3. DESCRIPTION OF MANUFACTURING PROCESS AND PROCESS CONTROLS [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

A flow diagram should be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests, or final product controls are conducted should be identified.

A narrative description of the manufacturing process, including packaging, that represents the sequence of steps undertaken and the scale of production, should also be provided. Novel processes or technologies and packaging operations that directly affect product quality should be described with a greater level of detail. Equipment should, at least, be identified by type (eg, tumble blender, in-line homogenizer) and working capacity, where relevant. An alternative to the detailed narrative can be the inclusion of a proposed master production record.

Steps in the process should have the appropriate process parameters identified, such as time, temperature, or pH. Associated numeric values can be presented as an expected range. Numeric ranges for critical steps should be justified in 3.2.P.3.4. In certain cases, environmental conditions (eg, low humidity for an effervescent product) should be stated.

Proposals for the reprocessing of materials should be justified. Any data to support this justification should be either referenced or filed in this section (3.2.P.3.3).

Additionally, for Biotech see Appendix 3.2.A.1 for facilities, if appropriate.

Reference ICH guidance Q6B.