

3.2.S.4. Control of Drug Substance [{Drug Substance Name}, {Manufacturer}]

5. JUSTIFICATION OF SPECIFICATION [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Justification for the drug substance specification should be provided including reference to Compendial standards, batch analysis results (Section 3.2.S.4.4), stability data, analytical and manufacturing variability, and data generated from multiple manufacturing sites.

Reference ICH guidances Q3A, Q3C, Q6A, and Q6B.