

4. CONTROLS OF CRITICAL STEPS AND INTERMEDIATES [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Critical Steps: Tests and acceptance criteria (with justification including experimental data) performed at critical steps identified in 3.2.S.2.2 of the manufacturing process to ensure that the process is controlled should be provided. Information should include the test method, acceptance criteria, and any justifications that may be required for non-standard test methods.

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

Reference ICH guidances Q6A and Q6B.

Additionally for Biotech: Stability data supporting storage conditions should be provided.

Reference ICH guidance Q5C.