



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Visual Inspection of Filled Ampoules for Qualification Activity

SOP No.:		Department:	Production
		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 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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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

