- Discard remaining samples from Fridge/Stability room.

2. General Sampling

2.1. Sampling of products for Stability testing is initiated by the Laboratory staff. Each week ,the Production Schedules are examined to determine which batches are required. The decision on which batches and which tests are required are based on Stability Programs**.**

2.2. Samples must be set down within 30 calendar days from the date of packaging.

2.3. Sufficient samples for chemical, physical and microbiological testing plus an overage for repeat testing are to be set down. The quantity of samples to be taken for Stability testing is given in **SOP MAN-125.**

2.4. All samples are to be stored at the temperatures specified in the Stability Protocol.

2.5. All products tested are to be stored in their usual containers, closures and packaging.

2.6. The frequency of testing points is recorded on the Stability & Trial cards. Samples for testing are sourced from the Stability Rooms or refrigerators.

2.7. Samples are stored in the fridge at 2-8°C and in the Stability rooms at the designated temperatures/humidity.
Ensure that all cartons are MARKED with BATCH NUMBER and EXPIRY DATE.

2.8. The temperature and humidity of the Stability rooms is monitored by the Plant Monitoring System.

2.9. When a batch is to be set down for Stability testing, the following details are filled in on the Stability/Trial card:

- Product name and strength,
- Container size and type
- Product code
- Batch number,
- Date of manufacture
- Storage temperature
- Quantity required from production
- Any relevant comments

The card is then sent to Production and warehouse office.

2.10. The Stability card then comes back to the Laboratory with the required samples. The Laboratory Technician in charge of Stability then completes the card with the following:

- The product Expiry date
- The Team
- Stability Specification no.(From Technical Service Master File, see SOP QMS-030)
- Sequence
- Tests to be performed
- Relevant testing points
- Container details (back of card)
- Any other comments
- Release results.

2.10.1. The Stability tests required are found by referring the Stability Specification folder.

* Initial results may be taken as the results of the batch release testing only if the release method is identical to the Stability method.	
L – Long term study	
I – Intermediate study	
A – Short term study	
25°C/60%RH	Long term storage to support marketing in Climatic Zone I & II.
25°C/40%RH	Long term storage to support semi-permeable containers
30°C/35%RH	Long term storage to support semi-permeable containers
30°C/60%RH	Accelerated storage conditions to replace 40°C/75%RH where allowed by guidelines or with flammable products.
40°C/25%RH	Accelerated storage conditions to support semi-permeable containers

6.5. Where a lower temperature long term storage condition in necessary (product instability), the six month accelerated condition should be performed.

7. Special Studies Stability (Trials)

7.1. When a permanent change is made and approved by the authorities, e.g. Method of Manufacture, Manufacture off site, or primary packaging material, which may affect the Stability, the first three (3) batches produced after the change must be included in the programme.

7.2. If a single batch is subject to any significant deviation during production, e.g. concerning formula, method of manufacture, or primary packaging material and this change is likely to affect the product stability, this batch must be included in the programme to give further Stability data.

7.3. The following modifications are typical of situations, which may require additional Stability studies.

- Changes in the manufacturing process of the bulk product
- Changes in the manufacturing site of the bulk product
- Changes in the formulation of the product
- New composition addition of the product
- Changes in the manufacturing process of the product
- Changes in the manufacturing site of the product
- Changes in the batch size of product
- Changes to the closure/container system (e.g. materials, size, configuration)
- Reprocessing of the drug product.

7.4. **Special Studies Arising from Manufacturing Changes**

7.4.1. The need for special studies, to support registration of specific manufacturing changes, shall be determined by a project team consisting of at least Technical, Regulatory, Production and Sourcing and Supply personnel.

7.4.2. An integrated Stability protocol or protocol is to be created.

7.4.3. The Project team will appoint a person responsible for responsible for coordinating all activities required to manufacture and pack the product and transport samples to the commercial Stability site.

7.4.4. The QA Manager of the site wishing to instigate a study shall agree the need for a study with other relevant sites (e.g. packaging or commercial Stability site).

