

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

#### **4. CONTROLS OF CRITICAL STEPS AND INTERMEDIATES [{DRUG PRODUCT NAME}, {DOSAGE FORM}]**

Critical Steps: Tests and acceptance criteria (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process should be provided to ensure that the process is controlled.

Intermediates: Information on the quality and control of intermediates isolated during the process should be provided.

Reference ICH guidances Q2A, Q2B, Q6A, and Q6B.