

3. MANUFACTURING PROCESS DEVELOPMENT [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The selection and optimization of the commercial manufacturing process described in 3.2.P.3.3, in particular its critical aspects, should be explained. Where relevant, the method of sterilization should be explained and justified.

Differences between the manufacturing processes used to produce pivotal clinical batches and the process described in 3.2.P.3.3 that can influence the performance of the product should be discussed.

Details on the process robustness including operating conditions, scale, and equipment should be summarized here including the discussion of any monitoring systems that evaluate critical attributes and process endpoints.