

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

1. STABILITY SUMMARY AND CONCLUSIONS [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

The types of studies conducted, protocols used, and the results of the studies should be summarized. The summary should include results, for example, from forced degradation studies and stress conditions, as well as conclusions regarding storage conditions and retest date or shelf life, as appropriate.

Number of batches should be confirmed with the FDA at the pre-NDA meeting but typically three batches manufactured at the pilot scale is the minimum. These should be from the same synthetic route as the proposed production process and of the same quality starting materials and container closure systems.

Protocol discussion should include discussion about parameters that are susceptible to change, any physicochemical, biological, and microbiological tests. Also note that stability studies may have additional testing that is not in the final drug substance release specifications.

Reference ICH guidances Q1A, Q1B, and Q5C.