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Pharmaceutical Photostability and Stabilization Technology

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During the production of this text our dear friend and coeditor Dr. Karl Thoma passed away. This book is dedicated to his memory and is a fitting memory of the principles he championed and the inspiration he gave us all for over four decades. Evidence of the magnitude of his contributions and the breadth of his work can be found throughout this text.

Those of us who have had the pleasure of knowing him as a friend or mentor will miss him deeply. I am honored to have had the pleasure of working on this final work with him.

Preface

For many millennia, the effects of photonic exposure on humans and materials have been known and chronicled in literature. Wurtman (1) presents a good introduction to "The Effects of Light on the Human Body."

Lachman, Schwartz, and Cooper (2) presented a good review of the field of photostability testing along with a review of the theory involved and a recommended cabinet design for use in the industry, which is still in use today in many laboratories.

For over seven decades, since the seminal works of Eisenbrand (3,4,5), Arny, Taub, and Steinberg (6,7), and Arny, Taub, and Blythe (8) no text devoted to the subject of photostability testing has been printed. Articles have appeared in several journals but no unified approach was given.

With the recognition that photostability testing was an integral part of the pharmaceutical development process, by the International Conference on Harmonization, efforts were made to develop a unified worldwide approach. Unfortunately, the process became more political than scientific, resulting in a less than clear guideline, as will be highlighted in many of the chapters of this book.

In the chapters that follow, world-renowned experts in the various subjects will present their areas of expertise in a clear and concise manner and discuss the pros and cons of the many alternatives available.

Recently, at least one manufacturer has sought to develop their own proprietary lamp and system, supposedly meeting International Conference on Harmonization requirements. Major problems of this approach are the lack of proper scientific justification and peer review, as well as the dependence on a sole source, available in only one country. The danger of this approach is well illustrated in the demise and resurrection of Vita-Lite Lamp.

The purpose of this text is to give the user an understanding of the fundamentals of the science involved so that they may make an informed choice as to which procedure is best for their purposes. After reading this text, the user should have a better understanding of the advantages and disadvantages of the various approaches advocated in the literature.

Karl Thoma
Joseph T. Piechocki

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