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

1. STABILITY SUMMARY AND CONCLUSION [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The types of studies conducted (forced degradation, photostability, and stress testing), protocols used, and the results of the studies should be summarized. The summary should include, for example, conclusions regarding storage conditions and shelf life, and, if applicable, in-use storage conditions and shelf life.

Typical requirements are three batches including a minimum of two at pilot scale. These batches should be the same formulation and container closure system as the marketed product and should include each strength and container closure system unless bracketed. Each batch should use a different lot of drug substance and different lots of critical excipients.

A statistical analysis of the data is not necessary if stability is obvious but may be helpful in showing lot to lot variability or justification of shelf life under various storage conditions..

Reference ICH guidances Q1A, Q1B, Q3B, Q5C, and Q6A.