PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 1 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets	
Label Claim:	**Each film coated tablet contains:** Aceclofenac IP …….. 100 mg Excipients ……q.s. **Color:** Titanium Dioxide IP
Mfg. Lic. No.:	
Product Lic. No.:	NA
Self-Life:	24 Months
MFR No.:	
Mfg. Date:	
Exp. Date:	
BMR ISSUED No.:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 2 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

1.0 MASTER FORMULA:

BILL OF RAW MATERIALS

S. No	Ingredients	Spec.	Qty. in mg Per Tablet	Overages %	Std. Qty. for 1 Lac. in Kg
Raw Material for Dry Mixing					
Active Ingredients-					
1.	Aceclofenac	IP	100.0	----	10.00#
Inactive Ingredients-					
2.	Starch	IP	60.0	------	6.00
3.	Microcrystalline Cellulose (MCCP)	IP	19.0	-----	1.90
4.	Lactose	IP	74.0	------	7.40
Raw Material for Binder Preparation-					
5.	PVPK-30	IP	5.0	----	0.50
6.	Purified Water	IP	QS	----	QS
Raw Material for Lubrication-					
7.	Ac-Di-Sol	IP	10.0	----	1.00
8.	Collidal Silicon Dioxide	IP	4.0	-----	0.40
9.	Magnesium Stearate	IP	4.0	-----	0.40
	Weight of Uncoated Tablets		**276 mg**		**27.60 Kg**
Coating-					
10.	Talcum	IP	0.5	-----	0.05
11.	White Redimix (Film coating)	IH	13.3	----	1.33
12.	Purified water	IP	QS	------	QS
	Weight of coated Tablets		**289.8 mg**		**28.98 Kg**

Note: # Aceclofenac IP adds after calculation.

	Prepared By	Checked By	Approved By
Signature			
Date			

CALCULATION SHEET

1- Aceclofenac IP is to be taken as per the formula given below:

Note: If assay of API is above 95.0% calculation not required.

Part A: To be calculated when single AR No.:
Assay on dried basis: _____ LOD: _____

PART A: To be Calculated when single A.R. No of **Aceclofenac IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

Assay on as such basis = $\frac{(100\text{-LOD}) \text{ X Assay on dried basis}}{100}$ = _____%

A.R. No. of Aceclofenac IP	Assay on as such basis (A1)	Actual quantity of this A.R. No. to be dispensed =
	----------%	$\frac{\text{____ x 100}}{\text{A1}}$ = ----------Kg

PART B: To be Calculated when more than one A.R. No's of **Aceclofenac IP** is to be used:

A.R. No. of Aceclofenac IP	Assay on as such basis (A1)	Actual quantity Available (b1) (Kg)	Qty. on 100 % assay basis = (b1) x (a1) ---------- Kg 100	Remaining qty. to be dispensed (e1) = Std. qty. -(d1)
				(e1) = _____ - _____ = Kg
TOTAL (Kg) ---		_____	(c1)=_____	

Assay of next AR No. ---------- (Assay on as such basis) (f1) = _____%

Actual quantity of this AR No. to be dispensed (g1) = $\frac{(e1) \times 100}{(f1)}$ =----------Kg

Therefore total quantity of **Aceclofenac IP** to be dispensed = (b1) + (g1) =_____Kg

Assay calculation:

Sign/Date		
Department	**Done By (Production)**	**Checked By (Q.A.)**

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

2.0 GENERAL INSTRUCTIONS:

- Current version of SOP's should be referred during operation.
- Dispensed raw material/bulk blend/ compressed tablets should be manufactured and stored at temperature not exceeding 27°C and RH NMT 55%
- In all the processing activities, nose mask, hand gloves, secondary gown etc. shall be wearied by the personnel.
- Attach all dispensing tags and cleaning status labels with BMR.
- Clean the equipment's after use as per the standard operating procedure.
- The Blend should be compressed within 15 days.
- The compressed tablets should be packed within 30days.

2.1 Line clearance of Dispensing:

Check the instructions given below and note the observation as Yes, NO or NA.

S.No.	Instructions	Yes/No/NA
1.	Is dispensing area clean and free from any materials of previous batches?	
2.	Whether balance is calibrated and have status label.	
3.	Scoops to be used for dispensing are clean.	
4.	LAF properly working and dispensing booth clean.	
5.	Air differential pressure, temperature and humidity with in limit (if applicable) Temp. ---------- ºC (NMT 27ºC), RH----------% (NMT 55.0%), DP…….. (0.5to1.5P or in mm of H_2O)	
6.	Material shall be least exposed to atmosphere.	
7.	Ensure proper gowning before entering to the dispensing area, suitable nose mask and surgical gloves shall be used while handling the material.	

Previous product name:		**Batch No.:**	
Differential pressure across RLAF and Room:	(Limit(Between 5 to 15 Pascal)		
Checked By (Production): **Sign & Date:**		**Verified By (IPQA):** **Sign & Date:**	

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 5 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

BILL OF RAW MATERIALS **(PRODUCTION COPY)**

S. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	Req. Qty. in Kg	Actual Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
						Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-											
Active Ingredients-											
1.	Aceclofenac IP	10.0#									
Inactive Ingredients-											
2.	Starch IP	6.00									
3.	Microcrystalline Cellulose (MCCP) IP	1.90									
4.	Lactose IP	7.40									
Raw Material for Binder Preparation-											
5.	PVPK-30 IP	0.50									
6.	Purified Water IP	QS									
Raw Material for Lubrication-											
7.	Ac-Di-Sol IP	1.00									
8.	Colloidal Silicon Dioxide IP	0.40									
9.	Magnesium Stearate IP	0.40									
Coating-											
10.	Talcum IP	0.05									
11.	White Redimix (Film Coating) IH	1.33									
12.	Purified water IP	QS									

Note: # Aceclofenac IP adds after calculation.

Dispensed by:
Stores
Date

Checked by:
Production
Date

Verified by:
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 6 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

BILL OF RAW MATERIALS **(STORE COPY)**

S. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	Req. Qty. in Kg	Actual Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
						Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-											
Active Ingredients-											
1.	Aceclofenac IP	10.0#									
Inactive Ingredients-											
2.	Starch IP	6.00									
3.	Microcrystalline Cellulose (MCCP) IP	1.90									
4.	Lactose IP	7.40									
Raw Material for Binder Preparation-											
5.	PVPK-30 IP	0.50									
6.	Purified Water IP	QS									
Raw Material for Lubrication-											
7.	Ac-Di-Sol IP	1.00									
8.	Collidal Silicon Dioxide IP	0.40									
9.	Magnesium Stearate IP	0.40									
Coating-											
10.	Talcum IP	0.05									
11.	White Redimix (Film Coating) IH	1.33									
12.	Purified water IP	QS									

Note: # Aceclofenac IP adds after calculation.

Dispensed by:
Stores
Date

Checked by:
Production
Date

Verified by:
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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Document No.:	**Effective Date:**	**Page No.:** 7 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

2.2 Weighing sheet:

Balance ID: _____

S. No.	Ingredients	Spec.	UOM	Std. Quantity (kg)	A.R No.	Issued Qty			Checked By (Production)	Verified by (IPQA)
						Tare wt.	Net wt.	Gr. Wt		
MATERIAL FOR GRANULATION:										
1.	Aceclofenac	IP								
2.	Starch	IP								
3.	Microcrystalline Cellulose (MCCP)	IP								
4.	Lactose	IP								
5.	PVPK-30	IP								
MATERIAL FOR LUBRICATION:										
1.	Ac-Di-Sol	IP								
2.	Colloidal Silicon Dioxide	IP								
3.	Magnesium Stearate	IP								

3.0 GRANULATION PROCESS: **Granulation started on:**_____

3.1 Line clearance of Granulation:

Previous product: _____, **Batch No.:**_____

Cleaning done by: _____, **Cleaned On:** _____,

S. No.	Instructions	Yes/No/NA	Checked By (Production)	Verified By (IPQA)
1	Ensure that all equipment and utensils are clean and dry and status board affixes (Record as per Table-1).			
2	Is area free from any materials of previous batch?			
3	Whether the container, sieve, scoops and auxiliary items are cleaned.			
4	Check the room temperature. Temp……..ºC (NMT 27ºC) and Differential pressure ……. Pascal (0.5to 1.5 Pascal or in mm of H_2O).			
5	AHU system under operation or not.			
6	Calibration status of Equipment/instrument complies or not.			
7	Balance calibration status is OK or not.			
8	Whether swab/rinse sample testing report complies or not? (if applicable)			
9	Whether the wall, floor and light in satisfactory condition?			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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Batch No.:	**Batch Size:**	**Supersedes No.:**

EQUIPMENT STATUS CHECKLIST

S. No.	Name of Equipment	Equipment ID No.	Observation (Should be clean and dried)	Checked (Production)	Verified By (IPQA)
1.	Shifter		Yes/No		
2.	Mass Mixture		Yes/No		
3.	Tray dryer		Yes/No		
4.	Multi-mill		Yes/No		
5.	Octagonal blender		Yes/No		
6.	Balance		Yes/No		
7.	SS scoop		Yes/No		

3.2 Sifting: Sift separately the following material and collect in poly bags/containers. Check sieve integrity before and after use.

SIFTING OF GRANULATION MATERIALS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd. By/ Date
			Before Use	After use				
Aceclofenac IP		40						
Lactose IP		40						
Starch IP		40						
PVPK-30 IP		40						
Microcrystalline Cellulose (MCCP) IP		40						

SIFTING OF BLENDING MATERIAL / LUBRICANTS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd By/ Date
			Before Use	After use				
Ac-Dil-Sol IP		40						
Colloidal Silicon Dioxide IP		40						
Magnesium Stearate IP		40						

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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3.3 MANUFACTURING PROCESS:

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Binder preparation:**					
	Prepare paste by taking **_____ Lts**. of hot **Purified Water** in SS jacketed paste kettle add (_____Kg) **PVPK-30** and dissolved completely.					
3.3.2	**Dry Mixing:**					
	Add **Aceclofenac** (_____ Kg)**, Starch** (_____ Kg)**, Microcrystalline Cellulose** (_____ Kg)**, Lactose** (____ Kg) **and Cross Carmellose Sodium** (2.5 Kg) **i**n RMG and run the impeller at slow speed approx. 20 minutes.					
3.3.3	**Wet granulation:**					
	Start the impeller of RMG at slow speed and add the binder paste slowly at the solution addition port. After complete addition of total quantity of binder solution, start the impeller and mix for 4 minutes.					
	Again run the impeller and chopper at fast speed for 5 minutes and mix the materials properly.					
	Add additional purified water if required. Additional purified water _____kg					
3.3.4	**Drying:**					
	Dry the granules at 75°C to 80°C temperature for approx. 30 min.					
	Air temperature: _____°C					
	Collect the granules from 5 different places of the tray and check loss on drying.					
	LOD. _____%w/w. Recommended LOD: (NMT 2 % w/w)					
3.3.5	**Sizing /Milling:**					
	Sift the dried granules through Vibratory sifter fitted with18# Sieve.					
	Before Use	**After Use**				
	Rusted: Yes / No	Rusted: Yes / No				
	Broken: Yes / No	Broken: Yes / No				
	Clean: Yes / No	Clean: Yes / No				
	Mill the oversize granules retained on sieve of vibratory sifter using multi-mill fitted with 1.5 mm screen. With knife forward direction at medium speed.					
	Before Use	**After Use**				
	Rusted: Yes / No	Rusted: Yes / No				

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
	Broken: Yes / No	Broken: Yes / No				
	Clean: Yes / No	Clean: Yes / No				
3.3.6	**Blending & Lubrication:**					
	Add **Ac-Di-Sol IP** (_____Kg) and **Colloidal Silicon Dioxide IP** (_____Kg) in blender with dried granules and mix it for 20 minutes.					
	Add **Magnesium Stearate IP** (_____Kg) in blender and mix for further for 5 minutes.					

GRANULE WEIGHING RECORD

Container No.	Tare wt. (Kg)	Gross wt. (Kg)	Net wt. (Kg)	Done By/ Date	Ckd By/ Date
1/					
2/					
3/					
4/					
5/					
6/					
7/					
8/					
9/					
10/					
Total					

4.0 SAMPLING OF BLEND:

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of granulation process.

_____
Checked By (Production)

- IPQA shall review batch card and visually inspect of the material for physical Appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Verified By (IPQA)

- After release from QC, IPQA shall paste the 'APPROVED" label on each container.

	Prepared By	Checked By	Approved By
Signature			
Date			

4.1 YIELD RECONCILIATION:

A = Theoretical batch size = …….. Kg / ……... tablets

B = Actual quantity of blend = …….. Kg

C = Samples = ….. ……..

D = Yield = B / A x100 **(Note: - Granulation yield NLT 99.00%)**

Loss Quantity: _____

Checked by (Production):
Date:

Verified by (QA):
Date:

BATCH MANUFACTURING RECORD

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5.0 COMPRESSION: **Started At: _____**

5.1 Line clearance:

Previous product: _____, Batch No.:_____

S. No.	Instructions	Observations	Checked (Production)	Verified By (IPQA)
1	Is area free from any materials of previous batch?	Yes/No		
2	Whether area and utensils cleaned?	Yes/No		
3	Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? Equipment ID No.: _____	Yes/No		
4	Check the room temperature, RH and differential pressure =……ºC (NMT 27ºC), RH=…… % (NMT 55%). Differential Pressure……..mm of H_2O (0.5to 1.5 mm of H_2O)	OK/NOT OK		
5	All the equipment shall be used during process are cleaned.	Yes/No		

5.2 Process:

	Compression Instruction	Observations	Checked (Production)	Verified By (IPQA)
5.2.1	Collect the approved granules from the granules store for compression.			
5.2.2	Ensure the correct punch set is assembled in the compression machine.			
5.2.3	Ensure the availability and online filling of Batch Document.			
5.2.4	Collect the tablets as per total no. of punches from each side and check them individually for any damages on upper and Lower Surface before continuing the operation of compression machine. Check and Record the observation and details of die & punch in the table A: **Die and punch verification**			
5.2.5	If compression time is less than one hour, minimum Three observations shall be recorded.			
5.2.6	Ensure that all the data of actual processing are entered in log book of individual equipment/Instrument.			
5.2.7	Collect the compressed tablets in polythene lined container. Weight the containers and record the weights in table given below, label them properly and transfer them to bulk store (Container number should be given as 1/x, 2/x…… where x is the total number of containers			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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Table: A-Die and punch verification

Punch Specification																								
Punch Details	Type	Prism: B Tooling 35 Stations.																						
	Upper Punches	9.5 mm (Round shape biconvex plain)																						**Dies:** 9.6 mm
	Lower Punches	9.5 mm (Round shape biconvex plain)																						
Upper Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											
Lower Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											

Checked by (Production):_____ **Verified By (IPQA):**_____

5.3 IN PROCESS CHECKS:

5.3.1 Specification:

S.No.	Parameters	Requirement	Frequency of Monitoring
1.0	**Description**	White colour round biconvex, plain both side.	At the start of machine
2.0	**Weight of 20 tablets**	5.52 gm± 3%	Every 30 Minutes
3.0	**Avg. weight**	276 mg ± 5%	Every 2 Hours
4.0	**Uniformity of**	276 mg ± 5%	Every 2 Hours
5.0	**Thickness**	3.8 ± 0.2 mm	Every 2 Hours
6.0	**Hardness**	NLT 3.0 kg/cm^2	Every 2 Hours
7.0	**Friability**	NMT 1%	Every 2 Hours
8.0	**DT**	NMT15 min	Every 2 Hours
9.0	**Diameter**	9.5 mm	At the start of machine
10.0	**Appearance**	------	Every 2 Hours
11.0	**Temperature**	NMT 27ºC	Every 2 Hours
12.0	**RH**	NMT 55%	Every 2 Hours

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

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5.4 In-process observation sheet for production:

Description:											
Diameter:											
Wt. of 20 Tabs. 5.52 gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 5.52 gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 3.8 ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3 kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White color round biconvex, plain both side.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required…

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Average Weight of Tablet:		**Frequency**	**Every 2 hours.**

Date:								
Time:								
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
Avg. Wt.								
Min wt.								
Max wt.								
Checked by								

Attached additional sheet if required…….

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

5.5 In-process observation sheet for IPQA

Description:											
Diameter:											
Wt. of 20 Tabs. 5.52 gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 5.52 gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 3.8 ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1%)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3 kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White color round biconvex, plain both side.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required……..

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

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Batch No.:	**Batch Size:**	**Supersedes No.:**

WEIGHT VARIATION OF 20 TABLETS

Average Weight of Tablet:		**Frequency**	**Every 2 hours.**

Date:								
Time:								
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
Avg. Wt.								
Min wt.								
Max wt.								
Checked by								

Attached additional sheet if required……..

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

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6.0 TABLET WEIGHING RECORD:

Container No.	Tare wt.	Gr. Wt.	Net wt.	Container No.	Tare wt.	Gr. Wt.	Net wt.
1/				**11/**			
2/				**12/**			
3/				**13/**			
4/				**14/**			
5/				**15/**			
6/				**16/**			
7/				**17/**			
8/				**18/**			
9/				**19/**			
10/				**20/**			
Total net weight of Tablets:							
Checked By (Sign & Date):							

7.0 SAMPLING:

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
Checked By (Production)

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Verified By (IPQA)

- After release from QC IPQA shall paste the **'APPROVED"** label on each drum.

8.0 YIELD RECONCILIATION:

•	Average weight of tablets (A)=: mg
•	Total weight of compressed tablets (B) = Kg.
•	Quantity of compressed tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
•	Samples (D)=
•	Yield= $\frac{C + D}{\text{Actual batch size}}$ x 100= **(Yield NLT: 98.50%)**

Checked By (Production):	**Verified By (IPQA):**

Loss Qty.: _____ Kg.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 19 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

9.0 COATING: **Date:**_____

9.1 Line clearance:

Previous product: _____, **Batch No.:**_____

S. No.	Instructions	Observations	Checked By	
			Production	QA
1	Ensure that Colloid mill, SS Tank, 100# sieve, coating pan, Spray gun and scoop are cleaned.	Yes/NA/NO		
2	Is area free from any materials of previous batch?	Yes/NA/NO		
3	Whether the scoops and auxiliary items are cleaned.	Yes/NA/NO		
4	Check the room temperature. Temp……..ºC (NMT 27ºC). & RH ……% (NMT 55%)	-		
5	Whether the Auxiliary items are cleaned.	Yes/NA/NO		
6	Whether the coating pan is cleaned and set as per SOP and have “CLEANED” label affixed.	Yes/NA/NO		
7	Balance calibration status is OK or not.	Yes/NA/NO		
8	Whether tablet approved or not?	Yes/NA/NO		
Differential pressure across RLAF and Room:		(Limit (Between 5to15 Pascal)		
Checked By:(Production):		**Verified By:(IP/QA)**		
Sign and Date:		**Sign and Date:**		

10.0COATING PROCESS:

Equipment ID to be used: _____ _____, Coating started on: _____

	Instructions	Std. time (min)	Observed time		Done By) (Sign & Date)	Checked By (Sign & Date)	Remarks
			From	To			
Solution preparation	Pass the solution in homogenizer to uniform suspension to avoid inclusion of air bubbles. Filter the suspension through 200 # muslin cloth cover the prepared suspension in the vessel securely for use before coating.	-					
	Keep aside with lid cover. Ensure Coating solution should be free from air bubbles.	-					
	Cover the prepared solution in the vessel securely for use before coating with labels affixed on vessel mentioning batch details.						
Coating of Tablet	Take sorted tablet in coating room	-					
	Fit the spray gun with 1.5mm diameter nozzle and set the atomizing air pressure at 2.5-4.0 kg/cm2. Start the exhaust system.	-					

	Prepared By	Checked By	Approved By
Signature			
Date			

	Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM2-3) and pre warm the tabs to obtain the bed temperature (42 to 48ºC).	-						
	Start the spraying solution over the tablet and let them be dry immediately.	-						
	After drying unload the coating tablets in pre-tare Polybag lined drum with status label.	-						
	Check and record the physical parameters of coated tablets as per given check sheet.	-						

11.0 COATING INPROCESS CHECKS: (Record the observation every half an hour)

Lot-I

Parameter	**Limit**	**Date**						
		Time						
Pan Speed	4 to 5 RPM							
Inlet Air Temperature	65to 75^{0}C							
Peristaltic Pump Speed	16 RPM							
Atomizing Air Pressure	2.5 to 4.0kg/cm^2							
Exhaust Air Temperature	42 to 48^{0}C							

Lot-II

Parameter	**Limit**	**Date**						
		Time						
Pan Speed	4 to 5 RPM							
Inlet Air Temperature	65to 75^{0}C							
Peristaltic Pump Speed	16 RPM							
Atomizing Air Pressure	2.5 to 4kg/cm^2							
Exhaust Air Temperature	42 to 48^{0}C							

Lot-III

Parameter	**Limit**	**Date**						
		Time						
Pan Speed	4 to 5 RPM							
Inlet Air Temperature	65 to 75^{0}C							
Peristaltic Pump Speed	16 RPM							
Atomizing Air Pressure	2.5 to 4 kg/cm^2							
Exhaust Air Temperature	42 to 48^{0}C							

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 21 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

PARAMETERS AFTER COATING: **Lot-I**

Tests	Specification	Production observation	IPQA observation
Description	White color round, biconvex tablets and plain both side.		
Weight of 20 tablets	5.80gm ± 3%		
Avg. weight	289.8 mg ± 5%		
Uniformity of weight	289.8 mg ± 5%		
Thickness	4.10 ± 0.2 mm		
Disintegration	NMT 30 Minutes		
Checked by (Production):		**Checked By (IPQA):**	

Lot-II

Tests	Specification	Production observation	IPQA observation
Description	White colour round, biconvex tablets and plain both side.		
Weight of 20 tablets	5.80gm ± 3%		
Avg. weight	289.8 mg ± 5%		
Uniformity of weight	289.8 mg ± 5%		
Thickness	4.10 ± 0.2 mm		
Disintegration	NMT 30 Minutes		
Checked by (Production):		**Checked By (IPQA):**	

Lot-III

Tests	Specification	Production observation	IPQA observation
Description	White colour round, biconvex tablets and plain both side.		
Weight of 20 tablets	5.80gm ± 3%		
Avg. weight	289.8 mg ± 5%		
Uniformity of weight	289.8 mg ± 5%		
Thickness	4.10 ± 0.2 mm		
Disintegration	NMT 30 Minutes		
Checked by (Production):		**Checked By (IPQA):**	

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 22 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

11.1 WEIGHING RECORD OF COATED TABLETS:

Container No.	Tare wt.	Gr. Wt.	Net wt.	Container No.	Tare wt.	Gr. Wt.	Net wt.
1/				11/			
2/				12/			
3/				13/			
4/				14/			
5/				15/			
6/				16/			
7/				17/			
8/				18/			
9/				19/			
10/				20/			
Total net weight of granules:							
Checked By(Sign & Date):							

11.2 VISUAL INSPECTION OF TABLET:

Date: _____

Time Duration		Quantity rejected	Done by
From	To		

Total weight of rejected tablets: _____ Good Tablet weight: _____

% Yield: _____

Checked by (Production): _____,
(Sign & Date)

Verified by (IPQA): _____
(Sign & Date)

11.3 SAMPLING:

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
Checked By (Production)

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Verified By (IPQA)

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac Tablets IP 100 mg	
Document No.:	**Effective Date:**	**Page No.:** 23 of 23
Batch No.:	**Batch Size:**	**Supersedes No.:**

11.4 YIELD RECONCILIATION:

•	Average weight of tablets (A)=: mg
•	Total weight of coated tablets (B) = Kg.
•	Quantity of coated tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
•	Samples (D)=
•	Yield= $\frac{C + D}{\text{Actual batch size}}$ 100 = **(NLT 98.00%)**
Checked By (Production):	**Verified By (IPQA):**

11.5 FINAL REVIEW OF BATCH CARD ON SHOP FLOOR:

Production manager/Designee shall review the batch card will give his comment, if any.

_____

Checked By (Prod. Mgr.)

12.0 ANY DEVIATION:

Deviation No.	**Reason for deviation**

_____

Checked By(Prod. Manager)

13.0 HISTORY SHEET:

BMR No.	**New BMR No.**	**Revision No.**	**Reason of revision**	**Change control No.**
	--	00	--	--

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			