



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Decartoning of Ampoules

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 7	

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 Ampoule Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

Ltd. Limited

No. Number

QA Quality Assurance

SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 PREREQUISITES:

6.1.1 Always open the shipper / box in inverted position of inside ampoules.

6.1.2 If any pack with crushed ampoule in it, should be discarded.

6.2 Ensure that ampoules 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 Invert the shipper / box and open empty ampoules shipper / box by removing adhesive tape.

6.6 Remove the ampoules from the box and check for any breakage, short out the rejected ampoules.

6.7 Transfer the good ampoules in tray.

6.8 Inspect the ampoules for any breakage or any other defect and observation as per **Annexure –I** & record in **Annexure-II**, Titled “**Log of De-Cartoning Ampoules**”.

6.9 In case of any ampoule breakage observed in shipper, quarantine that particular shipper / box / shrink in inverted position only in the dedicated marked area.



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6.10 Write Serial No. & Time of observation on each quarantined pack using black marker pen. It to be used after 100% individual ampoule inspection at end of De-Cartoning stage.

6.11 Load the good ampoules on conveyor for Washing & Depyrogenation.

6.12 After completion of good shipper / shrink, inform to In-Charge (IPQA & Production personnel) for starting the inspection of quarantined shipper / shrink.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure- I	Ampoule Defect During Visual Inspection	
Annexure- II	Log of De-Cartoning Ampoules	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of changes	Reason For change	Effective Date	Updated By



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ANNEXURE-I AMPOULE DEFECT DURING VISUAL INSPECTION

NECK CRACK BREAKAGE





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BREAKAGE AT BOTTOM



SPOT ON SURFACE





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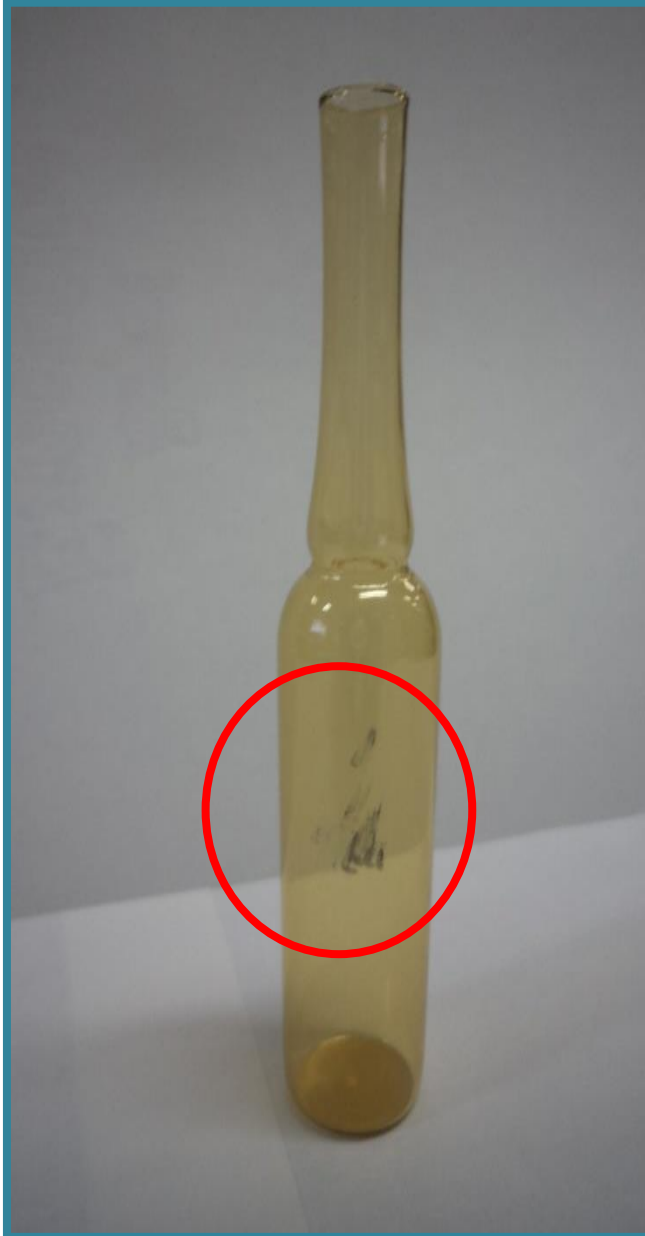
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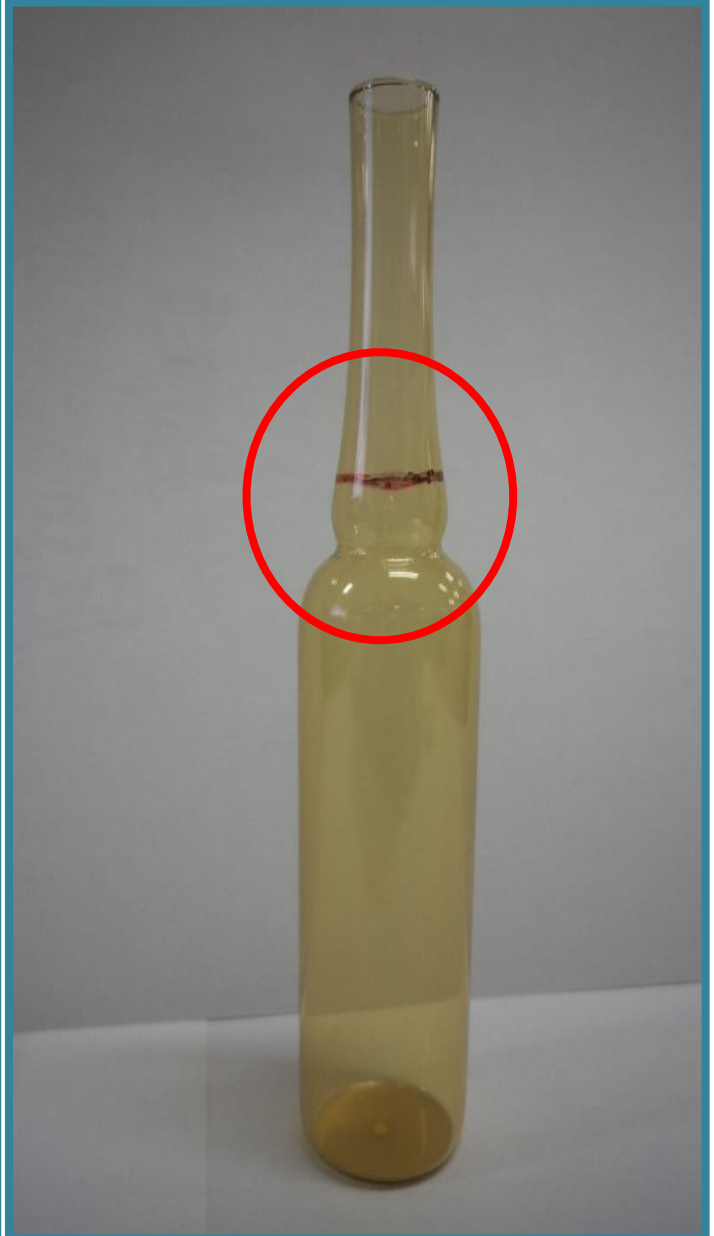
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DIRTY SURFACE



WRONG POSITION OF RING





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NARROW NECK

