

1. COMPONENTS OF THE DRUG PRODUCT [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

1.1. Drug Substance [{Drug Product Name}, {Dosage Form}]

The compatibility of the drug substance with the excipients listed in 3.2.P.1 should be discussed. Additionally, key physicochemical characteristics (eg, water content, solubility, particle size distribution, polymorphic or solid state form) of the drug substance that can influence the performance of the drug product should be discussed.

For combination products, the compatibility of drug substances with each other should be discussed.

1.2. Excipients [{Drug Product Name}, {Dosage Form}]

The choice of excipients listed in 3.2.P.1, their concentration, and the characteristics that can influence the drug product manufacturability and performance should be discussed relative to their respective functions.