Mnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnvvv

**CONFIDENTIAL–NOT TO BE REPRODUCED WITHOUT PERMISSION**

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| --- | --- | --- | --- |
| **Mfg. Date** |  | **Exp. Date** |  |

|  |  |
| --- | --- |
| **Storage Condition:** Keep in a cool dry place Protect from light | Market: Dummy  |
| Shelf Life: NA |
| **Reason for Revision:**  | **Mfg. Location: Nalagarh (Block-N2)** |
| Effective date: | **Review Period:** NA  |
| **BMR Supersedes No.:** NIL | **Product Code:** PQ |
| MMF No. | Standard Batch size | **Recovery added** | **Actual Batch Size**  |
| NA | 1000.0 ltr | NA | NA |
| **Reason for Issue:** For Performance Qualification of Manufacturing tank |

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| Contents of Batch Manufacturing Record |
| **Sr. No.** | **Process Stage** | **Page No.** |
| 1. | Dispensing of Materials | 2-4 |
| 2. | Manufacturing Process | 5 -6 |

STAGE 1: DISPENSING

|  |  |  |  |
| --- | --- | --- | --- |
| Equipment Name | **Equipment Code No.** | **Operation SOP No.** | **Cleaning SOP No.** |
| Reverse Laminar Air flow |  |  |  |
| Dispensing Tools |  |  |  |
| **Area:** Dispensing Area |  |  |  |
|  Check the following and take line clearance from QA as per SOP No.: \_\_\_\_Removal of previous product and batch , Equipment cleanliness , Area cleanliness , Status Labelling , Environmental condition , Balance calibration record , Equipment log sheets , Pressure differential of LAF .  |
|  | Checked by(Store) | Approved by(QA) |
| Sign & Date |  |  |

INSTRUCTIONS:

1. Follow gowning procedure for respective area
2. Use hand gloves, Safety goggles (wherever required) and nose mask during dispensing.
3. Dispense approved materials.
4. Dispensing of material is in single lots.
5. Dispensing of Extra Material is in single lot.

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| **Balances used** |
| **Stores**  | **Production** |
| Balance ID No. | Checked by  | Balance ID No. | Checked by  |
|  |  |  |  |
|  |  |  |  |
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**RAW MATERIAL ISSUANCE SHEET (Production copy)**

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| **Batch Size: 1000.0 Ltrs**  Date |
| S. No | Item Code | Ingredients | UOM | Std. Quantity(Kg) | Actual Quant--ity | Gross wt | Tare wt. | Net wt. | A.R. NO. | Issued by (store)  | Checked by (Production)  | \*Verified By Sign & Date |
| 1. |  | Paracetamol IP | Kg | 1.00\* |  |  |  |  |  |  |  |  |
| 2. |  | Sugar IP | Kg  | 150.00 |  |  |  |  |  |  |  |  |
| 3. |  | Propylene glycol IP | Kg | 10.00 |  |  |  |  |  |  |  |  |
| 6. |  | Purified water IHS |  | q.s. to 1000 L |  |  |  |  |  |  |  |  |

Calculation:

Exact quantity of Paracetamol IP required for a batch in kg is calculated using following formula.

\* Quantity of Paracetamol IP (in kg) = 1 x 100 X Batch size

 Assay on as such basis 1000

Corrected quantity of Paracetamol IP = kg

**STAGE 2: Line Clearance In Manufacturing Area Date:**

|  |  |  |
| --- | --- | --- |
| **Equipment Name** | **Equipment Code No.** | **Operation SOP No.** |
| 2000 ltrs sugar dissolving tank |  |  |
| 1000 ltrsS S Manufacturing Tank |  |  |
| Basket filter assembly |  |  |
| 3000 ltrs S S Holding tank  |  |  |
| Filter Press  |  |  |

Put “√” if complies and put “x” if does not complies in the check box.

|  |  |
| --- | --- |
|  Previous Product: | Batch No.: |
| Check the following and take line clearance from QA as per SOP No. \_\_\_\_\_\_\_\_\_\_\_\_\_Removal of previous product and batch , Equipment cleanliness , Area cleanliness , Status Labelling , Environmental condition , Balance calibration record , Equipment log sheets .  |
|  | Checked by (Production) | Approved by (QA) |
| Sign & Date |  |  |

INSTRUCTIONS:

Follow these general precautions before starting the manufacturing

1. Ensure all equipments are cleaned and having proper status label.
2. Ensure all gowning of the respective area is followed.
3. Ensure that all SOP’s are followed at all stage of manufacturing.
4. Maintain Raw material and finished product at temperature between 25°C± 2°C.

**STAGE 3: MANUFACTURING PROCESS**

 **●** Ensure that all the Raw materials weights are crosschecked before processing.

 **3.1 SOLUTION PREPARATION**  **Date :**

**Process:**

3.1.1. Take 250.0 L of Purified Water in 2000 ltrs sugar dissolving tank , heat up to 80°C, Add Sucrose under Continue stirring till total quantity of sucrose dissolves. Boil the syrup for 2 minutes. Cool to room temp. Filter the syrup through # 100 basket filter to 1000-liter ss vessel equipped with mechanical stirrer.

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| **Preparation of Sucrose Syrup**  |
|  | A.R. NO. | Quantity | Addition & Dissolving Time | Done by | Checked by |
| From | To |
| Purified Water  |  |  |  |  |  |  |
| Sucrose  |  |  |  |  |  |  |
| Temprature of liquid : | RPM : |
| Boiling time : | Observations:  |

|  |
| --- |
| **Filtration Record** |
| **Started at** | **Completed at** | **Done by** | **Checked by** |
|  |  |  |  |

3.1.2. Take 10.0 kg of propylene glycol in ss vessel, warm up to 60°C. Then add paracetamol in it, heat up to 80°C till get a clear solution. Cool to room temp; Transfer this solution to the syrup of step 3.1.1 under stirring. check for clarity of the solution.

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| **Record of preparation & Addition of paracetamol** |
|  | A.R. NO. | Quantity | Preparation , Dissolving & Addition Time | Done by | Checked by |
| From | To |
| Propylene glycol  |  |  |  |  |  |  |
| Paracetamol |  |  |  |  |  |  |
| Temperature of liquid :  |
| Clarity of the solution :  |

3.1.3 Make up the volume to 1000 liter with Purified Water stir for 30 minutes. Intimate the QC Department to collect the samples for analysis as per approved Performance qualification protocol.

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| --- |
| Volume make up  |
| A.R. NO. | Quantity  | Volume Makeup Time  | Stirring Time  | Done by | Checked by |
|  |  | From | To | From | To |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

3.1.4 Filter the solution through filter pad and take the syrup for bottle filling.

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|  **Filtration Record** |
| Date | **Started at** | **Completed at** | **Done by** | **Checked by** |
|  |  |  |  |  |

**Results:**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Location** | **Assay Content %**  |
| **01** | **Top** |  |
| **02** | **Middle** |  |
| **03** | **Bottom** |  |

**BMR. Verified by**

**Head Production \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Head QA \_\_\_\_\_\_\_\_\_\_\_\_\_**

Sign & Date Sign & Date