

3.2.P.1 Description and Composition of the Drug Product [{Drug Product Name}, {Dosage Form}]

A description of the drug product and its composition should be provided. The information provided should include, for example:

Description of the dosage form.

Composition (ie, list of all components of the dosage form and their amount on a per unit basis (including overages, if any)) the function of the components, and a reference to their quality standards (eg, compendial monographs or manufacturer's specifications)

Descriptions of accompanying reconstitution diluents. For a drug product supplied with reconstitution diluent(s), the information on the diluent(s) should be provided in a separate part "P", as appropriate.

Type of container and closure used for the dosage form and accompanying reconstitution diluent, if applicable

Overfill information (Justification for overfill belongs in 3.2.P.2.2.1)

Reference ICH guidances Q6A and Q6B.