

Biopharmaceutics and pharmacokinetics play a key role in the development of safer and more efficacious drug products. Application of these concepts makes possible better and more successful drug therapy in patients, allowing individualizing dosage regimens and improving therapeutic outcomes. Biopharmaceutic and pharmacokinetic principles are essential in the development of new and novel dosage forms.

Scientific developments and innovations in biopharmaceutics and pharmacokinetics have expanded exponentially since publication of the first edition in 1980. The first edition was based on a collaboration of two colleagues who saw a need to provide students with supplementary material to a pharmacy course. The *objectives* of the first edition were to:

1. Define the basic concepts in biopharmaceutics and pharmacokinetics.
2. Use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, and elimination.
3. Critically evaluate biopharmaceutic studies involving drug product equivalency and unequivalency.
4. Design and evaluate dosage regimens of drugs using pharmacokinetic and biopharmaceutic parameters.
5. Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them.

These basic objectives have been incorporated into each subsequent edition of this textbook. Due to the expansion of knowledge in this discipline, the authors saw a need for an edited edition that would include experts from academia, pharmaceutical research, and regulatory affairs. As editors of this edition, we kept the original objectives, starting with fundamental concepts followed by a holistic integrated approach that can be applied to practice. The contributors were tasked to provide objectives for each chapter that were commensurate with the overall objectives.

The publication of the eighth edition of *Shargel and Yu's Applied Biopharmaceutics and Pharmacokinetics* embodies more than four decades of scientific developments in the field. In planning for the eighth edition, we realized the need to organize the chapters in a more logical sequence starting with introductory and fundamental principles, developing these basic concepts and then applying these concepts to clinical situations. The new edition ends with a discussion of biopharmaceutics and pharmacokinetics in drug product development.

The eighth edition represents the collective contribution of experts with intimate knowledge and experience in the selected subject areas. Each chapter was written to include practical applications of the theoretical material. Frequently asked questions are included to provide a discussion of overall concepts. Practice problems, clinical examples and learning questions are included in each chapter to show how these concepts relate to practical situations.

This textbook remains unique in teaching basic concepts that may be applied to understanding complex issues that are essential for understanding drug development and safe and efficacious drug therapy. The primary audience is pharmacy students enrolled in pharmaceutical science courses in pharmacokinetics and biopharmaceutics. This text fulfills course work offered in separate or combined courses in these subjects. Secondary audiences

for this textbook are research, technological and development scientists in pharmaceuticals, biopharmaceuticals, and pharmacokinetics.

We would like to acknowledge the contributions of Andrew B.C. Yu, PhD. Dr. Yu provided valuable expertise in the writing of the first six editions and in editing the seventh edition of this textbook. Dr. Yu's input helped with the success of this textbook. As the first author, I would also like to acknowledge the input of our new editor, Murray Ducharme, PharmD. Dr. Ducharme has provided substantial guidance and expertise in organizing and editing this new eighth edition of *Shargel and Yu's Applied Biopharmaceutics and Pharmacokinetics*.

We are grateful to our contributors, readers, colleagues and students for their helpful feedback and support throughout the years.

Leon Shargel, PhD

Murray P. Ducharme, PharmD