

5. PROCESS VALIDATION AND/OR EVALUATION [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Process validation and/or evaluation studies for aseptic processing and sterilization should be included.

For Biotech:

Sufficient information should be provided on validation and evaluation studies to demonstrate that the manufacturing process (including reprocessing steps) is suitable for its intended purpose and to substantiate selection of critical process controls (operational parameters and in-process tests) and their limits for critical manufacturing steps (eg, cell culture, harvesting, purification, and modification).

The plan for conducting the study should be described and the results, analysis, and conclusions from the executed studies should be provided. The analytical procedures and corresponding validation should be cross-referenced (eg, 3.2.S.2.4, 3.2.S.4.3) or provided as part of justifying the selection of critical process controls and acceptance criteria.

For manufacturing steps intended to remove or inactivate viral contaminants, the information from evaluation studies should be provided in Appendix 3.2.A.2.