

Standard Operating Procedure

Title: Packed Tablet Sampling by Production Personnel For Testing

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1. Procedure

- 1.1. All Retention samples must be representative of saleable product.
- 1.2. Samples must be logged into Test and Retention Sample logbook ([Form-560](#)) by production staff and logged out by QA Personnel. Test Samples are taken by Laboratory Staff according to sample required by Finished Product Specification and Test Report. (See [SOP QMS-090](#))
- 1.3. Batch documents must also be logged into logbook ([Form-150](#)) by production staff. Batch Documentation should be received within 24 hours of completion of packing.
- 1.4. Packed Tablet Batch Documents and retention samples are evaluated by QA personnel . (See [SOP-QMS-090](#)). The required laboratory test Samples are taken by laboratory Staff from the retention samples and Sign the Logbook ([Form-560](#))
- 1.5. Stability samples must have the Orange Stability Card . The quantity required for stability is indicated in the "No. of boxes, which is located at the top right hand corner of the Stability Card ([Form-315](#)). The quantities indicated in the "Stability, column are to be taken ONLY from those batches where the Batch Documents have an Orange "Stability Card, attached to them but the amount to be taken on the Stability Card may vary from the amount indicated in the SOP. These samples are-in-addition-to those normally taken.
Note: All samples are to be in finished saleable pack for Stability and retention Samples.
- 1.6. Samples required for retention samples, stability and after-packing analysis, plus all part packs. Retention samples must be a representative from start, middle and end of manufacture.

2. Tablet Packing

2.1. Bulk Tablet Sampling (as raw material)

One tablet from every bulk container/ plastic bag is required to be placed in a sample jar for analysis by the Analytical Laboratory. (See [SOP WAR-080](#))

Each manufacturer s batch number is to be placed in a separately labelled sample jar.

After testing, these tablets are to be stored as retention Samples.

2.2. Finished Goods Sampling

Finished goods Sampling required for retention samples, test samples, stability and after-packing samples plus all part packs.

Note: Minimum number of Tablets for Retention Samples is 100 units.

2.2.1. Tablets in jars

Pack Size	Retention Sample
100 s	2 jars
1000 s	1 Jar

Note: Samples of each manufacturer s batch number must be given.

2.2.2. Tablets in blister packs

Pack Size	House Sample
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