	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BPR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 1 of 22
Batch No.:	**Batch Size:**	**Supersedes No.:**

ALU-ALU PACKING

Location:	
Block: Production Tablets (PT)	
Label Claim:	Each film coated tablet contains: Thiocolchicoside 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
Pack Style:	10 x 1 x 10 Tablets
Country Name:	Domestic
Mfg. Date:	
Exp. Date:	
BMR Issued No.:	
MRP:	
Party:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

Product Code:	**BPR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 2 of 22
Batch No.:	**Batch 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.

	Prepared By	Checked By	Approved By
Signature			
Date			

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Document No.:	**Effective Date:**	**Page No.:** 3 of 22
Batch No.:	**Batch 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 Alu/Alu Foil and Special /PVC/Alu 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 dispensing room	Equipment	Weighing Balance
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			

	Prepared By	Checked By	Approved By
Signature			
Date			

2.4 BILL OF PACKING MATERIALS:

(BPR Copy) **Date:** _____

S.No.	Items	Std. Qty. for 1 Lac. in kg/nos.	@Req. Qty. in kg/nos.	Issued Qty. in kg/nos.	A.R. No.	Issued by Store	Checked By	
							Prod.	QA
1	**Printed Aluminium Foil-** 0.025mm, Foil Width = 218 mm	4.50 Kg						
2	**Base Foil-** 0.14mm, Cold form Alu-Alu foil, Foil Width = 222 mm	16.00 Kg						
3	**Inner Carton -** Dim: 110 X 15 X 48 mm **(1x10 Tabs.)**	10000 Nos.						
4	**Outer Carton –** Dim: 162 X 52 X 114 mm **(10x1x10 Tabs.)**	1000 Nos.						
5	**5 PLY CORRUGATED BOX-** Dim (OD): 590 (L) x 342 (W) x 282(H) mm, **(50 Cartons per box 5x2x5)** Mkt.by address is printed in corr. box length panel in red colour.	20 Nos.						
6	**BOPP TAPE -** BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						

Note-@ ***Calculate the materials as per required batch size.***

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

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

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Document No.:	**Effective Date:**	**Page No.:** 5 of 22
Batch No.:	**Batch Size:**	**Supersedes No.:**

BILL OF PACKING MATERIALS

(STORE COPY) **Date:** _____

S.No.	Items	Std. Qty. for 1 Lac. in kg/nos.	@Req. Qty. in kg/nos.	Issued Qty. in kg/nos.	A.R. No.	Issued by Store	Checked By	
							Prod.	QA
1	**Printed Aluminium Foil-** 0.025mm, Foil Width = 218 mm	4.50 Kg						
2	**Base Foil-** 0.14mm, Cold form Alu-Alu foil, Foil Width = 222 mm	16.00 Kg						
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6	**BOPP TAPE -** BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						

Note-@ ***Calculate the materials as per required batch size.***

Dispensed By:
(Store)

Checked By:
(Prod. Supervisor)

Verified By:
(QA)

	Prepared By	Checked By	Approved By
Signature			
Date			

3.0 PACKING SPECIFICATION:

S.No.	Description	Over Printing Matter Standards (For Example only)	Over Printing Matter Actual	Checked By	
				Prod.	QA
A.	**Primary Packing:**				
1.	**ALU-ALU Blister:**				
	Alu-Alu Blister coding details	B. No.: MFG.: EXP.: M.R.P.Rs.: PER 10 TABS. INCL.OF ALL TAXES			
B.	**Secondary Packing:**				
1.	**Inner Carton**	Printed	**Carton details:** 1 x 10 Tablets		
	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Tablets			
2.	**Outer Carton**	Printed	**Carton details:** 10 x 1 x 10 Tablets		
	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Tablets			
C.	**Tertiary Packing**				
1.	**5 ply Shipper**	5 ply printed shipper			
	Shipper details	50 cartons in one 5 ply shipper			
	Shipper coding details	B.No.: MFG. EXP. Qty. 50 X 10 X 1 X 10 TABS.			
	Sealing of Shipper/BOPP Tape	Printed BOPP Tape in “H” type on top and bottom.			

	Prepared By	Checked By	Approved By
Signature			
Date			

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 Tablets of the batch to the primary cubicle.
- Produce the blister of 1x10 tablets using 218 mm printed aluminum foil & 222 mm base foil on a blister 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 tablets such inspected blisters should be packed inside each printed inner carton and should be duly overprinted with the respective batch legend. 10x1x10 tablets such inspected blisters should be packed inside each printed outer carton and should be duly overprinted with the respective batch legend.
- 50 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 Pre-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 blister 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.

	Prepared By	Checked By	Approved By
Signature			
Date			

3.3 Line clearance check (Initial/shift change over):

Line Clearance of Packing Line _____Please Tick √ If Yes & X If No or Not Applicable

S.No.	Clearance Checks	Date / Time									
1.	Product name:										
2.	Area Cleanliness below/ Balance/ Pallets/ etc.										
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 carton										
9.	Product Packaging Insert										
10.	Specimen of 5 Ply Shipper coding										
11.	Correctness of status label										
12.	Daily Verification of balances										
Checked by Production (Sign/Date)											
Verified by IPQA (Sign/Date)											

3.4 Verification of tablet 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;

No. of Stereos received from QA		No. of Stereos given to Operator		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		

	Prepared By	Checked By	Approved By
Signature			
Date			

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 printing details**		**Blister (ALU-ALU)**	**Inner Carton**	**Outer Carton**	**Shipper**
	Details on PM (for example)	**Actual details**				
1						
2	Batch No.:					
3	Mfg. Date:					
4	Exp. Date:					
5	M.R.P.: (Incl. of all taxes) Per 10 Tablets					
6	Qty.50x10x1x10 TABS.					
Packing	**Signature**					
	Date					
IPQA	**Signature**					
	Date					

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

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

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			
Checked 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 180°C to 200°C. Forming Temp150°C to 160°C.
8. Ensure proper Knurling and cutting length.
9. Check status label on Tablets containers.
10. Load the hopper with Tablets to be stripped.

	Prepared By	Checked By	Approved By
Signature			
Date			

11. Operate the Alu-Alu blister packing machine as per SOP.
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 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	To	To	To	To
Inspection of Blister done by				
Counting of Blister done by				
Carton printing checked by				
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				
Checked by				
Production/packing				
IPQA				

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

5.0 IN PROCESS CHECK:

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

S.No.	In process checks	Date / Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (Production)														

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

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Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
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In-process check by production at initial and every 30 min.

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (Production)														

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

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PRODUCTION DEPARTMENT

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

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (Production)														

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

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

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (Production)														

Attach additional sheet if required….

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

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

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Bi-Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (IPQA)														

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

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
7.	Foil shifting													
8.	Batch detail on foil													
9.	No. of tab/ Blister													
10.	Proper cutting of Blister													
11.	Leak test (Bi-Hourly)													
12.	Proper gluing of carton													
13.	No. of blister in one printed inner carton													
14.	No. of blister in one printed outer carton													
15.	Batch detail on printed inner/outer carton													
16.	Seal the outer carton with cello tape													
17.	No. of outer carton in one shipper													
18.	Batch details on shipper label													
19.	Pasting of BOPP tape													
Checked by (IPQA)														

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

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

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

S.No.	**In process checks**	**Date**												
		Time												
1.	Temp.													
2.	RH													
3.	Forming roller Temp.													
4.	Sealing roller Temp.													
5.	Check working of NFD by removing one tablet from each track													
6.	Tab. with foreign / black particle													
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19.	Pasting of BOPP tape													
Checked by (IPQA)														

Attach additional sheet if required….

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

	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BPR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 19 of 22
Batch No.:	**Batch Size:**	**Supersedes No.:**

6.0 SHIPPER WEIGHING RECORD:

Weight limit for filled shipper: _____ Kg to _____Kg

Shipper No.	Gross wt. In Kg.	Weighing done by	Shipper No.	Gross wt. In Kg.	Weighing done by
1.			26.		
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.					
25.					
Min. Shipper Weight:			**Max. Shipper Weight:**		
Checked By (Production Supervisor)			**Verify By (IPQA)**		

	Prepared By	Checked By	Approved By
Signature			
Date			

Product Code:	**BPR No.:**	
Product Name: Aceclofenac & Thiocolchicoside Tablets	**Generic Name:** Aceclofenac & Thiocolchicoside Tablets	
Document No.:	**Effective Date:**	**Page No.:** 20 of 22
Batch No.:	**Batch Size:**	**Supersedes No.:**

Loose Shipper No.:_____

7.0 RECONCILIATION OF PACKING MATERIAL:

S.No.	Material	Printed Aluminum foil	Base foil	Inner Cartons	Outer Cartons	Shippers
1.	Std. Qty.					
2.	Quantity Issued					
3.	Extra Qty. issued					
4.	Qty. used					
5.	Qty. returned (attach MRN)					
6.	Qty. destroyed after coding					
7.	Qty destroyed after pkg.					
8.	Total qty. destroyed					
9.	Qty. destroyed by					
Checked by Prod. (Sign/Date)						
Verified by IPQA (Sign/Date)						
10.	Remarks					

8.0 FINISH PRODUCT SAMPLING AND QUALITY CONTROL APPROVAL:

Production person shall raise the sample request and provide to IPQA for sampling. IPQA shall perform sampling as per respective SOP and sent to QC.

Requisition raised By (Packing Supervisor): _____ Sampled By (IPQA): _____

Sampling Details:

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

	Prepared By	Checked By	Approved By
Signature			
Date			

9.0 FINISHED GOODS TRANSFER TO FG STORES:

Transfer finished goods to FG Stores. Through transfer ticket & attach a copy of T.T. to BPR

Date: _____

Total No. of shippers packed	
Unit per shipper	
No. of Blister per Carton	
Qty of Tablets 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 Tablets 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:

$$\text{Yield} = \frac{\text{Total Quantity Packed (6) + Partial}}{\text{Batch size}} \times 100$$

= _____ x 100

= _____ % (NLT 97.0 %)

Remark: ……

……

_____ _____

(Packing Superviser) **(IPQA)**

	Prepared By	Checked By	Approved By
Signature			
Date			

11.0 DEVIATION APPROVAL:

Deviation No.	**Reason for deviation**

12.0 REVIEW OF BPR: **Date: _____**

Particulars	**Status**	**Checked By QA**
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 reports		
TR of Finished Product Pack		
COA of Finished Product		
FG Goods Transfer Note		
Final Dispatch Note		
Destruction and approvals		
Deviation and its Justification		
Reconciliation and Yields		

13.0 DISPATCH ADVICE:

(FOR THE USE OF QA ONLY)

Product: _____ **Batch No: _____**

Qty. Released: _____ **A.R. No: _____**

Released Date: _____

The BPR has been reviewed and the above batch is released for DISPATCH.

Signature of QA Manager/Designee: ***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			