	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
Document No.:	**Effective Date:**	**Page No.:** 1 of 25
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets (PT)	
Label Claim:	**Each film coated tablet contains:** Aceclofenac IP …… 100 mg Paracetamol IP ……. 325 mg Serratiopeptidase IP ……. 15 mg (30,000 enzymatic units of Serratiopeptidase as enteric coated granules) Excipients ……. q.s. **Colour:** Sunset Yellow FCF & 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, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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MASTER FORMULA:

BILL OF RAW MATERIALS

S.No.	Ingredients	Spec.	Qty. in mg Per Tablet	Overages %	Std. Qty. for 1.0 lac in kg
Raw Material for Dry Mixing-					
Active Ingredients-					
1.	Aceclofenac	IP	100	----	10.00#
2.	Paracetamol	IP	325	------	32.50#
Inactive Ingredients-					
3.	Starch	IP	100.00	------	10.00
4.	Microcrystalline Cellulose (MCCP)	IP	40.00	-----	4.00
5.	Lactose	IP	40.00	------	4.00
6.	Croscarmellose Sodium	IP	10.00	-------	1.00
Raw Material for Binder Preparation-					
7.	Starch for paste	IP	17.00	---	1.70
8.	PVPK-30	IP	5.00	----	0.50
9.	Purified Water	IP	QS	----	QS
Raw Material for Lubrication-					
10.	Serratiopeptidase	IP	15.00	40%	2.10#
11.	Magnesium Stearate	IP	7.00	-----	0.70
12.	Sodium Starch Glycolate	IP	10.00	-----	1.00
13.	Colloidal Silicon Dioxide (Aerosil)	IP	15.00	-----	1.50
14.	Talcum	IP	8.00	-----	0.80
15.	Croscarmellose Sodium	IP	15.00	----	1.50
Weight of Uncoated Tablets			**707.00 mg**		**71.3 Kg**
Coating-					
16.	Talcum	IH	0.50	-----	0.05
17.	Sunset Yellow FCF Redimix (SY50508)	IH	20.00	-----	2.00
18.	Ponceau 4R Supra	IH	0.20	-----	0.02
19.	Sunset Yellow Supra	IH	0.56	-----	0.056
20.	Purified Water	IP	QS	-----	QS
Weight of coated Tablets			**727.00 mg**		**73.38 Kg**

Note: # Aceclofenac, Paracetamol & Serratiopeptidase IP add after calculation if assay below 99 %.

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:		**BMR No.:**
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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 dispensed 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 (QA)**

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
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CALCULATION SHEET

2- Paracetamol 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 **Paracetamol 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 **Paracetamol 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 **Paracetamol IP** is to be used:

A.R. No. of Paracetamol **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. -(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 **Paracetamol 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			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
Document No.:	**Effective Date:**	**Page No.:** 5 of 25
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

3- Serratiopeptidase 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 **Serratiopeptidase 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 **Serratiopeptidase 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 **Serratiopeptidase IP** is to be used:

A.R. No. of **Serratiopeptidase 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 **Serratiopeptidase 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			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
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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

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

S.No.	Ingredients	Std. Qty. for 1 Lac. 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.	Paracetamol IP	32.50#									
Inactive Ingredients-											
3.	Starch IP	10.00									
4.	Microcrystalline Cellulose IP	4.00									
5.	Lactose IP	4.00									
6.	Cross Carmelose Sodium IP	1.00									
Raw Material for Binder Preparation-											
7.	Starch for paste IP	1.70									
8.	PVPK-30 IP	0.50									
9.	Purified Water IP	QS									
Raw Material for Lubrication-											
10.	Serratiopeptidase IP	2.10#									
11.	Magnesium Stearate IP	0.70									
12.	Sodium Starch Glycolate IP	1.00									
13.	Colloidal Silicon Dioxide (Aerosil) IP	1.50									
14.	Talcum IP	0.80									
15.	Cross Carmelose Sodium IP	1.50									
Coating-											
16.	Talcum	0.05									
17.	Sunset Yellow FCF Redimix (SY50508)	2.00									
18.	Ponceau 4R Supra IH	0.02									
19.	Sunset Yellow Supra IH	0.056									
20.	Purified water IP	QS									

Note: # Aceclofenac, Paracetamol& Serratiopeptidase IP adds after calculation if assay below 99%.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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Product Code:		**BMR No.:**
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BILL OF RAW MATERIALS **(STORE COPY)**

S. No.	Ingredients	Std. Qty. for 1 Lac. 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.	Paracetamol IP	32.50#									
Inactive Ingredients-											
3.	Starch IP	10.00									
4.	Microcrystalline Cellulose IP	4.00									
5.	Lactose IP	4.00									
6.	Cross Carmelose Sodium IP	1.00									
Raw Material for Binder Preparation-											
7.	Starch for paste IP	1.70									
8.	PVPK-30 IP	0.50									
9.	Purified Water IP	QS									
Raw Material for Lubrication-											
10.	Serratiopeptidase IP	2.10#									
11.	Magnesium Stearate IP	0.70									
12.	Sodium Starch Glycolate IP	1.00									
13.	Colloidal Silicon Dioxide (Aerosil) IP	1.50									
14.	Talcum IP	0.80									
15.	Cross Carmelose Sodium IP	1.50									
Coating-											
16.	Talcum	0.05									
17.	Sunset Yellow FCF Redimix (SY50508)	2.00									
18.	Ponceau 4R Supra IH	0.02									
19.	Sunset Yellow Supra IH	0.056									
20.	Purified water IP	QS									

Note: # Aceclofenac, Paracetamol& Serratiopeptidase IP adds after calculation if assay below 99%.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

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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.	Paracetamol	IP								
3.	Starch	IP								
4.	Microcrystalline Cellulose (MCCP)	IP								
5.	Lactose	IP								
6.	Cross Carmelose Sodium	IP								
7.	Starch for paste	IP								
8.	PVPK-30	IP								
MATERIAL FOR LUBRICATION:										
1.	Serratiopeptidase	IP								
2.	Magnesium Stearate	IP								
3.	Sodium Starch Glycolate	IP								
4.	Colloidal Silicon Dioxide	IP								
5.	Talcum	IP								
6.	Cross Carmellose Sodium	IP								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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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.			
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.	Sifter		Yes/No		
2.	Rapid granulation mixture (RMG)		Yes/No		
3.	Paste kettle		Yes/No		
4.	Full bed drying (FBD)		Yes/No		
5.	Multimill		Yes/No		
6.	Octagonal blender		Yes/No		
7.	Balance		Yes/No		
8.	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.

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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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								
Paracetamol								
Starch								
Microcrystalline Cellulose (MCCP)								
Lactose								
Cross Carmelose Sodium								
Starch for paste								
PVPK-30								

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				
Serratiopeptidase								
Magnesium Stearate								
Sodium Starch Glycolate								
Colloidal Silicon Dioxide								
Talcum								
Cross Carmellose Sodium								

3.3 MANUFACTURING PROCESS:

Step No.	Manufacturing Instruction	Eq. ID. No.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Binder Preparation-**					
	Dissolve **PVPK-30** (0.50Kg) in 10 liters of hot purified water in paste vessel and dissolve **Starch** (1.70 Kg) in 1.5 liters of Purified water in separate SS Container. Poured starch solution in PVPK-30 solution to make the paste. Check no lumps form.					
	Qty. of purified water ____ liters.					
3.3.2	**Dry Mixing:**					

	Prepared By	Checked By	Approved By
Signature			
Date			

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Step No.	Manufacturing Instruction	Eq. ID. No.	From	To	Done By/ Date	Ckd. By/ Date
	Add **Paracetamol** (____#Kg)**, Aceclofenac** (_____# Kg)**, Starch** (10.00 Kg)**, Microcrystalline Cellulose** (4.00 Kg)**, Lactose** (4.00 Kg) and **Cross Carmellose Sodium** (1.00 Kg) **i**n RMG and run the impeller at slow speed for 20 minutes.					
	Impeller speed (Slow/ Fast):_____ Chopper Speed (On/Off, Slow/Fast):_____					
3.3.3	**Wet granulation:**					
	Start the impeller of RMG 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 and chopper at slow speed and mix for 5 minutes.					
	Add additional purified water if required. Additional purified water _____ Lts.					
	Impeller speed (Slow/ Fast):_____ Chopper Speed (On/Off, Slow/Fast):_____					
	Run the impeller and chopper at slow speed for 3minutes and mixed the materials properly.					
	Impeller speed (Slow/ Fast):_____ Chopper Speed (On/Off, Slow/Fast):_____					
	Again run the impeller and chopper at fast speed for 2minutes and mixed the materials properly.					
	Impeller speed (Slow/ Fast):_____ Chopper Speed (On/Off, Slow/Fast):_____					
	Mentioned observation of process parameter in the table given below;					

Parameters	Observation
Ampere load of impeller before granulation	
Ampere load of impeller after granulation	
Ampere load of chopper after granulation	
Water Addition time	
Kneading time	
Total Qty. of Purified Water (Lts.)	

3.3.4	**Drying (FBD)-**					
	Dry the granules at 75°C to 80°C inlet temperature. Till 40°C to 45°C Outlet temperature is achieved by raking at every 10 min. and then at 30 min.					
	Inlet air temperature: _____°C Outlet temperature: _____°C Integrity of FBD Bag (OK/Not OK) Before: _____ After : _____					
	Shaking of Bag should be fixed after every 30 minutes for 1 minute.					

	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
	Collect the granules from 5 different places of the bowl and check loss on drying.					
	Recommended LOD: (NMT 2.0 % w/w) LOD. _____%w/w.					
3.3.5	**Sizing /Milling-**					
	Sift the dried granules through Vibratory sifter fitted with16# 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 **2mm** screen. With knife forward direction at medium speed.					
	Before Use	**After Use**				
	Rusted : Yes / No	Rusted : Yes / No				
	Broken : Yes / No	Broken : Yes / No				
	Clean : Yes / No	Clean : Yes / No				
3.3.6	**Blending & Lubrication-**					
	Add **Serratiopeptidase** (2.10#Kg), **Sodium Starch Glycolate** (1.00Kg), **Colloidal Silicon Dioxide** (1.50Kg), **Talcum** (0.80Kg) & **Croscarmellose Sodium** (1.50Kg) in blender with dried granules and mix it for 20 minutes.					
	Add **Magnesium Stearate** (0.70Kg) in blender and mix for further for 5 minutes.					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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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.

_____
Checked By (IPQA)

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

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): **Verified by (QA):**
Date: **Date:**

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
Document No.:	**Effective Date:**	**Page No.:** 15 of 25
Batch No.:	**Batch Size:**	**Supersedes No.:**

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

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Table: A-Die and punch verification

Punch Specification																								
Punch Details	Type	D- Tooling & ___ Station																						
	Upper Punches	17.80 x 8.2 mm (Caplet Shape with break line)																					Dies: 17.80 x 8.2 mm	
	Lower Punches	17.80 x 8.2 mm (Caplet Shape and 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	36	37	38	39	40	41	42	43	44	45	46
	Punch No.	47	48	49	50	51																		
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	36	37	38	39	40	41	42	43	44	45	46
	Punch No.	47	48	49	50	51																		

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 or off colour caplet shape tablet with one side break line.	At the start of machine
2.0	Weight of 20 tablets	14.14gm ± 3%	Every 30 Minutes
3.0	Avg. weight	707mg ± 5%	Every 2 Hours
4.0	Uniformity of weight	707mg ± 5%	Every 2 Hours
5.0	Thickness	5.2 ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3.0Kg/cm^2	Every 2 Hours
7.0	Friability	NMT 1%	Every 2 Hours
8.0	DT	NMT 15 min	Every 2 Hours
9.0	Length and Width	17.80 x 8.2 mm	At the start of machine

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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10.0	Appearance	White or off colour caplet shape tablet.	Every 2 Hours
11.0	Temperature	NMT 27 ° C	Every 2 Hours
12.0	RH	NMT 55%	Every 2 Hours

5.4 In-process observation sheet for production:

Description:											
Length and Width:											
Wt. of 20 Tabs. 14.14gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 14.14gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 5.2 ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3 Kg/cm^2)	LHS										
	RHS										
DT 15 min.	LHS										
	RHS										
Appearance: White or off colour caplet shape tablet with one side break line.	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, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
Document No.:	**Effective Date:**	**Page No.:** 18 of 25
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, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Batch No.:	**Batch Size:**	**Supersedes No.:**

5.5 In-process observation sheet for IPQA:

Description:											
Length & Width:											
Wt. of 20 Tabs. 14.14gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 14.14gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 5.2 ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3 Kg/cm^2)	LHS										
	RHS										
DT 15 min.	LHS										
	RHS										
Appearance: White or off colour caplet shape tablet with one side break line.	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, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
Document No.:	**Effective Date:**	**Page No.:** 20 of 25
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								

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

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Attached additional sheet if required……..

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.

_____
Checked By (IPQA)

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

7.1 YIELD RECONCILIATION:

•	Average weight of tablets (A)=: mg
•	Total weight of compressed tablets (B) = Kg.
•	$\text{Quantity of compressed tablet in Number (C)} = \frac{B}{A} \times 1000 \times 1000 =$
•	Samples (D)=
•	$\text{Yield} = \frac{C + D}{\text{Actual batch size}} \times 100 =$ **(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: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Batch No.:	**Batch Size:**	**Supersedes No.:**

8.0 COATING: **Date:_____**

8.1 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:**

8.2 COATING 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/cm^2. Start the exhaust system.	-					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Batch No.:	**Batch Size:**	**Supersedes No.:**

	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.	-					

8.3 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 $^{\mathbf{0}}$**C**							
Bed Temperature	40 to50 $^{\mathbf{0}}$**C**							

PARAMETERS AFTER COATING:

Tests	**Specification**	**Production observation**	**IPQA observation**
Description	Orange colour caplet shape tablet with one side break line.		
Weight of 20 tablets	14.54gm ± 3%		
Avg. weight	727mg ± 5%		
Uniformity of weight	727mg ± 5%		
Thickness	5.3± 0.2 mm		
Disintegration	NMT 30 minutes		

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

8.4 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/**			

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

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name: Aceclofenac, Paracetamol & Serratiopeptidase Tablets		**Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets
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Batch No.:	**Batch Size:**	**Supersedes No.:**

9/				**19/**			
10/				**20/**			
Total net weight of coated tab:							
Checked By(Sign & Date):							

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

8.6 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.

_____
Checked By (IPQA)

8.7 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):**

	Prepared By	Checked By	Approved By
Signature			
Date			

8.8 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.)

9.0 ANY DEVIATION:

Deviation No.	Reason for deviation

_____

Checked By (Prod. Manager)

10.0 HISTORY SHEET:

BMR No.	New BMR No.	Revision No.	Reason of revision
	--	00	--

	Prepared By	Checked By	Approved By
Signature			
Date			