 3.
[4] "Design Concepts for the Validation of a Water for Injection System," Parenteral Drug Association Inc., Technical Report No. 4.

PREFACE AND ACKNOWLEDGEMENT

The aim of this book is to provide for persons working with sterile pharmaceutical products a detailed account of the compatibility and stability of sterile formulations and packaging components. The intention is to present what is known in concise form, and to indicate how to avoid or resolve problems.

For hospital pharmacists, it is hoped that this book will serve as a valuable handy reference to assist them in identifying and solving the problems of sterile packaging. The tremendous increase in popularity of intravenous admixture programs makes it imperative that greater attention be paid to recognizing such problems. For manufacturing chemists involved in developing sterile pharmaceutical products, it is hoped that their awareness of the current knowledge of relevant physicochemical principles will enable them to design products that will have only minimal problems of compatibility and stability, both for the shelf life of the product and during its preparation and administration in hospital.

The book is arranged by type of interaction between formulation and packaging component, ie., sorption, leaching, and permeation, thus permitting an efficient presentation and analysis of common factors. Some important concepts are presented more than once, to ensure that they are not overlooked.

Ortho Pharmaceutical Corporation provided extensive assistance in the preparation of this book. We thank the Ortho librarians for their efficient help, the operators in the Ortho Word Processing Center, Mrs. Katie McAllister and Miss Karen Daniels for their patience and skill, and Miss Carol Neuwiesinger for her skillful drawing of the figures. Dr. Glenn Van Buskirk's thorough review of the manuscript lessened markedly the number of errors that may appear in the book.

Dr. Joseph Robinson and Dr. Michael Enzinger, as well as other members of the Research Committee of the Parenteral Drug Association, provided valuable comments and criticisms of the manuscript. Mr. Robert L. Buchanan of Tompkins Rubber Co. and Mr. Joseph Wong of Endo Laboratories Inc. provided helpful assistance in the initial literature search. Dr. David Frost, consultant editor, improved the readability of the text considerably.

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