

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

2. ANALYTICAL PROCEDURES [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

The analytical procedures cited in the specifications for the drug substance should be provided. Compendial methods should be referenced unless a modified version is used. If the Compendial method is modified it should be submitted as an Analytical procedure with a summary of where the method was altered.

Obsolete procedures that may be referenced in sections 3.2.S.4.4 or 3.2.S.7.3 should not be submitted.

Reference ICH guidances Q2A and Q6B.

Note to the Author: Please replace text in <<blue>> with hyperlinks to the relevant document as submitted with this section.

Copies of the noncompendial analytical procedures used to test drug substance are provided in this section. The noncompendial analytical procedures are listed below in the same order in which they are listed in 3.2.S.4.1.

Table 1: Analytical Procedures used to test {Drug Substance Name}

Test	Analytical Method	Attachment
		<<3.2.S.4.2-1>>
		<<3.2.S.4.2-2>>
		<<3.2.S.4.2-3>>
		<<3.2.S.4.2-4>>
		<<3.2.S.4.2-5>>