Standard Operating Procedure

Title: Example of Checklists for Batch Documentation

Procedure

To be carried out by an Authorised Production Person (Operator)

1. At the Completion of the Batch

1.1. At the completion of a batch (BPN), authorised process operator has to print out a "Batch Documentation Checklist" (**Form-555**) relevant to the product (e.g. Tablets) manufactured. Check all the records and documents are attached including the all MI sheets relevant to the batch.

2. Evaluation of Batch Documentation by Production staff

2.1. All documents listed on the Batch Documentation Checklist **must be evaluated and signed by an authorised production staff before they are sent to QA for evaluation.** Each document should be reviewed and any issues resolved prior to collection by QA.

NOTE: The Quality Assurance Staff responsible for evaluating batch documents **will raise a DR** if any of the following deficiencies are noted during **QA evaluation** of the batch documents:

2.1.1. Critical entries have been left blank, e.g. missing signature on line clearance.

2.1.2. Excessive (i.e. greater than 5) non-critical entries are missing. (A production operator may correct non-critical entries, e.g. missing one tick, without raising of a DR by QA).

2.1.3. An entry is recorded incorrectly and not corrected, e.g. incorrect date.

2.1.4. Multiple (i.e. greater than 5) entries are marked as corrected by operators, as this indicates there has been an absence of due care.

2.1.5. Missing documentation, records or forms that cannot be recovered within 1 working day.

2.2. Authorised Process operator has to complete "Section 1 and 2" of the batch documentation checklist (**Form-555**). While completing the checklist, ensure that the correct documentation has been included into the Batch Documentation and that the documentation is **complete** and **accurate**.

NOTE: Batch documentation must be completed within 24hours of booking out the last pallet for each batch.

2.3. Sample the batch samples in accordance with **SOP MAN-120.**

2.4. Documentation, which has not been identified on the specific checklists, must be returned to area Managers for assessment as to its relevance to be included into the Batch Documentation.

2.5. A Comment on the Batch Documentation Checklist must be made to indicate if extra documents are to be kept with the Batch Documents. (This comment is appropriate for Protocol purposes and to ensure Weight Check Sheets which are used for statistical purposes, are filed in the correct place.)

Batch Documentation Checklist For Tablet Packing

(Ref. SOP QMS-075; QMS-085; QMS-090)

Production is to complete Sections 1 & 2
Quality Assurance Department is to complete Section 3

SECTION 1

PRODUCT NAME:	**BPN:**	**CODE:**

Tick appropriate boxes	✓
Put a N/A against boxes which are NOT APPLICABLE	N/A

SECTION 2

The following manufacturing documents and samples must accompany the checklist:

	Production ✓	**Prod Initial**	**QA ✓**
MI Sheets for all the process phases			
Deviation Report Form (If any **DR** raised)			
Printed Material Sample Sheet/s			
Bulk Tablet Sampling Form/s **(if applicable)**			
Line Clearance, Opening and Cleaning Form/s			
Finished Good Retention **Samples**			
Material Transfer Order Form/s			
Vacuum Leak Test - Hourly Form			
Vacuum Leak Test - New Foil and PVC Roll Form			
In-Process Check - Shipper Form			
In-Process Check-Blister and Carton form			
Batch Reconciliation Sheet for Tablet Packing			
IBC Cleaning Tag/s			
IBC Identification Label/s			
Checkweigher Weight Record **(if applicable)**			
Pallet Booking Information			

If any deviation raised write the DR Number/s: **(Attach the copy of deviation report/s)**
If any work-order raised during the batch write the order number/s:

Name of authorised production person (print name):		
Signature of Authorised production person:		**Date:**

