

# Standard Operating Procedure

## Title: Evaluation of Batch Documentation and Release for Sale

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- 6.8. Check the printed material sample sheet (**Form-120**) and examine all required number of samples are attached, checked and signed by two authorised production operators according to SOP **MAN-055**. Check correct laboratory batch numbers are quoted on the printed samples.
  - 6.9. Check the correct quantity of retention samples are provided (See SOP **MAN-120**). Examine all retention samples physically for any defect or deviation from the requirement. Following are to be checked:
    - Correct BPN and code
    - Expiry date
    - Product Description and Strength/Concentration
    - Pack size
    - Check if there are leaflets enclosed if applicable
    - Check for security seals / holograms if applicable
    - Artwork check for FULLY packed product.Retention samples are given to laboratory for storing according to SOP LAB-045.
  - 6.10. Authorised QA Staff has to print out a QA Inspection sheet (**Form-565**) and start to fill up the Part A of the form. Tick batch documents are conform to legal and GMP requirement. Than send the Inspection sheet to authorised Laboratory person to fill up the Part B of the form (See SOP **LAB-065**).
  - 6.11. Check all other additional forms and records for correctness of the batch document.
  - 6.12. Authorised QA Staff checking the batch documents has to fill up the section 3 of the Batch document checklist (**Form-555**). Sign and date the checklist before sending the checklist to Authorised QA person to Release the batch.

### 7. Recording of Deviation Report

- 7.1. Check if any Deviation Report (DR) (**Form-450**) needs to be raised. Keep record of all the DR on the batch document checklist including the one raised by production personnel.
- 7.2. Check if the deviations are Production deviation (**DR1**) and affecting the particular BPN (See SOP **QMS-035**).
- 7.3. Send the DR to appropriate area managers for their response according to SOP **QMS-035**. **No batch can be released until all Deviation Reports are successfully completed, implemented and recorded.**
- 7.4. After completion of process related (**DR**) attach one copy with the batch document. For all other deviations follow SOP **QMS-035**.

### 8. QA Inspection Sheet

- 8.1. The QA Inspection Sheet (**Form-565**) summarises all tests required according the Finished Product Specification and Test Report (**TEM-145**) and whither the results are within the specification. Authorised Laboratory Staff has to fill up the Part B of the Inspection Sheet, raised for the particular BPN, against the completed Finished Product Specification and Test report and sign the form to complete. Send the Signed Inspection sheet to QA for final release. (See SOP **LAB-065**).

### 9. Release of Batches

- 9.1. Authorised QA Person responsible for batch release for sale will ensure the following before a batch is released for sale:
  - 9.1.1. Batch documents (completed MI Sheet, Forms and Records) are correctly checked for completeness and consistency.