VALIDATION PROTOCOL CUM REPORT

FOR

ESTABLISHMENT OF VISUAL DETECTION LIMIT

SUPERSEDES PROTOCOL No.	**Nil**
STUDY START DATE:	
STUDY COMPLETION DATE:	

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PROTOCOL CONTENT

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1. PROTOCOL PRE APPROVAL:

The protocol for establishment of visual detection limit of ……. has been initiated, checked and approved by the following functional heads. Further if any change in protocol are required, protocol will be revised and duly approved

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2. OBJECTIVE:

The objective of this protocol is to establish visual detection limit of ……... and define the responsibilities, verification of valid medical eye fitness, preparation of known concentration of solution with respect to Maximum allowable carry over, visual verification with sufficient intensity of source of light.

3. SCOPE:

3.1 This Validation protocol shall be applicable to establishment of visual detection of …….. Injection API at ……...

3.2 This protocol shall define the methods and documentation that shall be used to evaluate the suitability and accuracy of visual observer.

3.3 This protocol shall define methods used to determine the traces of leftover residue of previous product.

3.4 The training documentation associated with the Procedures shall be verified prior to start of the study.

4. RESPONSIBILITY:

To conduct the Visual Detection Limit of ……., a team shall be formed. The team shall contain the members from the Quality Control and Quality Assurance Departments. The Validation team is described through the following responsibility:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	Preparation, review and approval of Protocol for establishment of visual detection limit of ……...
	Protocol training.
	To monitor all Validation activities and ensuring the Validation as Per the protocol.
	To monitor protocol for completeness and technical accuracy.
	To review the data and approve the validated procedure, if found satisfactory.
Quality Control	To review of Protocol.
	To provide all applicable analytical procedures and documentation necessary for execution of this Protocol.
	To prepare the sample and provide all data.

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5. EXECUTION TEAM:

Following personnel shall be responsible for the execution of validation study:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance:	To Establish/ monitoring the activity and visual observation
Quality Control:	Sample preparation.

6. TRAINING RECORD:

Personal performing and involved in the establishment of visual detection program should be properly trained before they start cleaning process. The training records should be recorded.

7. WORST CASE PRODUCT DETAILS:

7.1 Product: …… Injection

7.2 Product Design:

Active Ingredient as Worst Case	…….
Pharmacopoeia Grade	IP
Strength	……. mg
Label Claim	Each ml Contains: …..……. mg
MACO	…… mcg/swab (10 x 10 cm^2)

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8. Verification of valid medical eye fitness:

Verify the medical report of all visual observers who are involved in the establishment of visual detection limit of ……. and routine IPQA visual verification**.**

S.No.	Name of Visual Observer	Review comment of medical eye fitness report	Eye checkup done at	Next due date
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				

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9. Establishment of LOD

9.1 Purpose: The Purpose of LOD is to evaluate the detection level of visual observer with respect to MACO value.

9.2 Study Design: The LOD is demonstrated by preparing samples (i.e. spiking known Qty. of API) at a level of 25%, 50 %, 75%, 100 % & 125 % concentration of MACO value in duplicate and spike/ spread on SS plate (10 cm x 10 cm) & Silicon Rubber plate (10 cm x 10 cm).

9.3 Procedure for Preparation of solution:-

Weigh accurately …… mg of ……. working standard in a 200 ml volumetric flask. Dissolve and mix with sufficient diluting solution. And make up the volume to a mark with diluting solution. Dilute further 1 ml this solution in 100 ml with volumetric flask. Dissolve and mix with sufficient diluting solution and make up the volume to a mark with diluting solution.

Spread on the surface of SS Plate and Food grade silicon coupons with help of glass rod if required:

Concentration	Coupon Code	ppm	Spread on SS plate 316 L & Food grade silicon coupons (10 cm x 10 cm & drying at 60°C)
25% of MACO	A		0.5 ml of …… ppm
50% of MACO	B		1.0 ml of …… ppm
75% of MACO	C		1.5 ml of ……..… ppm
100% of MACO	D		2.0 ml of ……..… ppm
125% of MACO	E		2.5 ml of ……..….ppm

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9.4 Observation of Observer:

Spared the prepared concentration of solution on the surface of 100 cm^2 coupon's as defined in above table and put the coupons in woven for complete dry of spread solution at 60ºc. And give that contaminated coupon to IPQA Observer for the observation.

S. No.	Name of Observer	Concentration Used for Contamination	Distance from Object (Coupon)	Intensity of Source of light	Calibration Status of Lux meter	Observation	Sign & Date of Eye Examiner
SS Coupon							
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					

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S. No.	Name of Observer	Concentration Used for Contamination	Distance from Object (Coupon)	Intensity of Source of light	Calibration Status of Lux meter	Observation	Sign & Date of Eye Examiner
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
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		25% (A)					
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		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					

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S. No.	Name of Observer	Concentration Used for Contamination	Distance from Object (Coupon)	Intensity of Source of light	Calibration Status of Lux meter	Observation	Sign & Date of Eye Examiner
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
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		125% (E)					
		25% (A)					
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		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					
		25% (A)					
		50% (B)					
		75% (C)					
		100% (D)					
		125% (E)					

10. FAILURE INVESTIGATION AND CORRECTIVE ACTION:

If any failure observed during process then investigate the route cause. On the basis of investigation necessary corrective action shall be implemented and again repeat the study.

11. DOCUMENTATION:

- After verifying visual cleanliness, record the observation in report.

12. REVALIDATION CRITERIA:

- Any major change in equipment
- Any change in molecule and value of MACO.
- Change in site location.

13. SUMMARY & CONCLUSION:

Provide the summary & conclusion on the basis of execution results.

Summary:-

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Conclusion:-

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14. REFERENCE:

- Active Pharmaceutical Ingredients Committee (APIC)
- EMA Protocol no.: EMA/CHMP/CVMP/SWP/246844/2018
- Parenteral Drug Association 29 (PDA)
- SOP for Cleaning Validation.

15. ABBREVIATIONS:

LOD	:	Limit of Detection
PDE	:	Permitted Daily Exposure
PDA	:	Parenteral Drug Association
Pvt.	:	Private
Ltd.	:	Limited
MACO	:	Maximum Allowable Carryover
API	:	Active Pharmaceutical Ingredient
Max.	:	Maximum
Min.	:	Minimum
mcg	:	Microgram
ml	:	Milliliter
NMT	:	Not More Than
%	:	Percentage
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure

16. REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New		

17. PROTOCOL CUM REPORT POST APPROVAL:

EXECUTED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			