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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Details** | |  | **Details of BMR** | | | | |
| Location: | Block: III (Compression – 6) (Coating - 1) | Issuance | | No. of Pages | Issued By  (QA) | Received By  (PD) |
| Label claim | Each Film-coated tablet contains 496.3 mg of Valganciclovir Hydrochloride equivalent to  450 mg of Valganciclovir. | First Issue (A) | |  |  |  |
| Market | EUROPE | Additional Issue  (B) | |  |  |  |
|  |  |  |
| Ref. MFC No. | VGC/TA/EU/001-00 | Total Pages | |  |  |  |
| Batch Size | 125,000 Tablets | Manufacturing Date (MM/YYYY) | |  | Expiry Date (MM/YYYY) |  |
| Product Code | 3011556 |
| Shelf Life | 2 Years | Allotted By (PD)  Signature & Date | |  | Checked By (QA)  Signature & Date |  |
| **Review of Executed BMR** | | | | |
| Supersede MPR | NA | Reviewed by  (Sign & Date) | PD | |  | |
| Ref.MPR No. (Blend) | 3011555† |
| Ref.B.No: (Blend) |  | QA | |  | |
| Storage Conditions | Store at 20°C to 25°C (68°F - 77°F) |

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| --- | --- | --- | --- | --- | --- | --- |
|  | **Prepared By** | **Approved By** | | | | **Authorized By** |
| **Department** | **QA** | **Production** | **R & D / Tech. Transfer** | **Regulatory Affairs** | **In-charge - QA** | **Head - QA** |
| **Name** |  |  |  |  |  |  |
| **Designation** |  |  |  |  |  |  |
| **Signature** |  |  |  |  |  |  |
| **Date** |  |  |  |  |  |  |

**† Current effective version to be referred**

**MANUFACTURING FORMULA:**

| **S. No.** | **Material**  **Code** | **Material Name &**  **Specification** | **Vendor Details** | **Quantity / Unit** | **UOM** | **Quantity / Batch** | **UOM** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|
| 1 | 3011555 | Blend for Valganciclovir 450 mg Tablets | -------- | 645.000 | mg | 80.625 | Kg |
| **† Film – Coating (12% m/m Suspension) \*\*** | | | | | | | |
| 2 | 1003021 | Opadry pink 15B24005, IHS | Colorcon | 19.350 | mg | 3.144 $ | Kg |
| 3 | 3001093 | Purified Water IHS/USP/Ph.Eur@ | ---- | 141.900 | mg | 23.059 $ | Kg |
| **Film Coated Tablet Mass** | | | | **664.350** | **mg** | **83.044** | **Kg** |
| \*\* Coating material calculated based on target Mass build-up of 3.0% (3.0 ± 0.5 % m/m) of core tablet Mass.  $ Includes about 30% overages to compensate process loss during the coating.  @ Purified water shall be dispensed by production personnel. It will not appear in the final product except in traces.  **† Dispensing to be done in two lots.**  **Note: Weigh the purified water as per least count of the weighing balance**. | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Dispensing Instructions**:   * 1. Follow the gowning procedures as per **SOP NO. WH012**   2. Wear safety nose masks and gloves to avoid contact with skin. (3M nose mask) (Personal Respirators)   3. Dispense only in the dispensing area.   4. Dispense only approved materials for production.   5. Check and ensure that all balances are calibrated before use.   6. Check the raw materials for Name, Material codes, Appearance (Visual check), Quantity, A.R. No. and Expiry /retesting date (if any) etc.,   7. Weigh each raw material in properly tared containers, polybags and label them accordingly.   8. Select the balance for dispensing materials based on the operating range displayed on the balance.  |  |  |  | | --- | --- | --- | | **List of abbreviation:** | | | | IH/IHS | : | In House Specification QA : Quality Assurance | | NMT | : | Not More Than WC : Water column | | NLT | : | Not Less Than Pa : Pascal | | USP | : | United States Pharmacopoeia mm : millimeter | | %m/m | : | Percentage Mass by Mass mg : Milligram | | RPM | : | Rotation per minute Kg : Kilogram | | ºC | : | Degree centigrade ADU : Air Displacement Unit | | SOP | : | Standard Operating Procedure WH : Ware House | | HEPA | : | High Efficiency Particulate Air No. : Number | | cGMP | : | Current Good Manufacturing Practices Qty. : Quantity | | RH | : | Relative Humidity PD : Production | | A.R. | : | Analytical Reference N : Newtons | | NA | : | Not Applicable ID : Identity | | Ph.Eur  DT  UOM | :  :  : | European Pharmacopoeia Emp. : Employee  Disintegration time UST : Upper Surface of the Tablet  Units of measure LST : Lower Surface of the Tablet | |

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| **Dispensing Area cGMP Check List:** | | | | |
| **Check the following** | | | **In Active Dispensing** | |
| **ROOM No.:\_\_\_\_\_\_\_\_\_\_\_** | |
| **Status** | |
| Area and dispensing booth cleanliness | | |  | |
| Previous product/Batch No. | | |  | |
| Removal of previous product material | | |  | |
| Balance calibration records | | |  | |
| Differential pressure of room **(Start of the activity) (\_\_\_\_\_\_\_\_\_ mm of WC)** | | | Men Entry: | Material Entry: |
| Differential pressure of room **(End of the activity)( \_\_\_\_\_\_\_\_\_ mm of WC)** | | | Men Entry: | Material Entry: |
| Temperature (0C) and relative humidity (%) (Start of the activity)(NMT 25°C & RH NMT 55%) | | |  | |
| Temperature (0C) and relative humidity (%) (End of the activity)(NMT 25°C & RH NMT 55%) | | |  | |
| Differential pressure of Dispensing Booth | **HEPA filter** | **Pa – Pa** |  | |
| **Intermediate filter** | **Pa – Pa** |  | |
| **Pre filters** | **Pa – Pa** |  | |
| **Checked by (Warehouse) (Sign & Date)** | | |  | |
| **Verified by (QA) (Sign & Date)** | | |  | |

**1.0 Weighing Record:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S. No.** | Name of ingredient | | Batch No. /GRN No. | **A.R. No.** | **Container**  **No.** | | **Gross**  **Weight (kg)** | **Tare**  **Weight (kg)** | | **Net**  **Weight (kg)** |
| 1 | Opadry Pink15B24005, IHS **1.572 Kg (lot –I)** | |  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
| **Total Net Mass ⇒** | | | | | | |  |
| Opadry Pink15B24005, IHS **1.572 Kg (lot –II)** | |  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
| **Total Net Mass ⇒** | | | | | | |  |
| **Refer Attached Printout (Attached / Not Attached).** | | | | | | | | | | |
| **Activity** | | **Weighing Balance ID** | | | | **Done By (Sign & Date)** | | | **Verified by (QA) (Sign & Date)** | |
| **Dispensing (WH)** | |  | | | |  | | |  | |
| **Cross Verification (PD)** | |  | | | |  | | |  | |

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| **COMPRESSION:**  **General Manufacturing & safety precautions:**   * 1. Avoid skin contact while handling and processing of product.   2. Wear hand gloves and mask when handling and processing of product.   3. If require use dust guard, goggles and earmuff to protect yourself.   4. During the entire production run keep all guards covered. If needed, vacuum the tablet press periodically and keep the working area clean. If any damage to the machine takes place, record such incidents and notify the supervisor immediately.   5. Do not put your hands near to the die table while the machine in running condition.   6. Never run the machine directly with power initially, always rotate the machine by hand to ensure that all moving parts are free.   7. Ensure earthing of the machine. |

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| --- | --- | --- | --- | --- | --- |
| **SUMMARY OF EQUIPMENT USED IN MANUFACTURING** | | | | | |
| **Name of the equipment** | **Equipment No.** | **Model / Type** | **Capacity / size** | **Manufacturer’s details** | **Operation SOP No. & Cleaning SOP No.** |
| Compression machine | PDE-1303 | XL 400SFP  29 Station – D Tooling | 10 – 100 RPM | KORSCH | PD425† |
| Combo Deduster cum metal trap | PDE-1304 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1009 / PDE-1010 | Metal Trap HS-30 | NA | Technofour | PD168† |
| Combo Deduster cum metal trap | PDE-1042/ PDE-1043 | Metal Trap HS30 | NA | Technofour | PD168† |
| Combo Deduster cum metal trap | PDE-1140/ PDE-1141 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1142/ PDE-1143 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1251 | Metal Trap HS30 | NA | Technofour | PD168† |
| Combo Deduster cum metal trap | PDE-1215/ PDE-1216 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-4011/ PDE-4012 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1422 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1492/ PDE-1502 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1525 | Metal Trap SS30PH | NA | Technofour | PD433† |
| Combo Deduster cum metal trap | PDE-1572/ PDE-1573 | Metal trap SS30PH | NA | M/s. Technofour Electronics Pvt. Ltd. | PD433† |
| Combo Deduster cum metal trap | PDE-1599/PDE-1600/ PDE-1601 | Metal trap SS30PH | NA | M/s. Technofour Electronics Pvt. Ltd. | PD433† |
| Automatic Coating Machine | PDE – 1011 | Neocota 75D | 36”  (915mm) | Neo Machine | PD209† |
| Automatic Tablet inspection machine | PDE-1154/ PDE – 1376/ PDE-1536 | Visitab 2 -C | NA | Proditec ACG PAM | PD352† |
| Automatic Tablet inspection machine | PDE – 1288/  PDE – 1341 | Visitab 2L | NA | ACG Pam Pharma Technologies Pvt. Ltd | PD418† |

**† Current effective version to be referred.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Activity** | **Date** | **Time** | **Differential pressure**  **(\_\_\_\_\_\_\_mm of WC)** | **Temperature**  **(NMT 25°C)** | **% Relative Humidity (NMT 40% RH)** | **Done By**  **(Sign & Date)** |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |

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| **Manufacturing Area cGMP Check List:**    Inspect the working area and equipment for cleanliness before use and ensure that the status tags are properly filled in.  **Area Clearance:**     |  |  | | --- | --- | | **Check the following** | **Status** | | Room Name & No. |  | | Previous Product & Batch No. |  | | Type of Area cleaning | **Type A /**  **Type B** | | Area Cleanliness | **Satisfactory /** **Not Satisfactory** |   **Note: Enter √ mark on the Type A /  Type B and Satisfactory / Not Satisfactory**  **Inspected By (PD)(Sign & Date) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked By (PD)(Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Equipment Clearance:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Equipment Name** | | **Equipment No.** | **Previous Product** | **Batch No.** | **Strength/Batch / Product /**  **Colour change over** | **Type of cleaning** |
| Compression Machine | | PDE – 1303 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1304 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1009/ PDE-1010 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1042/ PDE-1043 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1140/ PDE-1141 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1142/ PDE-1143 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1251 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1215/ PDE-1216 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-4011/ PDE-4012 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1422 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1492/ PDE-1502 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1525 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1572/ PDE-1573 |  |  |  |  |
| Combo Deduster cum metal trap | | PDE-1599/PDE-1600/ PDE-1601 |  |  |  |  |
| **Ensure that the lubricated blend is approved for compression**.  **Checked by (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Proceed / Do not proceed for production activity**  **Line clearance given by (QA) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | |

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| --- | --- |
| **Step No.** | **Process Instructions** |
| **2.0** | Check the Integrity of the All Gaskets Before use After Type “A” cleaning & After use Before Type “A” cleaning.  Record the observations in the given table **(Gasket Integrity Check).** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2.0** | **Gasket Integrity Check** | | | | |
| **Gasket Integrity Before use**  **(After Type “A” cleaning)**  **Batch No.\_\_\_\_\_\_\_\_\_\_\_\_** | | **Checked By**  **(Sign & Date)** | **Gasket Integrity After use**  **(Before Type “A” cleaning)**  **Batch No.\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Checked By**  **(Sign& Date)** | **Remarks** |
| **S / NS / NA ** | |  | **S / NS / NA ** |  |  |
| **Note: Enter √ mark on the S-Satisfactory / NS-Not Satisfactory/ NA-Not applicable** | | | | | |

**3.0 Transfer of Blend**

Check and record the Gross weight of blend before transferring into compression area. Record the weighing details in the given table.

| **S. No.** | **Product Code** | **In-process Product Name** | **Batch No.** | **A.R. No.** | **Approved Quantity (Kg)** | **Total Number of Containers / Bins** |
| --- | --- | --- | --- | --- | --- | --- |
|
| **1** | 3011555 | Blend for Valganciclovir 450 mg Tablets |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Step No.** | **Process Instructions** | | | | | | | | | | |
| **3.1** | **LUBRICATED BLEND WEIGHT: Check and record the Gross weight of blend before transferring into compression area.** | | | | | | | | | | |
| **Weighing Balance ID:** | | | | | | | | | | |
| **Bin / Container No.** | **Gross weight (Kg)** | **Weighed By (Sign & Date)** |  | **Bin / Container No.** | **Gross weight (Kg)** | **Weighed By (Sign & Date)** |  | **Bin / Container No.** | **Gross weight (Kg)** | **Weighed By (Sign & Date)** |
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| **4.0 Setting Up Of The Tablet Press**  4.1 Set up Tablet press with **16.7 x 7.8 mm, oval shaped**, bi-concave punches embossed with **‘J’** **on** **the** **lower punch** and **‘156’** **on** **upper punch**  With corresponding dies.    **5.0 Setting Up Of The METAL TRAP**  5.1 Set and check the Metal trap functioning using Standard blocks such as 0.30mm Ferrous, 0.50mm Stainless Steel, 0.30mm Non-Ferrous and  Non-metallic/ Neutral block.  5.2 **Testing frequency**: Startup, Middle and End of the Compression activity and after every intermittent stoppage.  5.3 **Acceptance Criteria:** Ferrous, Stainless steel & Non Ferrous shall be detected & rejected. Non-metallic/ Neutral block shall not be detected.  5.4 Record the details given in the table **(Performance Checks Record for METAL TRAP)**  **6.0 Compression Operation**  **6.1** **MACHINE SETTING OBSERVATIONS**  Perform Machine setting activity during compression operation and record the timings.     |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Equipment No.** | |  | | | | | | | |  | **Start time** | **End Time** | **Start time** | **End Time** | **Start time** | **End Time** | **Start time** | **End Time** | | **Time** |  |  |  |  |  |  |  |  | | **Sign & Date** |  |  |  |  |  |  |  |  | | **Machine setting Rejects (Kg)** |  | |  | |  | |  | | | **Challenge Test Rejects (kg)** |  | |  | |  | |  | | | **Total rejects (Kg)**  **(Machine setting+**  **Challenge test)** | |  | | | **Checked By (PD)**  **(Sign & Date)** | |  | |   **6.2 CHALLENGE TESTS DURING COMPRESSION**  **EQUIPMENT ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**    **6.2.1 Challenge test for Rejection Gate\***  Note: To be performed before every start-up (Put **√** if the observation meeting to expected result).   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Operation mode** | **Expected result** | **Date** | **Time** | | **Observation** | | **Done By (PD)** | **Verified By (QA)** | | **From** | **To** | **S1 / P1 / L / A** | **S2 /P2 / R / B** | | AWC OFF/ SET UP/ FORCE CONTROL OFF/ AUTOMATIC OFF MODE | Flap position should close good tablet path |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | | AWC ON/ PRODUCTION/ FORCE CONTROL ON/ AUTOMATIC ON MODE | Flap position should close reject tablet path |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |   \*Challenge test shall be performed as per current version of PD044†  **† Current effective version to be referred.**  **6.2.2 Challenge Test for Rejection Air Jet Blow system\***  To be performed before start-up for first batch after Type –A Cleaning (put a **√** mark if the AWC ON/ Production/ Force Control On/ Automatic On mode).   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Machine setting** | | | | **Performance Test for Rejection Air Jet Blow system** | | | | | | | | | | **Date** | **Time** | | **Done By**  **(PD)** | **Time** | | **AWC ON/ PRODUCTION/ FORCE CONTROL ON/ AUTOMATIC ON MODE** | **Side** | **Station No.** | **Tablet rejected /Not rejected** | **Done by**  **(PD)** | **Verified by**  **(QA)** | | **From** | **To** | **From** | **To** | |  |  |  |  |  |  |  | **S1 / P1 / L / A** |  |  |  |  | |  |  |  |  |  |  |  | **S2 /P2 / R / B** |  |  |  |  | |  |  |  |  |  |  |  | **S1 / P1 / L / A** |  |  |  |  | |  |  |  |  |  |  |  | **S2 /P2 / R / B** |  |  |  |  |   \*Challenge test shall be performed as per current version of PD044†  **† Current effective version to be referred.**  Note: If air jet blow system unable to set in such case intimate to engineering department for necessary action.  For single side rotary tablet press consider S1 side.  **6.3 Compression Operation – Startup**  6.4Load the blend into hopper of Tablet Press/Compression machine; Adjust the tablet press to get tablet parameters for as  follows. Perform the startup activity during compression operation and record the timings given in the table **(Compression Startup Record).**  Perform the in-process checks such as Description (UST and LST)\*, Mass, Friability, Thickness, Hardness and Disintegration time for No. of station  **+3** Tablets. As per **SOP No: PD044.** Record the details of In-process checks given in the table  **(Compression Startup Record).**   |  |  |  | | --- | --- | --- | | **S. No.** | **Parameter** | **Specification** | | 1 | Description | White to off white, Oval, biconvex tablets debossed with **‘J’** on one side and **‘156’** on the other side. | | 2 | Mass of Individual Tablet (mg) | 645.000 mg ± 5 % (613 mg to 677 mg) | | 3 | Mass of 10 tablets (g) | 6.450 g ± 3 % (6.26 g to 6.64 g) | | 4 | Hardness (N) | 170.0 N (130 N – 210 N) | | 5 | Thickness (mm) | 6.60 + 0.40 mm (6.2 mm to 7.0 mm) | | 6 | Disintegration Time (Minutes) | NMT 15 Minutes | | 7 | Friability (%m/m) | NMT 1.0 %m/m | | 8 | Tablet Press (29 Station) (KORSCH)  PDE – 1303 | **Validated speed 10-50 RPM**  **Optimum speed : 15-40 RPM** |   **† Current effective version to be referred.**  **Note : \*UST –Upper surface of the tablet and LST- Lower surface of the tablet** |
| **6.5 Compression Operation – After Startup checks**  6.6 If the tablet parameters are satisfactory, proceed for further compression. Record the operation details given in the table  **(Compression activity Operation Record After Startup).**  6.7 Inspect the tablets visually for physical defects and record the details given in the table. **(Physical Inspection of Compressed Tablets).**  6.8 Monitor the group Mass of 10 tablets periodically and record the details given in the table. **{Control Graph for Average Mass (g)}**    6.9 Monitor the tablets periodically for Mass, Thickness, Hardness, Friability and Disintegration time as per **SOP No: PD044.**  Record the In-process Checks given in the table. (**In-process Checks Record – During Compression).** |

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| **Step No.** | **Process details** | |
| **4.0** | **Setting Up Of The Tablet Press** | |
| 4.1 | Tooling code |  |

**6.6 Compression activity Operation Record after Startup**

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| **S.** **No.** | **Date** | **Start of the operation Time** | **End of the operation Time** | **Done By**  **(Sign & Date)** | **Checked By**  **(Sign & Date)** |
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| **Step No.** | **Process Instructions** | | |
| **7.0** | **Record the in-process Equipments ID.No.s which about use in operation** | | |
| **Equipment Name** | **ID No.** | |
| 7.1 | Weighing Balance |  | |
| 7.2 | Tablet Thickness Tester |  | |
| 7.3 | Friabilator |  | |
| 7.4 | Disintegrator |  | |
| 7.5 | Hardness Tester |  | |
| **8.0** | **Frequency of In-process checks for PD and QA (Refer SOP No: PD044).** | | |
| **In-process check** | **PD** | **QA** |
| 8.1 | Mass of 10 tablets | Every half an hour | NA |
| 8.2 | Mass of individual tablet | Production and QA alternatively every one hour. | |
| 8.3 | Thickness | Production and QA alternatively every one hour. | |
| 8.4 | Friability | Production and QA alternatively every one hour. | |
| 8.5 | Disintegration time | Production and QA alternatively every one hour. | |
| 8.6 | Hardness | Every half an hour alternatively by PD & QA | |
| 8.7 | Physical inspection | Production and QA alternatively every one hour | |

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| **5.4 Performance Checks Record For METAL TRAP** | | | | | | | | | | | | | | | |
| **METAL TRAP ID: PDE-1304, PDE-1009 / PDE-1010/ PDE-1042/ PDE-1043/ PDE-1140/ PDE-1141/ PDE-1142/ PDE-1143/ PDE-1251/**  **PDE-1215/ PDE-1216/ PDE-4011/ PDE-4012/ PDE-1422/ PDE-1492/ PDE-1502/ PDE-1525/ PDE-1572/ PDE-1573/ PDE–1599/ PDE–1600/PDE–1601** | | | | | | | | | | | | | | | |
| **Date & Time** |  | | |  | | |  | | |  | | |  | | |
| **Trial** | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| Ferrous (0.30 mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stainless-steel (0.50 mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non Ferrous (0.30mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-metallic /Neutral Block |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Result (Pass/Fail) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Done By (PD) (Sign & Date) |  | | |  | | |  | | |  | | |  | | |
| Checked by (PD) (Sign & Date) |  | | |  | | |  | | |  | | |  | | |

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| **5.4 (A) Performance Checks Record For METAL TRAP** | | | | | | | | | | | | | | | |
| **METAL TRAP ID: PDE-1304, PDE-1009 / PDE-1010/ PDE-1042/ PDE-1043/ PDE-1140/ PDE-1141/ PDE-1142/ PDE-1143/ PDE-1251/**  **PDE-1215/ PDE-1216/ PDE-4011/ PDE-4012/ PDE-1422/ PDE-1492/ PDE-1502/ PDE-1525/ PDE-1572/ PDE-1573/ PDE–1599/ PDE–1600/PDE–1601** | | | | | | | | | | | | | | | |
| **Date & Time** |  | | |  | | |  | | |  | | |  | | |
| **Trial** | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| Ferrous (0.30 mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stainless-steel (0.50 mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non Ferrous (0.30mm) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-metallic / Neutral Block |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Result (Pass/Fail) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Done By (PD) (Sign & Date) |  | | |  | | |  | | |  | | |  | | |
| Checked by (PD) (Sign & Date) |  | | |  | | |  | | |  | | |  | | |

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| **6.3** | **Perform startup activity during compression operation and record the timings.** | | | |
| **Equipment No.** |  | | |
| **Start of activity By** | **Time** |  |  |
| **Sign & Date** |  |  |

Note: Enter mark for detection and x mark for non-detection

6.4 (A) TABLET COMPRESSION START UP RECORD

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Mass of individual tablet (mg) | | | | | | | | Thickness (mm) | | | | | | | | | | Hardness (N) | | | | | | | | | | DT (min) | | Debossing | | | | | | Mass of 10 tablets (g) | | | | | | | | Friability (%m/m) | | |
| Minimum | Target | | Maximum | | | | | Minimum | | | | | | Target | | Maximum | | Minimum | | | Target | | | Maximum | | | | NMT | | UST | | LST | | | | Minimum | | | Target | | Maximum | | | NMT 1.0 | | |
| 613 | 645.000 | | 677 | | | | | 6.2 | | | | | | 6.60 | | 7.0 | | 130 | | | 170 | | | 210 | | | | 15 | | 156 | | J | | | | 6.26 | | | 6.450 | | 6.64 | | |
| **Description:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Parameter** | | **1** | | **2** | | **3** | | | **4** | | **5** | | | | **6** | **7** | **8** | | **9** | **10** | | **11** | **12** | | | **13** | **14** | | **15** | | **16** | | **17** | **18** | | | **19** | **20** | | **21** | | **22** | **23** | | **24** | **25** | |
| **UST\*** | |  | |  | |  | | |  | |  | | | |  |  |  | |  |  | |  |  | | |  |  | |  | |  | |  |  | | |  |  | |  | |  |  | |  |  | |
| **LST\*** | |  | |  | |  | | |  | |  | | | |  |  |  | |  |  | |  |  | | |  |  | |  | |  | |  |  | | |  |  | |  | |  |  | |  |  | |
| **Mass (mg)** | |  | |  | |  | | |  | |  | | | |  |  |  | |  |  | |  |  | | |  |  | |  | |  | |  |  | | |  |  | |  | |  |  | |  |  | |
| **Thickness (mm)** | |  | |  | |  | | |  | |  | | | |  |  |  | |  |  | |  |  | | |  |  | |  | |  | |  |  | | |  |  | |  | |  |  | |  |  | |
| **Hardness (N)** | |  | |  | |  | | |  | |  | | | |  |  |  | |  |  | |  |  | | |  |  | |  | |  | |  |  | | |  |  | |  | |  |  | |  |  | |
| **Parameter** | | **26** | | | **27** | | **28** | | | **29** | | | **30** | | **31** | **32** | **Refer Attached Printout for Individual Mass(mg), Thickness(mm),**  **Hardness (N) & Mass of 10 Tablets (g) ( Attached / Not attached )**  **\* Put mark for Debossing** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UST\*** | |  | | |  | |  | | |  | | |  | |  |  |
| **LST\*** | |  | | |  | |  | | |  | | |  | |  |  |
| **Mass (mg)** | |  | | |  | |  | | |  | | |  | |  |  |
| **Thickness (mm)** | |  | | |  | |  | | |  | | |  | |  |  |
| **Hardness (N)** | |  | | |  | |  | | |  | | |  | |  |  |
| **DT (min)** | | | | | | | | | | | | | | | | | **Mass of 10 Tablets (g)** | | | | | | | | | | | | | | | **Friability (%m/m)** | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| **End of activity By** | | | **Time** | | | | | | | | |  | | | | | | | | | | | | | **Verified By** | | | | | **Time** | | | | |  | | | | | | | | | | | |
| **Sign & Date** | | | | | | | | |  | | | | | | | | | | | | | **Sign & Date** | | | | |  | | | | | | | | | | | |

6.4 (B) TABLET COMPRESSION START UP RECORD

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Mass of individual tablet (mg) | | | | | | | | | Thickness (mm) | | | | | | | | | Hardness (N) | | | | | | | | | DT (min) | | | | Debossing | | | | Mass of 10 tablets (g) | | | | | | | | Friability (%m/m) | | |
| Minimum | | Target | | | | Maximum | | | Minimum | | | Target | | | Maximum | | | Minimum | | | Target | | | Maximum | | | NMT | | | | UST | | LST | | Minimum | | | Target | | Maximum | | | NMT 1.0 | | |
| 613 | | 645.000 | | | | 677 | | | 6.2 | | | 6.60 | | | 7.0 | | | 130 | | | 170 | | | 210 | | | 15 | | | | 156 | | J | | 6.26 | | | 6.450 | | 6.64 | | |
| **Description:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Parameter** | | | **1** | **2** | | | **3** | **4** | | **5** | | | **6** | **7** | | **8** | **9** | | **10** | **11** | | **12** | | | **13** | **14** | | **15** | | **16** | | **17** | | **18** | | **19** | **20** | | **21** | | **22** | **23** | | **24** | **25** |
| **UST\*** | | |  |  | | |  |  | |  | | |  |  | |  |  | |  |  | |  | | |  |  | |  | |  | |  | |  | |  |  | |  | |  |  | |  |  |
| **LST\*** | | |  |  | | |  |  | |  | | |  |  | |  |  | |  |  | |  | | |  |  | |  | |  | |  | |  | |  |  | |  | |  |  | |  |  |
| **Mass (mg)** | | |  |  | | |  |  | |  | | |  |  | |  |  | |  |  | |  | | |  |  | |  | |  | |  | |  | |  |  | |  | |  |  | |  |  |
| **Thickness (mm)** | | |  |  | | |  |  | |  | | |  |  | |  |  | |  |  | |  | | |  |  | |  | |  | |  | |  | |  |  | |  | |  |  | |  |  |
| **Hardness (N)** | | |  |  | | |  |  | |  | | |  |  | |  |  | |  |  | |  | | |  |  | |  | |  | |  | |  | |  |  | |  | |  |  | |  |  |
| **Parameter** | | | **26** | **27** | | | **28** | **29** | | **30** | | | **31** | **32** | | **Refer Attached Printout for Individual Mass(mg), Thickness(mm),**  **Hardness (N) & Mass of 10 Tablets (g) ( Attached / Not attached )**  **\* Put mark for Debossing** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UST\*** | | |  |  | | |  |  | |  | | |  |  | |
| **LST\*** | | |  |  | | |  |  | |  | | |  |  | |
| **Mass (mg)** | | |  |  | | |  |  | |  | | |  |  | |
| **Thickness (mm)** | | |  |  | | |  |  | |  | | |  |  | |
| **Hardness (N)** | | |  |  | | |  |  | |  | | |  |  | |
| **DT (min)** | | | | | | | | | | | | | | | | **Mass of 10 Tablets (g)** | | | | | | | | | | | | | | | | | **Friability (%m/m)** | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
| **End of activity By** | | | | **Time** | | | | | |  | | | | | | | | | | | | **Verified By** | | | | | | **Time** | | | | | |  | | | | | | | | | | |
| **Sign & Date** | | | | | |  | | | | | | | | | | | | **Sign & Date** | | | | | |  | | | | | | | | | | |

| **6.7 In-process Check Record – During Compression (Physical Inspection of Compressed Tablets)** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Details** | **Date** | **Time** | | **Date** | **Time** | **Date** | | **Time** | **Date** | | **Time** | **Date** | | **Time** |
|  |  | |  |  |  | |  |  | |  |  | |  |
| Description of tablets | Complies  /  Not complies  | | | Complies  /  Not complies  | | Complies  /  Not complies  | | | Complies  /  Not complies  | | | Complies  /  Not complies  | | |
| **Physical Inspection of Compressed Tablets (Take Approximately one rotation of compressed tablets)** Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories then the unit shall be counted as one nonconforming unit. | | | | | | | | | | | | | | |
| **Total Defects** |  | | | | | | | | | | | | | |
| Foreign product |  | |  | | | |  | | |  | | |  | |
| Embedded surface spots |  | |  | | | |  | | |  | | |  | |
| Broken tablets |  | |  | | | |  | | |  | | |  | |
| Capping |  | |  | | | |  | | |  | | |  | |
| Lamination |  | |  | | | |  | | |  | | |  | |
| Presence of hair |  | |  | | | |  | | |  | | |  | |
| Foreign odour |  | |  | | | |  | | |  | | |  | |
| Illegible debossing |  | |  | | | |  | | |  | | |  | |
| Porous surface |  | |  | | | |  | | |  | | |  | |
| Sticking |  | |  | | | |  | | |  | | |  | |
| Picking |  | |  | | | |  | | |  | | |  | |
| Chipping |  | |  | | | |  | | |  | | |  | |
| Projected edges |  | |  | | | |  | | |  | | |  | |
| Excess powder on tablet surface |  | |  | | | |  | | |  | | |  | |
| Others |  | |  | | | |  | | |  | | |  | |
| **Action taken** |  | |  | | | |  | | |  | | |  | |
| **Checked by**  **(Sign & date)** |  | |  | | | |  | | |  | | |  | |
| **Note: Enter √ mark on the**  Complies / Not complies | | | | | | | | | | | | | | |

| **6.7 In-process Check Record – During Compression (Physical Inspection of Compressed Tablets)** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Details** | **Date** | **Time** | | **Date** | **Time** | **Date** | | **Time** | **Date** | | **Time** | **Date** | | **Time** |
|  |  | |  |  |  | |  |  | |  |  | |  |
| Description of tablets | Complies  /  Not complies  | | | Complies  /  Not complies  | | Complies  /  Not complies  | | | Complies  /  Not complies  | | | Complies  /  Not complies  | | |
| **Physical Inspection of Compressed Tablets (Take Approximately one rotation of compressed tablets)** Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories then the unit shall be counted as one nonconforming unit. | | | | | | | | | | | | | | |
| **Total Defects** |  | | | | | | | | | | | | | |
| Foreign product |  | |  | | | |  | | |  | | |  | |
| Embedded surface spots |  | |  | | | |  | | |  | | |  | |
| Broken tablets |  | |  | | | |  | | |  | | |  | |
| Capping |  | |  | | | |  | | |  | | |  | |
| Lamination |  | |  | | | |  | | |  | | |  | |
| Presence of hair |  | |  | | | |  | | |  | | |  | |
| Foreign odour |  | |  | | | |  | | |  | | |  | |
| Illegible debossing |  | |  | | | |  | | |  | | |  | |
| Porous surface |  | |  | | | |  | | |  | | |  | |
| Sticking |  | |  | | | |  | | |  | | |  | |
| Picking |  | |  | | | |  | | |  | | |  | |
| Chipping |  | |  | | | |  | | |  | | |  | |
| Projected edges |  | |  | | | |  | | |  | | |  | |
| Excess powder on tablet surface |  | |  | | | |  | | |  | | |  | |
| Others |  | |  | | | |  | | |  | | |  | |
| **Action taken** |  | |  | | | |  | | |  | | |  | |
| **Checked by**  **(Sign & date)** |  | |  | | | |  | | |  | | |  | |
| **Note: Enter √ mark on the**  Complies / Not complies | | | | | | | | | | | | | | |

| **6.7 In-process Check Record – During Compression (Physical Inspection of Compressed Tablets)** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Details** | **Date** | **Time** | | **Date** | **Time** | **Date** | | **Time** | **Date** | | **Time** | **Date** | | **Time** |
|  |  | |  |  |  | |  |  | |  |  | |  |
| Description of tablets | Complies  /  Not complies  | | | Complies  /  Not complies  | | Complies  /  Not complies  | | | Complies  /  Not complies  | | | Complies  /  Not complies  | | |
| **Physical Inspection of Compressed Tablets (Take Approximately one rotation of compressed tablets)** Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories then the unit shall be counted as one nonconforming unit. | | | | | | | | | | | | | | |
| **Total Defects** |  | | | | | | | | | | | | | |
| Foreign product |  | |  | | | |  | | |  | | |  | |
| Embedded surface spots |  | |  | | | |  | | |  | | |  | |
| Broken tablets |  | |  | | | |  | | |  | | |  | |
| Capping |  | |  | | | |  | | |  | | |  | |
| Lamination |  | |  | | | |  | | |  | | |  | |
| Presence of hair |  | |  | | | |  | | |  | | |  | |
| Foreign odour |  | |  | | | |  | | |  | | |  | |
| Illegible debossing |  | |  | | | |  | | |  | | |  | |
| Porous surface |  | |  | | | |  | | |  | | |  | |
| Sticking |  | |  | | | |  | | |  | | |  | |
| Picking |  | |  | | | |  | | |  | | |  | |
| Chipping |  | |  | | | |  | | |  | | |  | |
| Projected edges |  | |  | | | |  | | |  | | |  | |
| Excess powder on tablet surface |  | |  | | | |  | | |  | | |  | |
| Others |  | |  | | | |  | | |  | | |  | |
| **Action taken** |  | |  | | | |  | | |  | | |  | |
| **Checked by**  **(Sign & date)** |  | |  | | | |  | | |  | | |  | |
| **Note: Enter √ mark on the**  Complies / Not complies | | | | | | | | | | | | | | |

| **6.7 In-process Check Record – During Compression (Physical Inspection of Compressed Tablets)** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Details** | **Date** | **Time** | | **Date** | **Time** | **Date** | | **Time** | **Date** | | **Time** | **Date** | | **Time** |
|  |  | |  |  |  | |  |  | |  |  | |  |
| Description of tablets | Complies  /  Not complies  | | | Complies  /  Not complies  | | Complies  /  Not complies  | | | Complies  /  Not complies  | | | Complies  /  Not complies  | | |
| **Physical Inspection of Compressed Tablets (Take Approximately one rotation of compressed tablets)** Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories then the unit shall be counted as one nonconforming unit. | | | | | | | | | | | | | | |
| **Total Defects** |  | | | | | | | | | | | | | |
| Foreign product |  | |  | | | |  | | |  | | |  | |
| Embedded surface spots |  | |  | | | |  | | |  | | |  | |
| Broken tablets |  | |  | | | |  | | |  | | |  | |
| Capping |  | |  | | | |  | | |  | | |  | |
| Lamination |  | |  | | | |  | | |  | | |  | |
| Presence of hair |  | |  | | | |  | | |  | | |  | |
| Foreign odour |  | |  | | | |  | | |  | | |  | |
| Illegible debossing |  | |  | | | |  | | |  | | |  | |
| Porous surface |  | |  | | | |  | | |  | | |  | |
| Sticking |  | |  | | | |  | | |  | | |  | |
| Picking |  | |  | | | |  | | |  | | |  | |
| Chipping |  | |  | | | |  | | |  | | |  | |
| Projected edges |  | |  | | | |  | | |  | | |  | |
| Excess powder on tablet surface |  | |  | | | |  | | |  | | |  | |
| Others |  | |  | | | |  | | |  | | |  | |
| **Action taken** |  | |  | | | |  | | |  | | |  | |
| **Checked by**  **(Sign & date)** |  | |  | | | |  | | |  | | |  | |
| **Note: Enter √ mark on the**  Complies / Not complies | | | | | | | | | | | | | | |

# 6.8 Control Graph for Average Mass (g)

**Std. Mass of 10 tablets: 6.450 g** ± **3% (6.26 g – 6.64 g) Validated speed: 10 – 50 RPM**

**Optimum speed: 15-40 RPM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Time** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Machine Speed (RPM)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **6.65** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.61 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.57 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.53 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.49 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.450** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.41 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.37 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.33 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.29 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.25** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| **Mass of 10 tablets (g)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Done By**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**6.8** **Control Graph for Average Mass (g)**

**Std. Mass of 10 tablets: 6.450 g** ± **3% (6.26 g – 6.64 g) Validated speed: 10 – 50 RPM**

**Optimum speed: 15-40 RPM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Time** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Machine Speed (RPM)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **6.65** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.61 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.57 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.53 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.49 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.450** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.41 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.37 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.33 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.29 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.25** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| **Mass of 10 tablets (g)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Done By**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**6.8** **Control Graph for Average Mass (g)**

**Std. Mass of 10 tablets: 6.450 g** ± **3% (6.26 g – 6.64 g) Validated speed: 10 – 50 RPM**

**Optimum speed: 15-40 RPM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** |  | |  | |  | |  | |  | |  | |  | | **Average Value of the graph: \_\_\_\_\_\_\_\_\_\_\_\_\_ mg** |
| **Time** |  | |  | |  | |  | |  | |  | |  | |
| **Machine Speed (RPM)** |  | |  | |  | |  | |  | |  | |  | |
| **6.65** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.61 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.57 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.53 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.49 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.450** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| 6.41 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.37 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.33 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 6.29 | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| **6.25** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** | **+** |
| **Mass of 10 tablets (g)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Done By**  **(Sign & Date)** |  | |  | |  | |  | |  | |  | |  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6.9 In-process Checks Record – During Compression** Note: A minimum of three In – process checks should be done during the entire compression process | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **2** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **3** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **4** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **5** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **6** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **7** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **8** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **9** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **10** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **11** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **12** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **13** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **14** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **15** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **16** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

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| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

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| **17** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **18** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **19** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **20** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

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| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

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| **21** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **22** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **23** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **24** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

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| **6.9 In-process Checks Record – During Compression** | | | | | | | |
| Mass of individual tablet (mg) | | | Thickness (mm) | | | Disintegration time (min) | Friability (%m/m) |
| Minimum | Target | Maximum | Minimum | Target | Maximum | NMT | NMT |
| 613 | 645.000 | 677 | 6.2 | 6.60 | 7.0 | 15 | 1.0 |

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| **25** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **26** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |
| **27** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| **28** | Tablet Mass (mg) |  |  |  |  |  |  |  |  |  |  |
| Thickness (mm) |  |  |  |  |  |  |  |  |  |  |
| Disintegration time (min) |  | | | | | | | | | |
| Friability (%m/m) |  | | | | | | | | | |
| **Time** |  | | | | | | | | | |
| **(Sign & Date)** |  | | | | | | | | | |
| Refer Attached Printout for Tablet Mass (mg), Thickness(mm), Disintegration time (min) & Friability (%m/m) ( Attached / Not attached) | | | | | | | | | | | |

**6.9.1 In-process Checks Record – During Compression**

**Individual Hardness (Limit: Min – 130 N, Target- 170 N, and Max – 210 N)**

Note: A minimum of three in – process checks should be done during the entire compression process.

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| **Date/ Time** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Tablet No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** |
| **1** |  |  |  |  |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Done By**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Refer Attached Printout ( Attached / Not attached )** | | | | | | | | | | | | |

**6.9.1 In-process Checks Record – During Compression**

**Individual Hardness (Limit: Min – 130 N, Target- 170 N, and Max – 210 N)**

Note: A minimum of three in – process checks should be done during the entire compression process.

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| **Date/ Time** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Tablet No.** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| **11** |  |  |  |  |  |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |  |  |  |  |  |
| **13** |  |  |  |  |  |  |  |  |  |  |  |  |
| **14** |  |  |  |  |  |  |  |  |  |  |  |  |
| **15** |  |  |  |  |  |  |  |  |  |  |  |  |
| **16** |  |  |  |  |  |  |  |  |  |  |  |  |
| **17** |  |  |  |  |  |  |  |  |  |  |  |  |
| **18** |  |  |  |  |  |  |  |  |  |  |  |  |
| **19** |  |  |  |  |  |  |  |  |  |  |  |  |
| **20** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Done By**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Refer Attached Printout ( Attached / Not attached )** | | | | | | | | | | | | |

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| **6.10 Compressed Tablets Containers Weighing Record Weighing balance ID No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | |
| **Container No.** | **Tare**  **Weight**  **(Kg)** | **Gross**  **Weight**  **(Kg)** | **Net**  **Weight**  **(Kg)** |  | **Container No.** | **Tare**  **Weight**  **(Kg)** | **Gross**  **Weight**  **(Kg)** | **Net Weight**  **(Kg)** |  | **Container No.** | **Tare**  **Weight**  **(Kg)** | **Gross**  **Weight**  **(Kg)** | **Net Weight**  **(Kg)** |
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|  |  |  |  |  |  |  |  | **Total Net Mass (Kg)** | |  | |
| **Weighed by (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | |
| 6.11 Yield and reconciliation   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | A | Standard batch Size | | | | | **80.625 Kg** | | B | Blend yield | | | | | \_\_\_\_\_\_\_\_\_\_\_Kg. | | C | Average Mass of compressed tablets in mg | | | | | \_\_\_\_\_\_\_\_\_\_\_mg | | D | Mass of compressed tablets | | | | | \_\_\_\_\_\_\_\_\_\_Kg. | | E | Samples | 1 | Sample quantity for analysis | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg |  | \_\_\_\_\_\_\_\_\_\_\_Kg | | 2 | IPQA Samples | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | 3 | Others (Specify if any) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | Total | | | | F | Rejects | 1 | Handling Loss | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg |  | \_\_\_\_\_\_\_\_\_\_ Kg | | 2 | Spillage | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | 3 | Setting rejects | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | 4 | Others$ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | Total | | | | G | Compression yield (D + E) x 100 / B | | | | | %\* | | H | Reconciliation (D+E+F) x 100 / B | | | | | %\*\* |   \* Compression yield limit 92% to 100%  \*\* Reconciliation limit 95% to100%  $ Others quantity can be defined as, ADU rejects, left over blend, Metal Trap Rejects and not limited to.  Note: Any outlier to the yield limit shall be handled as per SOP on Procedure for yield and Reconciliation of drug products (PD079†).  **Calculated by (Production) (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (QA) (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **† Current effective version to be referred** | | | | | | | | | | | | | |

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| **9.0 Compressed Tablets for Coating** | | | | |
| **Lot No.** | **Total Net Mass (Kg)** | **No. of Containers** | **Done By (PD) (Sign & Date)** | **Checked By (PD) (Sign & Date)** |
| **I** |  |  |  |  |
| **II** |  |  |  |  |

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| **Film - Coating**  **General Manufacturing Instructions & Safety precautions:**  1. Avoid skin contact while handling and processing of product.  2. Wear hand gloves and mask while handling and processing of product. (If required use the 3M nose mask and Personal Respirators)  3. Ensure that the tablets are free from powder.  4. Ensure earthing of the Coating machine.  5. Ensure that the shaft does not touch either the bottom or the side of the container/Solution Preparation vessel.  6. During spray make sure that the nozzles are not clogged. | | | | | | |
| **Activity** | **Date** | **Time** | **Differential pressure**  **(\_\_\_\_\_\_\_mm of WC)** | **Temperature**  **(NMT 25°C)** | **% Relative Humidity (NMT 40% RH)** | **Done By**  **(Sign & Date)** |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |
| Start of Activity |  |  |  |  |  |  |
| End of Activity |  |  |  |  |  |  |

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| **Manufacturing Area cGMP Check List:**  Inspect the working area and equipment for cleanliness before use and ensure that the status tags are properly filled in.    **Area Clearance:**     |  |  | | --- | --- | | **Check the following** | **Status** | | Room Name & No. |  | | Previous Product & Batch No. |  | | Type of Area cleaning | **Type A /** **Type B** | | Area Cleanliness | **Satisfactory /** **Not Satisfactory** |   **Note: Enter √ mark on the Type A /  Type B and Satisfactory / Not Satisfactory**  **Inspected By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Equipment Clearance:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Equipment Name** | **Equipment No.** | **Previous product** | **Batch No.** | **Strength /Batch/Product /**  **Colour change over** | **Type of cleaning** |
| Solution preparation vessel | PDA- |  |  |  |  |
| Agitation tank | PDA- |  |  |  |  |
| Automatic Coating Machine 36” | PDE – 1011 |  |  |  |  |
| **Checked By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approved By (QA)(Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | |

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| **Step No.** | **Process Instructions** |
| **10.0** | Check the Integrity of the All Gaskets Before use After Type “A” cleaning & After use Before Type “A” cleaning.  Record the observations in the given table **(Gasket Integrity Check).** |

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| **10.0** | **Gasket Integrity Check** | | | | |
| **Gasket Integrity Before use**  **(After Type “A” cleaning)**  **Batch No.\_\_\_\_\_\_\_\_\_\_\_\_** | | **Checked By**  **(Sign & Date)** | **Gasket Integrity After use**  **(Before Type “A” cleaning)**  **Batch No.\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Checked By**  **(Sign& Date)** | **Remarks** |
| **S / NS / NA ** | |  | **S / NS / NA ** |  |  |
| **Note: Enter √ mark on the S-Satisfactory / NS-Not Satisfactory/ NA-Not applicable** | | | | | |

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| **11.0 Suspension Preparation:**  11.1 Take Purified water in a S.S container equipped with a propeller stirrer.  11.2 Add **Opadry Pink 15B24005** slowly to the Purified water step no. **11.1** while stirring, increase the speed of stirrer if necessary. Avoid  formation of excessive foam during stirring. Continue stirring for **45 minutes** or till a smooth homogeneous suspension is obtained. Keep the  suspension under agitation, at slow speed, during the entire coating process  **12.0 Spray Rate Evaluation**  12.1Spray rate shall be checked initially / start of the coating process. Evaluate the spray rate by collecting the spray from all the guns individually at  Different Peristaltic pump RPM (Low to high range of limit) and measure the quantity sprayed from each gun.  12.2 Adjust/rectify the guns for proper uniform spray if any blockage / non uniform spray. Record the observations given in the table  **(Spray Rate Evaluation Record)**  **13.0 Warming of core Tablets**  Load Core tablets into coating pan and warm the tablets while jogging the pan until the tablet bed temperature reaches of **NMT 50°C.** Continue the  Warming of tablets for 5 to 10 minutes with intermittent jogging. Record the Mass of 50 warmed tablets given in the table **(Coating Monitoring Record)**  Prior to coating and calculate the average Mass of core tablets as below mentioned formula.   |  |  |  | | --- | --- | --- | | Mass of 50 warmed tablets (g) X 1000 |  | = mg | | 50 |   **14.0 Coating of Tablets:**  Start the coating pan and spray the film coating suspension and record the Mass gain of the tablets. Stop the coating when the average tablet Mass  gain is **3.0% m/m ± 0.5% m/m (2.5% m/m – 3.5% m/m)** of core tablet Mass. Record the parameters for every 30 minutes during the coating process  given in the table **(Coating Monitoring Record).** Destroy the remaining film coating suspension.  **15.0 Drying of Coated Tablets**:  15.1 After completion of coating process continue the drying of coated tablets at inlet temperature of **NMT 660C** for 15 – 20 min at jogging mode. Record  the parameters during the drying of coated tablets given in the table **(Coating Monitoring Record).**  15.2 Then decrease the temperature and cool down tablets to room temperature.  15.3 Un-load the tablets from coating pan in jogging mode into containers and update the weighing record.  15.4 Withdraw the in – process sample --- by QA as per **SOP QA023†.**  **† Current effective version to be referred.** |

**11.0** **Weighing Record: Balance ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Name of ingredient** | **A.R. No.** | **Container No.** | **Gross Weight (kg)** | **Tare Weight (kg)** | **Net Weight (kg)** | **Collected By (Sign & Date)** |
| Purified Water IHS/USP/Ph.Eur11.529 Kg (Lot-I) |  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Purified Water IHS/USP/Ph.Eur11.530 Kg (Lot-II) |  |  |  |  |  |  |
|  |  |  |  |  |  |
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| **Suspension Preparation** | | | | |
| --- | --- | --- | --- | --- |
| **Step No.** | **Process Instructions** | | **Lot - I** | **Lot - II** |
| **11.1** | Activity Start Time | |  |  |
| Sign & Date | |  |  |
| Solution Preparation vessel ID: | |  |  |
| Take **11.529 kg (Lot-I) / 11.530 kg (Lot-II)** of Purified Water in a S.S container equipped with a propeller stirrer. | | | |
| **11.2** | Add **1.572 Kg (Lot-I) / 1.572 Kg (Lot-II)** of  **Opadry Pink 15B24005** slowly to the purified water of step no. **11.1** while stirring. Increase the speed of stirrer if necessary. Avoid formation of excessive foam during stirring. Continue stirring for **45 minutes** or till to get a smooth homogeneous suspension is obtained. Keep the suspension under agitation, at slow speed, during the entire coating process. | Stirring Start Time |  |  |
| Stirring End Time |  |  |
| Suspension is homogenous | **Confirmed  /**  **Not Confirmed ** | **Confirmed  /**  **Not Confirmed ** |
| Suspension Agitation | Start time |  |  |
| End time |  |  |
| **Verified By (Sign & Date)** | | |  |  |
| **Note: Enter √ mark on the**  Confirmed  /Not Confirmed  | | | | |

1. **Setting of Coating Machine**

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| **Step No.** | **Process Instructions** | | |
| 12.1 | Set the spray guns and coating parameters as per the operating instructions to achieve the following parameters. | | |
| **Description** | Pink, Oval, biconvex, film-coated tablets debossed with **‘J’** on one side and **‘156’** on the other side. | |
| Parameters | **36” Automatic coating machine (Neocota)** | |
| Pan Speed (RPM) | 2.0 – 5.0 RPM (Observed RPM) | |
| No. of Guns | 03 | |
| **Spray Rate (gm/min)** | 49 – 142 gm/min | |
| **Spray Type** | Continuous | |
| **Atomized Air Pressure (Kg/cm2)** | 1.0 – 3.0 Kg/cm2 | |
| **Tablet Bed Temperature (0C)** | NMT 500C | |
| **Inlet Air Temperature (0C)** | NMT 660C | Done by (PD)  (Sign & Date):\_\_\_\_\_\_\_\_\_\_\_ |
| **Exhaust Temperature (0C)** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 0C (To be recorded) |
| **Gun Distance\* (cm)** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Cm (To be Recorded) |
| **% Mass gain / Tablet** | 3.0% m/m ± 0.5% m/m (2.5% m/m – 3.5% m/m) | |

**Note:** Perform the ‘In-process inspection during coating’ **(SOP No: PD070†). † Current effective version to be referred.**

**Note: \*Limits shall be finalized after completion of 20 batches.**

|  |  |  |  |  |  |  |  |  |  |  |
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| **12.2 Spray Rate Evaluation Record** | | | | | | | | | | |
| **Equipment ID: Weighing balance ID No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |  |
| **Trail No. (s)** | **Trail-1** | | | **Trail-2** | | | **Trail-3** | | |
| **RPM** |  | | |  | | |  | | |
| **Gun (s)** | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (B – A) (g/gun/min) | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (B – A) (g/gun/min) | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (B – A) (g/gun/min) |
| **Gun-I** |  |  |  |  |  |  |  |  |  |
| **Gun-II** |  |  |  |  |  |  |  |  |  |
| **Gun-III** |  |  |  |  |  |  |  |  |  |
| **Total Spray Rate (gm/min)** |  | | |  | | |  | | |
| **Done By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |

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| **12.2 Spray Rate Evaluation Record** | | | | | | | | | | |
| **Equipment ID: Weighing balance ID No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |  |
| **Trail No. (s)** | **Trail-1** | | | **Trail-2** | | | **Trail-3** | | |
| **RPM** |  | | |  | | |  | | |
| **Gun (s)** | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (D – C) (g/gun/min) | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (D – C) (g/gun/min) | 1. Mass of measuring jar before sample spray (g) | 1. Mass of measuring jar after sample spray (g) | Difference  (D – C) (g/gun/min) |
| **Gun-I** |  |  |  |  |  |  |  |  |  |
| **Gun-II** |  |  |  |  |  |  |  |  |  |
| **Gun-III** |  |  |  |  |  |  |  |  |  |
| **Total Spray Rate (gm/min)** |  | | |  | | |  | | |
| **Done By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |

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| **Coating Monitoring Record (Lot –I)** | | | | | |
| **Equipment ID** |  | | **Weighing Balance ID:** | **Balance ID** |  |
| Done By Name |  | | | Sign & Date: | |
| Activity Start Date |  | Core Tablet Container Nos. transferred into pan. | |  | |
| Activity Start Time |  | Gross Mass of containers/Bin complies | | Yes  / No  | |
| Gun Distance (cm) |  | Core Tablets Total Mass (Kg) | |  | |

| **Parameters / Details** | **Limits** | **13.0 Pre-Warming of Tablets** | | **14.0 Coating** Record the following every 30 minutes during the coating process for production | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **From** | **To** | **NA** | | | | | | | | | | |
| Date | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Time | NA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pan Speed (RPM) | 2.0–5.0 RPM (Observed RPM) |  | |  |  |  |  |  |  |  |  |  |  |  |
| Inlet Air Temp. (˚C) | NMT 660C |  | |  |  |  |  |  |  |  |  |  |  |  |
| Exhaust Air Temp. (°C) | To be recorded |  | |  |  |  |  |  |  |  |  |  |  |  |
| Bed Temp. (°C) | NMT 500C |  | |  |  |  |  |  |  |  |  |  |  |  |
| Average Mass of warmed tablet (mg) (y) | NA |  | | | | | | | | | | | | |
| Average Mass of 50 coated tablet (mg) [x] | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Mass build up per tablet (mg)  [z = x – y] | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Percentage Mass build up per tablet [z / y X100] (%) | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Atomizing Air Pressure (Kg/cm2) | 1.0 - 3.0 Kg/cm2 |  | |  |  |  |  |  |  |  |  |  |  |  |
| Peristaltic Pump Speed (RPM) | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| **Checked by (Sign & Date)** | NA |  | |  |  |  |  |  |  |  |  |  |  |  |

**Note: Enter √ mark on the** Yes  / No 

| **Coating Monitoring Record (Lot –I) (Contd….)** | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameters / Details** | **Limits** | **14.0 Coating (Contd…)** Record the following every 30 minutes during the coating process for production | | | | | | | | | | | **15.0 Coated Tablets Drying** | |
| **NA** | | | | | | | | | | | **From** | **To** |
| Date | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Time | NA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pan Speed (RPM) | 2.0–5.0 RPM (Observed RPM) |  |  |  |  |  |  |  |  |  |  |  |  | |
| Inlet Air Temp. (˚C) | NMT 660C |  |  |  |  |  |  |  |  |  |  |  |  | |
| Exhaust Air Temp. (°C) | To be recorded |  |  |  |  |  |  |  |  |  |  |  |  | |
| Bed Temp. (°C) | NMT 500C |  |  |  |  |  |  |  |  |  |  |  |  | |
| Average Mass of warmed tablet (mg) (y) | NA |  | | | | | | | | | | | | |
| Average Mass of 50 coated tablet (mg) [x] | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Mass build up per tablet (mg) [z = x – y] | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Percentage Mass build up per tablet [z / y X100] (%) | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Atomizing Air Pressure (Kg/cm2) | 1.0 - 3.0 Kg/cm2 |  |  |  |  |  |  |  |  |  |  |  | **End Activity By**  **Time: \_\_\_\_\_\_\_\_\_**  **(sign & date):**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| Peristaltic Pump Speed (RPM) | NA |  |  |  |  |  |  |  |  |  |  |  |
| **Checked by (Sign & Date)** | NA |  |  |  |  |  |  |  |  |  |  |  |  | | |

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| **Step No.** | **Process Instructions for (Lot – I)** | | | | | | | | | | | | | | | |
| **16.0** | **Physical Inspection of Coated Tablets (Frequency: PD and QA alternatively every one hour)** | | | | | | | | | | | | | | | |
| **Defects** |  | | | | | | | | | | | | | | | |
| **Date** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Time** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Foreign particle |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Broken tablets |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Capping |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Film peeling off |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Twins |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Illegible Debossing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mottling |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Surface not smooth |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non characteristic odour |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Chipping |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Color non- uniformity |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Checked by**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Defects Observed** |  | | | | | | | | | | | | | | | |
| **Action taken** |  | | | | | | | | | | | | | | | |
| **Note: Enter if no defects observed.** | | | | | | | | | | | | | | | | |

**15.3 Coated Tablets Weighing Record for (Lot-I) Balance ID No.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Container**  **No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |
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|  |  |  |  |  |  |  |  | **Total Net Mass (Kg)** | | |  |
| **Weighed by (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | |

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| Discard the left over coating suspension (Kg) |  |
| **Done by (Sign & Date)** |  |

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| **Coating Monitoring Record (Lot – II)** | | | | | |
| **Equipment ID** |  | | **Weighing Balance ID:** | **Balance ID** |  |
| Done By Name |  | | | Sign & Date: | |
| Activity Start Date |  | Core Tablet Container Nos. transferred into pan. | |  | |
| Activity Start Time |  | Gross Mass of containers/Bin complies | | Yes  / No  | |
| Gun Distance (cm) |  | Core Tablets Total Mass (Kg) | |  | |

| **Parameters / Details** | **Limits** | **13.0 Pre-Warming of Tablets** | | **14.0 Coating** Record the following every 30 minutes during the coating process for production | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **From** | **To** | **NA** | | | | | | | | | | |
| Date | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Time | NA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pan Speed (RPM) | 2.0–5.0 RPM (Observed RPM) |  | |  |  |  |  |  |  |  |  |  |  |  |
| Inlet Air Temp. (˚C) | NMT 660C |  | |  |  |  |  |  |  |  |  |  |  |  |
| Exhaust Air Temp. (°C) | To be recorded |  | |  |  |  |  |  |  |  |  |  |  |  |
| Bed Temp. (°C) | NMT 500C |  | |  |  |  |  |  |  |  |  |  |  |  |
| Average Mass of warmed tablet (mg) (y) | NA |  | | | | | | | | | | | | |
| Average Mass of 50 coated tablet (mg) [x] | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Mass build up per tablet (mg)  [z = x – y] | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Percentage Mass build up per tablet [z / y X100] (%) | NA |  | |  |  |  |  |  |  |  |  |  |  |  |
| Atomizing Air Pressure (Kg/cm2) | 1.0 - 3.0 Kg/cm2 |  | |  |  |  |  |  |  |  |  |  |  |  | |
| Peristaltic Pump Speed (RPM) | NA |  | |  |  |  |  |  |  |  |  |  |  |  | |
| **Checked by (Sign & Date)** | NA |  | |  |  |  |  |  |  |  |  |  |  |  | |

**Note: Enter √ mark on the** Yes  / No 

| **Coating Monitoring Record (Lot –II) (Contd….)** | | | | | | | | | | | | | | |
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| **Parameters / Details** | **Limits** | **14.0 Coating (Contd…)** Record the following every 30 minutes during the coating process for production | | | | | | | | | | | **15.0 Coated Tablets Drying** | |
| **NA** | | | | | | | | | | | **From** | **To** |
| Date | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Time | NA |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pan Speed (RPM) | 2.0–5.0 RPM (Observed RPM) |  |  |  |  |  |  |  |  |  |  |  |  | |
| Inlet Air Temp. (˚C) | NMT 660C |  |  |  |  |  |  |  |  |  |  |  |  | |
| Exhaust Air Temp. (°C) | To be recorded |  |  |  |  |  |  |  |  |  |  |  |  | |
| Bed Temp. (°C) | NMT 500C |  |  |  |  |  |  |  |  |  |  |  |  | |
| Average Mass of warmed tablet (mg) (y) | NA |  | | | | | | | | | | | | |
| Average Mass of 50 coated tablet (mg) [x] | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Mass build up per tablet (mg) [z = x – y] | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Percentage Mass build up per tablet [z / y X100] (%) | NA |  |  |  |  |  |  |  |  |  |  |  |  | |
| Atomizing Air Pressure (Kg/cm2) | 1.0 - 3.0 Kg/cm2 |  |  |  |  |  |  |  |  |  |  |  | **End Activity By**  **Time: \_\_\_\_\_\_\_\_\_**  **(sign & date):**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| Peristaltic Pump Speed (RPM) | NA |  |  |  |  |  |  |  |  |  |  |  |
| **Checked by (Sign & Date)** | NA |  |  |  |  |  |  |  |  |  |  |  |  | | |

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| **Step No.** | **Process Instructions for (Lot – II)** | | | | | | | | | | | | | | | |
| **16.1** | **Physical Inspection of Coated Tablets (Frequency: PD and QA alternatively every one hour)** | | | | | | | | | | | | | | | |
| **Defects** |  | | | | | | | | | | | | | | | |
| **Date** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Time** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Foreign particle |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Broken tablets |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Capping |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Film peeling off |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Twins |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Illegible Debossing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mottling |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Surface not smooth |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non characteristic odour |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Chipping |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Color non- uniformity |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Checked by**  **(Sign & Date)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Defects Observed** |  | | | | | | | | | | | | | | | |
| **Action taken** |  | | | | | | | | | | | | | | | |
| **Note: Enter if no defects observed.** | | | | | | | | | | | | | | | | |

**15.3 (A) Coated Tablets Weighing Record for (Lot-II) Balance ID No.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Container**  **No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |
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|  |  |  |  |  |  |  |  | **Total Net Mass (Kg)** | | |  |
| **Weighed by (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | |

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| Discard the left over coating suspension (Kg) |  |
| **Done by (Sign & Date)** |  |

**15.4 Sample collection for analysis:**

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| --- | --- | --- |
| Withdraw the samples for analysis -- by QA as per SOP QA023†. Record Sampled quantity | **Kg/G/No.s** |  |
| Sampled By (QA) | **Sign & Date** |  |

**17.0 AQL (ACCEPTANCE QUALITY LIMIT) CHECK:**

Collect the representative (pooled samples) samples from all the containers (as per the SOP No.: QA036†)

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| **Lot**  **No** | **Number of samples (items) collected for performing AQL** | **Number of Non-conforming items:** | | | **AQL**  **(PASS / FAIL)** | **Conclusion Inspection Required/**  **Not required** | **Total No. of AQL rejects** | **Done by (QA) (Sign & Date)** | |
| **Critical \* (No.s.)** | **Major\*\* (No.s.)** | **Minor\*\* (No.s.)** |
| **I** |  |  |  |  |  |  |  |  | |
| **II** |  |  |  |  |  |  |  |  | |
| **17.1** | **Grand Total No. of AQL rejects** | | | | | |  |  | |
| **\* In case of observations of any critical non-conformities an incident shall be raised as per the SOP No.: CQA005 and investigation shall be performed jointly by production and QA personnel’s to find the root cause. Based on the outcome of the investigation Head QA shall decide disposition of the batch / lot.**  **\*\* If total observations for either major nonconformities or minor nonconformities or both are above the limit then respective of batch / lot shall be given for 100 % inspection.**  **NOTE: Perform AQL as per the respective SOP No.: QA036†**  **† Current effective version to be referred.** | | | | | | | | | |
| **17.2** | Total Net Mass of coated tablets = (Lot-I) (Step No.15.3) +(Lot-II) (Step No.15.3 (A)) \_\_\_\_\_\_\_\_\_\_\_\_ + \_\_\_\_\_\_\_\_\_\_\_\_ = \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Kg  **Done By (Sign & Date):\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | |

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| **18.0 Yield and reconciliation:**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | I | Standard batch size | | | | | | **125,000 Tablets** | | J | Mass of compressed tablets taken from compression | | | | | | kg | | K | Average Mass of compressed tablets in mg | | | | | | mg | | L | Number of tablets after compression (J x 1000 x 1000/ K) | | | | | | No.s | | M | Mass of Coated tablets after coating. | | | | | | kg | | N | Average Mass of coated tablets in mg | | | | | | mg | | O | Number of tablets after coating (M x1000 x 1000/ N) | | | | | | No.s | | P | Samples | 1 | Sample quantity for analysis | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | No.s | | 2 | IPQA samples | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | | 3 | Others (Specify if any) | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | | Total | | | | | | Q | Rejects | 1 | | Handling loss | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | No.s | | 2. | | AQL Rejects | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | 3 | | Spillage | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | Total | | | | | | R | Coating Yield (O+P) / L x 100 | | | | | | %\* | | S | Reconciliation (O + P + Q) / L x 100 | | | | | | %\*\* | | T | Final Batch yield (O/I) x 100 | | | | | | %\*\*\* |   \* Coating yield limit 98% to100%.  \*\* Reconciliation limit 99% to 100%.  \*\*\* Final batch yield limit 82% to 100%.  Note: Any outlier to the yield limit shall be handled as per SOP on Procedure for Yield and Reconciliation of Drug Product (PD079†).    **Calculated by (Production) (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (QA) (Sign & Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **† Current effective version to be referred**  **19.0 Inspection**  **General & Manufacturing precautions:**  1. Avoid skin contact while handling and processing of product.  2. Wear hand gloves and mask when handling and processing of product.  3. Ensure earthing of the inspection machine.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Activity** | **Date** | **Time** | **Differential pressure**  **(\_\_\_\_\_\_\_mm of WC)** | **Temperature (°C)**  **(NMT 25°C)** | **% Relative Humidity**  **(NMT 40% RH)** | **Done By**  **(Sign & Date)** | | Start of Activity |  |  |  |  |  |  | | End of Activity |  |  |  |  |  |  | | Start of Activity |  |  |  |  |  |  | | End of Activity |  |  |  |  |  |  |   **Area Clearance:** Inspect the working area and equipment for cleanliness before use and ensure that the status tags are properly filled in.   |  |  | | --- | --- | | **Check the following** | **Status** | | Room Name & No. |  | | Previous Product & Batch No. |  | | Type of Area cleaning | **Type A /** **Type B** | | Area Cleanliness | **Satisfactory /** **Not Satisfactory** |   **Note: Enter √ mark on the Type A /  Type B and Satisfactory / Not Satisfactory**  **Inspected by (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Equipment Clearance:**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | **Equipment Name** | **Equipment No.** | **Previous Product** | **Batch No.** | **Strength/Batch/Product / Colour change over** | **Type of cleaning** | | Automatic Tablet inspection machine | PDE –1154/ PDE –1288/ PDE-1536  PDE – 1341/ PDE-1376 |  |  |  |  | | **Checked By (PD) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approved By (QA) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | |

**Manufacturing Instructions:**

**Tablet Inspection Record**

| **Step No.** | **Container No.** | **Name of the Inspectors** | **Start** | | **End** | | **Checked By**  **(Sign & Date)** |
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| **Date** | **Time** | **Date** | **Time** |
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**Note:** Short break shall be provided to the inspectors As per SOP PD120†.

**† Current effective version to be referred**

**Manufacturing Instructions:**

**Tablet Inspection Record**

| **Step No.** | **Container No.** | **Name of the Inspectors** | **Start** | | **End** | | **Checked By**  **(Sign & Date)** |
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| **Date** | **Time** | **Date** | **Time** |
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**Note:** Short break shall be provided to the inspectors As per SOP PD120†.

**† Current effective version to be referred.**

**21.0 Inspected Tablets Weighing Record for (Lot- I) Balance ID No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Container**  **No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |
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| **Weighed By (Sign & Date)\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | |
| **Total Net quantity (Kg) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Excluding sample quantity) Total sorting rejected tablets (No.s / Kg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | |

**21.1 Inspected Tablets Weighing Record for (Lot- II) Balance ID No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Container**  **No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |  | **Container No.** | | **Tare**  **Weight (kg)** | **Gross**  **Weight (kg)** | **Net**  **Weight (kg)** |
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| **Weighed By (Sign & Date)\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | |
| **Total Net quantity (Kg) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Excluding sample quantity) Total sorting rejected tablets (No.s / Kg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | |

**22.0 AQL (ACCEPTANCE QUALITY LIMIT) CHECK:**

Collect the representative (pooled samples) samples from all the containers (as per the SOP No.: QA036†)

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| **Lot**  **No.** | **Number of samples (items)**  **collected for performing AQL** | **Number of Non-conforming items** | | | **AQL**  **(PASS / FAIL)** | **Conclusion Inspection Required/**  **Not required** | **Total No. of AQL rejects** | **Done by (QA)**  **(Sign & Date)** |
| **Critical \* (No.s.)** | **Major\*\* (No.s.)** | **Minor\*\* (No.s.)** |
| **I** |  |  |  |  |  |  |  |  |
| **II** |  |  |  |  |  |  |  |  |
| **22.1** | **Grand Total No. of AQL rejects** | | | | | |  |  |
| **\* In case of observations of any critical non-conformities an incident shall be raised as per the SOP No.: CQA005 and investigation shall be performed jointly by production and QA personnel’s to find the root cause. Based on the outcome of the investigation Head QA shall decide disposition of the batch / lot.**  **\*\* If total observations for either major nonconformities or minor nonconformities or both are above the limit then respective of batch / lot shall be given for 100 % inspection.**  **NOTE: After completion of 100% inspection of the batch / lot, once again batch or lot shall be re-Subjected for AQL test.**  **NOTE: Perform AQL as per the respective SOP No.: QA036†** | | | | | | | | |
| **† Current effective version to be referred.** | | | | | | | | |

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| **23.0 Yield and reconciliation:**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | A” | Standard batch size | | | | | | **125,000 Tablets** | | B” | Mass of tablets taken from coating | | | | | | kg | | C” | Average Mass of coated tablets in mg | | | | | | mg | | D” | Number of tablets after coating (B” x1000 x 1000/ C”) | | | | | | No.s | | E” | Mass of inspected tablets | | | | | | kg | | F” | Number of tablets after inspection (E” x 1000 x 1000 / C”) | | | | | | No.s | | G” | Samples | 1 | | Sample quantity for analysis | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | No.s | | 2 | | IPQA samples | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | | 3 | | Others (Specify if any) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | | Total | | | | | | H” | Rejects | 1 | Sorting rejects | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | No.s | | 2 | Spillages | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | 3 | AQL Rejects | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | 4 | Others | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No.s | | Total | | | | | | I” | Inspection Yield (F”+ G”) / D” x 100 | | | | | | %\* | | J” | Reconciliation (F” + G” + H”) / D” x 100 | | | | | | %\*\* | | K” | Final Batch Yield (F” / A”)x 100 | | | | | | %\*\*\* |     \* Inspection yield limit 93% to 100%.  \*\* Reconcilation Limit 96% to 100%.  \*\*\* Final batch yield limit 82% to 100%.  Note: Any outlier to the yield limit shall be handled as per SOP on Procedure for Yield and Reconciliation of Drug Product (PD079†).    **Calculated by (Production) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by (QA) (Sign & Date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **† Current effective version to be referred.** |

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| **DEVIATIONS / INCIDENTS IF ANY**    **Production: Quality Assurance:**  **(Sign & Date) (Sign & Date)** |