

21

Impact of Pharmaceutical Product Quality on Clinical Efficacy

Vandana Soni¹, Vikas Pandey¹, Saket Asati¹ and Rakesh K. Tekade^{2,3}

¹Department of Pharmaceutical Sciences, Dr. H.S. Gour Central University, Sagar, Madhya Pradesh, India ²Department of Pharmaceutical Technology, School of Pharmacy, International Medical University, Kuala Lumpur, Malaysia ³National Institute of Pharmaceutical Education and Research (NIPER)-Ahmedabad, Gandhinagar, Gujarat, India

C) U T	LINE	
21.1 Introduction21.2 Risk Assessment and Management	732	21.3.4 Design Space and Control Strategy	747
of Medicine	734	21.4 Factors Affecting Drug Product	
21.2.1 Product Quality Defects	734	Performance	748
21.2.2 Medication Errors	735	21.4.1 Physicochemical Properties	
21.2.3 Known Side Effects	739	of Drug Substance	748
21.3 Elements of Pharmaceutical		21.4.2 Differences in Manufacturing Processes	752
Development	743	21.4.3 Differences in Excipients,	132
21.3.1 Quality Target Product Profile	744 745	Excipient Selection, and Quality Control	754
21.3.2 Critical Quality Attributes 21.3.3 Risk Assessment: Linking	743	21.5 Drug Product Quality and Drug	
Material Attributes and		Product Performance	759
Process Parameters to Drug Product CQAs	746	21.6 Scale-Up and Postapproval Changes	760