STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Terminal Inspection and Transfer of Finished Goods	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Terminal Inspection and Transfer of Finished Goods.

2.0 SCOPE:

This SOP is applicable for Terminal Inspection and Transfer of Finished Goods at ……

3.0 RESPONSIBILITY:

Officer/Executive- QA

4.0 ACCOUNTABILITY:

Head - QA

5.0 DEFINITION: Not Applicable.

6.0 PROCEDURE:

6.1 During secondary packing of batch, production personnel shall prepare intimation for Terminal Inspection in **"Terminal Inspection Intimation cum Inspection Report"**, as **Annexure-I**.

6.2 Intimation may be raised by production for terminal inspection in case of partial release.

6.3 IPQA person shall receive the intimation from production and select the Nos. of shippers for terminal inspection as per below mentioned criteria including first & last shipper and lower & higher weight shipper . Terminal inspection observation details shall be filled by QA in **"Terminal Inspection Check List", a**s per **Annexure-II.**

A	**Selection of Packed Corrugated Boxes**	
i)	10 or less	100%
ii)	11 to 100	20% of total C. boxes but not less than 10 Nos.
iii)	More than 100	10% of total C. boxes but not less than 20 Nos.
B	**Selection of Shrink Pack**	
i)	Less than 50	30%
ii)	Pack of 50 to 100	15% but not less than 15 Nos.
iii)	Pack more than 100	8% but not less than 15 Nos.

C	**Selection of Unit Pack**	
i)	Less than 50	30%
ii)	Pack of 50 to 100	15% but not less than 15 Nos.
iii)	Pack more than 100	8% but not less than 15 Nos.
D	**Following Parameters to be Checked, but not limited to:**	
i)	No. of shipper received	
ii)	Name of the product	
iii)	B. No., Mfg., Expiry, Retail. Price	
iv)	Spreading of ink on label	
v)	Quantity of unit pack Ampoules/Vial per shipper	
vi)	Quantity of Ampoules/vial per catch cover/carton	
vii)	BOPP tape printed/plain	
viii)	Quality of shipper (5ply/7ply/others)	

6.3.1 If any Critical defects shall be observed during terminal inspection, hold the batch for 100 % re-checking by production followed by re verification by QA. Details of critical defects are given below, but not limited to:

Critical Defects:

- Containers without Label/Reverse Label
- Containers or cartons without Batch Coding/Cut Batch Coding.
- Cartons without Containers/SWFI etc.
- Containers without Medicine.
- Crack or broken Containers
- Observation of particulate matter
- Sealing defects

6.3.2 In case of major defects hold the material and send to production packing department for necessary correction according to identified issue. Details of major defects are given below, but not limited to:

Major Defects:

- B. No., Mfg., Exp. and retail price on Carton/Labels is not readable.
- Weight/volume of drug is not within specified limit in Ampoule/Vials/bottles.
- Less or more quantity of unit packed in container.
- Spreading of ink on label & carton

6.3.3 In case of minor defects, solve the problem on-the-spot. Details of minor defects are given below are given below , but not limited to :

Minor Defects:

- Shipper has dent
- BOPP tape is not properly placed.
- Label on shipper is not properly placed.

6.3.4 After Corrective action IPQA Officer/Executive shall again check the defect marked and approve the product.

6.3.5 IPQA Pack stock inspector shall mention the Inspection details in **"Final Terminal Inspection Report"** as mentioned in Annexure-III

6.3.6 Partially batch can be transferred in case of any urgency after verification of complete documents of relevant product.

6.4 IPQA Officer/Executive shall check the final Terminal Inspection Check List along with respective products BMR/ BPR and after satisfactory review of all required documents, IPQA personnel shall mention their remark in required column of **"Terminal Inspection Intimation cum Inspection Report"** and submit to production personnel.

6.5 After receiving of satisfactory remark from IPQA personnel in **"Terminal Inspection Intimation cum Inspection Report"** production personnel shall generate the Transfer ticket for the said batch of product and submitted to IPQA Officer/Executive.

6.6 IPQA Personnel e shall check the Transfer .Ticket and match the quantity & other details of Transfer ticket with **"Terminal Inspection Intimation cum Inspection Report"** & also with respective product BPR and after satisfactory review of the same, IPQA personnel shall put their signature in Transfer ticket & handover to Production department for transfer of batch to FG warehouse.

6.7 After receiving of transfer ticket Production personnel shall transfer the batch to FG warehouse area along with Transfer ticket for awaiting of release. Two transfer tickets along with complete terminal inspection report shall be enclosed with respective product BPR.

6.8 Record the Inspection Report details in **"Terminal Inspection Record Log"** as mentioned in **Annexure-IV**.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
No.	Number
Ltd.	Limited
FG	Finished Goods
B. No.	Batch Number
T.T.	Transfer Ticket
Qty.	Quantity
Mfg.	Manufacturing
IPQA	In Process Quality Assurance
Exp.	Expiry
BMR	Batch manufacturing record
BPR	Batch packing records

8.0 ANNEXURE:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Terminal Inspection Intimation cum Inspection Report	
Annexure-II	Terminal Inspection Check List	
Annexure- III	Final Terminal Inspection Report	
Annexure- IV	Terminal Inspection Record Log	

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9.0 DISTRIBUTION:

- Master Copy — Quality Assurance
- Control Copy — Quality Assurance
- Control Copy — Production

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I
TERMINAL INSPECTION INTIMATION CUM INSPECTION REPORT

Date:-					
Floor		**Section**		**Line**	
Product Name				**Batch Size**	
Batch No.		**Mfg. Date**		**Exp. Date**	
Intact Packed Qty. Details			**Loose Packed Qty. Details**		
Total Packed Qty.			**Total No. of Packed C.B.**		
Product Type	**Sales/PS/Hospital Supply**				
Manufactured For:					

Officer/Executive - Production
Sign & Date

Head – Production
Sign & Date

T.I. Report No.		**Date**	
Intact Packed Qty.		**Loose Packed Qty.:**	
Total Packed Qty.:		**Total No. of Packed C.B.**	

QA Remark:

The Product Packed is/is not of Standard Quality and hence it May/May not be transferred to Finished Goods Store in "Under Test"/"Approved" Area.

Officer/Executive - QA
Sign & Date

Head – QA
Sign & Date

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ANNEXURE –II
TERMINAL INSPECTION CHECK LIST

Product Name		**Mfg. Date**	
Batch Number		**Exp. Date**	
Batch Size		**Date**	
Pack Size			

Item	Check Parameters		Qty. Checked	Observation	Remark
Corrugated Box	Packed shipper shall be checked and ensured that it is intact clean & un-mutilated.				
	No. of Ply shall be checked and it shall be same as mentioned in it's Specification.				
	Klass marking details must be checked and ensure that it is on the outer surface of all the C. Box.				
	Printed Matter on Packing Slip shall be identical with respect to Product's BMR/BPR (wherever & whatever is applicable.		Total No. of C.B. : Checked C.B. No. ↓		
	Product Name				
	Batch No.				
	Mfg. Date				
	Exp. Date				
	Pack Size				
	Manufactured By				
	Marketed By :				
Outer Carton / Shrink Wrapped Carton	Printed Matter on all the Outer Carton / Shrink Wrapped Carton shall be identical with respect to Product's BMR & BPR.		Total No. of Shrink Packed / Outer Carton Checked:		
	Additional Inserts				
	Batch coding information				
	Batch number				
	Mfg. Date				
	Exp. Date				
	*M.R.P. with (I.A.T.)				
	Ink quality				
Inner Carton /Tray/ Label of Container	Printed Matter on all the inner Carton / Label of Container / Container as well as it's Quality shall be identical with respect to Product's BMR & BPR. e.g. :		Total No. of Inner Carton /Container Checked:		

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	Packing Specification				
	Additional Inserts				
	Generic Name				
	Product Name				
	Batch number				
	Mfg. Date				
	Exp. Date				
	*M.R.P.				
	Ink quality	Ink should not is erase after small rubbing			
	Labeling	Improper labeling not allowed.			
	Cleanliness	Each Unit must be properly cleaned			

Checked By:
(Sign & Date)

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ANNEXURE –III
FINAL TERMINAL INSPECTION REPORT

Generic Name					**Shift**		**Date**		
Product Name					**Line**		**Transfer Detail**		
Batch No.		**Mfg Date**			**Section**		**Part**	**Qty.**	
Batch Size		**Exp. Date**		**Sale/P.S./Export/Other**			**Ist**		
MRP Rs./Unit		**Pack Size**					**IInd**		
MRP Rs./Carton		**Manufactured For**					**IIIrd**		
Sample Detail	**Control + Extra**			**Party**			**Stability**		

Packing Style			**Weight Range**	
S. No.	**Pack**	**Qty.**	**Mono Carton**	
1.	**Mono Carton Pack/ Tray Pack**			
2.	**Shrink**		**Shrink**	
3.	**Blister Pack**		**Outer Carton**	
4.	**Outer Carton Pack**			
5.	**Corrugated Box Pack**		**Corrugated Box**	
Total No. of Checked C. Box				
Total No. of Packed C. Box			**CB Ply**	

S. No.	**CB No.**	**Checked CB Wt.**	**Observation**	**Rechecked CB**	**Remarks**

Done By
Sign. & Date

Checked By (Prod.)
Sign. & Date

Verified By (QA)
Sign. & Date

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ANNEXURE –IV
TERMINAL INSPECTION RECORD LOG

S.No.	Product Name	B. No.	B. Size	Pack Size	Mfg.	Exp.	Transfer Qty.	Gross Yield	Net Yield	Rej. Qty	% Rejection	Sample Qty.	Transfer Date	Market	Sign & Date (QA)	Remarks