PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Visual Inspection of Filled Ampoules for Qualification Activity

SOP No.:		Department:	Production
SOP No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1.0 **OBJECTIVE**:

To lay down the procedure for Visual Inspection of Filled Ampoules for Qualification activity.

2.0 SCOPE:

This SOP is applicable for Visual Inspection of Filled Ampoules for Qualification Activity in Production of Ampoule Section.

3.0 **RESPONSIBILITY:**

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

No. Number
Ltd. Limited
NLT Not Less Th

NLT Not Less Than QA Quality Assurance

SOP Standard Operating Procedure

6.0 PROCEDURE:

- **6.1** Ensure the cleanliness of the Visual Inspection Booth before operation activity.
- 6.2 Check the clarity & foreign particle of washed ampoule for every hour from each nozzle after washing by adding of filtered water for Injection in washed ampoules after washing & record in Annexure-I, Titled Visual Inspection Record of Washed & Sterilized Ampoule.
- 6.3 Check the clarity of sterilized ampoule every hour after sterilization through tunnel by adding of filtered water for Injection after washing & record in Annexure-I, Titled Visual Inspection Record of Washed & Sterilized Ampoule.
- 6.4 100% filled and sealed ampoules will be checked for sealing defects, Glass piece, Less volume, High volume, Black particles, Fiber, White particles After filling & sealing.
- 6.5 After completion of visual inspection activity counts the different type of rejections & record in Annexure-II, Titled "Visual Inspection Record of Filled and Sealed Ampoule".

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Visual Inspection record of Washed & Sterilized Ampoule	
Annexure- II	Visual Inspection record of Filled and Sealed ampoule	

ENCLOSURES: SOP Training Record



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Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 4

8.0 DISTRIBUTION:

• Controlled Copy No.01 Quality Assurance

• Controlled Copy No.02 Production

• Master Copy Quality Assurance

9.0 **REFERENCES**:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 4

ANNEXURE-I VISUAL INSPECTION RECORD OF WASHED & STERILIZED AMPOULE

Block: Section:

Date	Time	Product Amp. Name Size		Type of Rejection after washing		Type of Rejection after washing Type of Rejection after steriliz		Type of Rejection after sterilization		Total Rej.	% age Rej.	Checked by Prod. (Sign &	Verified by QA (Sign & date)
				Clarity	Foreign Particle	Clarity	Foreign Particle		Rej.	date)	unic)		

Note: Calculate % of rejection	n by formula,		
	Total rejection x 100		
% of Rejection =		=	Limit NMT 2%
3	Total No of ampoules		



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SOF No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 4

ANNEXURE-II VISUAL INSPECTION RECORD OF FILLED AND SEALED AMPOULE

Block:

| Date | Time | Produc | Speed | Am | Tota | Type of Rejection | Total | Rej. |
| t Name | p. | 1 No. | Rej. |

Date	Tir	me	Produc t Name	roduc Speed Am Tota Type of Rejection Name p. 1 No.					Type of Rejection					Total Rej.	% age	ge ked d	Verifie d by
	From	То		Size	Size	of Am p.	Black	Glass	Fiber	Sealing	Whit e	High Vol.	Less Vol.	ï	Rej.	by Prod. (Sign & date)	QA (Sign & date)

Note: Calculate % of rejection	n by formula,		
	Total rejection x 100		
% of Rejection =		=	Limit NMT 2%
•	Total No of amnoules		