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

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			



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1.0	0	REPORT	' PRE -A	APPROVAL:
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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)			



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



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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.						
Responsible to review process validation protocol and report.							
	2. Responsible to collect sample as per process validation protocol.						
Microbiology 3. To analyze the samples as per sampling plan during process valid							
	maintain the records of the test results followed by the reporting of the results.						
	4. Review & submission of results to QA.						
	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.						
Production	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-REQUIS	ITE:
----------------	------

6.1 TRAINING RECORDS:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked by QA (Sign & Date)
1.						
2.						
3.						
4.						
5.				All personnel involved in		
6.				execution of this protocol shall be		
7.				trained in the required		
8.				procedure and shall be		
9.				documented		
10.						
11.						
12.						
13.						
14.						

Name	of the Trainer:				
Infere	nce:				
			Revie	wed By	

Quality Assurance (Sign & Date)



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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:			

Reviewed By_______Quality Assurance (Sign & Date)



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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			



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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:			
		Qu	eviewed By ality Assurance gn & Date)



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7.0	RAW MATERIALS &	: PRIMARY	PACKING MATERIAL	DISPENSING	VERIFICATION:
-----	-----------------	-----------	------------------	------------	---------------

7.1 RAW MATERIALS VERIFICATION

(I) Dispensed Quantity Verification:

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

(III) A. R. No. Verification:

S.No.	N. 0.7 H	A. R. No.			
	Name of Ingredient	Batch No.:	Batch No.:	Batch No.:	
1.	Lidocaine Hydrochloride Monohydrate Ph Eur				
Complied By QA (Sign & Date)					



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7.2 PACKING MATERIALS VERIFICATION

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

20 M (U	ml clear Glass olded Vials SP Type -1)	Batch No.:	Batch No.:	Batch No.:
1. M (U	olded Vials SP Type -1)			
1. M (U	olded Vials SP Type -1)			
Ru				
	alah an Dha a 20			
	.hh an Dlu a 20			
1111	nbber Plug 20 n Bromo butyl			
	ii bioiilo outyi			
A 1	uminum Seal			
	ip-off 20 mm			
wł	nite			
	lied By QA			
(Sign	n & Date)			
ference:				
				D : 1D
				Reviewed ByQuality Assurance
				(Sign & Date)



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8.0 CRITICAL PROCESS VARIABLES:

8.1 Sterilization of Equipments:

G4	Equipment	Process Variables		Batch No.	
Stage	Name				
	3.4.	Sterilization time (N	LT 30 mins.)		
	Mixing Vessel	Sterilization temp.	Min.		
	VCSSCI		Max.		
Sterilization	Sterilization time (N		LT 30 mins.)		
of	f Holding Vessel Starilia	Starilization town	Min.		
Equipment's		Sterilization temp.	Max.		
	Sterilization time (NL)		LT 30 mins.)		
	m/c parts	Ctarilization town	Min.		
		Sterilization temp.	Max.		
Complied By	Complied By QA (Sign./Date)				
Verified By (Verified By QA (Sign./Date)				

Inference:_				



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8.2 Preparation of Bulk Solution:

G4	Equipment	D	Batch No.	
Stage	Name	Process Variables		
		Zero Reading observation		
Vessel Load cell	Mixing Vessel	Reading after addition of Standard Weight		
Verification	Vesser	Reading after removal standard weight (should be zero)		
		Date of manufacturing		
		Capacity of mixing vessel		
Preparation	Mixing	Mixing Speed		
of Bulk Solution	Vessel	Mixing time		
50101011		Clarity of Solution		
		Date of sampling		
Complied By	QA (Sign. /	Date)		
Verified By (QA (Sign. / D	eate)		

Inference:			

8.3 Filtration of Bulk Solution:

Ctaga	Equipment	Duo cogg Vowighles	Batch No.	
Stage	Name	Process Variables		
		Filtration time		
		Filter Integrity of primary filter (Pre)		
F214 41		(Limit – 3172 mbar to 5000 mbar)		
Filtration	Cartridge	Filter Integrity of primary filter (Post)		
of Bulk	Filter	(Limit – 3172 mbar to 5000 mbar)		
Solution		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 I	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.	
		Clarity of Vials			
		Compressed air pressure	Min.		
		Limit (0.20 MPa–0.66MPa)	Max.		
	Vial	Recycled WFI-1 pressure	Min.		
Vials washing	washing	Limit (0.12 MPa–0.60MPa)	Max.		
	machine	Recycled WFI-2 pressure	Min.		
		Limit (0.12 MPa-0.60MPa)	Max.		
		Fresh WFI Limit	Min.		
		(0.07MPa - 0.30MPa)	Max.		
Complied By	QA (Sign. /	Date)	•		
Verified By (QA (Sign. / D	ate)			

Inference:	 	 	

8.5 Vials Sterilization:

Stage	Equipment	Pr	ocess Variables		Batch No.	
Stage	Name	11	ocess variables			
			Preheating 7 and	Min.		
			Zone (05 to10) Pa	Max.		
		Differentia	Heating zone	Min.		
		l Pressure in (Pa)	(06 to 12)Pa	Max.		
			Cooling zone (05 to10) Pa	Min.		
Vial	Sterilizatio n and		(03 1010) Fa	Max.		
Sterilization	Depyrogen atig tunnel		Preheating	Min.		
	aug tumei		zone	Max.		
		T	Heating zone (More than	Min.		
		Temperatur e in °C	320 ⁰ C)	Max.		
			Cooling zone (NMT 30°C)	Min.		
			(141411 30 C)	Max.		



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C40.00	Equipment	Duo anga Variablas	Batch No.	
Stage	Name	Process Variables		
		Speed of Conveyor (130 mm/min)		
Complied By	QA (Sign. /	Date)		
Verified By (QA (Sign. / D	ate)		

Inference:		 	

8.6 Hold Time Study:

C40.00	Equipment	Duo ooga Vordoblog	Batch No.
Stage	Name	Process Variables	
	Cleaned	Cleaning End Time	
	Mixing Vessel	Sterilization Start Time	
	vessei	Total Hold Time	
	Cleaned	Cleaning End Time	
After Cleaning	Holding Vessel	Sterilization Start Time	
	vessei	Total Hold Time	
	Cleaned	Cleaning End Time	
	Machine Parts	Sterilization Start Time	
	Paris	Total Hold Time	
		Sterilization End Time	
	Sterile Garments	Garments Uses Time	
		Total Hold Time	
After Sterilization	Sterilized	Sterilization End Time	
	Mixing Vessel	Manufacturing Start Time	
	v essei	Total Hold Time	
	Sterilized	Sterilization End Time	



Stage

Equipment

Name

PHARMA DEVILS

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Process Variables

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Batch No.

	Total Hold Time Sterilized Machine Parts Sterilization End Time Filling Start Time Total Hold Time Filling Start Time Total Hold Time Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: 8.7 Filling & Sealing of Vials: Stage Equipment Name Filling & Sealing Machine Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Verified By QA (Sign. / Date)							
Sterilized Machine Parts Sterilization End Time Filling Start Time Total Hold Time Filling & Sealing OA (Sign. / Date) Total Hold Time Total Hold Time Total Hold Time Filling & Sealing OA (Sign. / Date) Total Hold Time Filling & Sealing OA (Sign. / Date) Total Hold Time Total Hold T	Sterilized Machine Parts Sterilization End Time Filling Start Time Total Hold Time Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: Stage Equipment Name Filling & Sealing Machine Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Target fill volume 21 ml (Limit 20.5 ml to 21.5 ml) Sealing Quality Sealing Quality Sealing Machine Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Verified By QA (Sign. / Date)			Filtration Start Tim	e			
Sterilized Machine Parts Total Hold Time Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: Stage Equipment Name Filling & Sealing of Vials: Target fill volume 21 ml (Limit 20.5 ml to 21.5 ml) Sealing Machine Filling & Sealing Quality Sealing Machine Complied By QA (Sign. / Date)	Sterilized Machine Parts Filling Start Time Total Hold Time		, 3323	Total Hold Time				
Machine Parts Filling Start Time Total Hold Time	Machine Parts Filling Start Time Total Hold Time Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: 8.7 Filling & Sealing of Vials: Stage Equipment Name Process Variables Filling & Sealing of Vials: Stage Vial Line Filling & Sealing Machine Filling & Sealing Machine Filling & Sealing Machine Vial Line Filling & Sealing Quality Sealing Quality Sealing Quality Machine Speed Minimum Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)		C4:1: 1	Sterilization End Ti	ime			
Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: Stage Equipment Name Process Variables Process Variables	Complied By QA (Sign. / Date) Verified By QA (Sign. / Date) Inference: Stage Equipment Name Process Variables Batch No.		Machine	Filling Start Time				
Verified By QA (Sign. / Date) Inference: Stage Equipment Name Process Variables Batch No.	Verified By QA (Sign. / Date) Inference: Stage Equipment Name Process Variables Batch No.		Parts	Total Hold Time				
Inference: Stage Equipment Name Process Variables Batch No.	Stage Equipment Name Process Variables Filling & Sealing Wial Line Filling & Sealing Machine Filling & Sealing Machine Machine Maximum Complied By QA (Sign. / Date) Vial Sealing Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)		Complied 1	By QA (Sign. / Date)				
Stage Equipment Name Process Variables Filling & Sealing Wial Line Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Filling & Sealing Machine Complied By QA (Sign. / Date)	Stage Equipment Name Process Variables Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Stage Process Variables Batch No. Batch No. Batch No. Batch No. Batch No. Batch No. Sealing Ouality Machine Speed Minimum Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)		Verified B	y QA (Sign. / Date)				
Stage Equipment Name Process Variables Filling & Sealing Wial Line Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Filling & Sealing Machine Complied By QA (Sign. / Date)	Stage Equipment Name Process Variables Filling & Sealing Machine Filling & Sealing Machine Complied By QA (Sign. / Date) Stage Process Variables Batch No. Batch No. Batch No. Batch No. Batch No. Batch No. Sealing Ouality Machine Speed Minimum Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)	Inference:				l		
Stage Equipment Name	Stage Equipment Name							
Stage Equipment Name	Stage Equipment Name							
Stage Equipment Name	Stage Equipment Name							
Stage Equipment Name	Stage Equipment Name							
Stage Name Process Variables Target fill volume 21 ml (Limit 20.5 ml to 21.5 ml) Sealing Sealing Machine Machine Maximum Complied By QA (Sign. / Date)	Stage Name Process Variables Target fill volume 21 ml (Limit 20.5 ml to 21.5 ml) Sealing Sealing Machine Machine Maximum Complied By QA (Sign. / Date) Vial Line Filling & Sealing Quality Machine Speed Minimum Maximum Complied By QA (Sign. / Date)	8.7 Filling	& Sealing of	Vials:				
Filling & Sealing Machine 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)	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)	Stage		Process Var	riables		Batch No.	
Filling & Sealing Wachine Sealing Quality Machine Speed Minimum Maximum Complied By QA (Sign. / Date)	Filling & Sealing Machine Machine Speed Machine Speed Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)		77. 1 7.					
Machine Speed Minimum Maximum Complied By QA (Sign. / Date)	Machine Speed Machine Speed Maximum Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)		Filling & Sealing	Sealing Quality				
Complied By QA (Sign. / Date)	Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)	Seamig		Machine Speed	Minimum			
	Verified By QA (Sign. / Date)				Maximum			
Verified By QA (Sign. / Date)					l			
			Complied 1	By QA (Sign. / Date)				
	Inference:							
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				
		Inference:	Verified B	y QA (Sign. / Date)				



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8.8 Lea	K Test of Via	us:				
Stage	Equipme Name		Process Variables		Batch No.	
	Leak to		n Hold Time			
	Leak to	Observ	ation			
Filling &	Sealing Yield	i				
Complied	By QA (Sign	n. / Date)				
Verified I	By QA (Sign.	/ Date)				
Inference	:					
		PROCESS	VARIABLES:		Batch No.	
Stage	Equipment Name	Proc	ess Variables		Datell 140.	
		Process	From			
Labelling	Labelling	Time	То			
Labelling	Machine	Machine	Minimum			
		Speed	Maximum			
Finish	Packing	LabPacsize				
		Finish	ed Sample Qty.			
	king Yield					
Complied By QA (Sign. / Date) Verified By QA (Sign. / Date)						
Inference		/ Date)				
				Re	eviewed By	
					ality Assurance	

(Sign & Date)



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9.0 CRITICAL PROCESS PARAMETER:

9.1 Cleaning of Equipments:

Stago	Equipment	Process Parameter	Acceptance Criteria	Batch No.	
Stage	Name	1 Tocess 1 at ameter	Acceptance Criteria		
		Description	Clear colourless liquid		
	Wash Water	Clarity	Should be clear		
	from Mixing Vessel	рН	5.0 to 7.0		
		Conductivity	NMT 1.3 µs/cm		
		Description	Clear colourless liquid		
Cleaning of	Wash Water from Holding	Clarity	Should be clear		
Equipment's	Vessel	рН	5.0 to 7.0		
		Conductivity	NMT 1.3 µs/cm		
		Description	Clear colourless liquid		
	Rinse/Swab	Clarity	Should be clear		
	from m/c parts	рН	5.0 to 7.0		
	-	Conductivity	NMT 1.3 µs/cm		
Complied By	QA (Sign. / Dat	re)			
Verified By C	A (Sign. / Date))			

Inference:		



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9.2 Water for Injection:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.	
Stage	Equipment Name	1 Tocess 1 at affected	Acceptance Criteria		
		Description	Clear colourless liquid		
Water for	Mixing Vessel	рН	5.0 to 7.0		
Injection	(Before Batch Manufacturing)	Conductivity	NMT 1.3 μS/cm		
		BET	NMT 0.25 EU/ml		
Complied	By QA (Sign. / Dat	re)			
Verified I	By QA (Sign. / Date))			

Inference:

9.3 Preparation of Bulk Solution:

C40.00	Equipment	Due	aaga Dawamatan	A acomton as Cuitavia	Batch No.	
Stage	Name	Pro	cess Parameter	Acceptance Criteria		
	Bulk Mixing after 15 min.	Descripti	ion	A Clear colorless solution.		
	(Top)	pН		5.4 to 7.0		
Preparation of Bulk		Assay	Lidocaine	19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)		
Solution	Bulk Mixing after 15 min.	Descripti	ion	A Clear colorless solution.		
	(Bottom)	pН		5.4 to 7.0		
		Assay	Lidocaine	19.40 mg to 21.00 mg (97.0 % to 105.0 % of label claim)		



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Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.	
	1 (dilic	Description	A Clear colorless solution.		
		рН	5.4 to 7.0		
		Weight per ml	0.997 g/ml to 1.070 g/ml		
	Bulk Sample	Colour Index	NMT 0.200 AU		
	before Filtration	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. / Dat	·			
Verified By	QA (Sign. / Date)			

Verified By QA (Sign. / Date)

Inference:



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9.4 Filtration of Bulk Solution:

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

Inference:			

9.5 Before Vial Washing:

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

Inference:	



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9.6 Vials Washing & Sterilization:

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



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

Inference:		



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9.7 After Vial Washing:

	G4	Equipment	D D (Batch No.	
Ш	Stage	Name	Process Parameter	Acceptance Criteria		
	Vials	Vial washing	Bio-burden	NMT 10 CFU / 100 ml		
	washing	machine	Bio-buiden			

Infe	rence:
	CHCC.

9.8 Vials Filling & Sealing:

Stage	Equipment Name	- Process Parameter		Acceptance Criteria	Batch No.	
	Nitrogen gas from user point		Initial	Should be sterile after 14 days of incubation		
		Sterility	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		
Filling and			Middle	Should be sterile after 14 days of incubation		
Sealing			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		



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



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g.	Equipment	Process Parameter			Batch No.		
Stage	Name	Process P	arameter	Acceptance Criteria			
			Initial				
			Middle	Sub visible particles : (i) ≥ 10 micron - NMT 6000 / container (ii) ≥ 25 micron - NMT 600 / container			
			End				
		2,6- Dimethylan iline	Initial				
			Middle	NMT 400 PPM			
		mne	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				
		Preservativ e Content	Initial	Methyl Hydroxybenzoate BP 2 mg			
			Middle	1.600 mg to 2.400 mg (80.0 % to 120.0 % of label claim)			
			End				
		Bacterial	Initial	NMT 1.1 EU/mg of Lidocaine Hydrochloride			



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

Inference:		



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9.7 Finished Product:

Stage	Equipment Name	Process Parameter	Batch No.				
		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				
Finished Sample		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.				
		рН	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.				



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Stage	Equipment	Process Parameter	Acceptance Criteria		Batch No.		
Buge	Name	1 10CCSS 1 at affected	Acceptance Criter	14			
		2,6-Dimethylaniline	NMT 400 ppm				
		Particulate Contamination					
		Visible particles:	Should be free from any visible p	articulate matter			
		Sub visible particles:	(i) ≥ 10 micron - NMT 6000 / co (ii) ≥ 25 micron - NMT 600 / co				
	Assay: Each ml contains Lidocaine Hydrochloride Monohydrate Ph Eur 20		19.00 mg to 21.00 mg (95.0 % to 105.0 % of label claim)				
		Preservative Content	Release	Shelf Life			
		Methyl Hydroxybenzoate BP 2 mg	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:							

Reviewed By_______
Quality Assurance
(Sign & Date)



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10.0 VISUAL INSPECTION:

S.No.	Observations / Defects	Bate	Batch No.		
242 (04	0 88 61 1 111 11 11 11 11 11 11 11 11 11 11				
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				
Complie (Sign./Da	d By QA ate)				
Inferenc	e:				
			Reviewed ByQuality Assurance Sign & Date)		

FORMAT No.:



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11.0 LABELLING AND PACKING RESULTS & OBSERVATIONS:

Parameters	Batch No.:		Batch No.:		Batch No.:				
1 41 411100023	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)									

merence	
	Reviewed By
	Quality Assurance (Sign & Date)
	(Sign & Data)
	(Sign & Date)



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B. No. A. R. No.	Date of COA
B. No. A. R. No.	
B. No. A. R. No.	
B. No. A. R. No.	
B. No. A. R. No.	
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	Reviewed ByQuality Assurance (Sign & Date)



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13.0	DEVIATION (IF ANY):
14.0	SUMMARY & CONCLUSION:
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		



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

18 0	REPORT	POST	APPROVAL:
10.0		1 (//) 1	ALLINUVAL.

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)			