

Standard Operating Procedure

Title: Stability & Trial Testing Procedure

2.10.2. Under "Sequence" indicate in which months testing is required. Use this SOP to determine frequency of testing, and Stability Programs to determine which months and which testing sequence number.

2.10.3. When testing is complete, results are entered into the trial card.

3. General Requirements

- 3.1. Storage temperatures should be controlled to $\pm 2^{\circ}\text{C}$ and relative humidity at $\pm 5\% \text{RH}$. Excursions exceeding these ranges for more than 24 hours should be recorded.
- 3.2. Studies are carried out on closed primary packs, without secondary packaging except:
 - When secondary packaging affords additional protection.
 - When secondary packaging affords no additional protection but provides a convenient container for holding samples within the Stability rooms (e.g. box of tablet blister strips).
- 3.3. Primary packs selected for Stability should be representative of the entire batch. This does not preclude taking all samples from a specific portion of the packaging run, if they are deemed to be representative.
- 3.4. Primary packs containing liquid should be stored in an orientation that is most stressful along with control samples stored in an upright position.
- 3.5. Time zero is taken from the date samples are placed in Stability rooms.
- 3.6. Analysis should be completed within 30 calendar days.

4. General Data Generation and Analysis

- 4.1. Validated control methods for testing must be followed.
- 4.2. Testing is to be done in singlicate for Stability where method precision allows. If the test includes replicates, e.g. Dissolution, do a minimum number as required by the method. Testing is performed in duplicate for Trials unless indicated otherwise by the protocol.
- 4.3. Documented procedures shall be used to investigate OOS results and report any confirmed OOS to QA management. See SOP LAB-055.
- 4.4. Record all results. Normally this will only be one result, but if more than one determination was performed, compare each result with the specifications.
- 4.5. Trend analysis should be conducted annually.
- 4.6. Analytical results, which are numerical, are to be reported numerically not "complies" or "conforms" or "passes". This allows for data evaluation and analysis.
- 4.7. Testing dates are to be reported with each set of results.

5. Annual Maintenance Stability

- 5.1. Information regarding how many batches will be produced throughout the year is obtained from the preliminary master Production Schedules.
- 5.2. The number of batches placed on Stability and the frequency of testing designed to confirm the product exhibits the same Stability profile that was demonstrated on the first three batches. As suitable data is accumulated testing frequency can be reduced.