Pharmaceutical Recipe Setting in GMP Manufacturing

Part 2: Process Design and Recipe Development (Chapters 5–8)

This PDF contains Part 2 of the handbook covering:

Chapter 5: Critical Process Parameters (CPPs) Definition and identification of CPPs Equipment-specific CPP examples Alarm strategy and validation Chapter 6: Critical Quality Attributes (CQAs) Definition and relationship with CPPs Typical CQAs for oral solid dosage products Monitoring and trending Chapter 7: Recipe Development Process URS, Functional Specification, Design Specification Recipe configuration, simulation, verification and validation Release lifecycle Chapter 8: Recipe Approval Workflow Roles and responsibilities Electronic approvals Release checklist Periodic review
This edition is intended as a concise PDF companion to the detailed handbook response generated in chat. It is suitable for GMP training, CSV awareness, and pharmaceutical automation reference.