

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

2.1. Formulation Development [{Drug Product Name}, {Dosage Form}]

A brief summary describing the development of the drug product should be provided, taking into consideration the proposed route of administration and usage. The differences between clinical formulations and the formulation (ie, composition) described in 3.2.P.1 should be discussed. The discussion should include manufacturing process changes, container closure differences, and dosage form changes through the product's development along with rationale for changes and a discussion about any critical attributes that were identified during development.

If the product has any special attributes such as tablet scoring, overfill, co-packaged diluents, etc., they should be described and discussed in this section as well.

Results from comparative in vitro studies (eg, dissolution) or comparative in vivo studies (eg, bioequivalence) should be discussed when appropriate.

2.2. Overages [{Dosage Form}, {Dosage Form}]

Any overages in the formulations described in 3.2.P.1 should be described and justified. The justification should be in regards to manufacturing loss and the amounts of the overage should be justified in this section.

2.3. Physicochemical and Biological Properties [{Drug Product Name}, {Dosage Form}]

Parameters relevant to the performance of the drug product, such as pH, ionic strength, dissolution, redispersion, reconstitution, particle size distribution, aggregation, polymorphism, rheological properties, biological activity or potency, and/or immunological activity, should be addressed.

See Q6A Decision Tree #4 for polymorphism decisions.

See Q6A Decision Tree #7 for dissolution/disintegration decisions.