

BATCH PACKING RECORD

Product Name: PLACEBO

Document No.:

Effective Date:

Page No.: 1 of 12

Batch No.: DM

Batch Size:

Supersedes No.: Nil

Block : Production Tablets (PT)

Label Claim:	NA
Mfg. Lic. No.:	NA
Product Lic. No.:	NA
Self-Life:	NA
Pack Style:	NA
Country Name:	NA
Mfg. Date:	NA
Exp. Date:	NA
BMR Issued No.:	
MRP:	NA
Party:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

BATCH PACKING RECORD

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1.0 GENERAL INSTRUCTIONS:

- Good manufacturing practices should be followed during the entire process of packing.
- All the Equipments used for packing should be properly cleaned as per the relevant SOP.
- All the Equipments and containers should have proper status label with Stage, Product name, B. No., Mfg. Date etc.
- All the equipments should be operated as per the relevant SOP's only.
- Issued packing materials should be cross checked by production personnel against dispensing sheet before taking up for packing.
- Overwriting in BPR shall be strictly avoided & correcting shall be made as per SOP.
- All the activities should be carried out according to the BPR only. All the operations shall be carried out in clean and orderly manner.
- Any deviation in process shall be brought to knowledge of QA and prior approval of QA department should be taken.
- Critical parameters like temperature, Humidity and pressure differences should be checked and monitored.
- In process controls should be carried out throughout the packing operations as per relevant BPR and relevant SOP's.
- Ensure that all the packing materials, in process materials and finished goods should be placed in respective areas with proper label to avoid mix up.
- Attach additional issue sheets from QA, wherever required.
- Attach system generated data sheets wherever applicable.

	Prepared By	Checked By	Approved By
Signature			
Date			

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2.0 DISPENSING OF PACKING MATERIALS:

Date: _____

2.1 Instructions:

1. Follow the packing materials dispensing SOP.
2. Appropriate weighing balances should be used while issue.
3. Ensure that weighing balances are calibrated & Verified on daily basis.
4. Printed Al. Foil and Special /PVC should be issued in poly bags.
5. Each roll should be labeled separately.
6. Cartons should be issued in bundles.
7. Cartons should be kept in plastic/shippers crates covered with lid or supplier and properly labeled.
8. Carton should be closed with transparent Cello tape.
9. One complaint slip is pasted on inside flap of corrugated box.
10. Shippers should be issued in bundles with proper label.
11. Keep all issued materials on separate pallets in PM dispensing room.

2.2 Line Clearance Checks:

S.No.	Line Clearance Checks	Observation	Checked by QA
1.	Containers used for previous batch/product removed from area		
2.	All status labels of previous batch/products are removed		
3.	BPR or any other documents related to the previous batch / product are removed from area.		
4.	Absence of any previous product /batch remnants		
5.	Cleanliness of the area		
6.	Cleanliness of the area below balances/ pallets.		

2.3 Line clearance certificate for area and equipment:

Area	PM dispensing room	Equipment	Weighing Balance
Area Cleaned By:		Equipment No.:	
Checked By:		Equipment Cleaned By:	
Previous Product:		Batch No.:	
Checked By (Packing Supervisor):			
Sign & Date			
Line clearance Given By(IPQA):			
Sign & Date			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH PACKING RECORD**Product Name:** PLACEBO**Document No.:****Effective Date:****Page No.:** 4 of 12**Batch No.:** DM**Batch Size:****Supersedes No.:** Nil**2.4 BILL OF PACKING MATERIALS:**

(BPR Copy)

Date: _____

S. No.	Items	Std. Qty. for 1 Lac. In Kg/Nos.	@ Req. qty. In Kg/Nos.	Issued Qty. In Kg/Nos.	A.R. No.	Issued by Store	Checked By	
							Prod.	QA
1	Printed Aluminium Foil- 0.025, Foil Width = 272 mm	4.00 Kg						
2	Base Foil- Cold form Alu-Alu foil, Foil Width = 274 mm	32.00 Kg						

Note- @ Calculate the materials as per required batch size.**Dispensed By:**
(Store)**Checked By:**
(Prod. Supervisor)**Verified By:**
(QA)
Store copy page No.: 5 of 12

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH PACKING RECORD**Product Name:** PLACEBO**Document No.:****Effective Date:****Page No.:** 5 of 12**Batch No.:** DM**Batch Size:****Supersedes No.:** Nil**BILL OF PACKING MATERIALS****(STORE COPY)****Date:** _____

S. No.	Items	Std. Qty. for 1 Lac. In Kg/Nos.	@ Req. qty. In Kg/Nos.	Issued Qty. In Kg/Nos.	A.R. No.	Issued by Store	Checked By	
							Prod.	QA
1	Printed Aluminium Foil- 0.025, Foil Width = 272 mm	4.00 Kg						
2	Base Foil- Cold form Alu-Alu foil, Foil Width = 274 mm	32.00 Kg						

Note- @ Calculate the materials as per required batch size.**Dispensed By:**
(Store)**Checked By:**
(Prod. Supervisor)**Verified By:**
(QA)

	Prepared By	Checked By	Approved By
Signature			
Date			

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3.0 PACKING SPECIFICATION:

S. No.	Description	Over Printing Matter Standards (For Example only)	Over Printing Matter Actual	Checked By	
				Prod.	QA
A.	Primary Packing:				
	ALU-ALU Blister:				
1.	Alu-Alu Blister coding details	B. No.....			

3.1 STANDARD PACKING INSTRUCTIONS:

- Check and verify the status board/label.
- Line clearance certificate to be obtain from IPQA before starting any activity.
- Transfer the QC released tablets of the batch to the primary cubicle.
- Produce the blister of 1/1 tablets using 272 mm printed aluminum foil & 274 mm base foil on a blister packing machine. The blister should be duly overprinted with the respective batch legend.
- Blister sealing leak test should be performed periodically to monitor the sealing.
- Each blister should be visually inspected to reject the defective ones.

3.2 PACKING -

Date: _____

Instructions:

- a. Gowning should be follows as per SOP.
- b. Masks and gloves should be used in the primary packing.
- c. Check for the cleanliness of the area and equipment.
- d. Check the Temperature, Humidity, and differential Pressure as per BPR or as per SOP
- e. Check that batch/product is released by QC for packing before starting of packaging operations and transfer to primary packing.
- f. Check the status label on the area on the display board outside the packing cubical.
- g. Operate Alu-Alu blister packing machine as per SOP.
- h. Line clearance should be given take during any shift change.
- i. Line clearance procedure should also be followed in case of change in stereo or any major breakdown which can affect the packing quality.

	Prepared By	Checked By	Approved By
Signature			
Date			

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3.3 Line clearance check (Initial/shift change over):

Line Clearance of Packing Line _____ Please Tick If Yes & X If No or Not Applicable

S.No.	Clearance Checks	Date											
		Time											
1.	Product name: NA												
2.	Area Cleanliness below/ Balance/ Pallets/ etc.												
3.	Machine Cleanliness												
4.	Packaging material of previous product remove.												
5.	Over coding details on Blisters												
6.	Over coding details on unit carton												
7.	Pasting cello tape	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
8.	Over coding details on outer carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
9.	Product Packaging Insert	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
10.	Specimen of 5 Ply Shipper coding	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
11.	Correctness of status label	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
12.	Daily Verification of balances												
Checked by Production (Sign/Date)													
Verified by IPQA (Sign/Date)													

3.4 Verification of tablet received from core area:

Total Container No.	Total Weight	Checked by Production	Verified by IPQA

3.5 Stereo detail:

Issue the required number of stereos to operator and retrieve the same from them after completion of activity and record shall be maintained as per table given below;

No. of stereos received from QA		No. of stereos given to operator		No. of stereos returned by operator		Total No. of stereos submitted to QA		Submitted by (Packing)	Retrieved By (IPQA)
Carton	Blister	Carton	Blister	Carton	Blister	Carton	Blister		
NA		NA		NA		NA			

	Prepared By	Checked By	Approved By
Signature			
Date			

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3.6 Over coding detail for blister, carton and shipper

S.No.	Over printing details		Blister (ALU-ALU)
	Details on PM (for example)	Actual details	
1.	Product:		
2.	Batch No.:		
3.	Mfg. Date:	NA	NA
4.	Exp. Date:	NA	NA
5.	M.R.P.: (Incl. of all taxes) Per 10 Tablets	NA	NA
6.	Qty.	NA	NA
Packing	Signature		
	Date		
IPQA	Signature		
	Date		

Note: Which is not applicable mention NA and put tick mark which is applicable.

4.0 ALU-ALU BLISTERING:

4.1 Machine Setting:

1. Take line clearance from IPQA.

Line clearance certificate for area and equipments:			
Area		Equipment	ALU-ALU Machine
Area Cleaned By		Equipment No.	
Checked By		Equipment Cleaned By	
Previous Product		Batch No.	
Checked By (Packing Supervisor): Sign & Date			
Line clearance Given By(IPQA): Sign & Date			

2. Check the change parts as per product specification.
3. Mount the rollers and check the cavity alignment of sealing roller.
4. Mount BCP, and affix stereos.
5. Adjust forming & sealing temperature and pressure.

	Prepared By	Checked By	Approved By
Signature			
Date			

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6. Load the printed and plain foil, and adjust machine to smooth foil run and take out proof of Batch coding. Get the approval from packing supervisor and IPQA.
7. Set the sealing temperature 170°C to 190°C.
8. Ensure proper Knurling and cutting length.
9. Check status label on Tablets containers.
10. Load the hopper with Tablets to be stripped.
11. Operate the Alu-Alu blister packing machine as per SOP.
12. Check the leak test of blister as per Leak Test SOP. Record it in in-process control record.
13. Attach approved specimen sample to BPR duly signed by Packing Supervisor and QA Personnel.

4.2 General instruction :

1. Carry out Blistering operation after batch printing approval by production supervisor & IPQA.
2. Record the parameters at a stated frequency.
3. Carry out the Leak test as per SOP.
4. Note the changes in foil rolls and splices.
5. Check the coding on each splice and foil at the start and end. Check at least 1 meter section of each side.
6. Foil rolls / Splices should be numbered.
7. Attach the sample of every new foil roll and every splice in each roll with BPR.
8. Note the Machine start, stop and end time.

4.3 Alu-Alu Blister Packing Start up Control Checks:

1. Run the machine and collect few initial Blisters.
2. Check for Knurling, Cutting, sealing, batch overprinting, etc. and observation shall be recorded.
3. If the initial parameters are satisfactory, continue packing.
4. In process test observation shall be recorded both by packing and IPQA supervisor.

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Signature			
Date			

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5.0 IN PROCESS CHECK:

5.1 In-process check by production at initial and every 30 min.

S. No.	In process checks	Date											
		Time											
1.	Temp.												
2.	RH												
3.	Forming roller temperature												
4.	Sealing roller Temperature												
5.	Check working of NFD by removing one tablet from each track												
6.	Tab. with foreign / black particle												
7.	Foil shifting												
8.	Batch detail on foil												
9.	No. of tab/ Blister												
10.	Proper cutting of Blister												
11.	Leak test (Hourly)												
12.	Proper gluing of carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
13.	No. of Blister in one printed carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
14.	Batch detail on printed carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
15.	Seal the carton with cello tape	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
16.	No. of carton in one shipper	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
17.	Batch details on shipper label	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
18.	Pasting of BOPP tape	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (Production)													

	Prepared By	Checked By	Approved By
Signature			
Date			

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5.2 In-process check by IPQA for initial and every 60 min.

S. No.	In process checks	Date												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller temperature													
4.	Sealing roller Temperature													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Bi-hourly)													
12.	Proper gluing of carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
13.	No. of Blister in one printed carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
14.	Batch detail on printed carton	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
15.	Seal the carton with cello tape	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
16.	No. of carton in one shipper	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
17.	Batch details on shipper label	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
18.	Pasting of BOPP tape	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)														

	Prepared By	Checked By	Approved By
Signature			
Date			

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7.0 RECONCILIATION OF PACKING MATERIAL:

S.No.	Material	Printed Aluminum foil	Base foil
1.	Std. Qty.		
2.	Quantity Issued		
3.	Extra Qty. issued		
4.	Qty. used		
5.	Qty. returned (attach MRN)		
6.	Qty. destroyed after coding		
7.	Qty. destroyed after pkg.		
8.	Total qty. destroyed		
9.	Qty. destroyed by		
Checked by Prod. (Sign/Date)			
Verified by IPQA (Sign/Date)			
10.	Remarks		

	Prepared By	Checked By	Approved By
Signature			
Date			