

#### 3.2.P.4. Control of Excipients [{Drug Product Name}, {Dosage Form}]

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

The specifications for excipients should be provided. This should be completed for every excipient including those not found in the final product, (like water for a tablet). Reference the test method such as compendia or in-house methods

Reference ICH guidances Q6A and Q6B.

The quality control specifications for the excipients used in the manufacture of {Drug Product Name} are summarized in the table that follows.

### 3.2.P.4. Control of Excipients [ {Drug Product Name}, {Dosage Form} ]

**Table 1:      Quality Control Specifications**

Excipient	Test	Limit	Method

#### 3.2.P.4. Control of Excipients [{Drug Product Name}, {Dosage Form}]