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

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 1 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

| | |
|---|---|
| **Location:** | |
| **Block:** Production Tablets (PT) | |
| **Label Claim:** | Each uncoated tablet contains:<br>Betahistine Dihydrochloride IP…….… 8 mg<br>Excipients…… q.s. |
| **Mfg. Lic. No.:** | |
| **Product Lic. No.:** | **NA** |
| **Self-Life:** | ____ Months |
| **MFR No.:** | |
| **Mfg. Date:** | |
| **Exp. Date:** | |
| **BMR Issued No.:** | |
| **Party:** | |

| **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:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 2 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

## 1.0 MASTER FORMULA:

### BILL OF RAW MATERIALS

| Sr. No. | Ingredients | Spec. | Qty. In mg Per Tablet | Overages % | Std. Qty. for 1 Lac. In Kg |
|---|---|---|---|---|---|
| **Raw Material for Dry Mixing:** | | | | | |
| 1. | Betahistine Hydrochloride | IP | 8.24 eq. to 8.0 mg | 2 % | 0.84# |
| 2. | Microcrystalline Cellulose (MCCP) | IP | 87.88 | ---- | 8.788 |
| 3. | Lactose | IP | 105.20 | ---- | 10.52 |
| 4. | Maize Starch | IP | 13.00 | ---- | 1.30 |
| **Raw Material for Binder Preparation-** | | | | | |
| 5. | Sodium Methyl Paraben (M.P.S) | IP | 0.15 | ----- | 0.015 |
| 6. | Sodium Propyl Paraben (P.P.S) | IP | 0.07 | ----- | 0.007 |
| 7. | PVPK-30 | IP | 1.30 | ---- | 0.13 |
| 8. | Purified Water | IP | QS | --- | QS |
| **Raw Material for Lubrication-** | | | | | |
| 9. | Magnesium Stearate | IP | 1.30 | ---- | 0.13 |
| 10. | Purified Talcum | IP | 0.75 | ---- | 0.075 |
| 11. | Croscarmellose Sodium (Ac-Di-Sol) | IP | 8.0 | ---- | 0.80 |
| 12. | Sodium Starch Glycolate (Primogel) | IP | 4.0 | ----- | 0.40 |
| 13. | Colloidal Silicon Dioxide (Aerosil) | IP | 1.5 | ---- | 0.15 |
| **Weight of Uncoated Tablets** | | | **231.39 mg** | | **23.16 Kg** |

**Note:** # Betahistine Hydrochloride adds after calculation if assay below 100%.

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 3 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

## CALCULATION SHEET

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

**Note:** If assay of API is above 100.0% 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 **Betahistine Hydrochloride 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 **Betahistine Hydrochloride IP** | Assay on as such basis **(A1)** | Actual quantity of this A.R.No. to be dispensed = |
|---|---|---|
| | ----------% | $\frac{\text{\_\_\_\_\_\# x 100}}{\text{A1}}$ = ----------Kg |

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

| A.R. No. of **Betahistine Hydrochloride IP** | Assay on as such basis (a1) | Actual quantity Available (b1) (Kg) | Qty. on 100 % assay basis = $\frac{(b1) \text{ x } (a1)}{100}$ = _____ 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) = $\frac{(e1) \text{ x } 100}{(f1)}$ = _____ =----------Kg

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

**Assay calculation:**

| | | |
|---|---|---|
| **Sign/ Date** | | |
| **Department** | **Done by(Production)** | **Checked by (Q.A.)** |

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

# BATCH MANUFACTURING RECORD

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 4 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**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 weared 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.
- Follow cGMP during entire manufacturing.
- Verifying the product name, B. No. , batch size, ingredients at the time of product handling.

**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……..(6 to 10 Pascal) | |
| 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** | | | |

# PHARMA DEVILS

PRODUCTION DEPARTMENT

## BATCH MANUFACTURING RECORD

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 5 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

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

| Sr. No. | Ingredients | Std. 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. | Betahistine Hydrochloride IP | 0.840# | | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | | |
| 2. | Microcrystalline Cellulose (MCCP) IP | 8.788 | | | | | | | | | |
| 3. | Lactose IP | 10.520 | | | | | | | | | |
| 4. | Maize Starch for paste IP | 1.300 | | | | | | | | | |
| **Raw Material for Binder Preparation-** | | | | | | | | | | | |
| 5. | Sodium Methyl Paraben (M.P.S) IP | 0.015 | | | | | | | | | |
| 6. | Sodium Propyl Paraben (P.P.S) IP | 0.007 | | | | | | | | | |
| 7. | PVPK-30 IP | 0.130 | | | | | | | | | |
| 8. | Purified Water IP | QS | | | | | | | | | |
| **Raw Material for Lubrication-** | | | | | | | | | | | |
| 9. | Magnesium Stearate IP | 0.130 | | | | | | | | | |
| 10. | Purified Talcum IP | 0.075 | | | | | | | | | |
| 11. | Croscarmellose Sodium (Ac-Di-Sol) IP | 0.800 | | | | | | | | | |
| 12. | Sodium Starch Glycolate (Primogel) IP | 0.400 | | | | | | | | | |
| 13. | Colloidal Silicon Dioxide (Aerosil) IP | 0.150 | | | | | | | | | |

**Note:** # Betahistine Hydrochloride adds after calculation if assay below 100%.
**@** 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** | | | |

PHARMA DEVILS

PRODUCTION DEPARTMENT

# BATCH MANUFACTURING RECORD

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 6 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |



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

| Sr. No. | Ingredients | Std. 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. | Betahistine Hydrochloride IP | 0.840# | | | | | | | | | |
| **Inactive Ingredients-** | | | | | | | | | | | |
| 2. | Microcrystalline Cellulose (MCCP) IP | 8.788 | | | | | | | | | |
| 3. | Lactose IP | 10.520 | | | | | | | | | |
| 4. | Maize Starch for paste IP | 1.300 | | | | | | | | | |
| **Raw Material for Binder Preparation-** | | | | | | | | | | | |
| 5. | Sodium Methyl Paraben (M.P.S) IP | 0.015 | | | | | | | | | |
| 6. | Sodium Propyl Paraben (P.P.S) IP | 0.007 | | | | | | | | | |
| 7. | PVPK-30 IP | 0.130 | | | | | | | | | |
| 8. | Purified Water IP | QS | | | | | | | | | |
| **Raw Material for Lubrication-** | | | | | | | | | | | |
| 9. | Magnesium Stearate IP | 0.130 | | | | | | | | | |
| 10. | Purified Talcum IP | 0.075 | | | | | | | | | |
| 11. | Croscarmellose Sodium (Ac-Di-Sol) IP | 0.800 | | | | | | | | | |
| 12. | Sodium Starch Glycolate (Primogel) IP | 0.400 | | | | | | | | | |
| 13. | Colloidal Silicon Dioxide (Aerosil) IP | 0.150 | | | | | | | | | |

**Note:** # Betahistine Hydrochloride adds after calculation if assay below 100%.
**@** 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 Weight Verification Sheet:**

**Balance ID:** _____

| Sr. No. | Ingredients | Spec. | UOM | Std. Quantity (Kg) | A.R. No. | Issued Qty. Gr. wt. | Checked By (Production) | Verified by (IPQA) |
|---|---|---|---|---|---|---|---|---|
| **MATERIAL FOR GRANULATION:** | | | | | | | | |
| 1. | Betahistine Hydrochloride | IP | | | | | | |
| 2. | Microcrystalline Cellulose (MCCP) | IP | | | | | | |
| 3. | Lactose | IP | | | | | | |
| 4. | Maize Starch | IP | | | | | | |
| 5. | Methyl Paraben Sodium (M.P.S) | IP | | | | | | |
| 6. | Propyl Paraben Sodium (P.P.S) | IP | | | | | | |
| 7. | PVPK-30 | IP | | | | | | |
| **MATERIAL FOR LUBRICATION:** | | | | | | | | |
| 1. | Magnesium Stearate | IP | | | | | | |
| 2. | Purified Talcum | IP | | | | | | |
| 3. | Croscarmellose Sodium (Ac-Di-Sol) | IP | | | | | | |
| 4. | Sodium Starch Glycolate (Primogel) | IP | | | | | | |
| 5. | Colloidal Silicon Dioxide (Aerosil) | IP | | | | | | |

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 8 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**3.0 MANUFACTURING PROCESS:**

**3.1 Line clearance:**

**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. | | | |
| 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 (6 to 10 Pascal). | | | |
| 5 | Follow cGMP in all time process | | | |
| 6 | Calibration status of Equipment/instrument complies or not. | | | |
| 7 | Balance calibration and verification 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? | | | |

**Note: Verify the materials as per product BOM during receipt and at time of addition.**

**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. | Tray Drier | | Yes/No | | |
| 4. | Blender | | Yes/No | | |
| 5. | Balance | | Yes/No | | |
| 6. | S.S Scoop | | Yes/No | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
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| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**3.2 Sifting:** Sift separately the following material and collect in poly bags/containers.

**SIFTING OF GRANULATION MATERIALS**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Betahistine Hydrochloride | | | | | | | | |
| Microcrystalline Cellulose (MCCP) | | | | | | | | |
| Lactose | | | | | | | | |
| Maize Starch | | | | | | | | |
| Methyl Paraben Sodium (M.P.S) | | | | | | | | |
| Propyl Paraben Sodium (P.P.S) | | | | | | | | |
| PVPK-30 | | | | | | | | |

**SIFTING OF LUBRICANTS MATERIAL**

| Ingredient | Qty. In Kg | Sieve Size (#) | Sieve Integrity | | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|---|---|
| | | | Before Use | After use | | | | |
| Magnesium Stearate | | | | | | | | |
| Purified Talcum | | | | | | | | |
| Croscarmellose Sodium (Ac-Di-Sol) | | | | | | | | |
| Sodium Starch Glycollate | | | | | | | | |
| Colloidal Silicon Dioxide (Aerosil) | | | | | | | | |

**Note:** Check sieve integrity before and after use.

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

**3.3 MANUFACTURING PROCESS:**

A.R. No. of Purified Water: _____ pH of Purified Water: _____

| Step No. | Manufacturing Instruction | Eq. ID. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| **3.3.1** | **Binder preparation-** | | | | | |
| | In S.S jacketed paste kettle take **Purified Water** _____ Lts. heat it and dissolve **PVPK-30 (**_____ Kg) completely.<br>In another S.S container take **Purified Water** _____ Lts. and dissolve **Methyl Paraben Sodium (**_____ Kg) and **Propyl Paraben Sodium (**_____ Kg) one by one completely.<br>Then add in paste kettle with **PVPK-30** and prepared paste. | | | | | |
| | Qty. of **Purified Water**____ liters. | | | | | |
| **3.2.2** | **Dry Mixing-** | | | | | |
| | Load **Betahistine Hydrochloride** (_____# Kg), **Microcrystalline Cellulose (MCCP)** (_____ Kg), **Lactose** (_____ Kg) and **Maize Starch** (_____ Kg) in a Mass Mixture and run it at slow speed for 10 minutes. | | | | | |
| **3.3.3** | **Wet Granulation:** | | | | | |
| | Start the Mass Mixture 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 at slow speed and mix for 5 minutes. | | | | | |
| | Add additional **Purified Water** if required.<br>Additional **Purified Water** = _____Lts. | | | | | |
| **3.3.4** | **Drying:** | | | | | |
| | Dry the granules at 60°C to 70°C temperature for as per required time minutes. | | | | | |
| | Air temp._____ $^0$C | | | | | |
| | Collect the granules from 5 different places of the tray and check loss on drying. | | | | | |
| | LOD. _____%w/w. Recommended LOD: (NMT 2.0 % w/w) | | | | | |
| **3.3.5** | **Sizing/Milling:** | | | | | |
| | Mill the dried granules through multi mill at 750 RPM through 2mm screen. | | | | | |
| | **Before Use** | **After Use** | | | | |
| | Rusted: Yes/No | Rusted: Yes/No | | | | |
| | Broken: Yes/No | Broken: Yes/No | | | | |
| | Clean: Yes/No | Clean: Yes/No | | | | |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 11 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

| Step No. | Manufacturing Instruction | Eq. ID. | From | To | Done By/ Date | Ckd. By/ Date |
|---|---|---|---|---|---|---|
| | Again pass the milled granules through 20# sieve and then collected in cleaned polybags. | | | | | |
| | **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** | **Lubrication:** | | | | | |
| | Add **Purified Talcum** (____Kg), **Colloidal Silicon Dioxide (Aerosil)** (____Kg), **Sodium Starch Glycolate** (_____Kg) and **Croscarmellose Sodium (Ac-Di-Sol)** (____Kg) in blender with dried granules and mix it for 10 minutes. | | | | | |
| | Add **Magnesium Stearate** (____Kg) in blender and mix for further for 5 minutes. | | | | | |

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

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

**3.6 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:**

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 13 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**4.0 COMPRESSION:**

**Date: _____** **Started at: _____**

**4.1 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……..Pascal (6 to 10 Pascal) | OK/NOT OK | | |
| 5 | All the equipment shall be used during process are cleaned. | Yes/No | | |

**4.2 Process:**

| Sr. No. | Compression Instruction | Observations | Checked (Production) | Verified By (IPQA) |
|---|---|---|---|---|
| **1.** | Collect the approved granules from the granules store for compression. | | | |
| **2.** | Ensure the correct punch set is assembled in the compression machine. | | | |
| **3.** | Ensure the availability and online filling of Batch Document. | | | |
| **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.** | If compression time is less than one hour , minimum Three observations shall be recorded. | | | |
| **6.** | Ensure that all the data of actual processing are entered in log book of individual equipment/Instrument. | | | |
| **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:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 14 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

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

| **Punch Specification** | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Punch Details** | Type | Prism: B Tooling 35 Stations. | | | | | | | | | | | | | | | | | | | | | | |
| | Upper Punches | Diameter : 9.0 mm (Round shape and Plain ) | | | | | | | | | | | | | | | | | | Dies : 9.1 mm | | | | |
| | Lower Punches | Diameter : 9.0 mm (Round shape and 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):**_____

**4.3 IN PROCESS CHECKS:**

**4.3.1 Specification:**

| Sr. No. | Parameters | Requirement | Frequency of Monitoring |
|---|---|---|---|
| 1.0 | Description | White colour round shaped biconvex tablets and plain both side | At the start of machine |
| 2.0 | Weight of 20 tablets | 4.63 gm ± 3% | Every 30 Minutes |
| 3.0 | Avg. weight | 231.39mg ± 5% | Every 2 Hours |
| 4.0 | Uniformity of weight | 231.39 mg ± 5% | Every 2 Hours |
| 5.0 | Thickness | 3.3 ± 0.2 mm | Every 2 Hours |
| 6.0 | Hardness | NLT 3Kg/$cm^2$ | Every 2 Hours |
| 7.0 | Friability | NMT 1% | Every 2 Hours |
| 8.0 | DT | NMT 15 min | Every 2 Hours |
| 9.0 | Diameter | 9.0 mm ± 0.2 mm | At the start of machine |
| 10.0 | Temperature | NMT 27ºC | Every 2 Hours |
| 11.0 | RH | NMT 55% | Every 2 Hours |

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 15 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

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

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description:** | | | | | | | | | | | |
| **Diameter:** | | | | | | | | | | | |
| **Wt. of 20 Tabs.** **4.63 gm ± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs.** **4.63 gm ± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness (3.30 ±0.2mm)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability (NMT 1 %)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness (NLT 3 Kg/cm$^2$)** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT** **NMT 15 min** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance** White colour round shape biconvex tablets and 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:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 16 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**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** | | | |

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

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description:** | | | | | | | | | | | |
| **Diameter:** | | | | | | | | | | | |
| **Wt. of 20 Tabs. 4.63 gm ± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Wt. of 20 Tabs. 4.63 gm ± 3%** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Thickness (3.30 ±0.2mm)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Friability (NMT 1 %)** | **Date** | | | | | | | | | | |
| | **Time** | | | | | | | | | | |
| | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Hardness (NLT 3 Kg/cm$^2$)** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **DT NMT 15 min** | LHS | | | | | | | | | | |
| | RHS | | | | | | | | | | |
| **Appearance** White colour round shape biconvex tablets and 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:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 18 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**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** | | | |

Attached additional sheet if required……..

**4.6 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.

**4.7 TABLETS WEIGHING RECORD:**

| Container No. | Gross wt. | Tare wt. | Net wt. | Container No. | Gross 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):** | | | | | | | |

**4.8 VISUAL INSPECTION OF TABLETS:**

Machine No. _____ 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)**

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

**BATCH MANUFACTURING RECORD**

| | | |
|---|---|---|
| **Product Code:** | **BMR No.:** | |
| **Product Name:** | **Generic Name:** Betahistine Tablets IP | |
| **Document No.:** | **Effective Date:** | **Page No.:** 20 of 20 |
| **Batch No.:** | **Batch Size:** | **Supersedes No.:** Nil |

**4.9 YIELD RECONCILIATION:**

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

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

**Loss Qty.: _____ Kg.**

**5.0 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.)**

**6.0 ANY DEVIATION:**

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

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

**7.0 HISTORY SHEET:**

| BMR No. | New BMR No. | Revision No. |
|---|---|---|
| | --- | New BMR |

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