



Sample Preparation of Pharmaceutical Dosage Forms: Challenges and Strategies for Sample Preparation and Extraction

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This book is intended to serve as a resource for analysts in developing and troubleshooting sample preparation methods. These are critical activities in providing accurate and reliable data throughout the lifecycle of a drug product.

This book is divided into four parts:

- Part One covers dosage form and diluent properties that impact sample preparation of pharmaceutical dosage forms and the importance of sampling considerations in generating data representative of the drug product batch.
- Part Two reviews specific sample preparation techniques typically used with pharmaceutical dosage forms.
- Part Three discusses sample preparation method development for different types of dosage forms including addressing drug excipient interactions and post extraction considerations, as well as method validation and applying Quality by Design (QbD) principles to sample preparation methods.
- Part Four examines additional topics in sample preparation including automation, investigating aberrant potency results, green chemistry considerations for sample preparation and the ideal case where no sample preparation is required for sample analysis.

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