

Checked By

Approved By

PHARMA DEVILS

BATCH PACKING RECORD							
Product Code:			BPR No.:		•		
Product Name: Ac	ceclofenac (Sustaine	d	Generic Name:	Aceclofenac (Sustai	ned Release) &		
Release) & Rabepraz	zole Sodium Capsule	es	Rabeprazole Sodiu	ım Capsules			
Document No.:		Effecti	ive Date:	Page No.: 1 of	25		
Batch No.:		Batch	Size:	Supersedes No	.:		
Location:		•					
Block: Production Ca	psule (PC)						
	Each hard gela	tin capsule	contains:				
	_	·	200 mg				
Label Claim:		Rabeprazole Sodium IP					
	Excipients		q.s.				
	Approved colo	r used in er	npty gelatin shells and	pellets.			
Mfg. Lic. No.:							
Product Lic. No.:	NA						
Self-Life:	24 Months						
Pack Style:	10 x 1 x 10 Ca ₁	psules					
Country Name:	Domestic						
Mfg. Date:							
Exp. Date:							
BMR Issued No.:							
MRP:							
Party:							
		Iccued 1	By Stamp & Sign.				
		Issued	by Stamp & Sign.				
Responsibility	Name		Designation	Sign	Date		
Prepared By							



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:		
Product Name: Aceclofenac (Sustained		Generic Name: Aceclofenac (Sustained Release) &		
Release) & Rabeprazole Sodium Capsules		Rabeprazole Sodium Capsules		
Document No.:	Effectiv	ve Date:	Page No.: 2 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

1.0 GENERAL INSTRUCTIONS:

- ➤ Good manufacturing practices should be followed during the entire process of packing.
- All the Equipments used for packing should be properly cleaned as per the relevant SOP.
- > All the Equipments and containers should have proper status label with Stage, Product name, B. No., Mfg. Date etc.
- All the equipments should be operated as per the relevant SOP's only.
- Issued packing materials should be cross checked by production personnel against dispensing sheet before taking up for packing.
- Overwriting in BPR shall be strictly avoided & correcting shall be made as per SOP.
- All the activities should be carried out according to the BPR only. All the operations shall be carried out in clean and orderly manner.
- Any deviation in process shall be bought to knowledge of QA and prior approval of QA department should be taken.
- > Critical parameters like temperature, Humidity and pressure differences should be checked and monitored.
- > In process controls should be carried out throughout the packing operations as per relevant BPR and relevant SOP's.
- Ensure that all the packing materials, in process materials and finished goods should be placed in respective areas with proper label to avoid mix up.
- Attach additional issue sheets from QA, wherever required.
- Attach system generated data sheets wherever applicable.

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Release) & Rabeprazole Sodium Capsules	,	Rabeprazole Sodium	n Capsules	
Document No.:	Effectiv	ve Date:	Page No.: 3 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

2.0 DISPENSING OF PACKING MATERIALS:

Date: _____

2.1 Instructions:

- 1. Follow the packing materials dispensing SOP.
- 2. Appropriate weighing balances should be used while issue.
- 3. Ensure that weighing balances are calibrated & Verified on daily basis.
- 4. Printed Al. Foil and Special /PVC should be issued in poly bags.
- 5. Each roll should be labeled separately.
- 6. Cartons should be issued in bundles.
- 7. Cartons should be kept in plastic/shippers crates covered with lid or supplier and properly labeled.
- 8. Carton should be closed with transparent Cello tape.
- 9. One complaint slip is pasted on inside flap of corrugated box.
- 10. Shippers should be issued in bundles with proper label.
- 11. Keep all issued materials on separate pallets in PM dispensing room.

2.2 Line Clearance Checks:

S.No.	Line Clearance Checks	Observation	Checked by QA
1.	Containers used for previous batch/product removed from area		
2.	All status labels of previous batch/products are removed		
3.	BPR or any other documents related to the previous batch / product are removed from area.		
4.	Absence of any previous product /batch remnants		
5.	Cleanliness of the area		
6.	Cleanliness of the area below balances/ pallets.		

2.3 Line clearance certificate for area and equipment:

Area	PM dispensin	g room	Equipment	Weighing Balance
Area Cleaned By:			Equipment No.:	
Checked By:			Equipment Cleaned By:	
Previous Product:			Batch No.:	
Checked By (Packing Su Sign & Date	pervisor):			
Line clearance Given By	(IPQA):			
Sign & Date				

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Date			



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Effecti	ve Date:	Page No.: 4 of 25		
Batch S	Size:	Supersedes No.:		
	Effecti	Generic Name: A		

2.4 BILL OF PACKING MATERIALS:

(BPR Copy) Date: _____

S. No.	Items	Std. Qty. for 1 Lac.	@Req. Qty. in	Issued Qty. in Kg/Nos.	A.R. No.	Issued by	Checke	ed By
110.		in Kg/Nos.	Kg/Nos.	iii Kg/110s.		Store	Prod.	QA
	Printed Aluminium Foil -							
1	0.025 mm,	11.00 Kg						
	Foil Width = 155 mm							
	Base Foil-0.14 mm,							
2	Cold form Alu-Alu foil,	36.00 Kg						
	Foil Width = 155 mm							
3	INNER CARTON - Dim: 150	10,000						
3	X 15 X 90 mm (1 x 10 Caps.)	Nos.						
	OUTER CARTON -							
4	Dim: 162 X 95 X 155 mm	1000 Nos.						
	(10 x 1 x 10 Caps.)							
	5 PLY CORRUGATED							
	BOX- Dim (OD): 505 (L) x							
5	495 (W) x 330(H) mm,	34 Nos.						
	(30 Cartons per box 3x5x2)							
	Mkt. by address is printed in corr. box							
	length panel in blue color BOPP TAPE - BOPP Pre							
6	Printed	01 Nos.						
	48 mm x 65 mtrs.	01 1103.						

Note: @ Calculate the materials as per required batch size.

Dispensed By: Checked By: Verified By: (Store) (Prod. Supervisor) (QA)

	Prepared By	Checked By	Approved By
Signature			
Date			



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Document No.:	Effectiv	ve Date:	Page No.: 5 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

Store copy page No.: 5 of 24

BILL OF PACKING MATERIALS

(STORE COPY) Date: _____

S. No.	Items	Std. Qty. for 1 Lac.	@Req.	Issued Qty. in Kg/Nos.	A.R. No.	Issued	Checke	ed By
140.		in Kg/Nos.	Qty. in Kg/Nos.	iii ixg/110s.		by Store	Prod.	QA
	Printed Aluminium Foil -							
1	0.025 mm,	11.00 Kg						
	Foil Width = 155 mm							
	Base Foil-0.14 mm,							
2	Cold form Alu-Alu foil,	36.00 Kg						
	Foil Width = 155 mm							
3	INNER CARTON - Dim: 150	10,000						
3	X 15 X 90 mm (1 x 10 Caps.)	Nos.						
	OUTER CARTON -							
4	Dim: 162 X 95 X 155 mm	1000 Nos.						
	(10 x 1 x 10 Caps.)							
	5 PLY CORRUGATED							
	BOX- Dim (OD): 505 (L) x							
5	495 (W) x 330(H) mm,	34 Nos.						
	(30 Cartons per box 3x5x2)							
	<u> </u>							
6		01 Nos.						
6	Mkt. by address is printed in corr. box length panel in blue color BOPP TAPE - BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						

Note: @ Calculate the materials as per required batch size.

Dispensed By: Checked By: Verified By: (Store) (Prod. Supervisor) (QA)

	Prepared By	Checked By	Approved By
Signature			
Date			



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Document No.:	Effective Date:		Page No.: 6 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

3.0 PACKING SPECIFICATION:

	5.0 PACKING SPECIFICATION:							
S.	Description	Over Printing Matter Standards	Over Printing Matter Actual	Check	ed By			
No.		(For Example only)		Prod.	QA			
A.	Primary Packin	ng:						
1.	ALU-ALU Blis	ter						
	Alu-Alu Blister coding details	B. No.: MFG. EXP. M.R.P.Rs. PER 10 CAPS. INCL.OF ALL TAXES						
В.	Secondary Pac	king:						
	Inner Carton	Printed						
	Carton details	1 X 10 Capsules						
1.	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Capsules						
	Outer Carton	Printed						
	Carton details	10 X 1 X 10 Capsules						
2.	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Capsules						
C.	Tertiary Packi	ng						
	5 ply Shipper	5 ply printed shipper						
	Shipper details	30 cartons in one 5 ply shipper						
1.	Shipper coding details	B.No. MFG. EXP. Qty. 30 X 10 X 1 X 10 CAPS.						
	Sealing of Shipper/BOPP Tape	Pre PrintedBOPP Tape in "H" type	on top and bottom.					

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Document No.:	Effectiv	ve Date:	Page No.: 7 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

3.1 STANDARD PACKING INSTRUCTIONS:

- Check and verify the status board/label.
- All the materials of previous batches should be removed and line clearance certificate to be obtain from IPQA before starting any activity.
- Transfer the QC Released Capsules of the Batch to the primary cubicle.
- Produce the blister of 1x10 capsules using 155 mm printed aluminum foil & 155 mm base foil on an Alu-Alu packing machine. The blister should be duly overprinted with the respective batch legend.
- Blister sealing leak test should be performed periodically to monitor the sealing.
- Each blister should be visually inspected to reject the defective ones.
- 1x10 capsules such inspected blisters should be packed inside each printed inner carton and again 10 inner carton with blister packed inside each outer carton. The carton should be duly overprinted with the respective batch legend.
- 30 such inspected unit carton should be packed inside the each shipper.
- The shipper should be properly labeled using coder. The coding details should be overprint with the respective batch legend on the shipper label.
- Each shipper should be sealed using printed BOPP tape in "H" type on top and bottom.
- After completion of the batch packing, intimate IPQA department through the transfer ticket.
- Complete the BPR for reconciliation of the batch after that transfer the packed shippers to the Finish Goods Store.

3.2 PACKING - Date:

Instructions:

- a. Gowning should be follows as per SOP.
- b. Masks and gloves should be used in the primary packing.
- c. Check for the cleanliness of the area and equipment.
- d. Check the Temperature, Humidity, and differential Pressure as per BPR or as per SOP
- e. Check that batch/product is released by QC for packing before starting of packaging operations and transfer to primary packing.
- f. Check the status label on the area on the display board outside the packing cubical.
- g. Operate Alu-Alu packing machine as per SOP.
- h. Line clearance should be given take during any shift change.
- i. Line clearance procedure should also be followed in case of change in stereo or any major breakdown which can affect the packing quality.

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Release) & Rabeprazole Sodium Capsules	Rabeprazo	le Sodiun	n Capsule	S					
Document No.:	Effective Date:			Page No.: 8 of 25					
Batch No.:	Batch S	Batch Size:		Supers	edes No	.:			
3.3 Line clearance check (Initial/shift change over): Line Clearance of Packing Line Please Tick √ If Yes & X If No or Not Applicable									
					-	-	I		

C No	Cleaner of Charles	Date					
S.No.	Clearance Checks	Time					
1.	Product name:						
2.	Area Cleanliness below/ Balance/ etc.	Pallets/					
3.	Machine Cleanliness						
4.	Packaging material of previous product remove.						
5.	Over coding details on Blisters						
6.	Over coding details on unit carton						
7.	Pasting cello tape						
8.	Over coding details on outer cartor	1					
9.	Product Packaging Insert						
10.	Specimen of 5 Ply Shipper coding						
11.	Correctness of status label						
12.	Daily Verification of balances						
Check	Checked by Production (Sign/Date)						
Verific	Verified by IPQA (Sign/Date)						

3.4 Verification of capsules received from core area:

Total Container No. Total Weight		Checked by Production	Verified by IPQA

3.5 Stereo detail:

Issue the required number of stereos to operator and retrieve the same from them after completion of activity and record shall be maintained as per table given below:

	of Stereos ed from QA		ereos given perator	No. of Stereos returned by Operator		Total No. of Stereos submitted to QA		Submitted by (Packing)	Retrieved By (IPQA)
Carton	Blister	Carton	Blister	Carton	Blister	Carton	Blister		

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Document No.:	Effective Date:		Page No.: 9 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

3.6 Line clearance overprinting of carton:

- i. Line clearance of the area and machine.
- ii. Affix the specific batch stereo and prepare a specimen proof for the approval of packing supervisor and then by IPQA supervisor & affix in the BPR.
- iii. After approval start coding of carton and check the each carton for correctness and legibility of the batch detail.
- iv. In-process, rejection and destruction of rejected cartons shall be recorded.

Line clearance certificate for area and equipment					
Area:	Equipment:	Carton coding machine			
Area Cleaned By:	Equipment No.:				
Checked By:	Equipment Cleaned By:				
Previous Product:	Batch No.:				
Checked By (Packing Supervisor): Sign & Date					
Line clearance Given By(IPQA): Sign & Date					

Over coding detail for blister, carton and shipper

S.No.	Over printi	Blister	Inner	Outer	Shipper	
	Details on PM (for example)	Actual details	(ALU- ALU)	Carton	Carton	
1.						
2.	Batch No.:					
3.	Mfg. Date:					
4.	Exp. Date:					
5.	M.R.P.: (Incl. of all taxes) Per 10 Capsules					
6.	Qty. 30x10x1x10 CAPS.					
Packing	Signature					
Packing	Date					
IDOA	Signature					
IPQA	Date					

Note: Which is not applicable mention NA and put tick mark which is applicable.

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Document No.:	Effective Date:		Page No.: 10 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

3.7 Reconciliation of Packing Material:

S.No.	Particulars	Inner Cartons	Outer Cartons	Shipper
1.	Quantity Issued			
2.	Quantity coded			
3.	Good inspected quantity			
4.	Quantity rejected			
5.	Qty. destroyed			
6.	Qty. destroyed by			
Checkee	l by Prod. (Sign/Date)			
Verified	by IPQA (Sign / Date)			

3.8 Shipper coding:

- i. Arrange the klass marker of respective batch no. for coding on unit carton and arrange the alphabets for shipper label coding as per information given in the BMR and first take a specimen on carton and shipper label coding specimen on plain A4 size paper & get the approval from packing supervisor and then from IPQA.
- ii. After approval all the unit carton/shipper of the batch shall be coded and if any unit carton/shipper rejected during coding same shall be destructed and record shall be maintained.

4.0 ALU-ALU:

4.1 Machine Setting:

1. Take line clearance from IPQA.

Line clearance certificate for area and equipments:				
Area	Equipment	ALU-ALU Machine		
Area Cleaned By	Equipment No.			
Checked By	Equipment Cleaned By			
Previous Product	Batch No.			
Checked By (Packing Supervisor): Sign & Date				
Line clearance Given By (IPQA): Sign & Date				

- 2. Check the change parts as per product specification.
- 3. Mount the rollers and check the cavity alignment of sealing roller.
- 4. Mount BCP, and affix stereos.
- 5. Adjust forming & sealing temperature and pressure.
- 6. Load the printed and plain foil, and adjust machine to smooth foil run and take out proof of batch coding. Get the approval from packing supervisor and IPQA.
- 7. Set the sealing temperature 170°C to 220°C. Forming Temp165°C to 180°C.
- 8. Ensure proper Knurling and cutting length.
- 9. Check status label on capsules containers.
- 10. Load the hopper with capsules to be stripped.
- 11. Operate the Alu-Alu blister packing machine as per SOP.

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Document No.:	Effective Date:		Page No.: 11 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

- 12. Check the leak test of blister as per leak test SOP. Record it in in-process control record.
- 13. Attach approved specimen sample to BPR duly signed by Packing Supervisor and QA Personnel.

4.2 General instruction:

- 1. Carry out blistering operation after batch printing approval by production supervisor & IPQA.
- 2. Record the parameters at a stated frequency.
- 3. Carry out the leak test as per SOP.
- 4. Note the changes in foil rolls and splices.
- 5. Check the coding on each splice and foil at the start and end. Check at least 1 meter section of each side.
- 6. Foil rolls / Splices should be numbered.
- 7. Attach the sample of every new foil roll and every splice in each roll with BPR.
- 8. Note the machine start, stop and end time.

4.3 Alu-Alu Blister Packing Start up Control Checks:

- 1. Run the machine and collect few initial blisters.
- 2. Check for Knurling, Cutting, sealing, batch overprinting, etc. and observation shall be recorded.
- 3. If the initial parameters are satisfactory, continue packing.
- 4. In process test observation shall be recorded both by packing and IPQA supervisor as per table No.4.4
- 5. Reasons for machine stop should be recorded. In the following tables.

4.4 Secondary and tertiary packing:

- 1. Pack the number of blister in carton then followed by outer carton and finally in shipper as per requirement given in section 2.0 (packing specification).
- 2. Each carton and shipper shall weigh to identify the shortage if any.
- 3. Close the shipper by BOPP tape properly.
- 4. Person involve in the packing shall be recorded as per following table:

Date				
Time	То	То	То	То
Inspection of Blister done by				
Counting of Blister done by				
Carton				
Insertion of Blister & Carton done				
by				
Inspection of over coding on carton				
done by				
Shipper coding done by				
Insertion of Carton in shipper done by				
Shipper sealed and weighed by				

	Prepared By	Checked By	Approved By
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	ise) & Rabep	razole So	dium C	apsules		Rabeprazole Sodium Capsules								
Docu	iment No.:				Effecti	Effective Date: Page			ige N	o.: 12 o	of 25			
Batc	h No.:				Batch	Size	:		Sı	iperse	edes No).:		
Chec	ked by													
	uction/packir	ng												
IPQ	1	_												
	N PROCESS -process chec			t initial	and ever	ry 30 1	min.							
S.	In process	Date												
No.	checks	Time												
1.	Temp.													
2.	RH													
3.	Forming roll temperature													
4.	Sealing rolle Temperature													
5.	Check worki NFD by rem one capsule i each track	oving												
6.	Cap. with for black particle													
7.	Foil shifting													
8.	Batch detail	on foil												
9.	No. of cap./													
10.	Proper cuttin Blister	ig of												
11.	Leak test (Hourly)													
12.	Proper gluing carton	g of												
13.	No. of Bliste printed carto													
14.	Batch detail printed carto	on												
15.	Seal the carte													
16.	No. of cartor shipper	n in one												
17.	Batch details shipper label													
18.	Pasting of B												1	
Check	xed by (Produ	ection)												
			Prepare	ed By			Che	cked B	y		A	pprov	ed By	
Sign	ature													
Date	<u></u>													



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Document No.:	Effective Date:		Page No.: 13 of 25	
Batch No.:	Batch S	Size:	Supersedes No.:	

In-process check by production at initial and every 30 min.

C M-	In process	Date							
S.No.	checks	Time							
1.	Temp.								
2.	RH								
3.	Forming rolle temperature								
4.	Sealing roller Temperature								
5.	Check workin NFD by remo one capsule f each track	rom							
6.	Cap. with for black particle								
7.	Foil shifting								
8.	Batch detail on foil								
9.	No. of cap./ Blister								
10.	Proper cutting Blister	g of							
11.	Leak test (Hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed cartor	ı							
14.	Batch detail of printed carton	ı							
15.	Seal the carto								
16.	No. of carton shipper								
17.	Batch details shipper label	on							
18.	Pasting of BOPP tape								
Checke	d by (Product	ion)							

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Document No.:	Effectiv	ve Date:	Page No.: 14 of 25		
Batch No.:	Batch S	Size:	Supersedes No.:		

In-process check by production at initial and every 30 min.

C N	In process	Date							
S.No.	checks	Time							
1.	Temp.								
2.	RH								
3.	Forming rollo temperature								
4.	Sealing roller Temperature								
5.	Check working NFD by remore capsule freach track	oving							
6.	Cap. with for black particle								
7.	Foil shifting								
8.	Batch detail on foil								
9.	No. of cap./ Blister								
10.	Proper cutting of Blister								
11.	Leak test (Hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed carton	n							
14.	Batch detail of printed carton	n							
15.	Seal the carto								
16.	No. of carton shipper								
17.	Batch details on shipper label								
18.	Pasting of BOPP tape								
Checke	d by (Product	ion)							

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Document No.:	Effectiv	ve Date:	Page No.: 15 of 25		
Batch No.:	Batch S	Size:	Supersedes No.:		

In-process check by production at initial and every 30 min.

C.M.	In process	Date							
S.No.	checks	Time							
1.	Temp.								
2.	RH								
3.	Forming roll temperature								
4.	Sealing roller Temperature								
5.	Check worki NFD by remone capsule feach track	oving							
6.	Cap. with for black particle								
7.	Foil shifting								
8.	Batch detail on foil								
9.	No. of cap./ Blister								
10.	Proper cuttin Blister	g of							
11.	Leak test (Hourly)								
12.	Proper gluing carton								
13.	No. of Bliste printed carto								
14.	Batch detail of printed carton								
15.	Seal the carto	on with							
16.	No. of carton shipper								
17.	Batch details shipper label								
18.	Pasting of Bo	OPP tape							
Checke	d by (Product	ion)	-				1111		

Attach additional sheet if required....

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:			
Product Name: Aceclofenac (Sustained		Generic Name: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodium Capsules		Rabeprazole Sodium Capsules			
Document No.:	Effectiv	ve Date:	Page No.: 16 of 25		
Batch No.:	Batch S	Size:	Supersedes No.:		

5.2 In-process check by IPQA for initial and every 60 min:

S.No.	In process	Date						
5.110.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature	r						
4.	Sealing roller Temperature							
5.	Check workin NFD by remo one capsule fr each track	ving						
6.	Cap. with fore black particle	eign /						
7.	Foil shifting							
8.	Batch detail on foil							
9.	No. of cap./ Blister							
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail o printed carton							
15.	Seal the cartor cello tape							
16.	No. of carton shipper				 			
17.	Batch details of shipper label	on			 			
18.	Pasting of BO							
Checke	d by (IPQA)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:			
Product Name: Aceclofenac (Sustained		Generic Name: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodium Capsules		Rabeprazole Sodium Capsules			
Document No.:	Effectiv	ve Date:	Page No.: 17 of 25		
Batch No.:	Batch S	Size:	Supersedes No.:		

In-process check by IPQA for initial and every 60 min.:

S.No.	In process	Date						
S.No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature							
4.	Sealing roller Temperature							
5.	Check working NFD by remore capsule freach track	oving						
6.	Cap. with for black particle							
7.	Foil shifting							
8.	Batch detail	on foil						
9.	No. of cap./ I							
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail of printed carton	n						
15.	Seal the carto	on with						
16.	No. of carton shipper		 			 		
17.	Batch details shipper label	on						
18.	Pasting of BO	OPP tape						
Checke	d by (IPQA)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:				
Product Name: Aceclofenac (Sustained		Generic Name: Aceclofenac (Sustained Release) &				
Release) & Rabeprazole Sodium Capsules	,	Rabeprazole Sodium Capsules				
Document No.:	Effectiv	ve Date:	Page No.: 18 of 25			
Batch No.:	Batch S	Size:	Supersedes No.:			

In-process check by IPQA for initial and every 60 min.:

S.No.	In process	Date						
5.No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature							
4.	Sealing roller Temperature							
5.	Check working NFD by remove one capsule freach track	oving rom						
6.	Cap. with for black particle	eign /						
7.	Foil shifting							
8.	Batch detail of	on foil						
9.	No. of cap./ I							
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed cartor							
14.	Batch detail of printed cartor	ı						
15.	Seal the carto cello tape							
16.	No. of carton shipper							
17.	Batch details shipper label	on						
18.	Pasting of BO	OPP tape						
Checke	ed by (IPQA)							

Attach additional sheet if required....

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:					
`		Generic Name: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodium Capsules		Rabeprazole Sodium Capsules			
Document No.:	Effectiv	ve Date:	Page No.: 19 of 25		
Batch No.: Batch S		Size:	Supersedes No.:		

6.0 SHIPPER WEIGHING RECORD:

Weight limit for filled shipper:	Kg to	Kو
weight mint for thied shipper.	Kg to	Rg

Shipper No.	Gross wt. in Kg.	Weighing done by	Shipper No.	Gross wt. in Kg.	Weighing done by			
1.	3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 -		26.		gg			
2.			27.					
3.			28.					
4.			29.					
5.			30.					
6.			31.					
7.			32.					
8.			33.					
9.			34.					
10.			35.					
11.			36.					
12.			37.					
13.			38.					
14.			39.					
15.			40.					
16.			41.					
17.			42.					
18.			43.					
19.			44.					
20.			45.					
21.			46.					
22.			47.					
23.			48.					
24.			49.					
25.			50.					
Min. Shipper V	Weight:	<u></u>	Max. Shipper	Weight:	<u> </u>			
	Checked By (Production Supervisor)			Verify By (IPQA)				

	Prepared By	Checked By	Approved By
Signature			
Date			



	BATCI	H PA(CKING	REC	CORD					
Product Cod	e:			BP	R No.:		1			
	ne: Aceclofenac (Sus beprazole Sodium Ca			Generic Name: Aceclofenac (Sustained Release) & Rabeprazole Sodium Capsules						
Document N			Effectiv	•		25				
Batch No.: Batch			Batch S							
Shipper No.	Gross wt. in Kg.	Weighing done by			Shipper No.	Gross wt. in Kg.	Weighing done by			
Loose Shipper N	No.:									
	for filled shipper:				HING RECORD	•				
Shipper No.	Gross wt. In Kg.	Weig	ghing don	e bv	Shipper No.	Gross wt. In Kg.	Weighing done by			
51.			,		76.	g	·····gg			
52.					77.					
53.					78.					
54.					79.					
55.					80.					
56.					81.					
57.					82.					
58.					83.					
59.					84.					
60.					85.					
61.					86.					
62.					87.					
63.					88.					
64.					89.					
65.					90.					
66.					91.					
67.					92.					
68.					93.					
69.					94.					
70.					95.					
71.					96.					
72.					97.					
73.					98.					
74.					99.					

	Prepared By	Checked By	Approved By
Signature			
Date			



Date

PHARMA DEVILS

Product Cod	e:			BP	R No.:	1		
	ne: Aceclofenac (Sus				neric Name: A			ned Release) &
	beprazole Sodium Ca	psules			eprazole Sodiui			
Document No	0.:		Effectiv	ve Da	ate:	Page	No.: 21 of	£ 25
Batch No.:			Batch S	Size:		.:		
Shipper No.	Gross wt. In Kg.	Weig	hing don	e by	Shipper No.	Gross	wt. In Kg.	Weighing done by
75.					100.			
Min. Shipper Weight:					Max. Shipper			
Checked By (Production Supervisor)						Verif	fy By (IPQA	A)
Loose Shipper No.:								
	for filled shipper:	SHI			HING RECORDKg	•		
Shipper No.	Gross wt. In Kg.	Weig	shing don		Shipper No.	Gross	wt. In Kg.	Weighing done by
101.	_							
102.								
103.								
104.								
	_	1.0			~ · · · ·			1.7
	Prepare	d By			Checked By		Aj	pproved By
Signature								



Date

PHARMA DEVILS

BATCH PACKING RECORD										
Prod	luct Code:				BPR	No.:				
		e: Aceclofenac (Sus				eric Name: A		,	ined Re	lease) &
		eprazole Sodium Ca	apsules			prazole Sodiui	•			
Docu	ıment No.	•		Effect	tive Da	te:	Page	No.: 22 o	of 25	
Batch No.:			Batch	Size:		Super	Supersedes No.:			
Shipper No. Gross wt. In Kg. W		Weig	ghing do	ne by	Shipper No.	Gross	wt. In Kg.	Weig	ghing done by	
			<u> </u>							
			1						1	
Min.	Shipper W	eight:				Max. Shipper	Weight:			
		ed By (Production S	Supervi	isor)				fy By (IPQ	A)	
	Shipper No		NO M	A TEDIA	т.					
7.0 Kr	ECONCIL14	ATION OF PACKI	NG MA	ATERIA.	L:					
S.No.		Material	Print	ted Alum	inum fo	il Base foil	Inne		uter	Shippers
							Carto	ons Ca	rtons	
1.	Std. Qty.									<u> </u>
2.	Quantity Iss						_			<u> </u>
3.	Extra Qty. i	ssued								<u> </u>
4.	Qty. used									<u> </u>
5.		ed (attach MRN)					_			<u> </u>
6.		yed after coding								
7.		ved after pkg.	 				_			
8.	Total qty. d	•	 				_			
9.	Qty. destroy	yed by					-			
Check	ed by Prod	. (Sign/Date)								
Verifi	ed by IPQA	(Sign/Date)								
10.	Remarks		<u> </u>			T	† <u> </u>			
8.0 F	INISH PRO	DUCT SAMPLING	S AND	QUALI	TY CON	TROL APPRO	OVAL:			
D.			10		- 1 mmorri	1. 4- IDOA for	lina	IDO A che	11 marfo	
		erson shall raise the season solution SOP and sent to QC.		request a	na provi	de to IPQA for	sampling	;. IPQA sna	II perioi	rm sampling as
Re	equisition ra	nised By (Packing Su	apervis	or):		Sampled By	(IPQA):	:		
Ç _o .	muling Dot	aila.								
Sa	mpling Deta	ans:								
		Prepare	d Bv			Checked By		A	pprove	ed Bv
		Териге	u Dy			Checked By		11	pprove	tu Dy
Sign	ature									



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:		
Product Name: Aceclofenac (Sustained	Generic Name: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodium Capsules		Rabeprazole Sodium	n Capsules	
Document No.: Effective		ve Date:	Page No.: 23 of	25
Batch No.:	Batch S	Size:	Supersedes No.	•

S.No.	Sample detail	Quantity	Sampled By
1.	Sample for analysis		
2.	Control Samples		
3.	Stability Samples		
4.	Validation samples		
5.	Other sample		

9.0 FINISHED GOODS TRANSFER TO FG STORES:

Transfer f	finished goods to	FG Stores.	Through	transfer tic	cket & a	ttach a copy	of T.T.	to BPR
Date								

Total No. of shippers packed	
Unit per shipper	
No. of Blister per Carton	
Qty. of Capsules transferred to BSR	
Qty of shippers transferred to BSR	
Transfer note No.	
Sign of Packing Supervisor	
Sign of BSR Supervisor	

10.0 BATCH RECONCILIATION:

S.No.	Particulars	In Kgs.	In Nos.
1.	Qty. of Capsules received by packing department		
2.	Partial		
3.	Packing loss (Non recoverable)		
4.	Quantity actually transferred to FG Store		
5.	Sample		
5a.	Analysis Sample Qty.		
5b.	Control Samples Qty.		
5c.	Stability Sample Qty.		
5d.	Party Sample Qty.		
6.	Total packed Quantity (4+5a+5b+5c+5d)		
7.	Accountability=		

Reconciliation of Batch Yield:

 $\begin{array}{rcl} Yield & = & \underline{Total\ Quantity\ Packed\ (6) + Partial\ x\ 100} \\ & & Batch\ size \end{array}$

	Prepared By	Checked By	Approved By
Signature			
Date			



BATCH PACKING RECORD						
Product Code:			BPR No.:			
Product Name: Aceclofena	c (Sustained		Generic Name: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodiu	ım Capsules		Rabeprazole Sodium Capsules			
Document No.:		Effectiv	Effective Date:		24 of 25	
Batch No.:		Batch S	Size:	s No.:		
=		x 1	00			
=	% (NL	T 97.0 %)	1			
Remark:						
Kemark:	• • • • • • • • • • • • • • • • • • • •					
	• • • • • • • • • • • • • • • • • • • •					
					<u></u>	
(Packing Superviser)				(IPQA)		
11.0 DEVIATION APPROVA	L:					
Deviation No.	Reason for	deviation				
12.0 REVIEW OF BPR: Date:						
12.0 REVIEW OF BPR:			Date	e:	_	
12.0 REVIEW OF BPR: Particulars			Date Sta		Checked By QA	
					Checked By QA	
Particulars					Checked By QA	
Particulars Signature of Authorized Persons					Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures:					Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition					Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order					Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any					Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable)	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack COA of Finished Product	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack COA of Finished Product FG Goods Transfer Note	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack COA of Finished Product FG Goods Transfer Note Final Dispatch Note	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack COA of Finished Product FG Goods Transfer Note Final Dispatch Note Destruction and approvals	7				Checked By QA	
Particulars Signature of Authorized Persons Contents and Enclosures: PM Requisition PM Issue Order Excess material issue note, if any PM return note (if applicable) Specimens of Packing material In Process packing control report TR of Finished Product Pack COA of Finished Product FG Goods Transfer Note Final Dispatch Note Destruction and approvals Deviation and its Justification	7				Checked By QA	

	Prepared By	Checked By	Approved By
Signature			
Date			



BATCH PACKING RECORD						
Product Code:		BPR No.:	·			
Product Name: Aceclofenac (Sustained	1	Generic Nan	ne: Aceclofenac (Sustained Release) &			
Release) & Rabeprazole Sodium Capsule	s	Rabeprazole S	odium Capsules			
Document No.:	Effectiv	e Date:	Page No.: 25 of 25			
Batch No.:	Batch S	Size:	Supersedes No.:			
Product:		USE OF QA ON	Batch No:			
Qty. Released:			A.R. No:			
Released Date: The BPR has been reviewed and the abo	ove batch is	released for DI	SPATCH.			
Signature of QA Manager/Designee:		i	Date:			
14.0 HISTORY SHEET:						

BPR No.	New BPR No.	Revision No.	Reason of revision
		00	New BPR

	Prepared By	Checked By	Approved By
Signature			
Date			