

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

#### 1. SPECIFICATIONS [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The specifications for the drug product should be provided. This should include Description (Size, Shape, color), Identification, and other assays. Impurities including degradation products (Q6A Decision Tree #2) created during drug product manufacture or stability should be discussed as well. Note drug substance impurities belong in section 3.2.S.3.2.

Reference ICH guidances Q3B, Q6A, and Q6B.

The quality control specifications for {Drug Product Name} are provided in the table below.

**Table 1: Quality Control Specifications**

Test	Limit	Method