PROCESS VALIDATION REPORT

FOR

CIPROFLOXACIN OPHTHALMIC

SOLUTION BP 0.3% (5 ml)

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

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (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)			

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

2.0 OBJECTIVE:

- The objective of this report is to validate the manufacturing process for the Ciprofloxacin Hydrochloride Eye Drops BP 0.3% (5ml) manufactured at Three Piece 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 Ciprofloxacin Hydrochloride Eye Drops BP 0.3% (5 ml) manufactured at Three Piece Line of at First floor.
- 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.

DEPARTMENT	RESPONSIBILITIES
	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. 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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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						

Name of the Trainer: _____

Inference:

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Reviewed By_____
Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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.	Ciprofloxacin Hydrochloride BP			

S.No.	Stage	Primary packing material Specification No.	Primary packing material STP No.	Complied By QA (Sign & Date)
1.	Bottle, LDPE, White 5 ml			
2.	Nozzle, LDPE, Natural 5 ml			
3.	Caps HDPE, White, 20 mm			

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			

S.No.	Stage	SOP NO.	Complied By QA (Sign & Date)
1.	Bio burden		

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Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

6.3 EQUIPMENT DETAIL:

Name of Equipment/ Machine	Make	Identification No.	Done Date	Due Date	Calibration / Qualification Status
Mobile Mixing Vessel					
Holding Vessel					
Filling Machine					
Buffer vessel					
LAF for three-piece line					
Dynamic Pass Box					
Dynamic Pass Box					
Dynamic Pass Box					
Dynamic Pass Box					
Dynamic Pass Box					
Static Pass Box					
LAF For Filtration Room					
Autoclave					
Checkweigher					

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Reviewed By_____
Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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.	Ciprofloxacin Hydrochloride BP			
2.	Benzalkonium Chloride 10% w/v Solution IH			
3.	Mannitol BP			
4.	Glacial acetic acid BP			
5.	Sodium acetate anhydrous USP			
6.	Disodium Edetate BP			
7.	Sodium Hydroxide BP			
8.	Hydrochloric acid BP			
9.	Water for injection BP			
Complied By QA (Sign./Date)				

(II) Approved Manufacturer of API:

S.No.	Name of Ingredient	Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
1.	Ciprofloxacin Hydrochloride BP			
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.	Ciprofloxacin Hydrochloride BP			
Complied By QA (Sign./Date)				

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

7.2 PACKING MATERIALS VERIFICATION:

(I) Dispensed Quantity Verification, Approved Manufacturer Verification of PPM:

S.No.	Name of material	Dispensed Qty./ Approved Manufacturer		
		Batch No.:	Batch No.:	Batch No.:
1.	Bottle, LDPE, White 5ml			
2.	Nozzle, LDPE, Natural 5ml			
3.	Caps HDPE, White, 20 mm			
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 Materials:

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

Inference:_____

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

8.1.2 Sterilization of Equipment:

Stage	Equipment Name	Process Variables		Batch No.		
Sterilization of Equipment's	Mobile Mixing Vessel	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp. (NLT 122ºC)	**Min.**			
			Max.			
	Holding Vessel	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp. (NLT 122ºC)	**Min.**			
			Max.			
	M/c parts	**Sterilization time** (NLT 30 mins.)				
		Sterilization temp. (NLT 121.4ºC)	**Min.**			
			Max.			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

8.1.3 Preparation of Bulk Solution:

Stage	Equipment Name	Process Variables	Batch No.		
Vessel Load cell Verification	**Mobile Mixing Vessel**	Zero Reading observation			
		Reading after addition of Standard Weight			
		Reading after removal standard weight (should be zero)			
Preparation of Bulk Solution	**Mobile Mixing Vessel**	Date of manufacturing			
		Capacity of mobile mixing vessel			
		Temperature (before adding API)			
		Final pH			
		Mixing Speed			
		Mixing time			
		Final Volume make up			
		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 (NMT 2.5 kg)			

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Variables	Batch No.		
		Filtration time			
Complied By QA (Sign. / Date)					
Verified By QA (Sign. / Date)					

Inference:_____

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8.1.5 Hold Time Study:

Stage	Equipment Name	Process Variables		Batch No.		
After Cleaning	**Cleaned Mobile Mixing Vessel**	Cleaning End	Date			
			Time			
		Sterilization Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
	Cleaned Holding Vessel	Cleaning End	Date			
			Time			
		Sterilization Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
	Cleaned Machine Parts	Cleaning End	Date			
			Time			
		Sterilization Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
After Sterilization	**Sterile Garments**	Sterilization End	Date			
			Time			

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Variables		Batch No.		
		Garments Uses	Date			
			Time			
		Total Hold Time (NMT 48 Hours)				
	Sterilized Mobile Mixing Vessel	Sterilization End	Date			
			Time			
		Manufacturing Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
	Sterilized Holding Vessel	Sterilization End	Date			
			Time			
		Filtration Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
	Sterilized Machine Parts	Sterilization End	Date			
			Time			
		Filling Start	Date			
			Time			
		Total Hold Time (NMT 24 Hours)				
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

8.1.6 Filling & Screw Capping of Vials:

Stage	Equipment Name	Process Variables		Batch No.		
Filling & Screw Capping	Vial Line Filling & Screw Capping Machine	Target fill volume 5.1 ml (Limit 5.05 ml to 5.15 ml)				
		Nitrogen Pressure (NLT 1.0 kg/cm^2)				
		Sealing Quality				
		Dropper fixing Quality				
		Screw capping quality				
		Machine Speed	Minimum			
			Optimum			
			Maximum			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:_____

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8.1.7 Machine Speed Challenge Test:

8.1.7.1 At Minimum Speed: ……

Filling Nozzle	Batch no.	Batch no.	Batch no.
	Date	Date	Date
	Time	time	time
1			
2			
3			
4			
5			
6			

7			
8			
Complied by			
Verified by			

Inference:_____

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8.17.2 At Optimum Speed: …….

Filling Nozzle	**Batch no.**	**Batch no.**	**Batch no.**
	Date	**Date**	**Date**
	Time	**time**	**time**
1			
2			
3			
4			
5			
6			
7			
8			
Complied by			
Verified by			

Inference:_____

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

8.1.7.3 At Maximum Speed: ……

Filling Nozzle	Batch no.	Batch no.	Batch no.
	Date	Date	Date
	Time	time	time
1			
2			
3			
4			
5			
6			
7			
8			
Complied by			
Verified by			

Inference:_____

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Reviewed By_____
Quality Assurance
(Sign & Date)

8.1.8 Leak Test of Vials:

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

Inference:_____

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8.1.9 TORQUE TEST

Stage	Equipment Name	Process Variables	Batch No. (observation)					
Filling & Sealing	**Torque Test**	Observation (Lower Limit-00.319 NM) (Upper Limit- 00.585 NM)	**Min**	**Max.**	**Min**	**Max**	**Min**	**Max**
Complied By QA (Sign. / Date)								
Verified By QA (Sign. / Date)								

Inference:_____

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

8.2 NON CRITICAL PROCESS VARIABLES:

Stage	Equipment Name	Process Variables		Batch No.		
Labelling	**Labelling Machine**	Process Time	From			
			To			
		Machine Speed	Minimum			
			Optimum			
			Maximum			
		Label printing quality				
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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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

9.0 VISUAL INSPECTION:

S.No.	Observations / Defects	Batch No.		
1.	Date			
2.	Start Time:			
3.	Completion Time:			
4.	Dirty Vials			
5.	Vial without cap			
6.	Mould Defect			
7.	Broken Ratchet			
8.	Surface Particle			
9.	Improper Sealing			
10.	Improper Fixing of Cap			
11.	Leaked Vial			
12.	Total Qty. Rejected			
13.	Total Qty. Checked			
14.	Good Vials			
Rejection Yield (%)				
Complied By QA (Sign./Date)				
Verified By QA (Sign. / Date)				

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Reviewed By_____
Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

10.0 CRITICAL QUALITY ATTRIBUTES:

10.1 Cleaning of Equipment:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Cleaning of Equipment's	Wash Water from Mobile 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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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

10.2 Water for Injection:

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
Water for Injection	Mobile 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	4.0 to 5.0			
		Assay	0.291 % w/v to 0.321 % w/v (97.0 % to 107.0 % of label claim)			
	Bulk Mixing after 15 min.	**Description**	A clear colorless solution.			
		pH	4.0 to 5.0			

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
	(Bottom)	**Assay**	0.291 % w/v to 0.321 % w/v (97.0 % to 107.0 % of label claim)			
	Bulk Sample before Filtration	**Description**	A Clear colorless solution.			
		pH	4.0 to 5.0			
		Weight per ml	0.995 to 1.050 g/ml			
		Colour Index	NMT 0.200 AU			
		Osmolarity	260 mOsmol/kg to 340 mOsmol/kg			
		Assay: Each ml contains: Ciprofloxacin Hydrochloride BP eq. to Ciprofloxacin 0.3 %w/v	0.291 % w/v to 0.321 % w/v (97.0 % to 107.0 % of label claim)			
		Preservative Content: Benzalkonium Chloride BP 0.006 % w/v	0.00480% w/v to 0.00720% w/v (80.0% to 120.0% of label claim)			
		Bioburden	10 cfu / 100 ml			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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)						

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

10.5 Bottles 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.			
	Pre sterilized empty vial Dropper, Screw caps	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.			
	Filling and Sealing Machine	**Description**	Initial	A Clear, colorless solution free from foreign particulate matter filled in 5 ml opaque white bottles.			
			Middle				
			End				
		pH	Initial	4.0 to 5.0			
			Middle				
			End				
		Average filled volume	Initial	Not Less Than 5 ml			
			Middle				
			End				
		Uniformity	Initial	4.55 ml to 5.45 ml			

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PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
		of filled volume	Middle				
			End				
		Particulate Matter					
		Visible particles	Initial	Should be free from visible particles			
			Middle				
			End				
		For Sub Visible particles:					
		(i) Equal to or greater than 10 µm	Initial	NMT 1000 Particles/ml			
			Middle				
			End				
		(ii) Equal to or greater than 25 µm	Initial	NMT 100 Particles /ml			
			Middle				
			End				
		Assay	Initial	**Each ml contains:** Ciprofloxacin Hydrochloride BP eq. to Ciprofloxacin 0.3 %w/v 0.291 % w/v to 0.321 % w/v (97.0 % to 107.0 % of label claim)			
			Middle				
			End				
		Preservative	Initial	Benzalkonium Chloride			

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Parameter		Acceptance Criteria	Batch No.		
		Content	Middle	BP 0.006 % w/v 0.00480% w/v to 0.00720% w/v (80.0% to 120.0% of label claim)			
			End				
Complied By QA (Sign. / Date)							
Verified By QA (Sign. / Date)							

Inference:

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10.6 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 white bottles.			
		Identification				
		A. By HPLC (Diode array detector)	The retention time of the principal peak in the chromatogram obtained with solution (1) should be similar to that of the peak in the chromatogram obtained with solution (2).			
		B. By HPLC (for Preservative Content)	The retention time of the major peak of the sample solution should be corresponds to that of the standard solution obtained as directed in			

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
			the assay.			
		Average filled volume	Not Less Than 5 ml			
		Uniformity of filled volume	4.55 ml to 5.45 ml			
		Osmolarity	260 mOsmol/kg to 340mOsmol/kg			
		pH (Acidity)	4.0 to 5.0			
		Related Substance				
		Impurity C	NMT-0.40 %			
		Impurity E	NMT-0.30 %			
		Any other secondary Impurity	NMT- 0.20 %			
		Sum of all secondary Impurity	NMT-0.70 %			
		Test for Sterility	Should comply test of sterility.			
		Particulate Contamination				
		Visible particles:	Should be free from visible particles			
		Sub visible particles :	(i) ≥ 10 micron - NMT 1000 particles/ml (ii) ≥ 25 micron - NMT 100 particles/ml			
		Assay: Each ml contains: Ciprofloxacin Hydrochloride BP eq. to Ciprofloxacin 0.3 %w/v	0.285 % w/v to 0.330 % w/v (95.0 % to 110.0 % of label claim)			

PHARMA DEVILS

PRODUCTION DEPARTMENT

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

Stage	Equipment Name	Process Parameter	Acceptance Criteria	Batch No.		
		Preservative Content: Benzalkonium Chloride Solution BP 0.006 % w/v	For Information			
Complied By QA (Sign. / Date)						
Verified By QA (Sign. / Date)						

Inference:

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Reviewed By_____
Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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 Bottles (Complies/Does Not Complies)									
One labelled 5 ml in 5 ml Bottles each mono carton pack (Complies/Does Not Complies)									
Overprinting details on each mono carton (Complies/Does Not Complies)									
Placement of 25 mono carton pack in each shrink pack (Complies/Does Not Complies)									
Placement of 16 shrink pack in C. Box (1x16x25x5 ml in 5 ml bottles) pack 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:_____

_____

_____

Reviewed By_____
Quality Assurance
(Sign & Date)

PROCESS VALIDATION REPORT FOR CIPROFLOXACIN HYDROCHLORIDE EYE DROPS BP 0.3% (5 ml)

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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
STP	:	Standard Testing Procedure
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
BMR	:	Batch Manufacturing Record
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)			