

Q&A on ASEAN Stability Guideline

1. **Q:** Are stability testing parameters for example 'Friability' and 'Viscosity' and several others listed in the Stability guideline for finished product mandatory tests? Certain regulatory reviewers insist the inclusion of such testing parameters in the stability program citing these are mentioned in the ASEAN Stability guideline.

A: The listing of testing parameters for each dosage form in the ASEAN Stability Guideline is presented as a guide to the type of tests to be included in a stability study. It is not expected that every test listed be performed at each time point. The list of tests presented for each dosage form is not intended to be exhaustive, nor is it expected that every test listed be included in the design of a stability protocol for a particular finished pharmaceutical product. Similar guidance is also stated in Appendix 1 of the WHO's Stability testing of active pharmaceutical ingredients and finished pharmaceutical products – WHO Technical Report Series, No.1010, Annex 10, 2018.

https://extranet.who.int/prequal/sites/default/files/documents/TRS1010_Annex10.pdf

2. **Q:** Is 30°C/65% RH stability data acceptable for aqueous based drug products (e.g. oral liquids) packaged in semi-permeable containers, in lieu of 30°C/75% RH stability data?

A: The use of 30°C/65% RH stability data is generally considered a worse-case scenario than 30°C/75% RH stability data for aqueous based drug products packaged in semi-permeable containers. It is acceptable to use 30°C/65% RH stability data to support the physical, chemical, biological and microbiological stability of such products under Zone IVb conditions. Water loss studies, as per Section 4.7.3 of the ASEAN Stability Guidelines, should also be submitted in support of such products.