

3.2.P.3. Manufacture [{Drug Product Name}, {Dosage Form}]

5. PROCESS VALIDATION AND/OR EVALUATION [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Description, documentation, and results of the validation and/or evaluation studies should be provided for critical steps or critical assays used in the manufacturing process (eg, validation of the sterilization process or aseptic processing or filling). Viral safety evaluation should be provided in Appendix 3.2.A.2, if necessary.

Reference ICH guidance Q6B.