PROCESS VALIDATION REPORT

FOR

TRANEXAMIC ACID INJECTION BP

100 mg/ml (500 mg in 5 ml)

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

REPORT CONTENTS

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

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 Tranexamic Acid Injection BP 100 mg/ml (500 mg in 5 ml) manufactured at the ampoule 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:

- The scope of this report is to validate the manufacturing process of Tranexamic Acid Injection BP 100 mg/ml (500 mg in 5 ml) ampoule manufactured at Ampoule Line.
- **Type of validation:** Concurrent validation

4.0 RESPONSIBILITY:

DEPARTMENT	RESPONSIBILITIES
Quality Assurance	1. Responsible to prepare, review and approve process validation 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 report. 2. 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.

DEPARTMENT	RESPONSIBILITIES
	3. Review of analytical data & submission of analytical results to QA.
Microbiology	1. Responsible to review process validation 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 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: _____

Inference:

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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.	Primary Packing Material			

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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Reviewed By_____
Quality Assurance
(Sign & Date)

6.3 EQUIPMENT DETAILS:-

Name of Equipment / Machine	Make	Identification No.	Calibration/Qualification Status
Mixing Vessel			
Holding Vessel			
Ampoule washing machine			
Ampoule Filling & Sealing Machine			
Sterilization and Depyrogenating tunnel			
Automatic Optical Inspection machine			
Dynamic pass box			
Dynamic pass box			
LAF for Ampoule-2			
Buffer Vessel			
Visual inspection booth			
Autoclave			
Leak Test Apparatus			

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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.	Tranexamic Acid BP			
2.	Disodium Edetate BP			
3.	Sodium Hydroxide BP			
Complied By QA (Sign & Date)				

(II) A. R. No. Verification:

S.No.	Name of Ingredient	A. R. No.		
		Batch No.:	Batch No.:	Batch No.:
		Date:	Date:	Date:
1.	Tranexamic Acid BP			
Complied By QA (Sign & Date)				

(III) Approved Manufacturer of API:

S.No.	Name of Ingredient	Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
		Date:	Date:	Date:
1.	Tranexamic Acid BP			
Complied By QA (Sign & Date)				

7.2 PACKING MATERIALS VERIFICATION:

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

S.No.	Name of material	Dispensed Qty./ Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
1.	Clear Glass Ampoules 5 ml USP Type – I with Blue dot (OPC)			
Complied By QA (Sign & Date)				

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

8.0 CRITICAL PROCESS VARIABLES & NON CRITICAL PROCESS VARIABLES:

8.1 Critical Process Variables:

8.1.1 Dispensing of Raw Material:

Stage	Process Variables		Batch No.		
Dispensing	Temperature	NMT 25ºC			
	RH %	NMT 55%			
	Balance Verification				
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

8.1.2 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	Min.			

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

Stage	Equipment Name	Process Variables		Batch No.		
		Temp.	**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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8.1.3 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			
		Temperature (before adding API)			
		Final pH			
		Mixing Speed			
		Mixing time			
		Final Volume makeup			
		Clarity of Solution			
		Date of sampling			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.1.4 Filtration of Bulk Solution:

Stage	Equipment Name	Process Variables	Batch No.		
Filtration of Bulk Solution	Cartridge Filter	Filter Type			
		Make			
		Filter Pore Size			
		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)			
		Filtration Pressure			
		Filtration time			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.1.5 Ampoules Washing & Sterilization:

Stage	Equipment Name	Process Variables		Batch No.		
Ampoules washing	Ampoule washing machine	Clarity of Ampoules				
		Compressed air pressure Limit (0.20 MPa– 0.60MPa)	Min.			
			Max.			
		Recycled WFI-1 pressure Limit (0.20 MPa– 0.50MPa)	Min.			
			Max.			
		Recycled WFI-2 pressure Limit (0.12 MPa-0.50MPa)	Min.			
			Max.			
		Fresh WFI Limit (0.07MPa – 0.30MPa)	Min.			
			Max.			

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

Stage	Equipment Name	Process Variables			Batch No.		
Ampoule Sterilization	Sterilization and Depyrogenatig tunnel	Differential Pressure in (Pa)	Preheating Zone to room (05 to10) Pa	Min.			
				Max.			
			Heating zone to room (06 to 12)Pa	Min.			
				Max.			
			Cooling zone to room (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.			
		Speed of Conveyor (NMT110 mm/min)					
Complied By QA (Sign. / Date)							
Verified By QA (Sign. / Date)							

Inference:_____

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8.1.6 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	Sterile	Sterilization Cycle End Time			

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

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

Inference:

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8.1.7 Filling & Sealing of Ampoules:

Stage	Equipment Name	Process Variables		Batch No.		
Filling & Sealing	Ampoule Line Filling & Sealing Machine	Target fill volume 5.1 ml (Limit 5.05 ml to 5.15 ml)				
		Nitrogen Pressure				
		Sealing Height 69 ± 2 mm Limit (67 mm to 71 mm)	Min.			
			Max.			
		Sealing Quality				
		Machine Speed	Min.			
			Max.			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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8.1.8 Leak Test of Ampoules:

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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Quality Assurance
(Sign & Date)

8.2 NON CRITICAL PROCESS VARIABLES:

Stage	Equipment Name	Process Variables		Batch No.		
Labelling	**Labelling Machine**	Process Time	From			
			To			
		Machine Speed	Minimum			
			Maximum			
		Label printing quality				
Blister/ Tray packing	**Blister machine**	Process Time	From			
			To			
		Tray pack Forming temperature (135^0C to 155^0C)				
		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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(Sign & Date)

9.0 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 Ampoules			
Rejection Yield (%)				
Complied By QA (Sign./Date)				
Verified By QA (Sign. / Date)				

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PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

10.0 CRITICAL QUALITY ATTRIBUTES:

10.1 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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10.2 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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10.3 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	6.7 to 7.8			
		Assay	97.00 mg to 105.00 mg (97.0% to 105.0% of label claim)			
	Bulk Mixing after 15 min. (Bottom)	**Description**	A Clear, colorless solution.			
		pH	6.7 to 7.8			
		Assay	97.00 mg to 105.00 mg (97.0% to 105.0% of label claim)			
	Bulk Sample before Filtration	**Description**	A Clear, colorless solution.			
		pH	6.7 to 7.8			
		Weight per ml	0.995 to 1.05 g/ml			
		Colour Index	NMT 0.200 AU			
		Assay	97.00 mg to 105.00 mg (97.0 % to 105.0 % of label claim)			
		Bioburden	10 cfu / 100 ml			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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10.4 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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10.5 Before Ampoule Washing:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Ampoules washing	**Turn Table**	Bio-burden	For Informative			

Inference:

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10.6 Ampoules Washing and Sterilization:

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
Ampoules washing	**Ampoule washing machine**	Visual Inspection	Initial	Should be visually clean			
			Middle	Should be visually clean			
			End	Should be visually clean			
		LBPC	Initial	• Visible particles: Should be free from visible particles			
				• For sub visible particles : (ii)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			

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
				(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			
Ampoule washing	**Ampoule washing machine**	Bio-burden		NMT 10 CFU / 100 ml			
Ampoules Sterilization & Depyrogenation	**Sterilization and Depyrogenating 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 Depyrogenating tunnel	BET	Initial	NMT 0.25 EU/ml			
			Middle	NMT 0.25 EU/ml			
			End	NMT 0.25 EU/ml			
Verified By QA (Sign. / Date)							

Inference:

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10.7 Ampoules Filling & Sealing:

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
Filling and Sealing	**Nitrogen gas from user point**	Sterility	Initial	Should be sterile			
			Middle	Should be sterile			
			End	Should be sterile			
	Filling and Sealing Machine	**Description**	Initial	A clear, colorless solution free from foreign particulate matter filled in 5 ml clear glass ampoules.			
			Middle				
			End				
		Extractable Volume	Initial	NLT 5 ml			
			Middle				
			End				
		Acidity or Alkalinity	Initial	6.7 to 7.8			
			Middle				
			End				
		Particulate Contamination					
		Visible Particles	Initial	Should be free from any visible particulate matter			
			Middle				
			End				
		Sub-Visible Particles	Initial	(i) ≥ 10 micron - NMT 6000 / container (ii) ≥ 25 micron - NMT 600 / container			
			Middle				
			End				
		Assay	Initial	Each ml contains: Tranexamic Acid BP 100 mg 97.00 mg to 105.00 mg (97.0% to 105.0% of label claim)			
			Middle				
			End				
		Bacterial Endotoxins	Initial	Less than 35 IU per ml.			
			Middle				

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

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

Inference:

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10.8 Finished Product:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Finished Sample	--	**Description**	A clear colorless solution free from foreign particulate matter filled in 5 ml clear glass ampoules.			
		Identification				
		By IR	The Infrared absorption spectrum of the crystals should be concordant with the reference spectrum of tranexamic acid.			
		Extractable Volume	NLT 5 ml			
		Acidity or Alkalinity	6.5 to 8.0			
		Related Substance				
		Impurity A	NMT 1.00%			
		Impurity B	NMT 0.50%			
		Impurity C	NMT 0.10%			
		Impurity D	NMT 0.10%			
		Any Other Secondary Impurity	NMT 0.10%			
		Total Impurity	NMT 2.00%			
		Bacterial Endotoxins	Less than 35 IU per ml.			

PROCESS VALIDATION REPORT FOR TRANEXAMIC ACID INJECTION BP 100 mg/ml (500 mg in 5 ml)

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
		Test for Sterility	Should comply test of sterility.			
		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:** Tranexamic Acid BP 100 mg	95.00 mg to 105.00 mg (95.0 % to 105.0 % of label claim)			
Complied By QA (Sign. / Date)						
Verified 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 Ampoules (Complies/Does Not Complies)									
5 Labelled Ampoules 5 ml in (5 X 5 ml) each Tray pack (Complies/Does Not Complies)									
Overprinting details on Carton. (Complies/Does Not Complies)									
Placement of 5 Ampoules tray Pack in each carton Pack (1X5X5 ml) (Complies/Does Not Complies)									
Placement of 10 carton pack in each Shrink pack (1X10X5X5 ml in Shrink pack) (Complies/Does Not Complies)									
Placement of 8 Shrink pack in each C. Box (1X8X10X5X5 ml in 7 ply C. Box) (Complies/Does Not Complies)									
Overprinting details on 7 ply C. Box (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		NA	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)			