2. POST-APPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

The postapproval stability protocol and stability commitments are typically needed if a submission does not include long term stability data on 3 production batches. This is typically a commitment to initiate or continue studies and provide the data to the FDA.

Reference ICH guidances Q1A and Q5C.

The table below can be used to list "test" and "method" examples: test (Appearance) method (Visual (SOP 123-456)) or test (Identity) method (FT-IR (SOP 123-457)) with an "X" under the time points where this test would be performed. This table would likely be repeated so that all testing conditions can be described for the specific product (ie 25 ± 2°C/60 ± 5% RH, 30 ± 2°C /65% ± 5%RH, 40 ± 2°C/75% ± 5%RH).

Table 1: Stability of Production Lots

Test	Method	Time Point (Months)							
		0	6	12	18	24	36	48	60