PROCESS VALIDATION REPORT

FOR

LIDOCAINE INJECTION BP 2%w/v

20 ml

SUPERSEDE REPORT No.	**Nil**		
VALIDATION BATCH NUMBERS			
VALIDATION BATCH SIZE			
BATCH MFG. DATE			
BATCH EXP. DATE			

REPORT CONTENTS

1.0 REPORT PRE -APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- The objective of this report is to validate the manufacturing process for the Lidocaine Injection BP 2% w/v (20 ml) manufactured at the Liquid Vial Line.
- This study shall be conducted for the generation of sufficient data to establish documentary evidence that the manufacturing process including dispensing, CIP/SIP, bulk preparing, filtration, filling, sealing, visual inspection and packing process is suitable and appropriate for its intended purpose and validated process shall consistently meet the predefined specifications and quality attributes of the finished product.

3.0 SCOPE:

- This scope of this protocol is to validate the manufacturing process of Lidocaine Injection BP 2% w/v (20 ml) Liquid Vial manufactured at Liquid Vials Line.

4.0 RESPONSIBILITY:

DEPARTMENT	RESPONSIBILITIES
Quality Assurance	1. Responsible to prepare, review and approve process validation protocol and report. 2. To co-ordinate with cross functional teams to support the process validation execution and also responsible to monitor the execution of process validation. 3. Ensure that the facility/equipment's/instruments and utilities conform to the validated/calibrated state prior to the execution of process validation. 4. To review the trends/statistical evaluation for Critical Process Parameters (CPP) / Critical Quality Attributes (CQA) for every product manufactured at the site.
IPQA	1. To perform Process validation sampling as per sampling plan and submit them to Quality Control Department. 2. To monitor, verify and record critical process attributes. 3. To record and report any deviation either planned or unplanned happened during batch manufacturing.
QC	1. Responsible to review process validation protocol and report. 2. To analyze the samples as per sampling plan during process validation and to

DEPARTMENT	RESPONSIBILITIES
	maintain the records of the test results followed by the reporting of the results. 3. Review of analytical data & submission of analytical results to QA.
Microbiology	1. Responsible to review process validation protocol and report. 2. Responsible to collect sample as per process validation protocol. 3. To analyze the samples as per sampling plan during process validation and to maintain the records of the test results followed by the reporting of the results. 4. Review & submission of results to QA.
Production	1. Responsible to review process validation protocol and report. 2. Ensure that the current effective version of SOP's, Batch Records etc. are implemented and Concerned Personnel are trained. 3. Prior to execution of process validation batch to ensure that facility / equipment / instruments & utilities are in validated / calibrated state. 4. Execution of process validation and collection of routine in-process samples as defined in the batch manufacturing record.

5.0 REASON FOR REVALIDATION:

- Any major change in the manufacturing process which may affect the quality of the product.
- Any change in the batch size.
- Any change in the batch formula.
- Change in manufacturing site.
- Any modification in any critical equipment.
- Any major modification in the related utility system.
- Any change in the specification and/or change in the source of active pharmaceutical ingredient (API).
- Other

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6.0 PRE-REQUISITE:

6.1 TRAINING RECORDS:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked by QA (Sign & Date)
1.				All personnel involved in execution of this protocol shall be trained in the required procedure and shall be documented		
2.						
3.						
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Name of the Trainer: _____

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Reviewed By_____
Quality Assurance
(Sign & Date)

6.2 MASTER DOCUMENT VERIFICATION:

S.No.	Description	Document No.	Complied By QA (Sign & Date)
1.	Master Formula Record		
2.	Batch Manufacturing Record		
3.	Batch Packing Record		

S.No.	Stage	Raw material Specification No.	Raw material STP No.	Complied By QA (Sign & Date)
1.	Raw material			

S.No.	Stage	Primary packing material Specification No.	Primary packing material STP No.	Complied By QA (Sign & Date)
1.	20 ml clear Glass Molded Vials (USP Type -1)			
2.	Rubber Plug 20 mm Bromo butyl			
3.	Aluminum Seal Flip-off 20 mm white			

S.No.	Stage	In-process Specification No.	In-process STP No.	Complied By QA (Sign & Date)
1.	Bulk Solution			

S.No.	Stage	Finished Product Specification No.	Finished Product STP No.	Complied By QA (Sign & Date)
1.	Finished Product			

Inference:

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(Sign & Date)

6.3 EQUIPMENT DETAIL:-

Name of Equipment / Machine	Make	Identification No.	Calibration/Qualification Status
Mixing Vessel			
Holding Vessel			
Vial washing machine			
Vial Filling & Rubber Stoppering Machine			
Sterilization and Depyrogenating tunnel			
Buffer Vessel			
Sealing Machine			
Autoclave			
Mobile LAF			
Mobile Trolley			
Filter Integrity Machine			
Garment Washing Machine			
Dynamic Pass Box			
Dynamic Pass Box			
Sterile Garment Cabinet			
Ceiling Suspended Vertical LAF			
Vial Filling m/c LAF			
Vial Sealing m/c LAF			
Vial Automatic Inspection machine			

PROCESS VALIDATION REPORT FOR LIDOCAINE INJECTION BP 2% w/v, 20 ml

Name of Equipment / Machine	Make	Identification No.	Calibration/Qualification Status
Labeling Machine			
Blister Packing machine			
Domino Carton Coding Machine			
Carton Coding Machine			
Cooling Zone LAF			

Inference:

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Reviewed By_____
Quality Assurance
(Sign & Date)

7.0 RAW MATERIALS & PRIMARY PACKING MATERIAL DISPENSING VERIFICATION:

7.1 RAW MATERIALS VERIFICATION

(I) Dispensed Quantity Verification:

S.No.	Name of Ingredient	Dispensed Qty.		
		Batch No.:	Batch No.:	Batch No.:
		Date:	Date:	Date:
1.	Lidocaine Hydrochloride Monohydrate Ph Eur			
2.	Methyl Hydroxybenzoate BP			
3.	Sodium chloride BP			
4.	Sodium Hydroxide BP			
5.	Water for Injection BP			
Complied By QA (Sign & Date)				

(II) Approved Vendor of API:

S.No.	Name of Ingredient	Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
1.	Lidocaine Hydrochloride Monohydrate Ph Eur			
Complied By QA (Sign & Date)				

(III) A. R. No. Verification:

S.No.	Name of Ingredient	A. R. No.		
		Batch No.:	Batch No.:	Batch No.:
1.	Lidocaine Hydrochloride Monohydrate Ph Eur			
Complied By QA (Sign & Date)				

7.2 PACKING MATERIALS VERIFICATION

(I) Dispensed Quantity Verification & Approved Vendor of PPM:

S.No.	Name of material	Dispensed Qty./ Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
1.	20 ml clear Glass Molded Vials (USP Type -1)			
2.	Rubber Plug 20 mm Bromo butyl			
3.	Aluminum Seal Flip-off 20 mm white			
Complied By QA (Sign & Date)				

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

8.0 CRITICAL PROCESS VARIABLES:

8.1 Sterilization of Equipments:

Stage	Equipment Name	Process Variables		Batch No.		
Sterilization of Equipment's	**Mixing Vessel**	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp.	**Min.**			
			Max.			
	Holding Vessel	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp.	**Min.**			
			Max.			
	m/c parts	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp.	**Min.**			
			Max.			
Complied By QA (Sign./Date)						
Verified By QA (Sign./Date)						

Inference:_____

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8.2 Preparation of Bulk Solution:

Stage	Equipment Name	Process Variables	Batch No.		
Vessel Load cell Verification	Mixing Vessel	Zero Reading observation			
		Reading after addition of Standard Weight			
		Reading after removal standard weight (should be zero)			
Preparation of Bulk Solution	Mixing Vessel	Date of manufacturing			
		Capacity of mixing vessel			
		Mixing Speed			
		Mixing time			
		Clarity of Solution			
		Date of sampling			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.3 Filtration of Bulk Solution:

Stage	Equipment Name	Process Variables	Batch No.		
Filtration of Bulk Solution	Cartridge Filter	Filtration time			
		Filter Integrity of primary filter (Pre) (Limit – 3172 mbar to 5000 mbar)			
		Filter Integrity of primary filter (Post) (Limit – 3172 mbar to 5000 mbar)			
		Filter Integrity of Secondary filter (Pre) (Limit – 3172 mbar to 5000 mbar)			
		Filter Integrity of Secondary filter (Post) (Limit – 3172 mbar to 5000 mbar)			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.4 Vials Washing:

Stage	Equipment Name	Process Variables		Batch No.		
Vials washing	Vial washing machine	Clarity of Vials				
		Compressed air pressure Limit (0.20 MPa–0.66MPa)	Min.			
			Max.			
		Recycled WFI-1 pressure Limit (0.12 MPa–0.60MPa)	Min.			
			Max.			
		Recycled WFI-2 pressure Limit (0.12 MPa-0.60MPa)	Min.			
			Max.			
		Fresh WFI Limit (0.07MPa – 0.30MPa)	Min.			
			Max.			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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8.5 Vials Sterilization:

Stage	Equipment Name	Process Variables			Batch No.		
Vial Sterilization	Sterilization and Depyrogenatig tunnel	Differential Pressure in (Pa)	Preheating Zone (05 to10) Pa	Min.			
				Max.			
			Heating zone (06 to 12)Pa	Min.			
				Max.			
			Cooling zone (05 to10) Pa	Min.			
				Max.			
		Temperature in °C	Preheating zone	Min.			
				Max.			
			Heating zone (More than 320^0C)	Min.			
				Max.			
			Cooling zone (NMT 30^0C)	Min.			
				Max.			

Stage	Equipment Name	Process Variables	Batch No.		
		Speed of Conveyor (130 mm/min)			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.6 Hold Time Study:

Stage	Equipment Name	Process Variables	Batch No.		
After Cleaning	**Cleaned Mixing Vessel**	Cleaning End Time			
		Sterilization Start Time			
		Total Hold Time			
	Cleaned Holding Vessel	Cleaning End Time			
		Sterilization Start Time			
		Total Hold Time			
	Cleaned Machine Parts	Cleaning End Time			
		Sterilization Start Time			
		Total Hold Time			
After Sterilization	**Sterile Garments**	Sterilization End Time			
		Garments Uses Time			
		Total Hold Time			
	Sterilized Mixing Vessel	Sterilization End Time			
		Manufacturing Start Time			
		Total Hold Time			
	Sterilized	Sterilization End Time			

Stage	Equipment Name	Process Variables	Batch No.		
	Holding Vessel	Filtration Start Time			
		Total Hold Time			
	Sterilized Machine Parts	Sterilization End Time			
		Filling Start Time			
		Total Hold Time			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:

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8.7 Filling & Sealing of Vials:

Stage	Equipment Name	Process Variables		Batch No.		
Filling & Sealing	Vial Line Filling & Sealing Machine	Target fill volume 21 ml (Limit 20.5 ml to 21.5 ml)				
		Sealing Quality				
		Machine Speed	Minimum			
			Maximum			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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8.8 Leak Test of Vials:

Stage	Equipment Name	Process Variables	Batch No.		
	Leak test	Vacuum Hold Time			
		Observation			
Filling & Sealing Yield					
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.9 NON-CRITICAL PROCESS VARIABLES:

Stage	Equipment Name	Process Variables		Batch No.		
Labelling	**Labelling Machine**	Process Time	From			
			To			
		Machine Speed	Minimum			
			Maximum			
Finish	**Packing**	• Overprinting details • Labelling • Pack style and pack size				
		Finished Sample Qty.				
Total Packing Yield						
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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Reviewed By_____
Quality Assurance
(Sign & Date)

9.0 CRITICAL PROCESS PARAMETER:

9.1 Cleaning of Equipments:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Cleaning of Equipment's	Wash Water from Mixing Vessel	Description	Clear colourless liquid			
		Clarity	Should be clear			
		pH	5.0 to 7.0			
		Conductivity	NMT 1.3 µs/cm			
	Wash Water from Holding Vessel	Description	Clear colourless liquid			
		Clarity	Should be clear			
		pH	5.0 to 7.0			
		Conductivity	NMT 1.3 µs/cm			
	Rinse/Swab from m/c parts	Description	Clear colourless liquid			
		Clarity	Should be clear			
		pH	5.0 to 7.0			
		Conductivity	NMT 1.3 µs/cm			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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9.2 Water for Injection:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Water for Injection	Mixing Vessel (Before Batch Manufacturing)	Description	Clear colourless liquid			
		pH	5.0 to 7.0			
		Conductivity	NMT 1.3 µS/cm			
		BET	NMT 0.25 EU/ml			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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9.3 Preparation of Bulk Solution:

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
Preparation of Bulk Solution	**Bulk Mixing after 15 min. (Top)**	**Description**		A Clear colorless solution.			
		pH		5.4 to 7.0			
		Assay	**Lidocaine**	19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)			
	Bulk Mixing after 15 min. (Bottom)	**Description**		A Clear colorless solution.			
		pH		5.4 to 7.0			
		Assay	**Lidocaine**	19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)			

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
	Bulk Sample before Filtration	**Description**	A Clear colorless solution.			
		pH	5.4 to 7.0			
		Weight per ml	0.997 g/ml to 1.070 g/ml			
		Colour Index	NMT 0.200 AU			
		Assay: **Each ml contains:** Lidocaine Hydrochloride Monohydrate Ph Eur 20 mg	19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)			
		Preservative Content Methyl Hydroxybenzoate BP 2 mg	1.600 mg to 2.400 mg (80.0 % to 120.0 % of label claim)			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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9.4 Filtration of Bulk Solution:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Filtration of Bulk Solution	Bulk Sample After filtration	Sterility	Should be sterile after 14 days of incubation			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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9.5 Before Vial Washing:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Vials washing	Vial washing machine	Bio-burden	For Informative			

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9.6 Vials Washing & Sterilization:

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
Vials washing	Vial washing machine	LBPC	Initial	• Visible particles: Should be free from visible particles			
				• For sub visible particles : (i) Equal to or greater than 10µm - NMT 6000/container			
				(ii) Equal to or greater than 25µm - NMT 600/container			
			Middle	• Visible particles: Should be free from visible particles			
				• For sub visible particles : (i) Equal to or greater than 10µm - NMT 6000/container			
				(ii) Equal to or greater than 25µm - NMT 600/container			
			End	• Visible particles: Should be free from visible particles			
				• For sub visible particles : (i) Equal to or greater than 10µm - NMT 6000/container			
				(ii) Equal to or greater than 25µm - NMT 600/container			
		Clarity	Initial	Should be clear			
			Middle	Should be clear			

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
			End	Should be clear			
Vial Sterilization & Depyrogenation Tunnel	**Sterilization and Depyrogenatig tunnel**	Sterility	Initial	Should be sterile after 14 days of incubation			
			Middle	Should be sterile after 14 days of incubation			
			End	Should be sterile after 14 days of incubation			
	Sterilization and Depyrogenatig tunnel	BET	Initial	NMT 0.25 EU/ml			
			Middle	NMT 0.25 EU/ml			
			End	NMT 0.25 EU/ml			
Complied By QA (Sign. / Date)							
Verified By QA (Sign. / Date)							

Inference:

9.7 After Vial Washing:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Vials washing	**Vial washing machine**	Bio-burden	NMT 10 CFU / 100 ml			

Inference:

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9.8 Vials Filling & Sealing:

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
Filling and Sealing	**Nitrogen gas from user point**	Sterility	Initial	Should be sterile after 14 days of incubation			
			Middle	Should be sterile after 14 days of incubation			
			End	Should be sterile after 14 days of incubation			
	Sterilized Rubber Stopper	Sterility	Initial	Should be sterile after 14 days of incubation			
			Middle	Should be sterile after 14 days of incubation			
			End	Should be sterile after 14 days of incubation			
		BET	Initial	NMT 0.25 EU/ml			
			Middle	NMT 0.25 EU/ml			
			End	NMT 0.25 EU/ml			
		Visual	Initial	Should be visually clean			

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
		Inspection	Middle	Should be visually clean			
			End	Should be visually clean			
	Flip off Seal	Bio burden	Initial	NMT 10 CFU / 100 ml			
			Middle	NMT 10 CFU / 100 ml			
			End	NMT 10 CFU / 100 ml			
	Filling and Sealing Machine	**Description**	Initial	A clear colorless solution filled in clear glass molded vial 20 ml plugged with 20 mm Bromo butyl rubber stopper and sealed with 20 mm White flip off aluminum seal.			
			Middle				
			End				
		pH	Initial	5.4 to 7.0			
			Middle				
			End				
		Extractable volume	Initial	NLT 20.0 ml			
			Middle				
			End				
		Particulate Contamination	Initial	Visible particles: Should be free from any visible particulate matter			
			Middle				
			End				

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
			Initial	Sub visible particles : (i) ≥ 10 micron - NMT 6000 / container (ii) ≥ 25 micron - NMT 600 / container			
			Middle				
			End				
		2,6-Dimethylaniline	Initial	NMT 400 PPM			
			Middle				
			End				
		Assay	Initial	**Each ml contains:** Lidocaine Hydrochloride Monohydrate Ph Eur 20 mg 19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)			
			Middle				
			End				
		Preservative Content	Initial	Methyl Hydroxybenzoate BP 2 mg 1.600 mg to 2.400 mg (80.0 % to 120.0 % of label claim)			
			Middle				
			End				
		Bacterial	Initial	NMT 1.1 EU/mg of Lidocaine Hydrochloride			

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
		Endotoxins	Middle				
			End				
		Test of Sterility	Initial	Should comply test of sterility.			
			Middle				
			End				
Complied By QA (Sign. / Date)							
Verified By QA (Sign. / Date)							

Inference:

9.7 Finished Product:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Finished Sample	--	**Description**	A clear colorless solution filled in clear glass molded vial 20 ml plugged with 20 mm Bromo butyl rubber stopper and sealed with 20 mm white flip off aluminum seal.			
		Identification				
		A. By Chemical Reaction	A bluish-green precipitate is produced.			
		B. Melting Point	Melts at about 229˚C			
		C. Chloride	A curdled white precipitate should be formed. The precipitate should be dissolve easily with the possible exception of a few large particles which dissolve slowly.			
		D. By HPLC (methyl Hydroxybenzoate)	The retention time of the major peak of the sample solution should be corresponds to that of the standard solution obtained as directed in the assay.			
		pH	5.0 to 7.0			
		Related Substance				
		Unspecified impurities	NMT 0.10%			
		Total Unspecified impurities	NMT 0.50%			
		Bacterial Endotoxins	NMT 1.1 EU/mg of Lidocaine Hydrochloride			
		Extractable Volume	NLT 20.0 ml			
		Test of Sterility	Should comply test of sterility.			

Stage	Equipment Name	Process Parameter	Acceptance Criteria		Batch No.		
		2,6-Dimethylaniline	NMT 400 ppm				
		Particulate Contamination					
		Visible particles:	Should be free from any visible particulate matter				
		Sub visible particles :	(i) ≥ 10 micron - NMT 6000 / container (ii) ≥ 25 micron - NMT 600 / container				
		Assay: Each ml contains: Lidocaine Hydrochloride Monohydrate Ph Eur 20 mg	19.00 mg to 21.00 mg (95.0 % to 105.0 % of label claim)				
		Preservative Content Methyl Hydroxybenzoate BP 2 mg	Release	Shelf Life			
			1.600 mg to 2.400 mg (80.00% to 120.00% of label claim)	For Information			
Complied By QA (Sign. / Date)							
Verified By QA (Sign. / Date)							

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

10.0 VISUAL INSPECTION:

S.No.	Observations / Defects	Batch No.		
1.	Date			
2.	Start Time:			
3.	Completion Time:			
4.	Black Particles			
5.	White Particles			
6.	Improper Sealing			
7.	Others			
8.	Total Qty. Rejected			
9.	Total Qty. Checked			
10.	Good Vials			
Complied By QA (Sign./Date)				

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

11.0 LABELLING AND PACKING RESULTS & OBSERVATIONS:

Parameters	Batch No.:			Batch No.:			Batch No.:		
	Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Overprinting details on label of each vial (Complies/Does Not Complies)									
20 Labelled Vials 20 ml with leaflet in (1X20X20 ml) each inner carton pack. (Complies/Does Not Complies)									
Complied By QA (Sign./Date)									

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

12.0 ATTACHMENTS:

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B. No.	A. R. No.	Date of COA

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

13.0 DEVIATION (IF ANY):

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14.0 SUMMARY & CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

QA	:	Quality Assurance
PVP	:	Process validation Protocol
PVR	:	Process validation Report
IPQA	:	In-process Quality Assurance
SOP	:	Standard Operating Procedure
STP	:	Standard Testing Procedure
BMR	:	Batch Manufacturing Record
BPR	:	Batch Packing Record
BPT	:	Bubble point test
mg	:	Milligram
BET	:	Bacterial Endotoxin Test
ml	:	Milliliter
kg	:	Kilogram
cm	:	Centimeter
WFI	:	Water for Injection
HVAC	:	Heating Ventilation and Air Conditioning
IH	:	In-House

17.0 REVISION HISTORY:

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

18.0 REPORT POST APPROVAL:

COMPILED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			