

3.2.P.5. Control of Drug Product [{Drug Product Name}, {Dosage Form}]

2. ANALYTICAL PROCEDURES [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The analytical procedures cited in the specifications (3.2.P.5.1.) used for testing the drug product should be provided. Compendial methods should simply reference the compendia. Note that obsolete procedures such as those that may be referred to in 3.2.P.5.4. or those used in Stability studies do not need to be submitted or described here.

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 P.5.1.

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

Test	Analytical Method	Attachment
		<<P.5.2-1>>
		<<P.5.2-2>>
		<<P.5.2-3>>
		<<P.5.2-4>>
		<<P.5.2-5>>