



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department: Quality Assurance**

**SOP No.:**

**Title: In-process Control on the Packing Line**

**Effective Date:**

**Supersedes: Nil**

**Review Date:**

**Issue Date:**

**Page No.:**

### 1.0 OBJECTIVE:

To lay down the procedure for in-process check during packing.

### 2.0 SCOPE:

This procedure is applicable to the checking of the quality of finished product during strip packing, blister packing and secondary packing i.e. labeling cartons and shippers etc.

### 3.0 RESPONSIBILITY:

Officer/Executive-Production

Officer/Executive - Quality Assurance

Head – Quality Assurance

### 4.0 DEFINITION (S):

NA

### 5.0 PROCEDURE:

#### 5.1 General procedure:

- 5.1.1 On receipt of the information from production to start the packing of the finished product, QA shall give the line-clearance to start the process.
- 5.1.2 Check that Batch Packing Record is available and duly completed till current stage.
- 5.1.3 Check that overprinting on all relevant components is checked by production.
- 5.1.4 Check that information for packing is displayed on the packing line such as Product Name, Batch No., Batch Size, Mfg. Date and Exp. Date.
- 5.1.5 During line clearance, QA shall ensure that BPR is completed up to current stage and available to start the packing operation.

#### 5.2 Check the following points during in-process:

##### 5.2.1 Strips/Blisters:

- 5.2.2 Inspect the strip/blister at the start of operation and regular intervals as follows:
  - a) Appearance of strips /blisters like



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- Knurling of blister/strip
  - Cutting edges
  - Blister information
  - Any defect in appearance of blister/strip
- b) Check empty pocket or broken tablet/capsule in pocket.
- c) Overprinted matter on foil is clear and legible.
- d) Ensure that only approved Primary packaging material is issued.
- e) Carryout the leak test.

### 5.3 Carton, Shippers & labels:

- 5.3.1
- Overprinted text is clear and correct.
  - Ensure that only approved Secondary packaging material is issued.
  - Damaged and rejected material is separated.
  - Carton has suitable number of strips / blisters inside.
  - Carton packaging and shipper packaging should only done by trained persons in proper supervision.
  - Correct product and batch details on shipper.
  - Online carton weighing shall be performed.
  - Shipper weighing shall be performed and recorded.

### 5.4 Enter the details in the in-process checklist given in BPR.

**Note:** If any parameter during manufacturing is out of specification or out of range, circle or underline shall be given in batch record so that it shall be highlighted the out of specification or range results

### 6.0 ABBREVIATION(S):

BPR : Batch Packing Record

QA : In-process Quality Assurance

### 7.0 REFERENCE(S):

NA



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### 8.0 ANNEXURE (S):

Annexure I : In-process sheet of packing



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### 9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION



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### ANNEXURE I

### IN-PROCESS SHEET OF PACKING

Product :  
Batch No. :  
Batch Size :  
Stage : Primary Packing  
Primary Packing Machine :  
Start time :  
End time :  
Date :

Parameters	Limits	Observations Time	Observations Time
<b>Overprinting Detail</b>	Mfg.: Exp.: MRP.:		
<b>Empty Pocket</b>	Nil		
<b>Torn Pocket</b>	Nil		
<b>Broken Tablet</b>	Nil		
<b>Printing Data</b>	Should be legible and clear		
<b>Leak Test</b>	Nil		
<b>Proper Cutting</b>	Should be Proper (no opening should be seen visually)		
<b>Sign/Date</b>	_____		

**Remark :** The Product complies/does not comply with the specification

**Sign / Date :**



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### IN-PROCESS SHEET OF PACKING MATERIAL

Product :  
Batch No. :  
Batch size :  
Stage : Secondary Packing  
Start time :  
Date :

Parameters	Standards	Observations Time	Observations Time
Inner & Outer Carton overprinting	Mfg Dt : Exp Dt : M.R.P :		
Coding on Shipper	B. No. : Mfd. Dt. : Exp. Dt. :		
Qty. packed in inner carton			
Qty. packed in Shipper.			

**Remark :** The Batch details on the Inner/Outer Carton box and the shipper is satisfactory/not satisfactory.

**Sign/Date:**