STANDARD OPERATING PROCEDURE

Title: Visual Inspection of Parenteral Products

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 6	

1.0 OBJECTIVE:

To lay down the procedure for Visual Inspection of Parenteral Products.

2.0 SCOPE:

This SOP is applicable for Visual Inspection of Parenteral Products of Production Department.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

Ltd.	Limited
NLT	Not Less Than
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 Check the cleanliness of the Visual Inspection / Area Booth and take line clearance from QA department before operation.

6.2 Update the status board of Visual Inspection, as Product Name, Batch No., Mfg. Date, Exp. Date, Stage, sign, Date.

6.3 Unload the parenteral products after Leak Test / Terminal Sterilization and further transfer into plastic trays/carets for visual inspection.

6.4 Visual inspectors shall collect the trays / carets of filled of parenteral products and hold the specific quantity of specific size as mentioned in **Annexure-I** at a time in hand for visual inspection and inspect the filled parenteral product in white and black background for NLT 5 seconds each. (In case of Respules, five-five/single-single/lose to be inspected).

6.4.1 All individual Parenteral Products of **Ampoules** will be checked for sealing defects, Glass particle, Less volume, High volume, Black particles, Fiber, White particle and charring.

6.4.2 All individual Parenteral Products of **Dry powder** injection vials will be checked for Air Bubble, Moulded Vial, Sealing defects, cracked vial, Less fill weight, High fill weight, Broken Flip off Seal and Empty vial.

6.4.3 All individual Parenteral Products of **Three Piece** vials will be checked for Dirty Vial, Vial Without Cap, Mould defect, Broken Ratchet, Improper Sealing, Leaked vial, Surface Particle, Improper Fixing of Cap.

6.4.4 In case of **Respules** Inspect for Less Volume, High volume, Rough surface, De- shaped, foreign particles, Extra plastic, Leakages and Empty.
(For all type of defects of Parenteral Products, referred SOP).

6.5 Visual Inspection shall be performed under Black and White background separately for **NLT five second** each to detect the defective of Filled & Sealed Ampoules & Respules.

6.6 Visual Inspection shall be performed on the Roller rail of Visual Inspection machine each to detect the defective of Dry powder products.

6.7 Visual Inspection shall be performed of physically check the Individual vial each to detect the defective of Three piece Vial.

6.8 Rejected of Parenteral Products shall be kept in respective compartment of Visual Inspection Rejection Pigeon Box with lock & key system/Respective crates.

6.9 Good Parenteral Products to be collect in trays/carets with status label as **"INSPECTED"** and that particular are ready for labeling.

6.10 After completion of visual inspection activity, the lock of Rejection Pigeon Box will be opened in presence of IPQA personnel & counts the different type of rejections (or from Respective carets) record in **Annexure-II** & **Annexure-III** for Respective Line (For Ampoule and Respules product, rejection data shall be filled in respective BMR only).

6.11 After **Every hour** of visual inspection, **05 minutes eye rest** to be given to all visual inspectors.

6.12 Visual Inspection Defects of Parenteral products as per **Annexure-II**.

6.13 Annexure – III "Visual Inspectors Rotation Record" can be used on need basis.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sufficient visual quantity	
Annexure-II	List of Defected Parenteral Products	

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Annexure-III	Visual Inspectors Rotation Record	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production (I-Block)
- Controlled Copy No. 03 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

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ANNEXURE – I
SUFFICIENT VISUAL QUANTITY

S.No.	Reqiured Product for Visual Inspection	Quantity
1	1 ml Ampoule	04-06 nos.
2	2 ml Ampoule	03-05 nos.
3	3ml Ampoule	02-04 nos.
4	5 ml Ampoule	02-04 nos.
5	5 ml Respule	Five-Five/Single-Single/Lose
6	10 ml DPI Vial	Online Roller Rail of Visual Inspection Machine
7	5 ml & 10 ml Three Piece Vial	Single-Single Vial

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ANNEXURE – II
LIST OF DEFECTED PARENTERAL PRODUCTS

S.No.	DPI Section	S.No.	Ampoule Section
1.	Air Bubble	**1.**	Black particle
2.	High Fill Weight	**2.**	White particle
3.	Less Fill Weight	**3.**	Fiber
4.	Sealing defect	**4.**	Glass particle
5.	Broken flip off seal	**5.**	Less volume
6.	Cracked Vial	**6.**	High volume
7.	Empty Vial	**7.**	Sealing defect
8	Moulded vials	**8.**	Charring
S.No.	**Three Piece Eye Drops Section**	**S.No.**	**FFS Respule Section**
1.	Dirty Vial	**1.**	Less Volume
2.	Vial Without Cap	**2.**	High Volume
3.	Mould Defect	**3.**	Foreign Particle
4.	Broken Ratchet	**4.**	Rough Surface
5.	Surface Particle	**5.**	De-shaped
6.	Improper Sealing	**6.**	Extra Plastic
7.	Improper Fixing of Cap	**7.**	Leakage
8.	Leaked Vial	**8.**	Empty

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ANNEXURE-III
VISUAL INSPECTORS ROTATION RECORD

Block: **Line:** **Section:** **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)