HPLC METHODS FOR RECENTLY APPROVED PHARMACEUTICALS

George Lunn
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PREFACE

This book is a collection of procedures for the analysis of more than 390 pharmaceuticals using high-performance liquid chromatography (HPLC) and covers the literature up to the end of 2003. The current volume is a continuation of *HPLC Methods for Pharmaceutical Analysis*, published in four volumes from 1997 to 2000. The previous volumes described methods published in the literature through the middle of 1998.

The current work lists procedures for the analysis of drugs in three broad categories:

- Drugs that have been approved since the previous volumes were published.
- Drugs that were approved when the previous volumes were published but for which analytical methods were not then available in the literature.
- Drugs for which procedures allowing determination in a blood matrix have only become available since the previous volumes were published.

Please note that mention of a drug does not necessarily mean that it is currently approved for use in the United States or indeed in any country.

Despite the ready availability of computer-aided literature, searching this resource is not exploited as much as it might be. One reason for this reluctance is, of course, that a computer search merely produces a listing of possibly relevant references. Tedious and time-consuming searches in the library are necessary to find the most relevant reference that can be turned into a practical analytical procedure in the searcher's own laboratory. The reference finally chosen will, naturally, depend on the individual circumstances, such as the matrix in which the drug is present, availability of equipment, and so on. This book circumvents this lengthy process by providing a number of abstracted and evaluated procedures for the analysis of each drug. The analyst can rapidly identify a relevant procedure and put it into practice.

In addition to the analytical matrix, other factors may be important when choosing an analytical procedure. Accordingly, we have noted such features of the analytical procedures as sensitivity, mode of detection, other compounds that interfere with the analysis, other drugs that may be determined at the same time, and so on.

Readers familiar with our previous publications, *HPLC Methods for Pharmaceutical Analysis, Volumes 1–4* (George Lunn and Norman R. Schmuff, John Wiley, New York, 1997–2000) and *Handbook of Derivatization Reactions for HPLC* (George Lunn and Louise C. Hellwig, John Wiley, New York, 1998), will notice many similarities. The abstract structure is very similar, and the philosophy that the procedures
should be reproducible without reference to the original literature is unchanged. A new feature is that the retention times (in minutes) of other drugs that may be determined using the same system have been added in parentheses after the drug name. Other data, such as the limit of detection (LOD), may also be added. The retention time is the number without units. Unlike the previous volumes, this book is not available on a CD in an electronic form.

At the end of the book a Cumulative Index and a Cross-Index to Other Substances are provided. The Cumulative Index provides a comprehensive listing of the drugs covered in this book and the previous volumes. The Cross-Index lists the other compounds that may also be chromatographed under the conditions described in the monographs in this book. Using the information in the monographs it may be possible to develop chromatographic procedures for these compounds.

GEORGE LUNN
ACKNOWLEDGEMENTS

I am grateful for the use of the National Institutes of Health Library, the FDA Medical Library, and the National Library of Medicine and I would like to express my appreciation for the hard work of the staff of these libraries, particularly those diligent workers who reshelve the journal volumes after one of my forays. Although many people have helped with the preparation of this work the mistakes are my own. I would appreciate hearing from anyone who has corrections, comments, or suggestions. I can be reached at lunng@cderr.fda.gov.

The content of this volume does not necessarily reflect the views or policies of the Food and Drug Administration, nor does the mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. Also, mention of a drug does not necessarily mean that it is currently approved for use in the United States or indeed in any country.

G.L.