| | | |
|---|---|---|
|  | PHARMA DEVILS<br>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 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

***(BLISTER PACKING)***

| | |
|---|---|
| **Location:** | |
| **Block:** Production Tablets (PT) | |
| **Label Claim:** | **Each film coated tablet contains:**<br>Aceclofenac IP …… 100 mg<br>Paracetamol IP ……. 325 mg<br>Serratiopeptidase IP ……. 15 mg<br>(30,000 enzymatic units of Serratiopeptidase as enteric coated granules)<br>Excipients ……. q.s.<br>**Colour:** Sunset Yellow FCF & Titanium Dioxide IP |
| **Mfg. Lic. No.:** | |
| **Product Lic. No.:** | NA |
| **Self-Life:** | 24 months |
| **Pack Style:** | 10x10 Tablets |
| **Country Name:** | Domestic |
| **Change Control No.:** | NA |
| **Mfg. Date:** | |
| **Exp. Date:** | |
| **BMR ISSUED No.:** | |
| **MRP:** | |

| **Issued By Stamp & Sign.** |
|---|
| |

| Responsibility | Name | Designation | Sign | Date |
|---|---|---|---|---|
| **Prepared By** | | | | |
| **Checked By** | | | | |
| **Approved By** | | | | |

**BATCH MANUFACTURING RECORD**

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## 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** | | | |

PHARMA DEVILS

PRODUCTION DEPARTMENT

**BATCH MANUFACTURING RECORD**

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**2. DISPENSING OF PACKING MATERIALS:** **Date:** _____

**2.1Instructions:**

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 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 = 152 mm | 4.00 Kg | | | | | | |
| 2 | **Base Foil-** 0.25mm, Clear transparent PVC film, Foil Width = 156 mm | 22.00 Kg | | | | | | |
| 3 | **Carton -** Dim: 76 X 70 X 56 mm **(10x10 Tabs.)** | 1000 Nos. | | | | | | |
| 4 | **5 PLY CORRUGATED BOX-** Dim (OD): 465(L) x 435 (W) x 255 (H) mm, **(144 Cartons per box 6x6x4)** Mkt.by address is printed in corr. box. Plain Corr. Box. | 07 Nos. | | | | | | |
| 5 | **BOPP TAPE -** BOPP Pre Printed 48 mm x 65 mtrs. | 01 Nos. | | | | | | |

**Note:** @ Calculate the materials as per required Qty.

**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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| **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 = 152 mm | 4.00 Kg | | | | | | |
| 2 | **Base Foil-** 0.25mm, Clear transparent PVC film, Foil Width = 156 mm | 22.00 Kg | | | | | | |
| 3 | **Carton -** Dim: 76 X 70 X 56 mm **(10x10 Tabs.)** | 1000 Nos. | | | | | | |
| 4 | **5 PLY CORRUGATED BOX-** Dim (OD): 465(L) x 435 (W) x 255 (H) mm, **(144 Cartons per box 6x6x4)** Mkt.by address is printed in corr. box. Plain Corr. Box. | 07 Nos. | | | | | | |
| 5 | **BOPP TAPE -** BOPP Pre Printed 48 mm x 65 mtrs. | 01 Nos. | | | | | | |

**Note:** @ Calculate the materials as per required Qty.

**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. | **Blister:** | | | | |
| | Blister coding details | B.No.:<br>M.R.P.Rs.:<br>MFG.<br>EXP. INCL.OF ALL TAXES | | | |
| **B.** | **Secondary Packing:** | | | | |
| 1. | **Carton** | Printed | **Carton details:** 10x10 Tablets | | |
| | Outer Carton coding details | Batch No.:<br>Mfg. Date:<br>Exp. Date:<br>MRP Rs.:<br>(Incl. of all Taxes)<br>Per 10 Tablets | | | |
| **C.** | **Tertiary Packing** | | | | |
| 1. | **5 ply Shipper** | 5 ply printed Shipper | | | |
| | Shipper details | 144 cartons in one 5 ply Shipper | | | |
| | Shipper coding details | APFLAM-SP TABLETS<br>B.No.:<br>MFG.:<br>EXP.:<br>Qty. 144 X 10X10 TABS. | | | |
| | Sealing of Shipper/BOPP Tape | Printed BOPP Tape in “H” type on top and bottom. | | | |

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |

| | | |
|---|---|---|
| **Product Code:** | | **BMR No.:** |
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### 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 2x10 tablets using 152 mm printed aluminum foil & 156 mm base foil on 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.
- 10x10 tablets such inspected blisters should be packed inside each printed carton. The carton should be duly overprinted with the respective batch legend.
- 144 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 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** | | | |

| | | |
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**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** | **Carton** | **Shipper** |
|---|---|---|---|---|---|
| | **Details on PM (for example)** | **Actual details** | | | |
| 1 | | | | | |
| 2 | Batch No.: | | | | |
| 3 | Mfg. Date: | | | | |
| 4 | Exp. Date: | | | | |
| 5 | M.R.P.:<br>(Incl. of all taxes)<br>Per 10 Tablets | | | | |
| 6 | Qty. 144x10x10 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 | 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 BLISTERING:

### 4.1 Machine Setting:

1. Take line clearance from IPQA.

| **Line clearance certificate for area and equipments:** | | | |
|---|---|---|---|
| **Area** | | **Equipment** | **Blister 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.

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |

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 Tablets containers.
10. Load the hopper with Tablets to be stripped.
11. Operate the 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 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** | To | To | To | To |
| 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 | | | | |
| **Checked by** | | | | |
| **Production/packing** | | | | |
| **IPQA** | | | | |

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**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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | 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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | Pasting of BOPP tape | | | | | | | | | | | | | |
| **Checked by (Production)** | | | | | | | | | | | | | | |

| | **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.:** 15 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | Pasting of BOPP tape | | | | | | | | | | | | | |
| **Checked by (Production)** | | | | | | | | | | | | | | |

| | **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.:** 16 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | Pasting of BOPP tape | | | | | | | | | | | | | |
| **Checked by (Production)** | | | | | | | | | | | | | | |

Attach 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 |
| **Document No.:** | **Effective Date:** | **Page No.:** 17 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | Pasting of BOPP tape | | | | | | | | | | | | | |
| **Checked by (IPQA)** | | | | | | | | | | | | | | |

| | **Prepared By** | **Checked By** | **Approved By** |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |

| | | |
|---|---|---|
|  | PHARMA DEVILS<br>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 24 |
| **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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | Pasting of BOPP tape | | | | | | | | | | | | | |
| **Checked by (IPQA)** | | | | | | | | | | | | | | |

| | **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.:** 19 of 24 |
| **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 temperature | | | | | | | | | | | | | |
| 4. | Sealing roller Temperature | | | | | | | | | | | | | |
| 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 carton | | | | | | | | | | | | | |
| 14. | Batch detail on printed carton | | | | | | | | | | | | | |
| 15. | Seal the carton with cello tape | | | | | | | | | | | | | |
| 16. | No. of carton in one shipper | | | | | | | | | | | | | |
| 17. | Batch details on shipper label | | | | | | | | | | | | | |
| 18. | 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:** | | **BMR No.:** |
| **Product Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets | | **Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets |
| **Document No.:** | **Effective Date:** | **Page No.:** 20 of 24 |
| **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. | | | 25. | | |
| 2. | | | 26. | | |
| 3. | | | 27. | | |
| 4. | | | 28. | | |
| 5. | | | 29. | | |
| 6. | | | 30. | | |
| 7. | | | 31. | | |
| 8. | | | 32. | | |
| 9. | | | 33. | | |
| 10. | | | 34. | | |
| 11. | | | 35. | | |
| 12. | | | 36. | | |
| 13. | | | 37. | | |
| 14. | | | 38. | | |
| 15. | | | 39. | | |
| 16. | | | 40. | | |
| 17. | | | 41. | | |
| 18. | | | 42. | | |
| 19. | | | 43. | | |
| 20. | | | 44. | | |
| 21. | | | 45. | | |
| 22. | | | 46. | | |
| 23. | | | 47 | | |
| 24. | | | 48. | | |
| **Min. Shipper Weight:** | | | **Max. Shipper Weight:** | | |
| **Checked By (Production Supervisor)** | | | **Verify By (IPQA)** | | |
| | | | | | |

| | 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.:** 21 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Loose Shipper No.:_____**

**7.0 RECONCILIATION OF PACKING MATERIAL:**

| S.No. | Material | Printed Aluminum foil | Base foil | 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 | | | | |
| 10. | **Checked by Prod. (Sign/Date)** | | | | |
| 11. | **Verified by IPQA (Sign/Date)** | | | | |
| 12. | 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 sample | | |

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |

| | | |
|---|---|---|
| **Product Code:** | | **BMR No.:** |
| **Product Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets | | **Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets |
| **Document No.:** | **Effective Date:** | **Page No.:** 22 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**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** | |

**10.0BATCH RECONCILIATION:**

| S.No. | Particulars | In Kg | In No. |
|---|---|---|---|
| **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:**

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** | | | |

| | | |
|---|---|---|
| **Product Code:** | | **BMR No.:** |
| **Product Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets | | **Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets |
| **Document No.:** | **Effective Date:** | **Page No.:** 23 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**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:***

| | **Prepared By** | **Checked By** | **Approved By** |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |

| | | |
|---|---|---|
| **Product Code:** | | **BMR No.:** |
| **Product Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets | | **Generic Name:** Aceclofenac, Paracetamol & Serratiopeptidase Tablets |
| **Document No.:** | **Effective Date:** | **Page No.:** 24 of 24 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**14.0 HISTORY SHEET:**

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

| | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Signature** | | | |
| **Date** | | | |