

# Contents

## PHARMACEUTICAL DEVELOPMENT

<i>Table of Contents</i>	VIII
<i>Acronyms - Abbreviations</i>	XIII
<i>Introduction</i>	XV
<i>Preface</i>	XVI
<i>Forward</i>	XVII
<b>Chapter 1</b>	
<b>Regulatory</b>	1.1
- Pre-formulation checklist	1.3
<b>Documentation</b>	1.4
- SOP Control checklist	1.5
<b>Development Notebooks</b>	1.6
- Development Notebooks checklist	1.7
- SOP Control and Development Notebooks SOPs	1.8
<b>Chapter 2</b>	
<b>Developing the Formula -an Overview</b>	2.1
- Formulation checklist	2.2
- Development formulations - Oral Liquids	2.3
<b>Drug Development Checklist</b>	2.5
<b>Development Formula SOPs</b>	2.6
<b>Developing Liquid Formulations</b>	2.7
<b>Design Considerations for Oral Liquids</b>	2.12
<b>Product Development data - Case Histories</b>	2.13
<b>Product Development Guide and tabulations</b>	2.21
<b>Product Development Flowchart</b>	2.27
<b>Developing Liquid &amp; syrup preparations</b>	2.29
<b>Liquid &amp; Syrup Master Formulations</b>	2.31
<b>Purified Water - an essential ingredient</b>	2.33
<b>Do and Don'ts in Development</b>	2.35
<b>Purified Water - Checklist</b>	2.36
<b>Chapter 3</b>	
<b>Active Ingredients</b>	3.1
-Do's and Don'ts	3.2
-Active checklist	3.3
-Approved Suppliers Checklist	3.5
-Standard Operating Procedures, Actives	3.6

# Contents



<b>Chapter</b>	<b>4</b>	
<b>Semi active ingredients</b>		4.1
-Validating the Semi-active ingredients, Checklist		4.2
<b>Non active materials (excipients)</b>		4.3
-Checklist non active ingredient		4.5
-Standard Operating Procedures, Non actives		4.6
<b>Chapter</b>	<b>5</b>	
<b>Container closure systems</b>		5.1
-Container-liner-closure systems, Checklist		5.3
-Container-liner-closure systems, SOPs		5.4
-Packaging Components - Documentation Requirements		5.5
-Packaging Components - Description and Characteristics		5.11
-Packaging Components Documentation Requirements SOP		5.12
-Packaging Components - Compendial Test Requirements		5.16
<b>Chapter</b>	<b>6</b>	
<b>Manufacturing Instructions &amp; in-process controls</b>		6.1
Production In-process controls		6.2
Quality Control In-process Testing Schedule		6.3
- Manufacturing & Controls - Sampling procedures		6.4
- The manufacturing Instructions and Controls		6.5
- Manufacturing Flow Charts		6.16
- Fill Weight Verification		6.20
- Fill Weight Verification Tabulations		6.21
- Packaging trail and Disbursements		6.23
- Large scale Manufacturing Instructions		6.25
<b>Chapter</b>	<b>7</b>	
<b>In-process Quality Controls</b>		7.1
-Manufacturing in-process controls; Checklist		7.2
-In-process Quality Controls; SOPs		7.10
<b>Chapter</b>	<b>8</b>	
<b>Finished Product Specifications</b>		8.1
- Finished Product Specifications example and Checklist		8.2
- release Specifications		8.4
- Glossary and Terms		8.6
- Finished Product Specifications; Required SOPs		8.9

# Contents



<b>Chapter</b>	<b>9</b>	
<b>Process Optimization and Procedures</b>		9.1
Evaluation Product Specifications		9.3
Qualification of Preservative and Chelating Agent		9.4
Qualification of Preservative and Chelating Agent - Stability studies		9.6
<b>Chapter</b>	<b>10</b>	
<b>Scale-up Procedures</b>		10.1
- Scale-up procedures; checklist		10.4
- Scale-up procedures; SOPs		10.5
<b>Chapter</b>	<b>11</b>	
<b>Cleaning Limits</b>		11.1
Cleaning Limits Procedures; Checklist		11.6
Cleaning Validation Requirements; SOPs		11.8
<b>Chapter</b>	<b>12</b>	
<b>Analytical Validation Requirements</b>		12.1
-Analytical Testing Out of Specification		12.21
-Analytical Testing Do's and Don'ts		12.23
-Ruggedness and Robustness		12.24
-Impurities in Drug Substances		12.28
-Impurities Do's and Don'ts		12.37
-Impurities Glossary of terms		12.38
-Impurities Decision Trees		12.39
Analytical Post approval Changes -PAC-ALTS		12.42
PAC-ALTS Checklist		12.45
<b>Chapter</b>	<b>13</b>	
<b>Process Qualification Batch</b>		13.1
-Process Qualification Batch; Checklist		13.2
-Process Qualification Batch; SOPs		13.3
-Process Qualification Blend Analysis		13.5
-Process Qualification Blend Analysis - Do's and Don'ts		13.7
-Process Qualification - Qualifying Bulk Liquids		13.8
-Protocol		13.9

# Contents



<b>Chapter</b>	<b>14</b>	
<b>Pivotal batch</b>		14.1
-The Pivotal Batch		14.1
-Pivotal batch Checklist		14.2
-Pivotal batch SOPs		14.3
-Sampling and Testing the Pivotal Batch - Granules for liquid reconstitution		14.4
-Auditing the Pivotal batch		14.10
-Auditing the Pivotal batch Checklist		14.11
<b>Chapter</b>	<b>15</b>	
Exclusion of Biostudy Testing - Oral Liquids		15.1
<b>Chapter</b>	<b>16</b>	
<b>Technical Transfer Documentation</b>		16.1
<b>TTD Contents</b>		16.4
-Technical Transfer Documentation; checklist		16.5
-Technical Transfer Documentation; Pharmaceutical Part		16.7
-Technical Transfer Documentation; Analytical Part		16.10
<b>Chapter</b>	<b>17</b>	
<b>Process Validation batches</b>		17.1
-The Process Validation Batches; checklist		17.2
-Process Validation Requirements; SOPs		17.3
-Process Validation Master Plan		17.4
-Process Optimization Master Plan		17.7
-Process Validation Protocol - bulk Oral Liquids		17.8
<b>Chapter</b>	<b>18</b>	
<b>Pre--Approval Inspections &amp; Failures</b>		18.1
<b>PAI Audits</b>		18.5
<b>PAI Mock Inspections</b>		18.7
<b>PAI Summary</b>		18.8
<b>Pre--Approval Inspection Audit - Team Set Up</b>		18.9
<b>Pre--Approval Inspection Audit - Team Activities</b>		18.11

# Contents



<b>Chapter</b>	<b>19</b>	
<b>Stability Testing of Drug Substance and Drug Product I</b>		19.1
<b>Stability Testing of Drug Substance and Drug Product II</b>		19.15
<b>Stability Testing of Drug Substance and Drug Product II</b>		19.21
<b>Stability Testing Significant Change</b>		19.24
<b>Storage Conditions</b>		19.29
<b>Setting up a functional Stability Unit</b>		19.31
<b>Stability SOPs Development</b>		19.39

<b>Chapter</b>	<b>20</b>	
<b>Standard Operational Procedures</b>		
<b>Development SOPs</b>		20.1
<b>Index of Pharmaceutical Standard Operating Procedures</b>		20.5
<b>Index of Analytical Standard Operating Procedures</b>		20.9
<b>Index of Microbiological Standard Operating Procedures</b>		20.16
<b>Index of Stability Standard Operating Procedures</b>		20.21



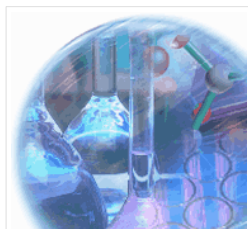
ISSN 0793 8632

*An on-going series*

*Additional Volumes in Preparation*

ISBN 0793 8640 - Electronic Version  
 Handbook Development 24 Volume Series  
 ISSN Series Number 0793 7792 - Electronic Version

Handbook of Pharmaceutical  
 Generic Development Series



# HPGD™

Handbook of Pharmaceutical Generic Development

Drug Development -Part I

ANDA Formula™ - Part II

© Copyright 1995 -2005 Locum International Ltd.

## 2006 Update Program

Part I and Part II: HandBook Generic Development Series

Ⓟ Volume 1	Edition 07 - 2006	Ⓟ Volume 9	Edition 07 - 2006
Ⓟ Volume 2	Edition 07 - 2006	Ⓟ Volume 10	Edition 07 - 2006
Ⓟ Volume 3	Edition 07 - 2006	Ⓟ Volume 11	Edition 07 - 2006
Ⓟ Volume 4	Edition 07 - 2006	Ⓟ Volume 12	Edition 07 - 2006
Ⓟ Volume 5	Edition 07 - 2006	Ⓟ Volume 13	Edition 07 - 2006
Ⓟ Volume 6	Edition 07 - 2006	Ⓟ Volume 14	Edition 07 - 2006
Ⓟ Volume 7	Edition 07 - 2006	Ⓟ Volume 15	Edition 07 - 2006
Ⓟ Volume 8	Edition 07 - 2006	Ⓟ Volume 16	Edition 07 - 2006



Initiation Date : January **2006**  
 Expiration Date : January **2007**  
 No of Years : **One (1)**  
 Update Period : January 2006; January **2007**.

Update License No:  
1.3.02-000

This Drug Development ANDA has been updated to **January** 2005 Office of Generic Drugs requirements. Handbook clients requiring to continue this annual service need only to become members of I.A.G.I.M. for the period of the update service required by the firm. The ANDA Update Program is renewed in December each year as a function of the firms requirements.

Warning: Copyright © 1985 -2005 Locum Publishing House Inc. - All Rights Reserved.

Neither this information or nor any part of the data contained therein may be reproduced, copied or transmitted in any form, modification or merged portion or by any means, electronic or mechanical, including printing photocopying, microfilming and recording, or by any information storage and retrieval system, without the prior written permission of the publishers. ™ Trademark - Locum Corporation, ™ Locum International Group

[info@locumusa.com](mailto:info@locumusa.com)

(See web site for IAGIM Application Membership form)

[info@iagim.org](mailto:info@iagim.org)

[info@locumUSA.com](mailto:info@locumUSA.com)

<http://www.locumUSA.com>