Specification of Drug Substances and Products

Description: Specification of Drug Substances and Products: Development and Validation of Analytical Methods is a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development and validation of analytical methods. This book is intended as more than a review of new regional guidelines, existing regulatory guidance, and industry practices. It provides a hands-on guide to understanding and applying these in practice. The authors discuss critical issues, novel approaches, and future directions while also providing insight into how International Guidelines were developed and the rationale behind them.

- Guide to industry best practices of analytical methodologies used in the specification of new drug substances and products (e.g. DOE, QbD)
- Critical assessment of the application of ICH guidelines on method validation and specification setting, written by experts involved in the development and application of the guidelines to aid understanding of requirements and what is expected by regulatory authorities
- Direct applicability to the day-to-day activities in drug development and the potential to increase productivity

Contents:

Part One: Basic Concepts and Definitions

Introduction

General Principles and Regulatory Considerations: Specifications

Application of Quality by Design (QbD) to the Development and Validation of Analytical Methods

General Principles and Regulatory Considerations: Method Validation

Part Two: Universal Tests

Description and Identification

Assay, and Impurities

Residual Solvents

Inorganic Impurities (Heavy Metals)

Part Three: Specific Tests: Drug Substances

Solid-State Characterization

Chiral Methods

Water Determination

Part Four: Specific Tests: Drug Products

Dissolution and Disintegration

Extractables and Leachables

Potency Assays for Biomolecules

Host Cell Protein Assays
Part Five: Pharmacopeial Methods
Pharmacopeial Methods and Tests
Part Six: Microbial Methods
Sterile and Non-Sterile Products
Part Seven: Biological Fluids

Biological Fluids

Ordering:

Order Online - [http://www.researchandmarkets.com/reports/2534673/](http://www.researchandmarkets.com/reports/2534673/)

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

- **Product Name:** Specification of Drug Substances and Products
- **Web Address:** http://www.researchandmarkets.com/reports/2534673/
- **Office Code:** SCPLHDEL

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Format</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard Copy (Hard Back)</td>
<td>USD 103 + USD 28 Shipping/Handling</td>
</tr>
<tr>
<td>Hard Copy (Paper back)</td>
<td>USD 103 + USD 28 Shipping/Handling</td>
</tr>
</tbody>
</table>

* Shipping/Handling is only charged once per order.

Contact Information
Please enter all the information below in **BLOCK CAPITALS**

- **Title:** Mr □ Mrs □ Dr □ Miss □ Ms □ Prof □
- **First Name:** ____________________________  **Last Name:** ____________________________
- **Email Address:** *
- **Job Title:** ____________________________
- **Organisation:** ____________________________
- **Address:** ____________________________
- **City:** ____________________________
- **Postal / Zip Code:** ____________________________
- **Country:** ____________________________
- **Phone Number:** ____________________________
- **Fax Number:** ____________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: ___________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World