3. STABILITY DATA [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Results of the stability studies (eg, primary registration batches, forced degradation studies and stress conditions) should be presented in an appropriate format such as tabular, graphic, or narrative. Information on the analytical procedures used to generate the data (as well as changes to these procedures) and validation of these procedures should be included. If the procedures are not the same as described in 3.2.S.4.2., the procedure should be described in this section.

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

Note to the Author: Please replace text in blue with hyperlinks to the relevant document. Replace the text contained within <<double angle brackets>> with text applicable to this submission.

The stability results for three primary stability batches and the three validation batches are detailed below. Data are provided in Table 1, Table 2, Table 3, Table 4, Table 5, Table 6, Table 7, Table 8 and Table 9 for primary batches and Table 10, Table 11, Table 12, Table 13, Table 14, Table 15, Table 16, Table 17, Table 18 for validation batches. >>

3.2.S.7. Stability [{Drug Substance Name}, {Manufacturer}]

Table 1: Stability data for <<Actual Lot No.>> Stored at <<Actual Conditions>>

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

Duplicate Table 1 as necessary to allow stability tables to be presented.

3.2.S.7. Stability [{Drug Substance Name}, {Manufacturer}]