

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

1. SPECIFICATION [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

The specification for the drug substance should be provided.

Examples:

Description:

Solid, Liquid, Color, etc

- Assays
- Identification tests like IR or HTLC-UV
- Counter ion information for salts
- Enantiomer identification and information on other impurities (Q6A Decision Tree #5)
- Stability indicating tests (HPLC, titration with impurities, etc)
- Impurities (Q5A Decision Tree #1)
- Residual Solvents
- Physiochemical properties (pH, melting range, etc)
- Particle size distribution (Q6A Decision Tree #3)
- Polymorphic form (Q6A Decision Tree #4)
- Water Content
- Inorganic Impurities (sulfated ash, heavy metals, etc)
- Microbial limits (Q6A Decision Tree #6)

Reference ICH guidances Q6A and Q6B.

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The quality control specifications for _____ drug substance are provided in the table below.

Table 1: Specifications for {Drug Substance Name}

Test	Acceptance Criteria	Analytical Method