PHARMA DEVILS

PRODUCTION DEPARTMENT

# BATCH MANUFACTURING RECORD

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 1 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

| | |
|---|---|
| **Label Claim:** | Each film coated tablet contains:<br>Aceclofenac IP …….. 100 mg<br>Paracetamol IP ……325 mg<br>**Colour:** Sunset Yellow FCF & Titanium Dioxide IP |
| **Mfg. Lic. No.:** | |
| **Product Lic. No.:** | **NA** |
| **Self-Life:** | 24 Months |
| **MFR No.:** | |
| **Mfg. Date:** | |
| **Exp. Date:** | |
| **BMR Issued No.:** | |
| **Party:** | **MAC** |

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

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

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## 1.0 MASTER FORMULA:

### BILL OF RAW MATERIALS

| S.No. | Ingredients | Spec. | Qty. in mg Per Tablet | Overages % | Std. Qty. for 2.0 Lac. in Kg |
|---|---|---|---|---|---|
| **Raw Material for Dry Mixing** | | | | | |
| **Active Ingredients-** | | | | | |
| 1. | Aceclofenac | IP | 100.00 | ---- | 20.00# |
| 2. | Paracetamol | IP | 325.00 | ---- | 65.00# |
| **Inactive Ingredients-** | | | | | |
| 3. | Starch | IP | 115.00 | ---- | 23.00 |
| 4. | Microcrystalline Cellulose (MCCP) | IP | 58.00 | ---- | 11.60 |
| 5. | Lactose | IP | 50.00 | ---- | 10.00 |
| 6. | Cross Carmelose Sodium | IP | 10.00 | ---- | 2.00 |
| **Raw Material for Binder Preparation-** | | | | | |
| 7. | Starch for paste | IP | 20.00 | ---- | 4.00 |
| 8. | PVPK-30 | IP | 5.00 | ---- | 1.00 |
| 9. | Purified Water | IP | QS | ---- | QS |
| **Raw Material for Lubrication-** | | | | | |
| 10. | Talcum | IP | 5.00 | ---- | 1.00 |
| 11. | Sodium Starch Glycolate | IP | 15.00 | ---- | 3.00 |
| 12. | Colloidal Silicon Dioxide | IP | 3.00 | ---- | 0.60 |
| 13. | Magnesium Stearate | IP | 9.00 | ---- | 1.80 |
| | **Weight of Uncoated Tablets** | | **715.00 mg** | | **143.00 Kg** |
| **Coating-** | | | | | |
| 14. | Sunset Yellow Redimix (Mediicoatt -HOH (SYP10805) | IH | 17.00 | ---- | 3.40 |
| 15. | Purified water | IP | QS | ---- | QS |
| | **Weight of Coated Tablets** | | **732.00 mg** | | **146.40 Kg** |

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

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

| | | |
|---|---|---|
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## CALCULATION SHEET

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

**Note:** If assay of API is above 99.0% calculation not required.

**Part A: To be calculated when single AR No.:_____**
**Assay on dried basis: _____ LOD: _____**

**PART A:** To be calculated when single A.R. No of **Aceclofenac IP** is to be used:
If calculated quantity is less than std. qty. then dispensed std. Qty.

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

| A.R. No. of **Aceclofenac IP** | Assay on as such basis **(A1)** | Actual quantity of this A.R. No. to be dispensed = |
|---|---|---|
| | ----------% | $\frac{20.00 \#\text{x } 100}{\text{A1}}$ = ----------Kg |

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

| A.R. No. of **Aceclofenac IP** | Assay on as such basis (A1) | Actual quantity Available (b1) (Kg) | Qty. on 100 % assay basis = (b1) x (a1) ---------- Kg 100 | Remaining qty. to be dispensed (e1) = Std. qty. -(c1) |
|---|---|---|---|---|
| | | | | (e1) = 20.00# -_____<br>= _____ Kg |
| | | | | |
| | | | | |
| | | | | |
| TOTAL (Kg) --- | | _____ | (c1)=_____ | |

Assay of next AR No. ---------- (Assay on as such basis) (f1) = _____%

Actual quantity of this AR No. to be dispensed (g1) = $\frac{(e1) \text{ x } 100}{(f1)}$ =----------Kg

Therefore total quantity of **Aceclofenac IP** to be dispensed = (b1) + (g1) =_____Kg

**Assay calculation:**

| | | |
|---|---|---|
| **Sign/ Date** | | |
| **Department** | **Done by (Production)** | **Checked by (QA)** |

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

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## CALCULATION SHEET

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

**Note:** If assay of API is above 99.0% calculation not required.

**Part A: To be calculated when single AR No.: _____**
**Assay on dried basis: _____ LOD: _____**

**PART A:** To be calculated when single A.R. No of **Paracetamol IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

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

| A.R. No. of **Paracetamol IP** | Assay on as such basis **(A1)** | Actual quantity of this A.R. No. to be dispensed = |
|---|---|---|
| | ----------% | $\frac{65.00\# \text{ x } 100}{A1}$ = ----------Kg |

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

| A.R. No. of **Paracetamol IP** | Assay on as such basis (A1) | Actual quantity Available (b1) (Kg) | Qty. on 100 % assay basis = (b1) x (a1) / 100 Kg | Remaining qty. to be dispensed (e1) = Std. qty. -(c1) |
|---|---|---|---|---|
| | | | | (e1) = 65.00# -_____ =_____Kg |
| | | | | |
| | | | | |
| | | | | |
| TOTAL (Kg) --- | | _____ | (c1)=_____ | |

Assay of next AR No. ---------- (Assay on as such basis) (f1) = _____%

Actual quantity of this AR no to be dispensed (g1) = $\frac{(e1) \text{ x } 100}{(f1)}$ =----------Kg

Therefore total quantity of **Paracetamol IP** to be dispensed = (b1) + (g1) =_____Kg

**Assay calculation:**

| | | |
|---|---|---|
| **Sign/ Date** | | |
| **Department** | **Done by (Production)** | **Checked by (QA)** |

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

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**2.0 GENERAL INSTRUCTIONS:**

- Current version of SOPs should be referred during operation.
- Dispensed raw material/bulk blend/ compressed tablets should be manufactured and stored at temperature not exceeding 27°C and RH NMT 55%
- In all the processing activities, nose mask, hand gloves, secondary gown etc. shall be wearied by the personnel.
- Attach all dispensing tags and cleaning status labels with BMR.
- Clean the equipment's after use as per the standard operating procedure.
- The Blend should be compressed within 15 days.
- The compressed tablets should be packed within 30 days.

**2.1 Line clearance of Dispensing:**

Check the instructions given below and note the observation as Yes, NO or NA.

| S.No. | Instructions | Yes/No/NA |
|---|---|---|
| 1. | Is dispensing area clean and free from any materials of previous batches? | |
| 2. | Whether balance is calibrated and have status label. | |
| 3. | Scoops to be used for dispensing are clean. | |
| 4. | LAF properly working and dispensing booth clean. | |
| 5. | Air differential pressure, temperature and humidity with in limit (if applicable)<br>Temp. ---------- ºC (NMT 27ºC), RH----------% (NMT 55.0%), DP…….. (0.5to1.5 P or in mm of $H_2O$) | |
| 6. | Material shall be least exposed to atmosphere. | |
| 7. | Ensure proper gowning before entering to the dispensing area, suitable nose mask and surgical gloves shall be used while handling the material. | |

| | | | |
|---|---|---|---|
| **Previous product name**: | | **Batch No.:** | |
| **Differential pressure across RLAF and Room:** | | (Limit(Between 5 to 15 Pascal) | |
| **Checked By (Production):**<br>**Sign & Date:** | | **Verified By (IPQA):**<br>**Sign & Date:** | |

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

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

| S. No. | Ingredients | Std. Qty. In Kg | Issued Qty. in Kg | A.R. No. | Weight in Kg | | | Wt. By Store | Ckd. By | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Gross | Tare | Net | | Prod. | QA |
| **Raw Material for Dry Mixing-** | | | | | | | | | | |
| **Active Ingredients-** | | | | | | | | | | |
| 1. | Aceclofenac IP | 20.00# | | | | | | | | |
| 2. | Paracetamol IP | 65.00# | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | |
| 3. | Starch IP | 23.00 | | | | | | | | |
| 4. | Microcrystalline Cellulose (MCCP) IP | 11.60 | | | | | | | | |
| 5. | Lactose IP | 10.00 | | | | | | | | |
| 6. | Cross Carmelose Sodium IP | 2.00 | | | | | | | | |
| **Raw Material for Binder Preparation-** | | | | | | | | | | |
| 7. | Starch for paste IP | 4.00 | | | | | | | | |
| 8. | PVPK-30 IP | 1.00 | | | | | | | | |
| 9. | Purified Water IP | QS | | | | | | | | |
| **Raw Material for Lubrication-** | | | | | | | | | | |
| 10. | Talcum IP | 1.00 | | | | | | | | |
| 11. | Sodium Starch Glycolate IP | 3.00 | | | | | | | | |
| 12. | Colloidal Silicon Dioxide (Aerosil) IP | 0.60 | | | | | | | | |
| 13. | Magnesium Stearate IP | 1.80 | | | | | | | | |
| **Coating-** | | | | | | | | | | |
| 14. | Sunset Yellow Redimix (Mediicoatt -HOH (SYP10805) IH | 3.40 | | | | | | | | |
| 15. | Purified Water IP | QS | | | | | | | | |

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

**Dispensed by**
**Stores**
**Date**

**Checked by**
**Production**
**Date**

**Verified by**
**QA**
**Date**

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

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



## BILL OF RAW MATERIALS (STORE COPY)

| S. No. | Ingredients | Std. Qty. In Kg | Issued Qty. in Kg | A.R. No. | Weight in Kg | | | Wt. By Store | Chkd. By | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Gross | Tare | Net | | Prod. | QA |
| **Raw Material for Dry Mixing-** | | | | | | | | | | |
| **Active Ingredients-** | | | | | | | | | | |
| 1. | Aceclofenac IP | 20.00# | | | | | | | | |
| 2. | Paracetamol IP | 65.00# | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | |
| 3. | Starch IP | 23.00 | | | | | | | | |
| 4. | Microcrystalline Cellulose (MCCP) IP | 11.60 | | | | | | | | |
| 5. | Lactose IP | 10.00 | | | | | | | | |
| 6. | Cross Carmelose Sodium IP | 2.00 | | | | | | | | |
| **Raw Material for Binder Preparation-** | | | | | | | | | | |
| 7. | Starch for paste IP | 4.00 | | | | | | | | |
| 8. | PVPK-30 IP | 1.00 | | | | | | | | |
| 9. | Purified Water IP | QS | | | | | | | | |
| **Raw Material for Lubrication-** | | | | | | | | | | |
| 10. | Talcum IP | 1.00 | | | | | | | | |
| 11. | Sodium Starch Glycolate IP | 3.00 | | | | | | | | |
| 12. | Colloidal Silicon Dioxide (Aerosil) IP | 0.60 | | | | | | | | |
| 13. | Magnesium Stearate IP | 1.80 | | | | | | | | |
| **Coating-** | | | | | | | | | | |
| 14. | Sunset Yellow Redimix (Mediicoatt -HOH (SYP10805) IH | 3.40 | | | | | | | | |
| 15. | Purified Water IP | QS | | | | | | | | |

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

**Dispensed by**
**Stores**
**Date**

**Checked by**
**Production**
**Date**

**Verified by**
**QA**
**Date**

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

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**2.2 Weight verification sheet:**

**Balance ID:** _____

| S.No. | Ingredients | Spec. | UOM | Std. Quantity (Kg) | A.R. No. | Issued Qty. Gross wt. | Checked By (Production) | Verified by (IPQA) |
|---|---|---|---|---|---|---|---|---|
| **MATERIAL FOR GRANULATION:** | | | | | | | | |
| 1. | Aceclofenac | IP | | | | | | |
| 2. | Paracetamol | IP | | | | | | |
| 3. | Starch | IP | | | | | | |
| 4. | Microcrystalline Cellulose (MCCP) | IP | | | | | | |
| 5. | Lactose | IP | | | | | | |
| 6. | Cross Carmelose Sodium | IP | | | | | | |
| 7. | Starch for paste | IP | | | | | | |
| 8. | PVPK-30 | IP | | | | | | |
| **MATERIAL FOR LUBRICATION:** | | | | | | | | |
| 1. | Talcum | IP | | | | | | |
| 2. | Sodium Starch Glycolate | IP | | | | | | |
| 3. | Colloidal Silicon Dioxide | IP | | | | | | |
| 4 | Magnesium Stearate | IP | | | | | | |

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

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**3.0 GRANULATION PROCESS:** **Granulation started on:_____**

**3.1 Line clearance of Granulation:**

**Previous product:** _____, **Batch No.:**_____

**Cleaning done by:** _____, **Cleaned On:** _____,

| S.No. | Instructions | Yes/No/NA | Checked By (Production) | Verified By (IPQA) |
|---|---|---|---|---|
| 1 | Ensure that all equipment and utensils are clean and dry and status board affixes (Record as per Table-1). | | | |
| 2 | Is area free from any materials of previous batch? | | | |
| 3 | Whether the container, sieve, scoops and auxiliary items are cleaned. | | | |
| 4 | Check the room temperature. Temp……..ºC (NMT 27ºC) and Differential pressure ……. Pascal (0.5to 1.5 Pascal or in mm of $H_2O$). | | | |
| 5 | AHU system under operation or not. | | | |
| 6 | Calibration status of Equipment/instrument complies or not. | | | |
| 7 | Balance calibration status is OK or not. | | | |
| 8 | Whether swab/rinse sample testing report complies or not? (if applicable) | | | |
| 9 | Whether the wall, floor and light in satisfactory condition? | | | |

**EQUIPMENT STATUS CHECKLIST**

| S.No. | Name of Equipment | Equipment ID No. | Observation (Should be clean and dried) | Checked (Production) | Verified By (IPQA) |
|---|---|---|---|---|---|
| 1. | Sifter | | Yes/No | | |
| 2. | Rapid granulation mixture (RMG) | | Yes/No | | |
| 3. | Paste kettle | | Yes/No | | |
| 4. | Fluid bed drying (FBD) | | Yes/No | | |
| 5. | Multimill | | Yes/No | | |
| 6. | Octagonal blender | | Yes/No | | |
| 7. | Balance | | Yes/No | | |
| 8. | SS Scoop | | Yes/No | | |

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

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**3.2 Sifting:** Sift separately the following material and collect in poly bags/containers. Check sieve integrity before and after use.

**SIFTING OF GRANULATION MATERIALS**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Aceclofenac | | 40 | | | | | | |
| Paracetamol | | 16 | | | | | | |
| Starch | | 40 | | | | | | |
| Microcrystalline Cellulose (MCCP) | | 40 | | | | | | |
| Lactose | | 40 | | | | | | |
| Cross Carmelose Sodium | | 40 | | | | | | |
| Starch for paste | | 40 | | | | | | |
| PVPK-30 | | 40 | | | | | | |

**SIFTING OF BLENDING MATERIAL/ LUBRICANTS**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Talcum | | 40 | | | | | | |
| Sodium Starch Glycolate | | 40 | | | | | | |
| Colloidal Silicon Dioxide | | 40 | | | | | | |
| Magnesium Stearate | | 40 | | | | | | |

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

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**3.3 MANUFACTURING PROCESS:**

| Step No. | Manufacturing Instruction | Eq. ID. No. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| **3.3.1** | **Binder preparation:** | | | | | |
| | Prepare paste by taking (____Lts.) of hot **Purified water** in SS jacketed paste kettle adds **PVPK-30** (_____Kg) and dissolved completely. Again in another SS. container take (___Lts.) **o**f **Purified Water** now add **Starch** (____Kg) and mix it properly. Then add **Starch paste** in paste kettle which contain **PVPK-30** and mix properly. | | | | | |
| **3.3.2** | **Dry Mixing:** | | | | | |
| | Load **Paracetamol** (____#Kg)**, Aceclofenac** (____# Kg), **Starch** (____Kg), **Microcrystalline Cellulose** (_____Kg), **Lactose** (____Kg) and **Cross Carmelose Sodium** (____Kg) in RMG and run the impeller at slow speed for 20 minutes. | | | | | |
| **3.3.3** | **Wet granulation:** | | | | | |
| | Start the impeller of RMG at slow speed and add the binder paste slowly at the solution addition port. After complete addition of total quantity of binder solution, start the impeller and chopper at slow speed and mix for 5 minutes. | | | | | |
| | Again run the impeller and chopper at fast speed for 3 minutes and mix the materials properly. | | | | | |
| | Add additional purified water if required. | | | | | |
| | Additional purified water _____ Lts. | | | | | |
| | **Mentioned observation of process parameter in the table given below;** | | | | | |

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

| | | | |
|---|---|---|---|
| **3.3.4** | **Drying (FBD):** | | |

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

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|---|---|---|
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| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

| Step No. | Manufacturing Instruction | Eq. ID. No. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| | Dry the granules at 75°C to 80°C inlet temperature. Till 40°C to 45°C Outlet temperature is achieved by raking at 10 min. and then at 30 min. | | | | | |
| | Inlet air temperature: _____°C<br>Outlet temperature: _____°C<br>Integrity of FBD Bag (OK/Not OK) Before: _____ After : _____ | | | | | |
| | Shaking of Bag should be fixed after every 30 minutes for 1 minute. | | | | | |
| | Collect the granules from 5 different places of the bowl and check loss on drying. | | | | | |
| | Recommended LOD: (NMT 2.0 % w/w) LOD _____%w/w | | | | | |
| **3.3.5** | **Sizing /Milling:** | | | | | |
| | Sift the dried granules through Vibratory sifter fitted with16# Sieve. | | | | | |

| Before Use | After Use |
|---|---|
| Rusted : Yes / No | Rusted : Yes / No |
| Broken : Yes / No | Broken : Yes / No |
| Clean : Yes / No | Clean : Yes / No |

| | | | | | |
|---|---|---|---|---|---|
| Mill the oversize granules retained on sieve of vibratory sifter using multimill fitted with **2 mm** screen. With knife forward direction at medium speed. | | | | | |

| Before Use | After Use |
|---|---|
| Rusted : Yes / No | Rusted : Yes / No |
| Broken : Yes / No | Broken : Yes / No |
| Clean : Yes / No | Clean : Yes / No |

| | | | | | | |
|---|---|---|---|---|---|---|
| **3.3.6** | **Blending & Lubrication:** | | | | | |
| | Add **Talcum** (____Kg), **Sodium Starch Glycolate** (_____Kg) and **Collidal Silicon Dioxide** (____Kg) in blender with dried granules and mix it for 20 minutes. | | | | | |
| | Add **Magnesium Stearate** (_____Kg) in blender and mix for further for 5 minutes. | | | | | |

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

**3.4 SAMPLING OF BLEND:**

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of granulation process.

_____
**Checked By (Production)**

- IPQA shall review batch card and visually inspect of the material for physical Appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
**Verified By (IPQA)**

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

**3.5 BLEND WEIGHING RECORD:**

| Container No. | Gross wt. (Kg) | Tare wt. (Kg) | Net wt. (Kg) | Done By/ Date | Ckd By/ Date |
|---|---|---|---|---|---|
| **1/** | | | | | |
| **2/** | | | | | |
| **3/** | | | | | |
| **4/** | | | | | |
| **5/** | | | | | |
| **6/** | | | | | |
| **7/** | | | | | |
| **8/** | | | | | |
| **9/** | | | | | |
| **10/** | | | | | |
| **11/** | | | | | |
| **12/** | | | | | |
| **13/** | | | | | |
| **Total** | | | | | |

**4.0 YIELD RECONCILIATION:**

A = Theoretical batch size = …….. Kg / …….... tablets

B = Actual quantity of blend = …….. Kg

C = Samples = ….. ……..

D = Yield = B / A x100 **(Note: - Granulation yield NLT 99.00%)** **Loss Quantity: _____**

**Checked by (Production):**
**Date:**

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

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 14 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**5.0 COMPRESSION:** **Started At: _____**

**5.1 Line clearance:**

**Previous product: _____, Batch No.:_____**

| S.No. | Instructions | Observations | Checked (Production) | Verified By (IPQA) |
|---|---|---|---|---|
| 1. | Is area free from any materials of previous batch? | Yes/No | | |
| 2. | Whether area and utensils cleaned? | Yes/No | | |
| 3. | Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed?<br>Equipment ID No.: _____ | Yes/No | | |
| 4. | Check the room temperature, RH and differential pressure =……ºC (NMT 27ºC), RH=…… % (NMT 55%).<br>Differential Pressure……..mm of $H_2O$ (0.5to 1.5 mm of $H_2O$) | OK/NOT OK | | |
| 5. | All the equipment shall be used during process are cleaned. | Yes/No | | |

**5.2 Process:**

| Compression Instruction | | Observations | Checked (Production) | Verified By (IPQA) |
|---|---|---|---|---|
| 5.2.1 | Collect the approved granules from the granules store for compression. | | | |
| 5.2.2 | Ensure the correct punch set is assembled in the compression machine. | | | |
| 5.2.3 | Ensure the availability and online filling of Batch Document. | | | |
| 5.2.4 | Collect the tablets as per total no. of punches from each side and check them individually for any damages on upper and Lower Surface before continuing the operation of compression machine. Check and Record the observation and details of die & punch in the table A: **Die and punch verification** | | | |
| 5.2.5 | If compression time is less than one hour, minimum Three observations shall be recorded. | | | |
| 5.2.6 | Ensure that all the data of actual processing are entered in log book of individual equipment/Instrument. | | | |
| 5.2.7 | Collect the compressed tablets in polythene lined container. Weight the containers and record the weights in table given below, label them properly and transfer them to bulk store (Container number should be given as 1/x, 2/x…… where x is the total number of containers | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 15 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Table: A-Die and punch verification**

| **Punch Specification** | | | |
|---|---|---|---|
| Punch Details | Type | D Tooling _____ Stations. | |
| | Upper Punches | 17.8 x 8.0 mm (Caplet shape with break line) | Dies: 17.8 x 8.0 mm |
| | Lower Punches | 17.8 x 8.0 mm (Caplet shape with plain) | |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Upper Punches | Punch No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| | Punch No. | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| | Punch No | 47 | 48 | 49 | 50 | 51 | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| Lower Punches | Punch No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| | Punch No. | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| | Punch No. | 47 | 48 | 49 | 50 | 51 | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |

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

**5.3 IN PROCESS CHECKS:**

**5.3.1 Specification:**

| S.No. | Parameters | Requirement | Frequency of Monitoring |
|---|---|---|---|
| 1.0 | Description | Caplet shape with one side break line | At the start of machine |
| 2.0 | Weight of 20 tablets | 14.3 gm ± 3% | Every 30 Minutes |
| 3.0 | Avg. weight | 715 mg ± 5% | Every 2 Hours |
| 4.0 | Uniformity of weight | 715 mg ± 5% | Every 2 Hours |
| 5.0 | Thickness | 5.20 ± 0.2 mm | Every 2 Hours |
| 6.0 | Hardness | NLT 5.0 $Kg/cm^2$ | Every 2 Hours |
| 7.0 | Friability | NMT 1% | Every 2 Hours |
| 8.0 | DT | NMT 15 min. | Every 2 Hours |
| 9.0 | Length and Width | 17.8 mm x 8.0mm ± 0.2 mm | At the start of machine |
| 10.0 | Appearance | White colour caplet shape tablets | Every 2 Hours |
| 11.0 | Temperature | NMT 27 ° C | Every 2 Hours |
| 12.0 | RH | NMT 55% | Every 2 Hours |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 16 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**5.4 In-process observation sheet for production:**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description:** | | | | | | | | | | | |
| **Length X Width:** | | | | | | | | | | | |
| **Wt. of 20 Tabs.** (14.3 gm ± 3%) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs.** (14.3 gm ± 3%) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness** (5.20 ± 0.2 mm) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability** (NMT 1 %) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness** ($NLT\ 5.0\ Kg/cm^2$) | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT** (NMT 15 min.) | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance:** White colour caplet shape tablet with one side break line. | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Temperature (NMT 27°C)** | ---- | | | | | | | | | | |
| **RH (NMT 55%)** | ---- | | | | | | | | | | |
| **Done By** | | | | | | | | | | | |

**Attached additional sheet if required…**

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 17 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**WEIGHT VARIATION OF 20 TABLETS**

| | | | |
|---|---|---|---|
| **Average Weight of Tablet:** | | **Frequency** | **Every 2 hours.** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Date:** | | | | | | | | |
| **Time:** | | | | | | | | |
| **1.** | | | | | | | | |
| **2.** | | | | | | | | |
| **3.** | | | | | | | | |
| **4.** | | | | | | | | |
| **5.** | | | | | | | | |
| **6.** | | | | | | | | |
| **7.** | | | | | | | | |
| **8.** | | | | | | | | |
| **9.** | | | | | | | | |
| **10.** | | | | | | | | |
| **11.** | | | | | | | | |
| **12.** | | | | | | | | |
| **13.** | | | | | | | | |
| **14.** | | | | | | | | |
| **15.** | | | | | | | | |
| **16.** | | | | | | | | |
| **17.** | | | | | | | | |
| **18.** | | | | | | | | |
| **19.** | | | | | | | | |
| **20.** | | | | | | | | |
| **Avg. wt.** | | | | | | | | |
| **Min. wt.** | | | | | | | | |
| **Max. wt.** | | | | | | | | |
| **Checked by** | | | | | | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 18 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

Attached additional sheet if required…….

**5.5 In-process observation sheet for IPQA:**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description:** | | | | | | | | | | | |
| **Length X Width:** | | | | | | | | | | | |
| **Wt. of 20 Tabs.** (14.3 gm ± 3%) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs.** (14.3 gm ± 3%) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness** (5.20 ± 0.2 mm) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability** (NMT 1 %) | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness** ($NLT\ 5.0\ Kg/cm^2$) | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT** (NMT 15 min.) | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance:** White colour caplet shape tablet with one side break line. | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Temperature (NMT 27°C)** | ---- | | | | | | | | | | |
| **RH (NMT 55%)** | ---- | | | | | | | | | | |
| **Done By** | | | | | | | | | | | |

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 19 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Attached additional sheet if required……..**

**WEIGHT VARIATION OF 20 TABLETS**

| | | | |
|---|---|---|---|
| **Average Weight of Tablet:** | | **Frequency** | **Every 2 hours.** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Date:** | | | | | | | | |
| **Time:** | | | | | | | | |
| **1.** | | | | | | | | |
| **2.** | | | | | | | | |
| **3.** | | | | | | | | |
| **4.** | | | | | | | | |
| **5.** | | | | | | | | |
| **6.** | | | | | | | | |
| **7.** | | | | | | | | |
| **8.** | | | | | | | | |
| **9.** | | | | | | | | |
| **10.** | | | | | | | | |
| **11.** | | | | | | | | |
| **12.** | | | | | | | | |
| **13.** | | | | | | | | |
| **14.** | | | | | | | | |
| **15.** | | | | | | | | |
| **16.** | | | | | | | | |
| **17.** | | | | | | | | |
| **18.** | | | | | | | | |
| **19.** | | | | | | | | |
| **20.** | | | | | | | | |
| **Avg. wt.** | | | | | | | | |
| **Min. wt.** | | | | | | | | |
| **Max. wt.** | | | | | | | | |
| **Checked by** | | | | | | | | |

Attached additional sheet if required……..

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 20 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**5.3 SAMPLING:**

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
**Checked By (Production)**

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
**Checked By (IPQA)**

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

**5.4 COMPRESSED TABLET WEIGHING RECORD:**

| Container No. | Gr. wt. | Tare wt. | Net wt. | Container No. | Gr. wt. | Tare wt. | Net wt. |
|---|---|---|---|---|---|---|---|
| **1/** | | | | **11/** | | | |
| **2/** | | | | **12/** | | | |
| **3/** | | | | **13/** | | | |
| **4/** | | | | **14/** | | | |
| **5/** | | | | **15/** | | | |
| **6/** | | | | **16/** | | | |
| **7/** | | | | **17/** | | | |
| **8/** | | | | **18/** | | | |
| **9/** | | | | **19/** | | | |
| **10/** | | | | **20/** | | | |
| **Total net weight of Tablets:** | | | | | | | |
| **Checked By (Sign & Date):** | | | | | | | |

**6.0 YIELD RECONCILIATION:**

- Average weight of tablets (A)=: mg
- Total weight of compressed tablets (B) = Kg.
- Quantity of compressed tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
- Samples (D)=
- Yield= $\frac{C + D}{\text{Actual batch size}}$ x 100= **(Yield NLT: 98.50%)**

| | |
|---|---|
| **Checked By (Production):** | **Verified By (IPQA):** |

**Loss Qty.: _____ Kg.**

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 21 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**7.0 COATING:** **Date:**_____

**7.1 Line clearance:**

**Previous product:** _____, **Batch No.:**_____

| S.No. | Instructions | Observations | Checked By | |
|---|---|---|---|---|
| | | | Production | QA |
| 1. | Ensure that Colloid mill, SS Tank, 100# sieve, coating pan, Spray gun and scoop are cleaned. | Yes/NA/NO | | |
| 2. | Is area free from any materials of previous batch? | Yes/NA/NO | | |
| 3. | Whether the scoops and auxiliary items are cleaned. | Yes/NA/NO | | |
| 4. | Check the room temperature. Temp…..ºC(NMT 27ºC) & RH ……%(NMT 55%) | - | | |
| 5. | Whether the Auxiliary items are cleaned. | Yes/NA/NO | | |
| 6. | Whether the coating pan is cleaned and set as per SOP and have "CLEANED" label affixed. | Yes/NA/NO | | |
| 7. | Balance calibration status is OK or not. | Yes/NA/NO | | |
| 8. | Whether tablet approved or not? | Yes/NA/NO | | |

Differential pressure across RLAF and Room: ( Limit (Between 5to15 Pascal)

**Checked By:(Production):** **Verified By:(IP/QA)**

**Sign and Date:** **Sign and Date:**

**7.2 COATING PROCESS:**

Equipment ID to be used: _____ _____, Coating started on: _____

| | Instructions | Std. time (min) | Observed time | | Done By) (Sign/ Dt.) | Ckd. By (Sign/Dt.) | Remarks |
|---|---|---|---|---|---|---|---|
| | | | From | To | | | |
| **Solution preparation** | Pass the solution in homogenizer to uniform suspension to avoid inclusion of air bubbles. Filter the suspension through 200 # muslin cloth cover the prepared suspension in the vessel securely for use before coating. | - | | | | | |
| | Keep aside with lid cover. Ensure Coating solution should be free from air bubbles. | - | | | | | |
| | Cover the prepared solution in the vessel securely for use before coating with labels affixed on vessel mentioning batch details. | | | | | | |
| **Coating of Tablet** | Take sorted tablet in coating room | - | | | | | |
| | Fit the spray gun with 1.5 mm diameter nozzle and set the atomizing air pressure at 2.5-4.0 kg/cm$^2$. Start the exhaust system. | - | | | | | |
| | Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM 2-3) and pre warm the tabs to obtain the bed temperature (42 to 48ºC). | - | | | | | |
| | Start the spraying solution over the tablet and let them be dry immediately. | - | | | | | |

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | After drying unload the coating tablets in pre-tare Polybag lined drum with status label. | - | | | | | |
| | Check and record the physical parameters of coated | - | | | | | |

**7.3 COATING INPROCESS CHECKS: (Record the observation every half an hour)**

**Lot-I**

| **Parameter** | **Limit** | **Date** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Time** | | | | | | | | | | | |
| Pan Speed | 4 to 5 RPM | | | | | | | | | | | | |
| Inlet Air Temperature | 65to 75$^0$ C | | | | | | | | | | | | |
| Peristaltic Pump Speed | 16 RPM | | | | | | | | | | | | |
| Atomizing Air Pressure | 2.5 to 4.0Kg/cm$^2$ | | | | | | | | | | | | |
| Exhaust Air Temperature | 42 to 48 $^0$**C** | | | | | | | | | | | | |

**Lot-II**

| **Parameter** | **Limit** | **Date** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Time** | | | | | | | | | | | |
| Pan Speed | 4 to 5 RPM | | | | | | | | | | | | |
| Inlet Air Temperature | 65to 75$^0$ C | | | | | | | | | | | | |
| Peristaltic Pump Speed | 16 RPM | | | | | | | | | | | | |
| Atomizing Air Pressure | 2.5 to 4Kg/cm$^2$ | | | | | | | | | | | | |
| Exhaust Air Temperature | 42 to 48 $^0$**C** | | | | | | | | | | | | |

**Lot-III**

| **Parameter** | **Limit** | **Date** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Time** | | | | | | | | | | | |
| Pan Speed | 4 to 5 RPM | | | | | | | | | | | | |
| Inlet Air Temperature | 65to 75$^0$ C | | | | | | | | | | | | |
| Peristaltic Pump Speed | 16 RPM | | | | | | | | | | | | |
| Atomizing Air Pressure | 2.5 to 4.0Kg/cm$^2$ | | | | | | | | | | | | |
| Exhaust Air Temperature | 42 to 48 $^0$**C** | | | | | | | | | | | | |

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 23 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Lot-IV**

| **Parameter** | **Limit** | **Date** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Time** | | | | | | | | | | | |
| Pan Speed | 4 to 5 RPM | | | | | | | | | | | | |
| Inlet Air Temperature | 65to 75$^0$ C | | | | | | | | | | | | |
| Peristaltic Pump Speed | 16 RPM | | | | | | | | | | | | |
| Atomizing Air Pressure | 2.5 to 4.0Kg/cm$^2$ | | | | | | | | | | | | |
| Exhaust Air Temperature | 42 to 48 $^0$C | | | | | | | | | | | | |

**7.4 PARAMETERS AFTER COATING:** **Lot-I**

| **Tests** | **Specification** | **Prod. observation** | **IPQA observation** |
|---|---|---|---|
| Description | Orange color caplet shape tablets with one side break line. | | |
| Weight of 20 tablets | 14.64 gm ± 3% | | |
| Avg. weight | 732 mg ± 5% | | |
| Uniformity of wt. | 730 mg ± 5% | | |
| Thickness | 5.30 ± 0.2 mm | | |
| Disintegration | NMT 30 Minutes | | |
| **Checked by (Production):** | | **Checked By (IPQA):** | |

**Lot-II**

| **Tests** | **Specification** | **Prod. observation** | **IPQA observation** |
|---|---|---|---|
| Description | Orange colour caplet shape tablets with one side break line. | | |
| Weight of 20 tablets | 14.64 gm ± 3% | | |
| Avg. weight | 732 mg ± 5% | | |
| Uniformity of wt. | 730 mg ± 5% | | |
| Thickness | 5.30 ± 0.2 mm | | |
| Disintegration | NMT 30 Minutes | | |
| **Checked by (Production):** | | **Checked By (IPQA):** | |

**Lot-III**

| **Tests** | **Specification** | **Prod. observation** | **IPQA observation** |
|---|---|---|---|
| Description | Orange colour caplet shape tablets with one side break line. | | |
| Weight of 20 tablets | 14.64 gm ± 3% | | |
| Avg. weight | 732 mg ± 5% | | |
| Uniformity of wt. | 730 mg ± 5% | | |
| Thickness | 5.30 ± 0.2 mm | | |
| Disintegration | NMT 30 Minutes | | |
| **Checked by (Production):** | | **Checked By (IPQA):** | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 24 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Lot-IV**

| Tests | Specification | Prod. observation | IPQA observation |
|---|---|---|---|
| Description | Orange colour caplet shape tablets with one side break line. | | |
| Weight of 20 tablets | 14.64 gm ± 3% | | |
| Avg. weight | 732 mg ± 5% | | |
| Uniformity of wt. | 730 mg ± 5% | | |
| Thickness | 5.30 ± 0.2 mm | | |
| Disintegration | NMT 30 Minutes | | |

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

**7.5 SAMPLING:**

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
**Checked By (Production)**

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
**Checked By (IPQA)**

**7.6 WEIGHING RECORD OF COATED TABLETS:**

| Container No. | Gr. wt. | Tare wt. | Net wt. | Container No. | Gr. wt. | Tare wt. | Net wt. |
|---|---|---|---|---|---|---|---|
| **1/** | | | | **11/** | | | |
| **2/** | | | | **12/** | | | |
| **3/** | | | | **13/** | | | |
| **4/** | | | | **14/** | | | |
| **5/** | | | | **15/** | | | |
| **6/** | | | | **16/** | | | |
| **7/** | | | | **17/** | | | |
| **8/** | | | | **18/** | | | |
| **9/** | | | | **19/** | | | |
| **10/** | | | | **20/** | | | |
| **Total net weight of coated tablets:** | | | | | | | |
| **Checked By (Sign & Date):** | | | | | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** Aceclofenac & Paracetamol Tablets | **Generic Name:** | |
| **Document No.:** | **Effective Date:** | **Page No.:** 25 of 26 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**7.7 VISUAL INSPECTION OF TABLET:**

Date: _____

| Time Duration | | Quantity rejected | Done by |
|---|---|---|---|
| From | To | | |
| | | | |
| | | | |
| | | | |

Total weight of rejected tablets: _____ Good Tablet weight: _____

% Yield: _____

**Checked by (Production): _____,**
**(Sign & Date)**

**Verified by (IPQA): _____**
**(Sign & Date)**

**8.0 YIELD RECONCILIATION:**

- Average weight of tablets (A)=: mg
- Total weight of coated tablets (B) = Kg.
- Quantity of coated tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
- Samples (D)=
- Yield= $\frac{C + D}{\text{Actual batch size}}$ 100 = **(NLT 98.00%)**

| | |
|---|---|
| **Checked By (Production):** | **Verified By (IPQA):** |

**9.0 FINAL REVIEW OF BATCH CARD ON SHOP FLOOR:**

Production manager/Designee shall review the batch card will give his comment, if any.

_____
**Checked By (Prod. Mgr.)**

**10.0 ANY DEVIATION:**

| Deviation No. | Reason for deviation |
|---|---|
| | |

_____
**Checked By (Prod. Manager)**

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

**11.0 HISTORY SHEET:**

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

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