PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: De-Cartoning of Vials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for De-Cartoning of Vials 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 vials 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 vials 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 vials from the Shipper/ box and kept on inspection table under illuminated light to inspect physical defects (mold defect/crack vials /scratch vials/ spot on vials /body neck variation) and kept in pigeon hole rejection box under lock and key condition and good vials to be transfer for washing process with the help of SS plate.

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

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7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
QA	Quality Assurance
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 Vials	
Annexure- II	Type of Defective Vials	

9.0 DISTRIBUTION:

- Controlled Copy No.01 Production
- Controlled Copy No.01 Quality Assurance
- 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 – I

	PRODUCTION
	LOG OF DE-CARTONING VIALS

Area: **Location:**

Date	Product Name	Batch No.	Operation Time		Quantity of De-Cartoned Vials	Defective / Rejected Vials Detail in Nos.	Done By Sign & Date	Checked By Sign & Date	Remarks
			From	To					

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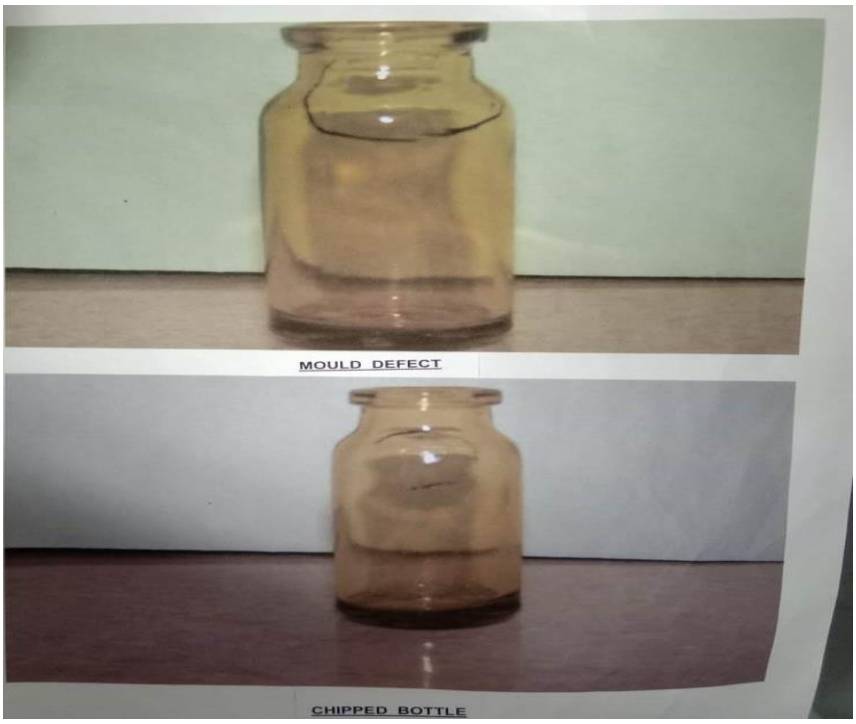
ANNEXURE – II

	PRODUCTION
	TYPES OF DEFECTIVE VIALS



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