3. STABILITY DATA [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Results of the stability studies should be presented in an appropriate format (eg, tabular, graphic, narrative). Information on the analytical procedures used to generate the data and validation of these procedures should be included if the analytical method is not provided in 3.2.P.5.2. The data provided should include the primary registration batches, forced degradation and stress studies.

A statistical report may be included with this section if one is required to interpret the data.

Information on characterization of impurities is located in 3.2.P.5.5.

Reference ICH guidances Q1A , Q1B, Q2A, Q2B, and Q5C.

Note to the Author: Please replace the text contained within <<double angle brackets>> with text that is applicable to the submission.

The stability results for three primary stability batches and the three validation batches are detailed below. Table 1 lists the various stability tables in this section.

Note: Table 1 serves as an overall table of contents to help the reviewer find the stability table they may be interested in. The actual columns or rows will need to be amended based on what is important and unique about the various stability tables being submitted for a specific product.

Table 1:   Stability Data for <<>>

Product	Table	Lot Number	Storage Condition
<<>>	Table 2		
	Table 3		
	Table 4		
	Table 5		

3.2.P.8. Stability [{Drug Product Name}, {Dosage Form}]

Table 2: **Stability data for <<LOT>> Stored at <<CONDITIONS>>**

Product: **Package Lot:**   **API Lot:**

Product Lot: **Container/Closure:**   **Storage Condition:**

Manufacturer: **Packager:**   **Study Init Date:**

Manufacture Date: **Package Date:**

Time Points (Month)

Test	Specifications	Initial	3 months	6 months	9 months	12 months	18 months

Duplicate Table 2 as necessary to allow stability tables to be presented. The actual format and layout of the cells will depend on the nature of the product being described here.

3.2.P.8. Stability [{Drug Product Name}, {Dosage Form}]