	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 1 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location: ……	
Block: Production Tablets	
Label Claim:	Each film coated tablet contains: Thioclchicoside IP …… 4 mg Aceclofenac IP …….. 100 mg Excipients ……q.s. **Colour:** 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: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 2 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

MASTER FORMULA:

BILL OF RAW MATERIALS

S. No	Ingredients	Spec.	Qty. in mg Per Tablet	Overages %	Qty. for 1Lac. In Kg
Raw Material for Dry Mixing					
Active Ingredients-					
1.	Aceclofenac	IP	100.00	----	10.00
2.	Thiocolchicoside	IP	4.00	----	0.40
Inactive Ingredients-					
3.	Microcrystalline Cellulose (MCCP)	IP	10.00	----	1.00
4.	Starch	IP	40.00	----	4.00
5.	Lactose	IP	74.00	----	7.40
Raw Material for Binder Preparation-					
6.	PVPK-30	IP	5.00	----	0.50
7.	Isopropyl Alcohol	IP	50.00	----	5.00
Raw Material for Lubrication-					
8.	Colloidal Silicon Dioxide	IP	4.00	----	0.40
9.	Croscarmellose Sodium (Ac-Di-sol)	IP	10.00	----	1.00
10.	Magnesium Stearate	IP	3.00	----	0.30
	Weight of Uncoated Tablets		**250.00 mg**		**25.0 kg**
Coating- (Film Coated)					
11.	White Redimix (Medicoat Uni WT335)	IH	12.00	-----	1.20
12.	Purified water	IP	QS	-----	QS
	Weight of coated Tablets		**262.00 mg**		**26.2 kg**

Note: # Aceclofenac & Thiocolchicoside IP add after calculation.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 3 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

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

Note: If assay of API is above 99.0% 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 = $\frac{(100\text{-LOD}) \times \text{Assay on dried basis}}{100}$ = _____%

A.R. No. of **Aceclofenac IP**	Assay on as such basis **(A1)**	Actual quantity of this A. R. No. to be dispensed =
	----------%	$\frac{\#\times 100}{A1}$ = ----------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) / 100 Kg	Remaining qty. to be dispensed (e1) = Std. qty. -(c1)
				(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			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

Document No.:	**Effective Date:**	**Page No.:** 4 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

2- Thiocolchicoside IP is to be taken as per the formula given below:

Note: If assay of API is above 99.0% 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 **Thiocolchicoside IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

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

A.R. No. of **Thiocolchicoside IP**	Assay on as such basis **(A1)**	Actual quantity of this A. R. No. to be dispensed =
	----------%	$\frac{\#\times 100}{A1}$ = ----------Kg

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

A.R. No. of **Thiocolchicoside IP**	Assay on as such basis (A1)	Actual quantity Available (b1) (Kg)	Qty. on 100 % assay basis = (b1) x (a1) / 100 Kg	Remaining qty. to be dispensed (e1) = Std. qty. -(c1)
				(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 **Thiocolchicoside IP** to be dispensed = (b1) + (g1) =_____Kg

Assay calculation:

Sign/ Date		
Department	**Done By (Production)**	**Checked By (QA)**

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 5 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

2.0 GENERAL INSTRUCTIONS:

- Current version of SOPs 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			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 6 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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

S. No.	Ingredients	Batch Qty. In Kg	@ Req. Qty. in Kg	Issued 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	10.00									
2.	Thiocolchicoside IP	0.40									
Inactive Ingredients-											
3.	Microcrystalline Cellulose (MCCP) IP	1.00									
4.	Starch IP	4.00									
5.	Lactose IP	7.40									
Raw Material for Binder Preparation-											
6.	PVPK-30 IP	0.50									
7.	Isopropyl Alcohol IP	5.00									
Raw Material for Lubrication-											
8.	Colloidal Silicon Dioxide IP	0.40									
9.	Croscarmellose Sodium (Ac-Di-sol) IP	1.00									
10.	Magnesium Stearate IP	0.30									
Coating-											
11.	White Redimix IH (Medicoat Uni WT335)	1.20									
12.	Purified water IP	QS									

Note: # Aceclofenac & Thiocolchicoside IP add after calculation.

@ Calculate the materials as per required batch size.

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: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 7 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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

S. No.	Ingredients	Batch Qty. In Kg	@ Req. Qty. in Kg	Issued 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	10.00									
2.	Thiocolchicoside IP	0.40									
Inactive Ingredients-											
3.	Microcrystalline Cellulose (MCCP) IP	1.00									
4.	Starch IP	4.00									
5.	Lactose IP	7.40									
Raw Material for Binder Preparation-											
6.	PVPK-30 IP	0.50									
7.	Isopropyl Alcohol IP	5.00									
Raw Material for Lubrication-											
8.	Colloidal Silicon Dioxide IP	0.40									
9.	Croscarmellose Sodium (Ac-Di-sol) IP	1.00									
10.	Magnesium Stearate IP	0.30									
Coating-											
11.	White Redimix IH (Medicoat Uni WT335)	1.20									
12.	Purified water IP	QS									

Note: # Aceclofenac & Thiocolchicoside IP add after calculation.

@ Calculate the materials as per required batch size.

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: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

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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)
						Gr. wt.	Tare wt.	Net wt.		
MATERIAL FOR GRANULATION:										
1.	Aceclofenac	IP								
2.	Thiocolchicoside	IP								
3.	Microcrystalline Cellulose (MCCP)	IP								
4.	Starch	IP								
5.	Lactose	IP								
6.	PVPK-30	IP								
MATERIAL FOR LUBRICATION:										
1.	Colloidal Silicon Dioxide	IP								
2.	Croscarmellose Sodium (Ac-Di-sol)	IP								
3.	Magnesium Stearate	IP								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

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?			

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		

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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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								
Thiocolchicoside IP								
Microcrystalline Cellulose (MCCP) IP								
Starch IP								
Lactose IP								
PVPK-30 IP								

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				
Colloidal Silicon Dioxide IP								
Croscarmellose Sodium (Ac-Di-sol) IP								
Magnesium Stearate IP								

	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. No.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Binder preparation:**					
	Take SS Container and dissolve **PVPK-30** (_____ Kg) in _____liters of **Isopropyl Alcohol**. Mixed the materials propyl.					
3.3.2	**Dry Mixing:**					
	Add **Thiocolchicoside** (____Kg)**, Aceclofenac (_____ Kg), Starch** (_____Kg)**, Microcrystalline Cellulose (MCCP)** (_____ Kg) and **Lactose** (_____ Kg) **i**n Mass Mixture and run the impeller at slow speed for 20 minutes.					
3.3.3	**Wet Granulation:**					
	Start the impeller of mass mixture at slow speed and add the binder slowly at the solution addition port. After complete addition of total quantity of binder solution, start the impeller at slow speed and mix for ____ minutes.					
	Again run the impeller at fast speed for ____ minutes and mixed the materials properly.					
3.3.4	**Drying:**					
	Dry the granule at 75°C to 80°C temperature is achieved.					
	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)					
3.3.4	**Sizing /Milling:**					
	Sift the dried granules through Vibratory sifter fitted with___# 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 multimill fitted with **2 mm** screen. With knife forward direction at medium speed.					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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Step No.	Manufacturing Instruction	Eq. ID. No.	From	To	Done By/ Date	Ckd. By/ Date
	Before Use	**After Use**				
	Rusted : Yes / No	Rusted : Yes / No				
	Broken : Yes / No	Broken : Yes / No				
	Clean : Yes / No	Clean : Yes / No				
3.3.5	**Blending & Lubrication:**					
	Add **Colloidal Silicon Dioxide** (_____ Kg) & **Croscarmellose Sodium (Ac-Di-sol)** (_____ Kg) to the dried granules.					
	Add **Magnesium Stearate** (_____ Kg) in blender and mix for further for _____ minutes.					

GRANULE WEIGHING RECORD

Container No.	Gross wt. (Kg)	Tare 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	Tooling: B Type & Station: 35																						
	Upper Punches	Diameter: 9 mm (SC plain)																						Dies : 9.0 mm
	Lower Punches	Diameter: 9 mm (SC 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	Round shape biconvex tablets plain both side.	At the start of machine
2.0	Weight of 20 tablets	5.00gm ± 3%	Every 30 Minutes
3.0	Avg. weight	250 mg ± 5%	Every 2 Hours
4.0	Uniformity of weight	250 mg ± 5%	Every 2 Hours
5.0	Thickness	3.70 ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 5.0 Kg/cm^2	Every 2 Hours
7.0	Friability	NMT 1%	Every 2 Hours
8.0	DT	NMT 15 min	Every 2 Hours
9.0	Diameter	9.0 mm ± 0.2 mm	At the start of machine
10.0	Appearance	White colour round shape biconvex tablets plain both side.	Every 2 Hours
11.0	Temperature	NMT 27 ° C	Every 2 Hours
12.0	RH	NMT 55%	Every 2 Hours

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**
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5.4 In-process observation sheet for production:

Description:											
Diameter:											
Wt. of 20 Tabs. 5.00gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 5.00gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 3.70mm ± 0.2mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1.0 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 5.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White colour round shape biconvex tablets 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.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 17 of 24
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

Product Code:	**BMR No.:**
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

Document No.:	**Effective Date:**	**Page No.:** 18 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

5.5 In-process observation sheet for IPQA

Description:											
Diameter:											
Wt. of 20 Tabs. 5.00gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 5.00gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 3.70mm ± 0.2mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1.0 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 5.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White colour round shape biconvex tablets 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			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 19 of 24
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

Product Code:	**BMR No.:**
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

Document No.:	**Effective Date:**	**Page No.:** 20 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

6.0 TABLET WEIGHING RECORD:

Container No.	Gr. Wt.	Tare wt.	Net wt.	Container No.	Gr. Wt.	Tare 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			

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	Homogenize Pass the solution in homogenizer to uniform suspension to avoid inclusion of air bubbles. Filter the suspension through ____ # cover the prepared suspension in the vessel securely for use before coating. The dispersion, if required; Pass through _____# muslin cloth.	-					
	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			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets
Document No.:	**Effective Date:** / **Page No.:** 22 of 24
Batch No.:	**Batch Size:** / **Supersedes No.:**

Solution preparation	Instructions	Std. time (min)	Observed time		Done By) (Sign & Date)	Checked By (Sign & Date)	Remarks
			From	To			
	Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM……..) and pre warm the tabs to obtain the bed temperature (_____ºC).	-					
	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):

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/cm2							
Exhaust Air Temperature	42 to 48^0 **C**							
Bed Temperature	40 to50^0 **C**							

PARAMETERS AFTER COATING:

Tests	Specification	Production observation	IPQA observation
Description	White colour biconvex round shape tablets plain both side.		
Weight of 20 tablets	5.24 gm ± 3%		
Avg. weight	262 mg ± 5%		
Uniformity of weight	262 mg ± 5%		
Thickness	3.90 mm ± 0.2		
Disintegration	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: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

Document No.:	**Effective Date:**	**Page No.:** 23 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

11.1 WEIGHING RECORD OF COATED TABLETS:

Container No.	Gr. wt.	Tare wt.	Net wt.	Container No.	Gr. wt.	Tare 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 coated tablets:							
Checked By (Sign & Date):							

11.2 VISUAL INSPECTION OF TABLET:

Machine No. _____ 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: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets

Document No.:	**Effective Date:**	**Page No.:** 24 of 24
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			