PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME Gatifloxacin Eye Drops	**PRODUCT CODE**	**EFFECTIVE DATE**	
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BATCH MANUFACTURING RECORD

PRODUCT NAME : **GATIFLOXACIN EYE DROPS**

GENERIC NAME : **Gatifloxacin Eye Drops**

LABEL CLAIM : **Composition**

Gatifloxacin eq. to Anhydrous Gatifloxacin …..0.3% w/v

Benzalkonium Chloride Solution IP……0.02%v/v

(As preservative)

Sterile Aqueous vehicle……q.s.

STRENGTH : **0.3%w/v, 0.02%v/v**

MANUFACTURING LICENSE No. : **.....**

STANDARD BATCH SIZE : **500 L**

ACTUAL BATCH SIZE :

PACK SIZE : **5 ml & 3 ml filling in 5 ml Vial**

MANUFACTURING DATE :

EXPIRY DATE :

SHELF LIFE : **24 Months**

BLOCK/ PRODUCRTION LINE : **Three Piece Line**

MARKET : **Domestic/Export**

DATE OF COMMENCEMENT :

DATE OF COMPLETION :

BATCH YIELD (%) :

PRODUCT OF (Company Name) : **.....**

BMR ISSUED BY (QA) :

DATE :

	Prepared By **QA**	**Checked By** **Production**	**Approved By** **Head QA**	**Authorized By** **Head Operations**
Sign				
Date				
Name				

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1.0 QUANTITATIVE FORMULA:

A) RAW MATERIAL:

Material Code	Material Name	Vendor Name	Specification	Label Claim (%w/v)	Unit	Overages	Qty. Required as per Standard Batch Size (500 Liter)
	Gatifloxacin eq. to Anhydrous Gatifloxacin	--	IH	0.3% w/v	Kg	3%	1.714*
	Benzalkonium Chloride Solution	--	IP	0.02%v/v	Ltr.	20%	0.120
	Sodium Chloride	--	IP	--	Kg	--	3.500
	Disodium Edetate	--	IP	--	Kg	--	0.050
	Mannitol	--	IP	--	Kg	--	2.000
	Sodium Hydroxide (Pellets)	--	IP	--	Kg	--	0.175
	Hydrochloric Acid	--	IP	--	Ltr.	--	0.100#
	Sodium Hydroxide (Pellets)	--	IP	--	Kg	--	0.075#
	Water For Injections	--	IP	--	Ltr.	--	q.s.

* Material has been taken equivalent to 100% assay on as is basis considering the minimum assay NLT: 98% (OAB) & Maximum % of Water content NMT: 8.0 %w/w.

This quantity is used for pH adjustment only.

B) PRIMARY PACKAGING MATERIAL:

Material Code	Name of Material	Unit	Qty. Required as per Standard Batch Size (500 Liter)	
	THREE PCS. WHITE E/E BT. 5 ML W/CAP	Nos.	For 5 ml	97,114 Vials**
	THREE PCS. WHITE E/E BT. 5 ML W/CAP	Nos.	For 3 ml	159,375 Vials**

****** 2% excess quantity of material to compensate processing loss.

2.0 CALCULATION:

2.1 Required Quantity of Gatifloxacin eq. to Anhydrous Gatifloxacin IH:-

Label Claim: 0.3%w/v, Overages: 3%, Label Claim with Overages: 0.309%w/v,

Assay NLT : 98.0 %(OAB), Maximum Water Content NMT: 8 %w/w,

Required quantity of Raw material = $\frac{\text{Label Claim (with Overages) X100X Batch Size}}{\text{Assay of Raw Materials X (100-Water Content)}}$

= $\frac{0.309 \text{ X } 100 \text{ X } 500}{98 \text{ X } (100-8)}$

= 1.7136 Kg / Standard Batch Size

= **1.714 Kg / Standard Batch Size.**

2.2 The below calculation is to be used when the quantity of "Gatifloxacin IH" required for Actual Batch Size is available from one A.R. No.

A.R. No.:_____

Assay of Raw Material (P) = _____

Water Content (NMT) (Q) = _____

Required Quantity of Raw Material:

$$= \frac{\text{Label Claim (With Overages) x 100 x Batch Size}}{\text{P x (100-Q)}}$$

= _____

Total Quantity of Gatifloxacin IH = _____ Kg

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2.3 The below calculation is to be used when the quantity of "Gatifloxacin IH" required for Actual Batch Size (A), available from more than one A.R. No.

1. For First A.R. No. :

A.R. No.:_____

Assay of Raw Material (P) = _____

Water Content (NMT) (Q) = _____

Quantity of this A.R. No. (B):_____ Kg.

$$\text{Batch Size from first A.R. No. (C)} = \frac{\text{Assay of Raw Material X (100-Q) X B}}{\text{Label Claim (with overages) X 100}} \text{ Liter.}$$

Batch Size from first A.R. No. (C) = _____ Liter.

Remaining Batch Size (D) = Actual Batch size (A) – Batch size Batch Size from first A.R. No. (C)

(D) = _____ - _____ Liter.

(D) = _____ Liter

2. For Next A.R. No. :

A.R. No. :_____

Assay of Raw Material (P) = _____

Water Content (NMT) (Q) =_____

$$\text{Required Quantity of Raw Material :(E)} = \frac{\text{Label Claim(with overages) X 100 X Remaining Batch Size (D)}}{\text{Assay of Raw Material X (100-Q)}} \text{Kg.}$$

Required Quantity of Raw Material :(E) = _____ Kg.

Required Quantity of Raw Material :(E) = ——— Kg.

Total qty. of Gatifloxacin IH to be dispensed = (A) + (E) = _____ kg

2.4 Calculation for Actual Batch Size (In Terms of Vials)

$$= \frac{\text{Actual Batch Size in Liters x1000}}{\text{Fill Volume}}$$

= _____

= _____ Vials.

Calculation Done By	**Calculation Checked By**	**Calculation Verified By**
(Production)	**(Production)**	**(QA)**
(Sign & Date)	**(Sign & Date)**	**(Sign & Date)**

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***** Attach the Assay Report of Raw Material used for Batch Size calculation.

Attach the Assay Report of Used Raw Material

3.0 PRE DISPENSING / MANUFACTURING INSTRUCTIONS:

- Follow the Manufacturing Instructions carefully and strictly, before proceeding for any Operation / Activity.
- Follow all the "current Good Manufacturing Practices" during entire procedure of Manufacturing.
- Ensure that equipment and area is clean.
- Ensure that proper gowning of persons working in the area.
- All the activities that are related to Equipment Cleaning, Operations, Material Handling and Process Controls, shall be carried out strictly as per respective Standard Operating Procedure.
- Environmental Conditions like Temperature, Relative Humidity and Differential Pressure shall always be maintained within the specified limits before / during processing.
- Aseptic Processing Area Gowning shall be strictly followed throughout the Manufacturing Operations.
- Gloves must be worn at all the times while handling the equipments / during processes.
- Before starting any activity check and ensure the supply of required utilities.
- Line Clearance shall be taken by the concerned department Officer / Executive and given by QA Officer / Executive.
- Approved Water for Injection shall be used for Batch Manufacturing.
- Report of Purified Water / WFI should comply and shall be recorded in BMR.
- In case of Product Change, Samples of all the Critical Equipments shall be tested for Rinse Water / Swab and the report of same shall be attached at specified place in BMR.
- Integrity of Filters shall be checked before and After Filtration of Bulk Solution by Diffusion / Bubble Point Test Method and attach the report in BMR at specified place.
- Ensure that Machine Parts and Accessories, Garments etc. are sterilized before start up of Aseptic Filtration and Filling.
- Attach the Steam Clox indicator on the Thermograph.
- Attach the signed Thermograph and Temperature Printout at specified page.
- Used Equipment(s) and any Spillage in the Area shall be cleaned thoroughly, effectively and immediately.

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4.0 DISPENSING OF RAW AND PRIMARY PACKING MATERIALS:

4.1 DISPENSING OF RAW MATERIALS:

4.1.1 LINE CLEARANCE: (SOP No.:.....)

Previous Material / Product : _____

Batch No. : _____ Date / Time : _____

S.No.	Line Clearance Checks	OK / Not OK / NA	Checked By Warehouse Officer / Executive	Verified By QA Officer / Executive
NA	**Dispensing**			
1.	Check the "Status Board" of the Dispensing Area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BPCR of Present Batch to be processed.			
2.	Check the cleanliness of the Dispensing Room and ensure that it is free from the remains of the previous Batch / Product and check the availability of Cleaning & Sanitization Record.			
3.	Check the Calibration Status of the Balances to be used for Dispensing.			
4.	Check the Temperature & Relative Humidity (RH) in Dispensing Room. (It should be within specified range). **Temperature = NMT 25^{0}C, RH = NMT 55%**	___ ^{o}C ____ %		
5.	Check the approval status of Raw Materials.			
6.	Check the intactness of Raw Material containers.			
7.	Check and verify, the Item code No. & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip.			
8.	Check and ensure that RLAF is clean, verify the log books and check the working of RLAF.			
9.	Ensure entries in logbooks are online.			
10.	Check the Waste bins, it should be clean.			

Note: After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____ Line Clearance Given By Sign / Date_____
(WH Officer / Executive) (QA Officer / Executive)

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4.2 DISPENSING OF PRIMARY PACKING MATERIALS:

4.2.1 LINE CLEARANCE: (SOP No.:.....)

Previous Material / Product : _____

Batch No. : _____ Date / Time : _____

S.No.	Line Clearance Checks	OK / Not OK / NA	Checked By Warehouse Officer / Executive	Verified By QA Officer / Executive
NA	**Dispensing**			
1.	Check the "Status Board" of the Dispensing Area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BPCR of Present Batch to be processed.			
2.	Check the cleanliness of the Dispensing Area and ensure that it is free from the remains of the previous Batch / Product and check the availability of Cleaning & Sanitization Record.			
3.	Check the Calibration Status of the Balances to be used for Dispensing.			
4.	Check the Temperature in Dispensing Room. (It should be within specified range). **Temperature = NMT 25ºC**	___ ºC		
5.	Check the approval status of Primary Packing Materials.			
6.	Check the intactness of Packing Material containers.			
7.	Check and verify, the Item code No. & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip.			
9.	Ensure entries in logbooks are online.			
10.	Check the Waste bins, it should be clean.			

Note: After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(WH Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

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Affix the Line Clearance Label For Dispensing of Raw and Primary Packing Materials

4.2.2 **ENVIRONMENTAL MONITORING:** At the time of start of Dispensing, after every one hour and after every breakdown.

4.2.2.1 During Dispensing of Raw Material and Primary Packaging Material, check Environmental Conditions are within limits (**i.e. Temp. NMT 25ºC & Relative Humidity (RH) NMT 55%)** and record in Environment Monitoring Record at the time of start of dispensing, after every two hours and after completion of dispensing.

Date/ Time (Hrs.)	**Room No. /Name**	**Temperature (NMT 25°C)**	**% RH Limit (NMT 55%)**	**Done By (Warehouse Officer) (Sign/Date)**	**Checked By (QA Officer) (Sign/Date)**	**Remarks**

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4.3 DISPENSING OF RAW MATERIALS:

Balance ID. No.: _____

Material Code	Material Name	Vendor Name	Specifi -cation	Std. Qty.	Required Qty.	Date of Dispensing	Dispensing		Issued Qty.	A.R No.	No. of Packs
							Started At	Completed At			
	Gatifloxacin eq. to Anhydrous Gatifloxacin	--	IH	1.714*							
	Benzalkonium Chloride Solution	--	IP	0.120							
	Sodium Chloride	--	IP	3.500							
	Disodium Edetate	--	IP	0.050							
	Mannitol	--	IP	2.000							
	Sodium Hydroxide (Pellets)	--	IP	0.175							
	Hydrochloric Acid	--	IP	0.100#							
	Sodium Hydroxide (Pellets)	--	IP	0.075#							
	Water For Injections	--	IP	q.s.							

Dispensed By (WH) **Received By (Production)** **Verified By (QA)**

Sign & Date ———— **Sign & Date ————** **Sign & Date ————**

4.4 DISPENSING OF PRIMARY PACKING MATERIALS:

Material Code	Material Name	Units	Std. Qty.		Required Qty.	Issued Qty.	No. of Packs	A.R. No.
	THREE PCS. WHITE E/E BT. 5 ML W/CAP	Nos.	For 5 ml	97,114 Vials**				
	THREE PCS. WHITE E/E BT. 5 ML W/CAP	Nos.	For 3 ml	159,375 Vials**				

** 2% excess quantity of material to compensate Processing Loss.

Dispensed By (WH) **Received By (Production)** **Verified By (QA)**

Sign & Date ———— **Sign & Date ————** **Sign & Date ————**

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AFFIX THE QA APPROVED COPY OF RAW MATERIAL & PRIMARY PACKING MATERIAL ISSUANCE / DISPENSING NOTE

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5.0 VERIFICATION OF DISPENSED MATERIALS (ON PRODUCTION FLOOR):

Balance ID. No.: _____ Date: _____

Calibration Status (Ok / Not Ok):_____

- Verify the dispensed Raw Material containers as per Material Requisition Slip after receiving on Production Floor.
- Verify the dispensed Primary Packing Materials as per Material Requisition Slip after receiving on Production Floor.

5.1 Verification of Dispensed Raw Materials :

S.No.	Material Code	Material Name	Specifi-cation	Issued Quantity	Unit	A.R. No.	No. of Packs	Checked By Production (Officer / Executive)	Verified By QA (Officer / Executive)
1	10006557	Gatifloxacin eq. to Anhydrous Gatifloxacin	IH		Kg				
2	10002265	Benzalkonium Chloride Solution	IP		Ltr.				
3	10007000	Sodium Chloride	IP		Kg				
4	10001102	Disodium Edetate	IP		Kg				
5	10001337	Mannitol	IP		Kg				
6	10001552	Sodium Hydroxide (Pellets)	IP		Kg				
7	10002125	Hydrochloric Acid	IP		Ltr.				
8	10001552	Sodium Hydroxide (Pellets)	IP		Kg				
9	--------	Water For Injections	IP		Ltr.				

5.2 Verification of Dispensed Primary Packing Materials :

Material Code	Material Name	Units	Issued Quantity	No. of Packs	A.R. No.	Checked By Production (Officer / Executive)	Verified By QA (Officer/ Executive)
20022634	THREE PCS. WHITE E/E BT. 5 ML W/CAP-LUP	Nos.					
20022634	THREE PCS. WHITE E/E BT. 5 ML W/CAP-LUP	Nos.					

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Affix the Raw Material & Primary Packing Material Dispensing Labels

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6.0 LIST OF EQUIPMENTS / MACHINES TO BE USED FOR MANUFACTURING:

S.No.	Name of Equipment / Machine	Three Piece Line Equipment / Machine Identification No.
1.	Compact Three Piece Filling Machine	
2.	High Pressure & High Vacuum Steam Sterilizer	
3.	Dynamic Pass Box (Garment Washing & Preparation Area To 2000 mm wide Corridor)	
4.	Dynamic Pass Box (Garment Washing & Preparation Area To 1300 mm wide Corridor)	
5.	Dynamic Pass Box (Material Entry To 1300 mm Wide MFG. Corridor)	
6.	Dynamic Pass Box (Equipment Washing To 1300 mm Wide MFG. Corridor)	
7.	Dynamic Pass Box (Unit Preparation To 1300 mm Wide Mfg. Corridor)	
8.	Dynamic Pass Box (Unit Preparation To 1500 mm Wide Sterile Corridor)	
9.	Dynamic Pass Box (L type) (1500 mm Wide Sterile Corridor to 1300 mm Wide Mfg. Corridor)	
10	Dynamic Pass Box (Disinfectant preparation to 1800 mm Wide corridor)	
11	Dynamic Pass Box (Buffer zone to Decartoning)	
12	Dynamic Pass Box (Material Entry to Decartoning)	
13	Dynamic Pass Box (Decartoning To Scrap Out)	
14	Dynamic Pass Box (Scrap out to 1500 mm Wide Sterile Corridor)	
15	Dynamic Pass Box (Entry Material to 1085 Wide Corridor)	
16	Dynamic Pass Box (CH-2 to 1500 mm Sterile Corridor)	
17	Laminar Air Flow (Table mounted) (Garment Washing & preparation Area)	
18	Laminar Air Flow Celling mounted) (Unit preparation & sterilization area)	
19	Laminar Air Flow (Celling mounted)(Disinfectant filtration room)	
20	Laminar Air Flow (Bench type) (Filling room)	
21	Laminar Air Flow (Celling mounted) (Machine tools & tubing)	
22	Laminar Air Flow (Celling mounted) (Buffer zone)	
23	Laminar Air Flow (Celling mounted) (Nozzle side)	
24	Laminar Air Flow (Celling mounted)(Capping side)	

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S.No.	Name of Equipment / Machine	Three Piece Line Equipment / Machine Identification No.
25	Laminar Air Flow (Celling mounted)(Filtration room -1)	
26	Laminar Air Flow (Celling mounted)(Filtration room -2)	
27	Laminar Air Flow (Celling mounted)(Filtration room -2)	
28	Laminar Air Flow (Celling mounted) (Buffer zone)	
29	Laminar Air Flow (Celling mounted) (cooling zone)	
30	Laminar Air Flow (Celling mounted) (Filling side)	
31	Laminar Air Flow (Mobile LAF)	
32	Laminar Air Flow (Table mounted) (Disinfectant Preparation)	
33	Pressure Vessel (50 L)	
34	Pressure Vessel (100 L)	
35	SS Jacketed Holding Vessel (500 Ltr)	
36	SS Jacketed Holding Vessel (400 Ltr)	
37	SS Jacketed Holding Vessel (500 L)	
38	SS Jacketed Holding Vessel (200L)	
39	SS Jacketed Mfg. Vessel (500L)	
40	SS Jacketed Mfg. Vessel (100L)	
41	SS Jacketed Mfg. Vessel (400L)	
42	SS Jacketed Mfg. Vessel (500L)	
43	Dynamic Dress Cabinet	
44	Dynamic Dress Cabinet	
45	Dynamic Dress Cabinet	
46	Dynamic Dress Cabinet +LAF	
47	Membrane Filtration Assembly	
48	CIP-SIP Module	
49	Filter Integrity Tester	
50	Pre Filter Housing	

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S.No.	**Name of Equipment / Machine**	**Three Piece Line** **Equipment / Machine Identification No.**
51	Final Filter Housing	
52	Final Filter Housing	
53	Weighing Balance	
54	pH Meter	
55	Nitrogen Gas Filter	
56	Air Sampling Filter	

6.1 LIST OF COMPONENT TO BE USED FOR MANUFACTURING

S.No.	**Name of Component**	**Equipment Identification No.**
1.	Pre filter with Housing 1.0µ (Manufacturing)	
2.	Final Filter with Housing 0.22µ (Manufacturing)	
3.	Final Filter with Housing 0.22µ (Holding)	
4.	Nitrogen Gas Filter	
5.	Air Assembly Filter	
6.	pH Meter	
7.	Integrity Tester	
8.	Electronic Balance	

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7.0 PROCESSING OF MACHINE PARTS & ACCESSORIES:

7.1 LINE CLEARANCE (SOP No.: QAH/057):

Previous Material / Product : _____

Batch No. : _____ Date / Time : _____

S. No.	Line Clearance Checks	OK / Not OK / NA	Done by Production Officer/Executive	Checked By QA Officer/Executive
NA	**Washing and Sterilization of Machine Parts & Accessories**			
1.	Check the "Status Board" of the Unit Preparation Area for following details: Product Name, Batch No., Mfg. Date, Batch Size and ensure that the details are matching with the BPCR to be processed.			
2.	Check the cleanliness of the Unit Preparation Area and ensure that it is free from the remains of the previous Batch / Product check the availability of Cleaning & Sanitization Record.			
3.	Check the cleanliness of Autoclave and ensure that it is free from the remains of the previous Batch / Product.			
4.	Check the Temperature of Unit Preparation Area. It should be within specified range. **Temperature Limit: NMT 25ºC**	___ ^{o}C		
6.	Check the "Status Label" of "Autoclave".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

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Affix the Line Clearance Label for Processing and Sterilization of Machine Parts

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7.2 INSTRUCTIONS:

a. Follow SOP for Cleaning of Filling Assembly.

b. Visually check cleanliness of each and every washed article.

c. Send the Rinse Water / Swab sample for analysis and attach the Release Report prior to Sterilization (if applicable).

d. Record the details of equipment washed.

e. Store the washed Machine Parts and accessories under LAF.

f. Report of Water for Injection Complies / does not comply.

A. R. No.: _____Checked By (QA) / Date : _____.

7.3 DETAILS OF EQUIPMENT WASHED FOR FILLING: Date: _____

S.No.	Equipments and Accessories	Qty.	Cleaned By (Operator Name)	Checked By Production (Officer / Executive)
1.	Manifold Filling			
2.	Filling Needle – Filling Machine Nozzle Mounting Bracket			
3.	Silicon Tubes			
4.	Hopper – Sterilized Vials			
5.	Chute – Sterilized Vials			
6.	Hopper – Dropper			
7.	Chute – Dropper			
8.	Dropper Pressing Head Assembly			
9.	Hopper – Screw Cap			
10.	Chute – Screw Cap			
11.	Capping Head Assembly			
12.	Nut of Hoppers			
13.	Scissor			
14.	SS Forceps			
15.	Nitrogen Gas Flushing Nozzles			
16.	Other (If Any)			
a.				
b.				
c.				
d.				

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Attach the Rinse Water Analysis / Swab Release Report (If applicable)

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7.4 STERILIZATION & DRYING OF MACHINE PART & ACCESSORIES:

- Follow **SOP.....**
- for Operation of Autoclave.
- Sterilization Record details in Table below.

STERILIZATION CYCLE:

Load Pattern No. : _____

Sterilization Temperature: 121.4^0C

Sterilization Time: 30 Minutes

Date	Run No.	Sterilization Cycle					Qty.	Done By Production (Operator)	Checked By Production (Officer/Executive)
		Cycle Started At	Temp. Attained At	Temp. Attained Till	Total Sterilization Time	Cycle Completed At			

DRYING CYCLE:

Vacuum: -0.300 bar

Drying Time: 5 Minutes

Date	Drying Cycle				Quantity	Done By (Operator)	Checked By Production (Officer/Executive)
	Post Vacuum Started At	Vacuum Attained At	Cycle Completed At	Total Drying Time			

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

PRODUCT NAME Gatifloxacin Eye Drops	**PRODUCT CODE**	**EFFECTIVE DATE**	
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7.5 BMR REVIEW UP-TO STERILIZATION & DRYING OF MACHINE PART & ACCESSORIES:

	Checked By **Production Officer / Executive**	**Reviewed By** **QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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Attach the Thermograph and Print out of Autoclave Cycle For Machine Parts and Accessories

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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8.0 PREPARATION OF GARMENTS:

8.1 LINE CLEARANCE (SOP No.:.....):

Previous Material / Product : _____

Batch No. : _____ Date / Time : _____

S.No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Washing and Sterilization of Garments**			
1.	Check the "Status Board" of the Unit Preparation Area.			
2.	Check the cleanliness of the Unit Preparation Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check the cleanliness of the Garment Washing Machine and ensure that it is clean.			
4.	Check the Temperature & RH of Unit Preparation Area. It should be within specified range. **Temperature Limit: NMT 25ºC**	___ ºC		
6.	Check the cleanliness of Autoclave and ensure that it is free from the remains of the previous Batch / Product.			
7.	Check the "Status Label" of "Autoclave".			
8.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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Affix the Line Clearance Label for Garment Washing and Sterilization

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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8.2 INSTRUCTIONS:

- Wash the garments as per **SOP.....**
- Sterilize the washed garments in Autoclave as per **SOP.....**
- Collect the washed garments, and record following details:
  - Garment Washing Machine ID No. : _____
  - Washing Cycle No. : _____
  - Date of Garment Washing : _____
  - No. of Garments Washed : _____
  - Checked By Production Officer / Executive (Sign.& Date) : _____

8.3 STERILIZATION OF GARMENTS:

Load Pattern No. : _____

Sterilization Temperature: 121.4^{0}C

Sterilization Time: 30 Minutes

Date	Run No.	Sterilization Cycle					Qty.	Done By (Operator)	Checked By Production (Officer/Executive)
		Cycle Started At	Temp. Attained At	Temp. Attained Till	Total Sterilization Time	Cycle Completed At			

DRYING CYCLE:

Vacuum: -0.600 bar

Drying Time: 10 Minutes

Date	Drying Cycle				Quantity	Done By (Operator)	Checked By Production (Officer/Executive)
	Post Vacuum Started At	Vacuum Attained At	Cycle Completed At	Total Drying Time			

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BATCH PRODUCTION AND CONTROL RECORD

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8.4 BMR REVIEW UP-TO STERILIZATION OF GARMENTS STAGE:

	Checked By **Production Officer / Executive**	**Reviewed By** **QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

Attach the Thermograph and Print out of Autoclave Cycle For Washed Garments

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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9.0 VESSEL (COMPOUNDING & HOLDING) CLEANING AND STERILIZATION DETAILS:

9.1 COMPOUNDING VESSEL CLEANING AND STERILIZATION DETAILS:

9.1.1 LINE CLEARANCE (SOP No.:.....):

Previous Product : _____

Batch No. : _____ Date / Time : _____

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Vessel (Compounding) Cleaning & Sterilization**			
1.	Check the "Status Board" of the Manufacturing Area.			
2.	Check the cleanliness of the Manufacturing Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check the Temperature of Manufacturing Area. It should be within specified range. Temperature Limit: NMT 25ºC	___ ºC		
4.	Check the Differential Pressure of Manufacturing Area w.r.t. Manufacturing Area Corridor. It Should be within specified range.			
5.	Check the cleanliness of CIP & SIP Module.			
6.	Check the "Status Label" of "CIP & SIP Module".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

9.2 HOLDING VESSEL CLEANING AND STERILIZATION DETAILS:

9.2.1 LINE CLEARANCE (SOP No.:.....):

Previous Product : _____

Batch No. : _____ Date / Time : _____

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Vessel (Holding) Cleaning & Sterilization**			
1.	Check the "Status Board" of the Holding Area.			
2.	Check the cleanliness of the Holding Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Checked availability of cleaned dedicated machine accessories including silicon tubing.			
4.	Check the Temperature of Holding Area. It should be within specified range. **Temperature Limit: NMT 25ºC**	___ ºC		
5.	Check the Differential Pressure of Holding Area w.r.t. Aseptic Area Corridor. It Should be within specified range.			
6.	Check the cleanliness of CIP & SIP Module.			
7.	Check the "Status Label" of "CIP & SIP Module".			
8.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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Affix the Line Clearance Label for Cleaning & Sterilization of Vessels (Compounding & Holding)

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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9.3 INSTRUCTIONS:

a. Follow SOP for Cleaning of Vessel using CIP/SIP Module.

b. Visually check cleanliness of each washed vessel (Compounding & Holding).

c. Install cleaned dedicated silicon tubing on machine.

d. Send the Rinse Water / Swab sample for analysis and attach the Release Report prior to Sterilization (if applicable).

e. Report of Purified Water Complies/does not Comply.

A.R. No.: _____Checked By (QA) / Date : _____.

f. Report of Water for Injection Complies / does not comply.

A.R. No.: _____Checked By (QA) / Date : _____.

g. Follow SOP for Sterilization of Compounding and Holding Vessel using CIP/SIP Module.

9.4 CLEANING & STERILIZATION:

Sterilization Temperature: 122.6^{0}C **Sterilization Pressure:** 1.1 to1.5 kg/cm^2

Sterilization Time: 30 Minutes **Date: _____**

Date	Equipment Name	Equipment ID No.	Sterilization Cycle						Done By (Operator)	Checked By Production (Officer/ Executive)
			Started At	Temp. Attained At	Temp. Attained Till	Total Sterilization Time	Sterilization Pressure	Completed At		
	Mixing vessel, pre & final filters cleaning									
	Mixing vessel pre & final filters sterilization									
	Holding vessel cleaning & Filter Cleaning									
	Holding vessel sterilization & filter Sterilization									

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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10.0 BATCH MANUFACTURING:

10.1 LINE CLEARANCE (SOP No.:.....):

Previous Product : _____

Batch No. : _____ Date / Time : _____

S. No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/ Executive)
NA	**Batch Manufacturing**			
1.	Check the "Status Board" of the Manufacturing Area.			
2.	Check the cleanliness of the Manufacturing Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check & ensure that Temperature & RH in Manufacturing Area is within specified limit. **(Temperature Limit = NMT 25^{0}C, RH Limit = NMT 55%)**	____^{0}C ____%		
4.	Check & ensure that Differential Pressure of Manufacturing Area is with in specified limit.			
5.	Check & ensure that the Compounding Vessel, and Accessories are cleaned & sterilized.			
6.	Check the "Status Label (Name of Product, Batch No., Date, Stage)" of "Compounding Vessel".			
7.	Check & ensure the Availability of Approved Raw Material in the Manufacturing Area.			
8.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

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BATCH PRODUCTION AND CONTROL RECORD

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Affix the Line Clearance Label for Batch Manufacturing

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10.2 MANUFACTURING PROCESS:

Date: _____

Batch Manufacturing Start Time: _____ Batch Manufacturing End Time: _____

S. No.	Manufacturing Procedure	QTY. of Raw Material	Observation			Time		Done By Production (Sign / Date)	Checked By QA (Sign / Date)
			Temp	pH	Other Specific (observation)	From	To		
1.	Collect 350 L WFI IP (80ºC–85^{0}C) 500 L Batch size, in a mixing Vessel. Cool to (40ºC–50^{0}C) and bubble 0.22µ filtered Nitrogen gas for 30 min.								
2.	Add Gatifloxacin into step 1 and dissolve it completely by adding 5% Hydrochloric Acid solution. Check the pH. Adjust the pH (pH limit: 4.9 to 5.1) using 5% Sodium Hydroxide solution.								
3.	In a separate SS vessel collect approximately 100 L of WFI IP 500 L Batch size, and add dissolve Disodium Edetate IP, Mannitol IP, Sodium Chloride IP and Benzalkonium Chloride solution IP. Stir the solution for 10 min. Ensure that each ingredient has dissolved before addition of the next ingredient.								
4.	Add the bulk solution of step 3 into the bulk solution of step 2 under continuous stirring and stirring for 10 minutes at 250 rpm								
5.	Check the pH of the bulk solution (**Limit:4.8 to 6.0**). Adjust the pH using 5% Sodium Hydroxide solution.								
6.	Make up the final volume of the bulk solution with WFI IP and stir the solution for 15 min 250 RPM.								

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BATCH PRODUCTION AND CONTROL RECORD

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S. No.	**Manufacturing Procedure**	**QTY. of Raw Material**	**Observation**			**Time**		**Done By Production (Sign / Date)**	**Checked By QA (Sign / Date)**
			Temp	**pH**	**Other Specific (observation)**	**From**	**To**		
7.	Check the pH of the bulk solution (**Limit: 4.8 to 6.0**).								
8.	Intimate QA to withdraw an aliquot of solution and send sample to QC for analysis								

Collection of Bulk Sample:

- After receiving intimation from Production, QA personnel shall withdraw the sample from Bulk Solution.

Sampled Quantity: 100 ml

Bulk Sample Collected by (QA): _____ Sign / Date: _____

10.3 BMR REVIEW UP-TO BATCH MANUFACTURING STAGE:

	Checked By Production Officer / Executive	**Reviewed By QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

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BATCH PRODUCTION AND CONTROL RECORD

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Attach the Bulk Solution Release Report

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11.0 BATCH FILTRATION:

11.1 LINE CLEARANCE (SOP No.:.....):

Previous Product : _____

Batch No. : _____ Date / Time : _____

S.No.	Line Clearance Checks	OK/ Not OK/ NA	Done by Production (Officer/Executive)	Checked By QA (Officer/Executive)
NA	**Batch Filtration**			
1.	Check the "Status Board" of Filtration Area.			
2.	Check the cleanliness of Filtration Area and ensure that it is free from the remains of the previous Batch / Product.			
3.	Check & ensure that Temperature & RH in Filtration Area is within specified limit. **(Temperature Limit = NMT 25^{0}C, RH Limit = NMT 55%)**	____^{0}C ____%		
4.	Check the Differential Pressure of Filtration Area w.r.t. Aseptic Area Corridor. It Should be within specified range.			
5.	Check & ensure that the Holding Vessel, Filters and Accessories are cleaned & sterilized.			
6.	Check the "Status Label (Name of Product, Batch No., Date, and Stage)" of "Holding Vessel".			
7.	Check the Waste bins, it should be clean.			

Note: After complete checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

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BATCH PRODUCTION AND CONTROL RECORD

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Affix the Line Clearance Label for Batch Filtration

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BATCH PRODUCTION AND CONTROL RECORD

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11.2 INSTRUCTIONS:

a. Check the Integrity of Filter by Bubble Point Test/Diffusion Test as per **SOP.....** before and after all filtration**.**

b. Send samples of the bulk-filtered solution to QC for testing of Description, Assay and pH.

11.2.1 PRODUCT FILTER DETAILS: Filter the solution from compounding to holding and holding to machine as below mention filtration train.

Compounding to Holding				**Holding to Filling Vessel**			
Filter	**Size**	**MOC**	**Make**	**Filter**	**Size**	**MOC**	**Make**
1.0 µ	10 ``	Poly Propylene	Pall or Millipore	--	--	--	--
0.2 µ	10``	PVDF	Pall or Millipore	0.2 µ	10``	PVDF	Pall or Millipore

Date: _____

Filtration Started At: _____ **Filtration Completed At_____**

S. No.	**Procedure**	**Equipment Number**	**Time**		**Observation**	**Done By Production (Sign / Date)**	**Checked By QA (Sign / Date)**
			From	**To**			
1.	Perform the bubble point test of the final filter before mixing as per SOP (Pre- filtration)				*		
2.	Start the filtration from compounding vessel to holding (pressure) vessel applying 0.2 micron filtered air pressure.						
3.	Perform the bubble point test of the final filter after mixing vessel (post) as per SOP.				*		
4.	Perform the bubble point test of the final filter after Holding Vessel as per SOP (Pre- filtration)						
5.	Start the filtration from Holding Vessel to filtration vessel applying 0.2µ Filter nitrogen pressure						
6.	Perform the bubble point test of the final filter after Holding Vessel as per SOP (Post- filtration)						

***** Write OK/Not OK after performing the filter Integrity Test and also attach the Filter Integrity Report. `

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Attach the Filter Integrity Report

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12.0 RECONCILIATION OF BULK SOLUTION:

Date				
Standard Batch Size				
S.No.	**Stage**	**Qty. in Liters**	**Done By (Production)**	**Checked By (QA)**
1.	Batch Size			
2.	**Rejections / Losses**			
2A	Loss During Batch Manufacturing			
	Total Rejection / Loss			
3	**Samples**			
3A	**QA Sample**			
	• Clarity Sample			
	Production Sample			
	• Sample for pH adjustment			
	• Clarity Sample			
	• Bulk Sample for Analysis			
3B	Validation Samples			
3C	Other Samples (If Any)			
4	**Total Samples**			
5	Total Solution Filtered			

$$\text{\% Batch Yield (Limit: NLT 99 \%)} = \frac{\text{Total Quantity of Solution Filtered}}{\text{Actual Batch Size}} \times 100$$

Note: In case of High / Low Yield, Fill Yield Deviation Note.

Reason for deviation (if any):

_____

_____

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12.1 BMR REVIEW UP-TO RECONCILIATION OF BULK SOLUTION STAGE:

	Done By Production Officer / Executive	**Checked By QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

13.0 TRANSFER OF PRE - STERILIZED MATERIALS IN ASEPTIC AREA:

- Check the Physical Integrity of the Poly bags.
- Transfer Pre - Sterilized Vials Dropper & Screw Cap to the Aseptic Processing Area as per SOP-No.**HPD/008** through Dynamic Pass Box.
- Record the weighing details in the Table below:

WEIGHING DETAILS:

Balance ID. No.: _____ **Calibration Status (Ok/Not Ok):_____**

Date	**Poly bags.**	**Gross Wt. (Kg)**	**Tare Wt. (Kg)**	**Net Wt. (Kg)**	**Done By Production (Officer / Executive)**	**Checked By QA (Officer / Executive)**
Total						

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BATCH PRODUCTION AND CONTROL RECORD

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14.0 VIAL FILLING AND CAPPING:

14.1 LINE CLEARANCE (SOP No.:.....):

Previous Product : _____

Batch No. : _____ Date / Time : _____

S. No.	Line Clearance Checks	OK / Not OK/ NA	Done by Production Officer/Executive	Checked By QA Officer/Executive
NA	**Vial Filling and Capping**			
1.	Check the "Status Board" outside the Filling and Capping Room and match with the BPCR for following details: Product Name, B. No, Mfg. Date, Exp. Date, Batch Size etc.			
2.	Check Filling and Capping Room is duly cleaned and free from remains of the previous Batch.			
3.	Check Filling and Capping Machine is duly cleaned and free from remains of the previous Batch.			
4.	Check the Temperature and Relative Humidity (RH) of Filling and Capping Room (It should be within specified range). **Temperature (Limit: NMT 25^0C) RH (Limit: NMT 55%)**	___ ^{o}C ___ %		
5.	Check the Differential Pressure of the Aseptic Filling Area. (It should be within specified range).			
6.	Check the Release / Approval status of the filtered solution to be used for Aseptic Filling.			
7.	Check and ensure the QC Release status of Pre - Sterilized Vials, Dropper and Screw Caps.			
8.	Check the Sterilization Cycles (Machine Parts, and other aids used in Aseptic Filling) details from the print out / record, and ensure Sterilization is done as per the Pre - defined Cycle.			
9.	Check and ensure that the LAF is switched ON minimum 30 minutes before start of the activity and the pressure differential across HEPA filter is within limit.			
10.	Ensure the Filtered Solution is stored under LAF.			
11.	Check and ensure whether the Media Settle Plates are available for exposing in area to monitor Viable Count.			
12.	Ensure that the Non – Viable Particle Count has been performed before line set up and the results are within Acceptance Criteria.			

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S. No.	Line Clearance Checks	OK / Not OK/ NA	Done by Production Officer/Executive	Checked By QA Officer/Executive
13.	Check and ensure that the sampling of N_2 gas is performed from the user point.			
14.	Ensure Balance Calibration has been done.			
15.	Ensure logbooks of the area are online.			

Note: **1.** After checking as per checklist QA Officer / Executive shall give the Line Clearance of the Area / Activity by signing on the 'Line Clearance Label'.

2. After completion of Filling and Capping, Affix the Line Clearance Label at the specified page in the BPCR.

3. Attach the Sterility Report of N_2 Gas Used During Aseptic Filling.

4. Attach the Swab Release Report for Area & Equipment.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

PHARMA DEVILS

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Affix the Line Clearance Label for Filling, Dropper Fixing and Screw Capping

14.2 INSTRUCTIONS:

- Follow proper Gowning Procedure as per **SOP.**
- Follow Good Manufacturing practices in Aseptic Area as per **SOP.**
- Follow **SOP** for Assembly and setting of Filling Unit consisting of advanced PTS (Pressure & Time Setting).
- Discard & destroy the vials filled during Adjustment of Fill Volume or Rejected during Filling and Capping.
- Check and ensure that N_2 Gas Filter Integrity has been performed.
- Check Volume Variation of Filled Vials from each filling Head at One Hour Interval by Production and at Two Hours Interval by QA, record the observations in the In - Process Table.
- Sanitize the Hands during whole Operation with 70% IPA as and when required.

14.3 FILLING PARAMETERS SETTING & OPERATION:

- Perform the Active Air Sampling under LAF and surrounding area.
- Expose the Media Plates for Microbial Monitoring once in a day.
- Transfer the solution to the filling area. Ensure that the Pressure inside Pressure Vessel is maintained in between 0.4 Kg to 0.5Kg.
- Cut the Polybag of Sterilized vials & transfer at a time in storage hopper of m/c storage hopper. (As Its Designed Capacity).
- Cut the Polybag of sterilized dropper fixer & transfer in vibratory bowl feeder of dropper.
- Cut the Polybag of sterilized screw cap & transfer in vibratory bowl feeder of cap.
- Ensure that during filling operation 6 heads are used for Pre Nitrogen Flushing and 6 heads are used for Post Nitrogen flushing.
- Ensure that filling nozzle is adjusted at proper height w.r.t. vial size in Nozzle mounting Bracket.
- Set the required height of the dropper pressing head.
- Make sure that caps are flowing freely from the vibratory bowl feeder to the dispenser.
- Ensure that cap dispenser is set at required height.
- Set the required height of the dropper Pressing Head.
- Set the Torque and height of the Capping Head.

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- **Adjust following Parameter for Vial Filling and Capping Machine:**

S.No.	Parameters	Standard Value	Set Value
1.	Nitrogen Pressure	NLT 2 Kg / cm^2	

14.4 EMPTY BOTTLE WEIGHT CHECK RECORD

- Collect 10 Vials Sets and Calculate Average Weight of Empty Vial and Ensure that All Filled & Screw Capped Vials is Under Acceptance Limit.
- Record the initial weight of Good Empty Vials in the table below:

Date	Time	Weight in gm.										Average Weight	Checked by Production (Officer / Executive)	Verified by QA (Officer / Executive)
		1	2	3	4	5	6	7	8	9	10			

For 5 ml

- Total Average Weight of Empty Vial : _____gm
- Target Fill Volume : 5.2 ml
- Fill Volume Limit: Between : 5.1 ml to 5.3 ml
- Weight / ml : _____ gm per ml at 25°C
- Lower Weight Range for Filled Vials : 5.1 ml x wt/ml + Empty Vial Weight
  : _____ gm
- Upper Weight Range for Filled Vials : 5.3 ml x wt/ml + Empty Vial Weight
  : _____ gm

For 3 ml

- Total Average Weight of Empty Vial : _____gm
- Target Fill Volume : 3.2 ml
- Fill Volume Limit: Between : 3.1 ml to 3.3 ml
- Weight / ml : _____ gm per ml at 25°C
- Lower Weight Range for Filled Vials : 3.1 ml x wt/ml + Empty Vial Weight
  : _____ gm
- Upper Weight Range for Filled Vials : 3.3 ml x wt/ml + Empty Vial Weight
  : _____ gm

Adjust following Parameters:

- Standard / Target Fill Volume : **5.2 ml.**
- Upper Limit of Individual Volume : **5.3 ml.**
- Lower Limit of Individual Volume : **5.1 ml.**

➢ Filling Started at : Date : _____ Time : _____

➢ Filling Completed at : Date : _____ Time : _____

Adjust following Parameters:

- Standard / Target Fill Volume : **3.2 ml.**
- Upper Limit of Individual Volume : **3.3 ml.**
- Lower Limit of Individual Volume : **3.1 ml.**

➢ Filling Started at : Date : _____ Time : _____

➢ Filling Completed at : Date : _____ Time : _____

➢ Run the Vial Filling and Capping Machine**.** Stopper and adjust the Fill Volume and Dropper / Screw Capping. Record the Observations in table below.

➢ Once Machine setting done, Inform QA person to take Volume for another set of vials from each Filling Head. After confirmation of the result (Fill Volume, Dropper Setting and Screw Capping) from QA, start operation of Vial Filling and Capping Machine**.**

Date	Time	Volume in ml from Individual Filling Head						Average Fill Volume in ml	Dropper Fixing Quality	Screw Capping Quality	Checked by	
		1	2	3	4	5	6				Production	QA

➢ No. of Vials Discarded / Destroyed: _____.

➢ Corresponding Qty. of Filtered Solution: _____ L.

➢ No. of Vials used by Production & QA for Volume Variation: _____.

➢ Corresponding Qty. of Filtered Solution: _____ L.

➢ Any other sample: _____.

14.5 BMR REVIEW UP-TO FILLING STAGE:

	Checked By Production Officer / Executive	Reviewed By QA Officer / Executive
Name		
Sign & Date		
Emp. Code		

PHARMA DEVILS

BATCH PRODUCTION AND CONTROL RECORD

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14.6 ASEPTIC AREA ENVIRONMENT MONITORING RECORD :

Frequency: Initially & after every One Hour by Production & QA alternatively.

Date	Time	Room No. / Name	Temp. (°C) (Limit NMT 25ºC)	% RH (Limit NMT NMT55%)	Pressure Differential (Limit 60 -65 Pascal)	Checked By Production (Officer/Executive)	Verified By QA (Officer/Executive)

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14.7 INPROCESS CHECKS DURING VIAL FILLING & CAPPING:
Frequency: Initially, after every One Hour by Production & QA alternatively & at the end of the Process.

Filling & Capping M/c ID No.: **Date:_____**

Filling Technician's Name : (1) (2) (3)

Time	Volume in ml from Individual Filling Head						Fill Volume			Dropper Fixing Quality	Piercing Quality	Screw Capping Quality	Checked by Production / QA
	1.	2.	3.	4.	5.	6.	Min.	Max.	Average				

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Time	**Volume in ml from Individual Filling Head**						**Fill Volume**			**Dropper Fixing Quality**	**Piercing Quality**	**Screw Capping Quality**	**Checked by Production / QA**
	1.	**2.**	**3.**	**4.**	**5.**	**6.**	**Min.**	**Max.**	**Average**				

FORMAT No.: .....

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14.8 INPROCESS CHECKS DURING VIAL CAPPING:

Leak Test: Frequency: Initially, after every Two Hour by Production & QA alternatively & at the end of the Process.

- With draw 8 vials after Filling & Capping and Perform Leak Test as per **SOP.**
- Record the observations in the table given below: **Date: _____**

Time	**Leak Test / Head No.**								**Done By (Production/QA)**
	1.	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**	**8.**	

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14.9 RECONCILIATION OF FILLED VIALS (AFTER WEIGHING) :

Date	
Standard Fill Volume	

S.No.	**Stage**	**Qty. in Nos.**	**Qty. in Liter**	**Done By (Production)**	**Checked By (QA)**
1.	Batch Size				
2.	Total Nos. of Vials Filled & Capped				
3.	**Rejections / Losses**				
3A.	Initial & Volume Adjustment				
3B.	Rejection During Filling				
3C.	Rejection during weighing				
4.	**Total Rejection / Loss**				
5.	No of Good Vials for Leak Test +SFT+FT+IPQC				

Stage Yield (Limit: NLT 99 %)

$$\text{\% Batch Yield (Limit: NLT 98 \%)} = \frac{\text{No. of Good Vials Transfered for Physical Inspection}}{\text{Actual Batch Size}} \times 100$$

14.10 BMR REVIEW UP-TO RECONCILIATION OF FILLED VIALS STAGE:

	Done By Production Officer / Executive	**Checked By QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

15.0 VISUAL INSPECTION OF FILLED AND SCREW CAPPED VIALS:

15.1 LINE CLEARANCE (SOP.....):

Previous Product : _____

Batch No. : _____ Date / Time: _____

NA	Line Clearance Checks	OK/ Not OK/ NA	Checked By Production (Officer/Executive)	Verified By QA (Officer/Executive)
NA	**Visual Inspection**			
1.	Check the "Status Board" out side the Optical Inspection Area and match with the BPCR for following details: Product Name, B. No., Mfg. Date, Exp. Date, Batch Size etc.			
2.	Check Optical Inspection Area is duly cleaned and free from remains of the previous batch.			
3.	Check the Container meant for collection of the defective Vials; it must be clean and status label on container should match with details of batch to be inspected.			
4.	Ensure logbooks of the area are online.			

Note: After checking as per checklist QA Officer / Executive shall give the line clearance of the area by signing on the 'Line Clearance Label'.

Checked By Sign / Date _____
(Production Officer / Executive)

Line Clearance Given By Sign / Date_____
(QA Officer / Executive)

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BATCH PRODUCTION AND CONTROL RECORD			
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15.2 INSTRUCTIONS:

- Record the Defects of vials in Table.

15.3 PHYSICAL INSPECTION RECORD:

Date	Time		Type of Rejection			Total	Inspected By (Operator)	Checked By (QA Officer)
	From	To	M	O	S			
Total								

Note: M = Moulding defects, **O** = Other, **S**=Screw Capping Defect.

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16.0 RECONCILIATION AFTER PHYSICAL INSPECTION:

Date					
Standard Fill Volume					
S. No.	**Stage**	**Qty. in Nos.**	**Qty. in Liter**	**Done By (Production)**	**Checked By (QA)**
1.	Batch Size				
2.	Total No. of Vials Received After Weighing				
3.	**Rejections / Losses**				
3A	Rejection during Physical Inspection				
	Total Rejection / Loss				
4.	No. of Good Vials transferred for Packing				

Stage Yield (Limit: NLT 99 %)

$$\text{\% Batch Yield (Limit: NLT 97 \%)} = \frac{\text{No. of Good Vials Transfered for Packing}}{\text{Actual Batch Size}} \times 100$$

16.1 BMR REVIEW UP-TO RECONCILIATION AFTER PHYSICAL INSPECTION STAGE:

	Done By Production Officer / Executive	**Checked By QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

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17.0 SUMMARY OF MACHINE BREAKDOWN (If Any):

- Record the details of Machine Breakdown during any stage of Batch Manufacturing in table below:

S. No.	Date	Time	Stage	Type of Break Down*	Break Down		Total Down Time (Hrs.)	Recorded By (Production)	Verified By (QA)
					From	To			

*** Machine Down Time Codes:**

A. Machine Cleaning
B. Machine Break Down
C. Lunch / Dinner / Tea
D. Material Problem
E. Machine Setting
F. Other

18.0 MATERIAL RETURN DETAILS (If Any)

- Record the Material Return details (If Any) in table below:

S.No.	Name of Material	A.R. No.	Quantity	Reason for Return

Material Returned By (Production)	Sign Date: _____
Returned Material Verified By (QA)	Sign Date: _____
Material Received By (Ware House)	Sign Date: _____

Note: Attach QA approved copy of Material Return Note (MRN).

Material Returned By **Production** **(Officer / Executive)**	**Checked By** **QA** **(Officer / Executive)**	**Material Received By** **Ware House** **(Officer / Executive)**

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19.0 IN – PROCESS OBSERVATIONS (To be Filled by QA only)

S. No.	Date / Time	Observations	Informed To Production (Officer/Executive)	Observed By IPQA (Officer / Executive)	Action taken by Production (Officer/Executive)	Verified By QA (Officer/Executive)

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20.0 SCRAP TRANSFER RECORD:

- **Before Transferring the Scrap, check and ensure that:**
  - Droppers, Screw Caps etc. are kept in double lined Polyethylene bags and labeled.
  - Empty Vials are kept in double lined Polyethylene bags and labeled.
  - Discarded Vials during Filling and Sealing are kept in separate double lined Polyethylene bags and labeled.
- **Details of all the Scrap sent to Scrap Yard shall be mentioned in the Scrap Transfer Form and recorded in table below:**

S. No.	Type of Scrap	No. of Containers / Bags	Weight in Kg (Approx.)	Scrap Transferred By Production (Officer /Executive)	Verified By QA (Officer / Executive)
1.	Droppers				
2.	Screw Caps				
3.	Discarded Vials during Filling and Sealing				
4.	Vials used for IPQA Observations				
5.	Rejected Gloves				
6.	**Other Scrap (If Any)**				
A.					
B.					
C.					

21.0 QUALITY CONTROL SAMPLING

- Send the Intimation Slip to QA Dept. to withdraw the samples of Filled Vials for complete Analysis.

Sampling, Analysis and Batch Release Details

Intimated By (Production) Sign, Time & Date	Intimation Received By (QA) Sign, Time & Date	Sampled By (QA) Sign, Time & Date	Qty. Sampled

- After receiving the Analysis Report from QC, fill the A.R. No: _____

QA Officer / Executive Sign: _____ Date: _____ Time: _____

NOTE: Attached Scrap Transfer Form.

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Attached Scrap Transfer Form

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22.0 RECONCILIATION:

22.1 Reconciliation of Primary Packing Material:

Date						
S. No.	**Stage**	**Vials**	**Droppers**	**Screw Caps**	**Done By (Production)**	**Checked By (QA)**
1.	Batch Size					
2.	No. of Good Vials transferred for Packing					
3.	**Rejections / Losses**					
3A.	Loss During Volume / Machine Adjustment					
	Loss during filling					
	Loss during dropper fixing					
	Loss during capping					
	Less Volume Rejection during Weighing					
	Rejection during Physical Inspection					
4.	**Total Rejection / Loss**					
4A.	**QA Sample**					
	• Volume Variation Sample					
	• Leak Test Sample					
	Production Sample					
	• Volume Variation Sample					
	• Leak Test Sample					
4B.	Validation Samples					
4C.	Other Samples (If Any)					
	Total Samples					
5.	Total No. of Used Primary Packing Material (Step No. 2+4)					
6.	Total Primary Packing Material Loss (Step No. 3)					
7.	Variance [NMT 1%] [1-(6+7)] /1*100					

22.2 BMR REVIEW UP-TO RECONCILIATION OF PRIMARY PACKING MATERIAL STAGE:

	Done By **Production Officer / Executive**	**Checked By** **QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

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22.3 Batch Reconciliation After Physical Inspection:

Date					
Standard Fill Volume					
S.No.	**Stage**	**Qty. in Nos.**	**Qty. in Liter**	**Done By (Production)**	**Checked By (QA)**
1.	Batch Size				
2.	No. of Good Vials transferred for Packing				
3.	**Rejections / Losses**				
3A.	Loss During Volume Adjustment				
	Loss during Filling				
	Loss during dropper fixing				
	Loss during capping				
	Rejection during Physical Inspection				
	Total Rejection / Loss				
4.	**Samples**				
4A.	**QA Sample**				
	• Volume Variation Sample				
	• Leak Test Sample				
	Production Sample				
	• Volume Variation Sample				
	• Leak Test Sample				
	Validation Samples				
	Other Samples (If Any)				
	Total Samples				
5.	Total No. of Vials Filled (2+4)				
6.	Total Solution Loss (3)				
7.	Variance [NMT 1%] [1-(5+6)] /1*100				

Stage Yield (Limit: NLT 99 %)

$$\text{\% Batch Yield (Limit: NLT 96 \%)} = \frac{\text{No. of Good Vials transfered for Packing}}{\text{Actual Batch Size}} \times 100$$

Note: In case of High / Low Yield, Fill Yield Deviation Note.

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BATCH PRODUCTION AND CONTROL RECORD

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Reason for deviation (if any):

_____

_____

_____

22.4 BMR REVIEW UP-TO RECONCILIATION AFTER PHYSICAL INSPECTION STAGE:

	Done By **Production Officer / Executive**	**Checked By** **QA Officer / Executive**
Name		
Sign & Date		
Emp. Code		

The Batch Released / Not Released for Packing: _____ on Date: _____.

Checked By Sign / Date **Head - Production**	**Reviewed By Sign / Date** **Head - QA**

Certificate for Batch Manufacturing:

I, the undersigned, approved technical staff having prescribed qualification & experience, hereby confirm that the above batch is manufactured under my direction & supervision. All process relating to the selection, weighing and measuring of raw material & processing during various stages are performed by trained personnel. All statutory requirements prescribed for manufacturing under Drugs & Cosmetics Act, 1940 & CGMP standards are duly followed.

Competent Technical staff for Mfg (Name): ----------

(Sign) ----------

(Emp. Id) ----------

23.0 REVISION HISTORY:

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00				