**PROCESS CONTROL STRATEGY (PCS)**

*Product: [PRODUCT NAME]*

*Generated on: [DATE]*

# 1. Quality Target Product Profile (QTPP)

This section summarizes the QTPP elements and rationales.

# 2. Critical Quality Attributes (CQAs)

CQAs and phase-appropriate acceptance criteria.

# 3. Process Overview & Unit Operations

High-level overview of unit operations and their purpose.

# 4. Parameters & Controls

Parameters by unit operation, classification (CPP/pCPP/nCPP/PM), targets, ranges, and IPCs.

# 5. Control Strategy Matrix (Unit Operation × CQA)

Matrix indicating where attributes are controlled, monitored, or tested.

# 6. CPP / IPC Mapping

Mapping of parameters to IPCs and specification elements.

# 7. Acceptance Criteria (Phase-Appropriate)

Phase-based acceptance criteria for CQAs with increasing stringency.

# 8. Per-Unit Operation Narrative

Narratives describing how parameters and IPCs control CQAs, with risk-based justifications.

# 9. Phase-Appropriate Justifications

Narrative justification aligned to ICH Q8–Q12 principles and development phase.