| | | |
|---|---|---|
| | PHARMA DEVILS<br>PRODUCTION DEPARTMENT | |
| **BATCH MANUFACTURING RECORD** | | |

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 1 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

| | |
|---|---|
| **Location:** | |
| **Block:** Production Tablets (PT) | |
| **Label Claim:** | **Each film coated tablet contains:**<br>Atorvastatin Calcium IP<br>Eq. to Atorvastatin ……..10mg<br>Excipients …….q.s.<br>**Colour:** Titanium Dioxide IP |
| **Mfg. Lic. No.:** | |
| **Product Lic. No.:** | **NA** |
| **Self-Life:** | 24 Months |
| **MFR No.:** | |
| **Mfg. Date:** | |
| **Exp. Date:** | |
| **BMR ISSUED No.:** | |

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

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 2 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**1.0 MASTER FORMULA:**

**BILL OF RAW MATERIALS**

| S. No | Ingredients | Spec. | Qty. In mg Per Tablet | Overages % | Qty. for 1 Lac. in kg |
|---|---|---|---|---|---|
| **Raw Material for Dry Mixing** | | | | | |
| **Active Ingredients-** | | | | | |
| 1. | Atorvastatin Calcium Eq. to Atorvastatin | IP | 10.41eq. to 10 mg | 5% | 1.093# |
| **Inactive Ingredients-** | | | | | |
| 2. | Lactose DC L 15 | IP | 91.00 | ----- | 9.10 |
| 3. | Microcrystalline Cellulose | IP | 22.50 | ----- | 2.25 |
| 4. | Sodium Lauryl Sulphate | IP | 3.00 | ----- | 0.30 |
| **Lubrications-** | | | | | |
| 5. | Magnesium Stearate | IP | 3.00 | ----- | 0.30 |
| 6. | Colloidal Silicon Dioxide (Aerosil) | IP | 2.00 | ----- | 0.20 |
| 7. | Cross Carmellose Sodium | IP | 6.00 | ----- | 0.60 |
| 8. | Sodium Lauryl Sulphate | IP | 6.00 | ----- | 0.60 |
| | **Weight of Uncoated Tablets** | | **143.91mg** | | **14.443Kg** |
| **Coating-** | | | | | |
| 9. | White Coat Redimix (Medicoat Uni WT335) | IH | 10.00 | ----- | 1.00 |
| 10. | Isopropyl Alcohol | IP | 100.00 | ----- | 10.00 Lts. |
| 11. | Methylene Chloride | IP | 50.00 | ----- | 5.00 Lts |
| | **Weight of coated Tablets** | | **153.91mg** | | **15.443Kg** |

**Note:** # Atorvastatin Calcium IP adds after calculation if assay below 95%.

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 3 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

## CALCULATION SHEET

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

**Note:** If assay of API is above 95.0% 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 **Atorvastatin Calcium IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

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

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

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

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

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

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

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

**Assay calculation:**

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

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 4 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**2.0 GENERAL INSTRUCTIONS:**

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

**2.1 Line clearance of Dispensing:**

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

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

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

**Differential pressure across RLAF and Room:**_____ (Limit(Between 5 to 15 Pascal)

| | | | |
|---|---|---|---|
| **Checked By (Production): Sign & Date:** | | **Verified By(IPQA): Sign & Date:** | |

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

## BATCH MANUFACTURING RECORD

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 5 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

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

| Sr. No. | Ingredients | Qty. for 1 Lac. In Kg | @ Req. Qty. in Kg | Issued Qty. in Kg | A.R. No. | Weight in Kg | | | Wt. By Store | Chkd. By | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Gross | Tare | Net | | Prod. | QA |
| **Raw Material for Dry Mixing-** | | | | | | | | | | | |
| **Active Ingredients-** | | | | | | | | | | | |
| 1. | Atorvastatin Calcium IP | 1.093# | | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | | |
| 2. | Lactose DCL 15 IP | 9.10 | | | | | | | | | |
| 3. | Microcrystalline Cellulose IP | 2.250 | | | | | | | | | |
| 4. | Sodium Lauryl Sulphate IP | 0.30 | | | | | | | | | |
| **Lubrications-** | | | | | | | | | | | |
| 5. | Magnesium Sterarate IP | 0.30 | | | | | | | | | |
| 6. | Colloidal Silicon Dioxide (Aerosil) IP | 0.20 | | | | | | | | | |
| 7. | Cross Carmellose Sodium IP | 0.60 | | | | | | | | | |
| 8. | Sodium Lauryl Sulphate IP | 0.60 | | | | | | | | | |
| **Coating-** | | | | | | | | | | | |
| 9. | White Coat Redimix (Medicoat Uni WT335) | 1.00 | | | | | | | | | |
| 10. | Isopropyl Alcohol | 10.00 Lts. | | | | | | | | | |
| 11. | Methylene Dichloride (MDC) IP | 5.00 Lts. | | | | | | | | | |

**Note:** # Atorvastatin Calcium IP adds after calculation if assay below 95%.

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

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

**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:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 6 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |



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

| Sr. No. | Ingredients | Qty. for 1 Lac. In Kg | @ Req. Qty. in Kg | Issued Qty. in Kg | A.R. No. | Weight in Kg | | | Wt. By Store | Chkd. By | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Gross | Tare | Net | | Prod. | QA |
| **Raw Material for Dry Mixing-** | | | | | | | | | | | |
| **Active Ingredients-** | | | | | | | | | | | |
| 1. | Atorvastatin Calcium IP | 1.093# | | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | | |
| 2. | Lactose DCL 15 IP | 9.10 | | | | | | | | | |
| 3. | Microcrystalline Cellulose IP | 2.250 | | | | | | | | | |
| 4. | Sodium Lauryl Sulphate IP | 0.30 | | | | | | | | | |
| **Lubrications-** | | | | | | | | | | | |
| 5. | Magnesium Sterarate IP | 0.30 | | | | | | | | | |
| 6. | Colloidal Silicon Dioxide (Aerosil) IP | 0.20 | | | | | | | | | |
| 7. | Cross Carmellose Sodium IP | 0.60 | | | | | | | | | |
| 8. | Sodium Lauryl Sulphate IP | 0.60 | | | | | | | | | |
| **Coating-** | | | | | | | | | | | |
| 9. | White Coat Redimix (Medicoat Uni WT335) | 1.00 | | | | | | | | | |
| 10. | Isopropyl Alcohol | 10.00 Lts. | | | | | | | | | |
| 11. | Methylene Dichloride (MDC) IP | 5.00 Lts. | | | | | | | | | |

**Note:** # Atorvastatin Calcium IP adds after calculation if assay below 95%.

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

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

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

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

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

**2.2 Weighing sheet:**

**Balance ID:** _____

| Sr. No. | Ingredients | Spec. | UOM | Std. Quantity (Kg) | A.R. No. | Issued Qty. | | | Checked By (Production) | Verified by (IPQA) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Gr. wt. | Tare wt. | Net wt. | | |
| **MATERIAL FOR DRY MIXING:** | | | | | | | | | | |
| 1. | Atorvastatin Calcium | IP | | | | | | | | |
| 2. | Lactose DC L15 | IP | | | | | | | | |
| 3. | Microcrystalline Cellulose | IP | | | | | | | | |
| 4. | Sodium Lauryl Sulphate | IP | | | | | | | | |
| **MATERIAL FOR LUBNRICATIONS:** | | | | | | | | | | |
| 5. | Magnesium Stearate | IP | | | | | | | | |
| 6. | Colloidal Silicon Dioxide | IP | | | | | | | | |
| 7. | Cross Carmellose Sodium | IP | | | | | | | | |
| 8. | Sodium Lauryl Sulphate | IP | | | | | | | | |

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

**3.1 Line clearance of Granulation:**

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

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

| Sr. 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? | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 8 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**EQUIPMENT STATUS CHECKLIST**

| Sr. No. | Name of Equipment | Equipment ID. No. | Observation (Should be clean and dried) | Checked (Production) | Verified By (IPQA) |
|---|---|---|---|---|---|
| 1. | Sifter | | Yes/No | | |
| 2. | Mass Mixture | | Yes/No | | |
| 3. | Octagonal blender | | Yes/No | | |
| 4. | Balance | | Yes/No | | |
| 5. | SS Scoop | | Yes/No | | |

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

**SIFTING OF MATERIALS FOR DRY MIXING**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Atorvastatin Calcium | | | | | | | | |
| Lactose DC L15 | | | | | | | | |
| Microcrystalline Cellulose | | | | | | | | |
| Sodium Lauryl Sulphate | | | | | | | | |

**SIFTING OF MATERIALS FOR LUBRICATIONS**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Magnesium Stearate | | | | | | | | |
| Colloidal Silicon Dioxide | | | | | | | | |
| Cross Carmellose Sodium | | | | | | | | |
| Sodium Lauryl Sulphate | | | | | | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 9 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**3.3 MANUFACTURING PROCESS:**

| Step No. | Manufacturing Instruction | Eq. ID. No. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| 3.3.1 | **Dry Mixing:** | | | | | |
| | Load **Atorvastatin Calcium (____#Kg), Lactose DCL 15 (____ Kg), Microcrystalline Cellulose (____Kg)** and **Sodium Lauryl Sulphate (____Kg)** in a mass mixer and run at slow speed for 10 minutes.<br>Collect the granules in a clean polybags and send it for slugging. | | | | | |

**3.3.2 Slugging of dry mix material:**

**Line clearance of compression M/C for slugging:** **Slugging Started At: _____**

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

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

| Sr. No. | Instructions | Yes/No/NA | Checked By (Production) | Verified By (IPQA) |
|---|---|---|---|---|
| 1 | Is area free from any materials of previous batch? | | | |
| 2 | Whether area and utensils cleaned? | | | |
| 3 | Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? Equipment ID. 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 $H_2O$) | | | |

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

| Punch Specification | | | |
|---|---|---|---|
| Punch Details | Type | B Tooling & ___ Station | |
| | Upper Punches | 11 mm | Dies : 11.1 mm |
| | Lower Punches | 11mm | |

**Note: Hardness of the tablets as per requirement and collect the slugged in a clean poly bags.**

| | | |
|---|---|---|
| 3.3.3 | **Milling & Sifting of slugged materials :** | |
| | Milling the slugged tablet through milt mill at 750 RPM through **0.5 mm** screen | |
| | Again pass the milled materials through **80#** sieve and then collected in cleaned poly bags. | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 10 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

| Step No. | Manufacturing Instruction | Eq. ID. No. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| **3.3.4** | **Lubrication:** | | | | | |
| | Load **Colloidal Silicon Dioxide (Aerosil)** (____Kg), **Sodium Lauryl Sulphate** (____Kg) and **Crosscarmellose Sodium** (____Kg) in blender with sifted granules from stage 3.3.3 and mix it for 10 minutes. | | | | | |
| | Add **Magnesium Stearate** (____Kg) in blender and mix it for further for 2-3 minutes. | | | | | |
| **3.3.5** | Send intimation form to QC department for testing. | | | | | |

**4.0 SAMPLING OF BLEND:**

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

_____
**Checked By (Production)**

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

_____
**Checked By (IPQA)**

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

**4.1 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/** | | | | | |
| **Total** | | | | | |

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

**4.2 YIELD RECONCILIATION:**

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

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

C = Samples = ….. ……..

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

**Loss Quantity: _____**

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 12 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

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

**5.1 Line clearance:**

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

| Sr. 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:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 13 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

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

| **Punch Specification** | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Punch Details** | Type | Prism: B Tooling, 35-Station | | | | | | | | | | | | | | | | | | | | | | |
| | Upper Punches | Diameter: 7.16 mm (Round SC plain) | | | | | | | | | | | | | | | | | | | | | Dies 7.17mm | |
| | Lower Punches | Diameter:7.16 mm (Round SC 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 | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| **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 | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |

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

**5.3 IN PROCESS CHECKS:**

**5.3.1 Specification:**

| S.No. | Parameters | Requirement | Frequency of Monitoring |
|---|---|---|---|
| 1.0 | Description | White colour, round shape SC plain on both sides | At the start of machine |
| 2.0 | Weight of 20 tablets | 2.878gm± 3% | Every 30 Minutes |
| 3.0 | Avg. weight | 143.91mg ± 3% | Every 2 Hours |
| 4.0 | Uniformity of weight | 143.91mg ± 7.5% | Every 2 Hours |
| 5.0 | Thickness | 3.3 ± 0.2 mm | Every 2 Hours |
| 6.0 | Hardness | NLT 2.0 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 | Diameter | 7.17mm | At the start of machine |
| 10.0 | Temperature | NMT 27 ° C | Every 2 Hours |
| 11.0 | RH | NMT 55% | Every 2 Hours |

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

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 14 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**Description:**

**Diameter:**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Wt. of 20 Tabs. 2.878gm± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs. 2.878gm± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness 3.3 ± 0.2 mm** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability (NMT 1 %)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness (NLT 2.0 Kg/cm$^2$)** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT NMT 15 min.** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance** White colour round shape tablets plain both side. | 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<br>PRODUCTION DEPARTMENT | |
| | **BATCH MANUFACTURING RECORD** | |

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 15 of 21 |
| **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:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 16 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

Attached additional sheet if required…….

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

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description:** | | | | | | | | | | | |
| **Diameter:** | | | | | | | | | | | |
| **Wt. of 20 Tabs. 2.878gm± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs. 2.878gm± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness 3.3 ± 0.2 mm** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability (NMT 1 %)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness (NLT 2.0 Kg/cm$^2$)** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT NMT 15 min.** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance** White colour round shape tablets plain both side. | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Temperature (NMT 27°C)** | ---- | | | | | | | | | | |
| **RH (NMT 55%)** | ---- | | | | | | | | | | |
| **Done By** | | | | | | | | | | | |

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

| | | |
|---|---|---|
| | PHARMA DEVILS<br>PRODUCTION DEPARTMENT | |
| **BATCH MANUFACTURING RECORD** | | |

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 17 of 21 |
| **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** | | | | | | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 18 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

Attached additional sheet if required……..

**6.0 SAMPLING:**

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

_____
**Checked By (Production)**

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

_____
**Verified By (IPQA)**

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

**7.0 TABLET WEIGHING RECORD:**

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

**8.0 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:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 19 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**9.0 COATING:** **Date:**_____

**9.1 Line clearance**

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

| Sr. 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:**

**9.2 COATING PROCESS:**

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

| | Instructions | Std. time (min) | Observed time | | Done By) (Sign & Date) | Checked By (Sign & Date) | Remarks |
|---|---|---|---|---|---|---|---|
| | | | From | To | | | |
| **Solution preparation** | Take (____ Lts.) **IPA** in SS container and dissolve **White Coat Redimix** (____Kg) and then added **MDC** (_____Kg) in above solution. | - | | | | | |
| | Now filter the above solution through 200# nylon cloth in clean SS Container. | | | | | | |
| **Coating of Tablet** | Take sorted tablet in coating room | - | | | | | |
| | Fit the spray gun with 1.5mm diameter nozzle and set the atomizing air pressure at 2.5-4.0 Kg/cm$^2$. Start the exhaust system. | - | | | | | |
| | Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM……..) and pre warm the tabs to obtain the bed temperature (_____ºC). | - | | | | | |
| | Start the spraying solution over the tablet and let them be dry immediately. | - | | | | | |
| | After drying unload the coating tablets in pre-tare Polybag lined drum with status label. | - | | | | | |
| | Check and record the physical parameters of coated | - | | | | | |

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | tablets as per given check sheet. | | | | | | | |

**10.0COATING INPROCESS CHECKS: (Record the observation every half an hour)**

| **Parameter** | **Limit** | **Date** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Time** | | | | | | | | | | |
| Pan Speed | 4 to 5 RPM | | | | | | | | | | | |
| Inlet Air Temperature | 65to 75$^0$ C | | | | | | | | | | | |
| Peristaltic Pump Speed | 16 RPM | | | | | | | | | | | |
| Atomizing Air Pressure | 2.5 to 4.0 Kg/cm$^2$ | | | | | | | | | | | |
| Exhaust Air Temperature | 42 to 48 **$^0$C** | | | | | | | | | | | |
| Bed Temperature | 40 to50**$^0$C** | | | | | | | | | | | |

**10.1 PARAMETERS AFTER COATING:**

| **Tests** | **Specification** | **Production observation** | **IPQA observation** |
|---|---|---|---|
| Description | White colur round shape SC plain on both sides | | |
| Weight of 20 tablets | 3.078gm± 3% | | |
| Avg. weight | 153.91mg ± 3% | | |
| Uniformity of weight | 153.91mg ± 7.5% | | |
| Thickness | 3.43 ± 0.2 mm | | |
| Hardness | NLT 4 Kg/cm$^2$ | | |
| Disintegration | NMT 30 Min. | | |
| **Checked by (Production):** | | **Checked By (IPQA):** | |

**10.2 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.

_____
**Verified By (IPQA)**

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Atorvastatin Calcium IP Tablets | |
| **Document No.:** | **Effective Date:** | **Page No.:** 21 of 21 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** |

**10.3 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):** | | | | | | | |

**10.4 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):** |

**11.0 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.)**

**12.0 ANY DEVIATION:**

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

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

**11.0 HISTORY SHEET:**

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

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