



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Procedure for De-Cartoning and Cleaning of Tube, Bottle and Jar	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for De-Cartoning and Cleaning of Tube, Bottle & Jar.

2.0 SCOPE:

This SOP is applicable for De-cartoning and Cleaning of Tube, Bottle & Jar in Ointment section.

3.0 RESPONSIBILITY:

Production Officer/Executive

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR Batch Production and Control Record
IPQA In-Process Quality Assurance
No. Number
SOP Standard Operating Procedure

6.0 PROCEDURE :

6.1 PRECAUTION:

6.1.1 Use hand Gloves, goggles and nose mask during the Cleaning of Bottle & Jar in Production Area.

6.1.2 Use hand Gloves and nose mask during the De-cartoning of Tube in Production Area.

6.2 GENERAL REQUIREMENT:

6.2.1 Check the cleanliness of De-Cartoning Table/ Cassette Box/ Blue and red Crate.

6.2.2 Check the "CLEANED" Status label on Table/ Cassette Box/ Blue and red Crate.

6.2.3 Remove the "CLEANED" status label from Table/ Cassette Box/ Blue and red Crate and affix the "INPROCESS" label.

6.2.4 Take Line Clearance from IPQA.

6.3 OPERATION:

6.3.1 PROCEDURE FOR DE-CARTONING OF TUBE:

6.3.1.1 Check the issued Quantity of Tubes according to BPCR in De-Cartoning Area.



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6.3.1.2 Put the packed Tray/Box on the De-Cartoning Table & remove the Shrink & Tray/De-Boxing Using Knife/Paper Cutter.

6.3.1.3 Collect the Shrink / Box in the Waste Bin.

6.3.1.4 Inspect the Tubes for any defect & Collect the Damage Tubes in the Reject Bin/Red Crate with status label.

6.3.1.5 Load the Cassette Box/ Blue Crate with ok tubes.

6.3.1.6 Transfer Cassette Box/ Blue Crate into respective filling area through hatch.

6.3.1.7 Rejected tube, make OLR or transfer scrap and Entry of Rejected Tubes in the BPCR.

6.3.1.8 After Completion of Batch affix "TO BE CLEANED" status Label on Table/ Cassette Box/ Blue Crate.

6.3.2 PROCEDURE FOR DE-CARTONING AND CLEANING OF BOTTLE:

6.3.2.1 Check the issued Quantity and A.R. No. of Bottles & Jar according to BPCR in De Cartoning Area.

6.3.2.2 Put the packed Tray/Box on the De-Cartoning Table & open the Shrink & Tray/De-Boxing Using Knife/Paper Cutter from opposite side.

6.3.2.3 Inspect the Bottles & Jar visually for any defect & Collect the Damage Bottles & Jar in the reject Bin/ Red Crate with status label.

6.3.2.4 One by one, Bottles clean with Air Jet Cleaning machine or manually.

6.3.2.5 Cleaned Bottles put in the cleaned Blue Crate with status label.

6.3.2.6 Filled Blue Crate transfer into respective filling area through hatch.

6.3.2.7 Rejected bottles, make OLR or transfer to scrap and Entry of Rejected Bottle in the BPCR.

6.3.2.8 After Completion of Batch affix "TO BE CLEANED" status Label on Table/ Blue and red Crate.

6.3.3 PROCEDURE FOR DE-CARTONING AND CLEANING OF JAR:

6.3.3.1 Check the issued Quantity and A.R. No. of Jar according to BPCR in De-Cartoning Area.

6.3.3.2 Put the packed Tray/Box on the De-Cartoning Table & open the Shrink & Tray/De-Boxing Using Knife/Paper Cutter from opposite side.

6.3.3.3 Inspect the Jar visually for any defect & Collect the Damage Bottles & Jar in the reject Bin/ Red Crate with status label.



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6.3.3.4 One by one, Bottles clean with Air Jet Cleaning machine. Record the Details in “EQUIPMENT LOG BOOK”.

6.3.3.5 Cleaned Jar put in the cleaned Blue Crate with status label and cover with poly bag.

6.3.3.6 Put the Blue Crate in the static pass box of filling area.

6.3.3.7 Make OLR and Entry of Rejected Jar in the BPCR.

6.3.3.8 After Completion of Batch affix “TO BE CLEANED” status Label on Table/ Blue and red Crate.

6.3.4 CLEANING:

6.3.4.1 Ensure that the Table/ Cassette Box/ Blue Crate have a “TO BE CLEANED” Status label.

6.3.4.2 Remove the “TO BE CLEANED” label from the De-cartoning Table/ Cassette Box/ Blue & Red Crate.

6.3.4.3 Wet mop (70% IPA) the Table/ Cassette Box/ Blue Crate with Lint Free Cloth, followed by Dry Mopping.

6.3.4.4 Affix a “CLEANED” status label on Table/ Cassette Box/ Blue & Red Crate.

7.0 ANNEXURES:

Not Applicable.

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change control No.	Details of Changes	Reason for Change	Effective Date	Updated By