



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Visual Inspection of Filled and Sealed Low Density Polyethylene (LDPE) Bottles

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a procedure for the Visual Inspection of Filled and Sealed Low Density Polyethylene (LDPE) Bottles.

2.0 SCOPE:

This SOP is applicable for the Visual Inspection of Filled and Sealed Low Density Polyethylene (LDPE) Bottles in packing area.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

SOP Standard Operating Procedure

LDPE Low Density Polyethylene

Ltd. Limited

etc. Etcetera

QA Quality Assurance

No. Number

NLT Not Less Than

Pvt. Private

CB Corrugated Box

USP United States Pharmacopeia

6.0 PROCEDURE:

6.1 Before the starting of the visual activity, must be insure cleanliness of visual inspection booth and recorded it in concern logbook. After assurance of the cleaning of the visual inspection booth take line clearance from QA department.

6.2 Ensure that the Lot-wise bottles shall be received for packing, so that lot wise packing shall be performed, it should reflect on the print out of corrugated box weight.

For e.g.: Packed CB. No. : 1 to 100 (Lot No.-01)

Packed CB. No. : 101 to 200 (Lot No.-02)

Packed CB. No. : 201 to 300 (Lot No.-03)



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Note: If two lots packed in one CB, mark star (*) and remarks shall be written on print out for the lot wise bottles in that particular CB, Sign and Verified by shall be done by Production and QA.

6.3 Pick up two bottles at a time from the side row of conveyor belt for Visual Inspection.

6.4 All individual bottles will be checked for sort out the following defects mentioned below:-

- | | | |
|-----------------------------|-----------------------------|-----------------------------------|
| 1. Dip line on body surface | 6. High volume | 11. Extra plastic on head |
| 2. Embossing Problem | 7. Black particle (Surface) | 12. Low volume |
| 3. Hanger cut | 8. De-shaped | 13. Improper Head Formation |
| 4. Tip Cut | 9. Extra plastic on neck | 14. Extra plastic on bottom joint |
| 5. Collar cut | 10. Rough surface | 15. Black Particle (In Solution). |

Note: For Pictures please refer Format.

6.5 Sufficient time must be provided to allow for through inspection of each container. Inspect the bottle NLT 10 sec {5(Five) seconds in black and 5(Five) seconds white background} by gently swirl or invert the container, ensuring that particle is not suspended in the solution. Shown in **Step-I, Step-II & Step-III** in **Annexure-I** record the presence of any particles.

6.6 Apply Protective (Dust) Cap for visually inspected good bottle and remove this, keep them in middle row of conveyor as shown in **STEP-IV** in **Annexure-I**.

6.7 After completion of visual inspection activity, Rejection Box (Pigeon Box) will be checked in presence of IPQA personnel & count the different type of rejection as well a record in BPR.

Note: - Pigeon Box shall be always kept in Lock and Key, and shall be open only in front of QA.

6.8 No visual inspector should work continuous for more than **two hour** at inspection booth. Rotate every visual inspector after every **two hour** and record the visual inspector's rotation detail in **Annexure-II**, Titled "**Visual Inspectors Rotation Record**".

6.9 Incase no rotation due to shortage of visual inspector give the minimum **5 (Five) minutes** Eye rest by closing the light and head down on the visual platform. Rest should be recorded in **Annexure-II**, Titled "**Visual Inspectors Eye Rest Record**."

6.10 Type of defect observed during visual inspection are as show in **Annexure-V**, Titled- "**Defect Observed during Visual Inspection**".

6.11 **CONDITION / PARAMETER:**

6.11.1 Before starting visual inspection of a new batch, ensure that line is cleared from previous product.



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6.11.2 Line clearance shall be taken by the Packing Officer / Executive from QA Officer / Executive prior to start activity.

6.11.3 To avoid Stress on eyes do not carry on visual inspection continuously for more than **two hour**.

6.11.4 Every visual inspector should undergo eyesight checkup at every six month interval as per SOP.

6.11.5 All the visual Inspectors shall be re-qualified and the list shall be updated / revised, at every 6 months \pm 15 days as per SOP.

6.11.6 Record the Light Intensity monitoring details in Annexure –III at a frequency of Weekly / on installation of new lamp.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Visual Inspection of Filled & Sealed Low Density Polyethylene (LDPE) Bottles	
Annexure-II	Visual Inspectors Rotation Record	
Annexure-III	Light Intensity Record	
Annexure-IV	Visual Booth Light Intensity Status Label	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

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

9.0 REFERENCE:

- Schedule – M “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- USP - United States Pharmacopeia, Visual Inspections of Injections (1790).

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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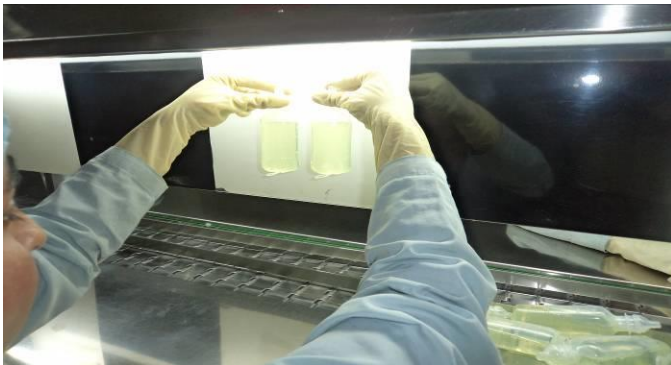
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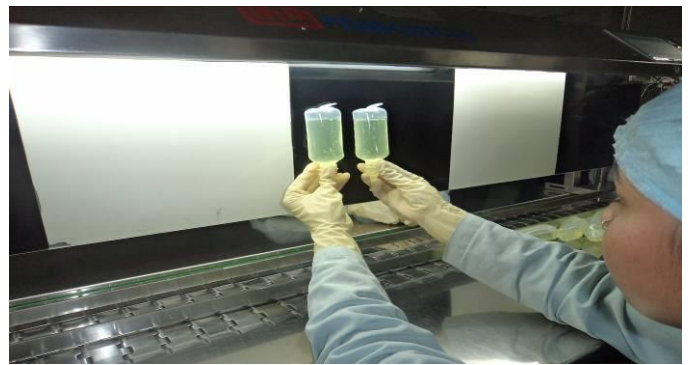
ANNEXURE – I

VISUAL INSPECTION OF FILLED & SEALED LOW DENSITY POLYETHYLENE (LDPE) BOTTLES

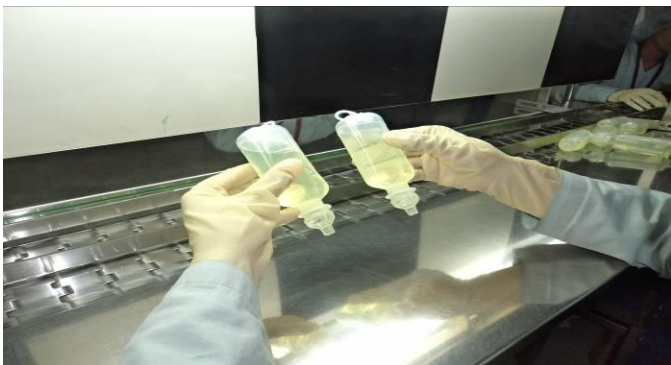
STEP-I



STEP-II



STEP-III



STEP-IV





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ANNEXURE-II VISUAL INSPECTORS ROTATION RECORD

Block: ... **Line:** ... **Section:** Packing **Date:**

S.No.	Name of Visual Inspectors (Group – A)	S.No.	Name of Visual Inspectors (Group – B)

VISUAL INSPECTION PERIOD:

Visual Inspection Time for Group-A		Eye Rest Time		Remarks	Visual Inspection Time for Group-B		Eye Rest Time		Remarks
From	To	From	To		From	To	From	To	

Checked By:
(Sign & Date)

Reviewed By:
(Sign & Date)



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ANNEXURE-IV

VISUAL BOOTH LIGHT INTENSITY STATUS LABEL

Equipment Name : _____

Equipment Location : _____

Equipment ID. No. : _____

Light Intensity Checked On : _____

Light Intensity Check Due On : _____

Done By (Sign & Date) : _____

Checked By (sign & Date) : _____