6. JUSTIFICATION OF SPECIFICATIONS [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Justification for the proposed drug product specifications should be provided. The basis should be from Compendial standards, Batch analysis results (3.2.P.5.4), Stability study results (3.2.P.8.3), Analytical and manufacturing variability, and manufacturing data from different sites. If it is desired to justify omitting some tests, this justification should be included here as well (Reference Q6A).

Reference ICH guidances Q3B, Q6A, and Q6B.