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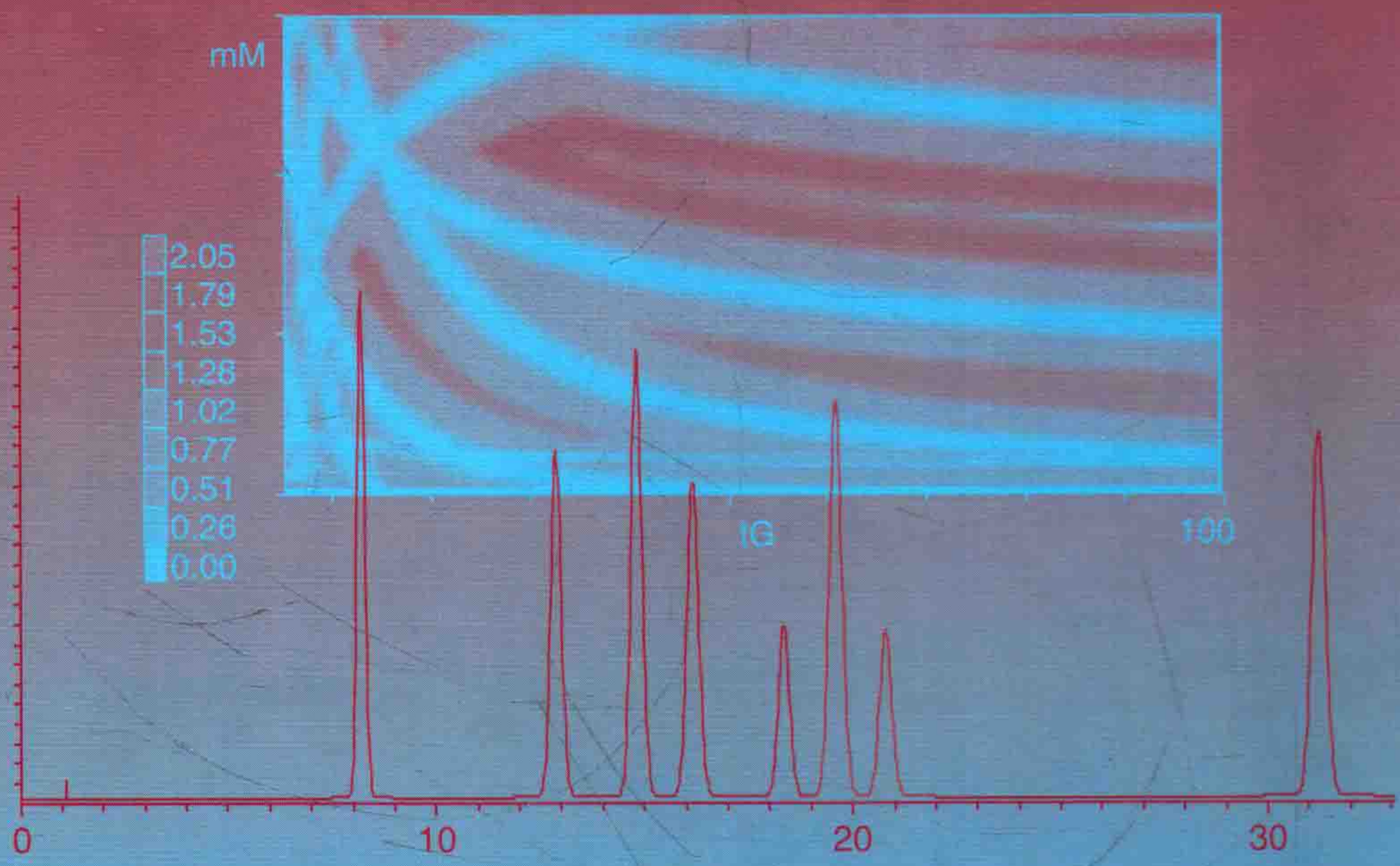
HANDBOOK OF PHARMACEUTICAL ANALYSIS BY HPLC

Edited by
Satinder Ahuja
Michael W. Dong



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SEPARATION SCIENCE AND TECHNOLOGY

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HANDBOOK OF PHARMACEUTICAL ANALYSIS BY HPLC

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SEPARATION SCIENCE AND TECHNOLOGY

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PREFACE

High-pressure liquid chromatography is frequently called high-performance liquid chromatography (both are abbreviated HPLC or, simply, LC) because it offers improved performance over classical liquid chromatography. HPLC is the premier analytical technique in pharmaceutical analysis, which is predominantly used in the pharmaceutical industry for a large variety of samples. It is the method of choice for checking the purity of new drug candidates, monitoring changes or scale-ups of synthetic procedures, evaluating new formulations, and scrutinizing quality control/assurance of final drug products. To support each new drug application or commercial product, tens of thousands of HPLC tests are conducted by a host of dedicated scientists to assure the potency and quality of the new drug product.

Presently there is no definitive text in HPLC that specifically addresses the needs of the busy pharmaceutical scientist on the pivotal subject of pharmaceutical analysis. This handbook strives to offer a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. The *Handbook of Pharmaceutical Analysis by HPLC* can be broadly classified into six major sections:

1. Overview, theory, instrumentation, and columns (Chapters 1–4)
2. HPLC methods and practices, including sample preparation and ion chromatography (Chapters 5–9)
3. Regulatory aspects of ICH guidelines, instrumental calibration, and validation (Chapters 10–12).
4. HPLC applications: assays, impurity evaluation, dissolution testing, cleaning validation, high-throughput screening, and chiral separations (Chapters 13–18).

5. Post-chromatographic and tandem techniques: LC/MS, LC/NMR, and chromatographic data handling (Chapters 19–21)
6. New developments in HPLC (Chapter 22).

Each of the 22 chapters (see table of contents), written by selected experts in their respective fields, provides the reader with an in-depth understanding of HPLC theory, hardware, methodologies, regulations, applications, and new developments.

The main focus of this book is on small drug molecules and pharmaceutical dosage forms. This handbook provides practical guidelines using case studies on sample preparation, column or instrument selection, and summaries of "best practices" in method development and validation, as well as "tricks of the trade" in HPLC operation. It captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening, and chiral separations) in addition to nuances in interpreting ICH guidelines and instrument qualification. The book also highlights novel approaches in HPLC and the latest developments in hyphenated techniques, such as LC-NMR or LC-MS, and in data handling.

We would like to thank the authors for their contributions, which have enabled us to put together a unique handbook that provides the reader with an in-depth understanding of HPLC theory, hardware, methodologies, regulations, and applications. Their excellent contributions will serve as a definitive reference source for laboratory analysts, researchers, managers, and executives in industry, academe, and government agencies, who are engaged in various phases of analytical research and development or quality control.

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