



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: De-Cartoning of Ampoules	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for De-Cartoning of Ampoules.

2.0 SCOPE:

This SOP is applicable for De-Cartoning of Ampoules in Production area at

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 PREREQUISITES:

- 6.1.1** If any shipper observed with broken Ampoules that shipper shall be used after 100% physical verification of vials.
- 6.2** Ensure that vials boxes are clean and free from dust.
- 6.3** Verify the quantity and size of Ampoules as per Batch Manufacturing Record (BMR).
- 6.4** Remove shrink wrap or strapping from the box.
- 6.5** Shipper/box to be open by removing adhesive tape.
- 6.6** Take out the Ampoules from the Shipper/ box and kept on inspection table under illuminated light to inspect physical defects (mold defect/black particle/scratch in surface/broken Bottom/broken neck) and kept in pigeon hole rejection box under lock and key condition and good Ampoules to be transfer for washing process with the help of SS plate.



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6.7 After completion of De-Cartoning activity all Rejected Ampoules to be count in the present of Production and IPQA Officer and record the detail in **Annexure-I**, Titled as “**Log of De-Cartoning Ampoules**”.

7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
UV	Ultraviolet Light
IPQA	In-Process Quality Assurance
BMR	Batch Manufacturing Record
SS	Stainless Steel

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure- I	Log of De-Cartoning Ampoules	
Annexure- II	Type of Defective Ampoules	

9.0 DISTRIBUTION:

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

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 – II

TYPES OF DEFECTIVE AMPOULES



BLACK PARTICLE



BROKEN BOTTOM



BROKEN NECK



SCRATCH IN SURFACE