

**PHARMACEUTICAL DEVELOPMENT  
ICH HARMONISED TRIPARTITE GUIDELINE**

**TABLE OF CONTENTS**

<b>PART I:</b>	<b>7</b>
<b>PHARMACEUTICAL DEVELOPMENT</b>	<b>7</b>
<b>1. INTRODUCTION</b>	<b>7</b>
1.1 Objective of the Guideline	7
1.2 Scope	8
<b>2. PHARMACEUTICAL DEVELOPMENT</b>	<b>8</b>
2.1 Components of the Drug Product	11
2.1.1 Drug Substance	11
2.1.2 Excipients	12
2.2 Drug Product	13
2.2.1 Formulation Development	13
2.2.2 Overages	15
2.2.3 Physicochemical and Biological Properties	15
2.3 Manufacturing Process Development	16
2.4 Container Closure System	18
2.5 Microbiological Attributes	19
2.6 Compatibility	20
<b>3. GLOSSARY</b>	<b>21</b>
<b>PART II:</b>	<b>22</b>
<b>PHARMACEUTICAL DEVELOPMENT - ANNEX</b>	<b>22</b>
<b>1. INTRODUCTION</b>	<b>23</b>

<b>2. ELEMENTS OF PHARMACEUTICAL DEVELOPMENT</b>	<b>26</b>
2.1 Quality Target Product Profile	26
2.2 Critical Quality Attributes	26
2.3 Risk Assessment: Linking Material Attributes and Process Parameters to Drug Product CQAs	28
2.4 Design Space	29
2.4.1 Selection of Variables	29
2.4.2 Describing a Design Space in a Submission	29
2.4.3 Unit Operation Design Space(s)	30
2.4.4 Relationship of Design Space to Scale and Equipment	31
2.4.5 Design Space Versus Proven Acceptable Ranges	31
2.4.6 Design Space and Edge of Failure	32
2.5 Control Strategy	32
2.6 Product Lifecycle Management and Continual Improvement	35
<b>3. SUBMISSION OF PHARMACEUTICAL DEVELOPMENT AND RELATED INFORMATION IN COMMON TECHNICAL DOCUMENTS (CTD) FORMAT</b>	<b>35</b>
3.1 Quality Risk Management and Product and Process Development	36
3.2 Design Space	36
3.3 Control Strategy	37
3.4 Drug Substance Related Information	37
<b>4. GLOSSARY</b>	<b>38</b>
<b>Appendix 1. Differing Approaches to Pharmaceutical Development</b>	<b>40</b>
<b>Appendix 2. Illustrative Examples</b>	<b>42</b>