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| 1. **PRODUCT INFORMATION :** | |
| **MANUFACTURING LICENSE NO.** | **758** |
| **MATERIAL CODE (SAP CODE)** | **INBLD0004** |
| **NAME OF THE PRODUCT** | **IODISED PEPTONE** |
| **LABEL CLAIM** | **NA** |
| **STORAGE CONDITION** | **STORE IN A TIGHTLY CLOSED CONTAINER** |
| **SHELF LIFE** | **1 YEAR** |
| **MARKET** | **NA** |
| **MANUFACTURING DATE** |  |
| **EXPIRY DATE** |  |
| **BMR EFFECTIVE DATE** |  |

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| 1. **SIGNATURE LOG:** | | | | |
| **Sr. No** | **EMP Code** | **Name** | **Full Signature** | **Initial** |
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| 1. **QUANTITY CALCULATIONS:** |
| Based on the Total Solid Content (Standard value: 65 %)  Quantity to be added in the Peptone = Standard Quantity X 65 \_\_  Actual Solid Content in the RM consignment    1) 1st T.R. No:  55 kg x 65  Quantity required =  Actual solid content in 1st T.R. no. of Peptone Conc.    = X = \_\_\_\_\_\_\_\_\_ kg  ( \_\_\_\_\_\_\_\_\_ )    ( Quantity required for 2nd TR no = Calculated quantity of 1st TR - stock available of 1st TR)    \_\_\_\_\_\_\_\_\_\_\_\_\_\_ - \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ = \_\_\_\_\_\_\_\_\_\_ kg      2) If 1st T.R. No. quantity is insufficient for batch then to calculate the quantity required from 2nd T.R. number, use below formula :    Qty. required of 2nd T.R. No. X solid content of 1ST T.R. No.  Quantity required =  Solid content of 2nd T.R.    = X = \_\_\_\_\_\_\_\_\_ kg  ( \_\_\_\_\_\_\_\_\_\_ ) |

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| 1. **RAW MATERIAL DISPENSING:** | |
| * 1. **General Instructions:** | |
| **Sr. No.** | **Instructions** |
|  | Follow current versions of SOPs available. |
|  | Ensure personnel involved in dispensing activity should not be suffering from any sickness, having wound, open lesions or cuts to work in the area. |
|  | Ensure the area must be cleaned and sanitized. |
|  | Verify the cleaning of equipment, utensils, tools etc. as per SOP No. T/RMD (II)/SOP/013 |
|  | Ensure status label of the equipment’s, utensils, tools etc. |
|  | Dispense all raw materials as per SOP No. T/RMD(II)/SOP/003 |

* 1. **CHECKLIST – DISPENSING (LINE CLEARANCE): T/RMD/LAF/04**

| **Sr. No.** | **Check Point** | | **Observation** | **Verified By** | |
| --- | --- | --- | --- | --- | --- |
| **Store** | **QA** |
|  | Name of Previous Product Name |  | |  |  |
|  | Batch No. of previous product |  | |  |  |
|  | To Verify the area is clean. | |  |  |  |
|  | To Verify the all equipment’s are clean & labeled | |  |  |  |
|  | To Ensure the Temperature / Humidity in area NMT 25°C (± 2°C) and NMT 60% | | \_\_\_\_\_\_ oC  \_\_\_\_\_\_ % |  |  |
|  | To Ensure the calibration of balances | |  |  |  |
|  | Record the Magnehelic gauge reading of Pre filter (Limit: 0.2 – 3.0 mmwc) | | \_\_\_\_\_\_\_\_\_ |  |  |
|  | Record Magnehelic gauge reading of intermediate filter (Limit: 0.2 – 6.0 mmwc) | | \_\_\_\_\_\_\_\_\_ |  |  |
|  | Record Magnehelic gauge reading of HEPA filter (Limit: 7 -15 mmwc) | | \_\_\_\_\_\_\_\_\_\_ |  |  |

* 1. **CHECKLIST – DISPENSING (LINE CLEARANCE): T/RMD/LAF/07**

| **Sr. No.** | **Check Point** | | **Observation** | **Verified By** | |
| --- | --- | --- | --- | --- | --- |
| **Store** | **QA** |
|  | Name of Previous Product Name |  | |  |  |
|  | Batch No. of previous product |  | |  |  |
|  | To Verify the area is clean. | |  |  |  |
|  | To Verify the all equipment’s are clean & labeled | |  |  |  |
|  | To Ensure the Temperature / Humidity in area NMT 25°C (± 2°C) and NMT 65% | | \_\_\_\_\_\_ oC  \_\_\_\_\_\_ % |  |  |
|  | To Ensure the calibration of balances | |  |  |  |
|  | Record Magnehelic gauge reading of Pre filter (Limit: 1.0 – 3.0 mmwc) | | \_\_\_\_\_\_\_\_\_ |  |  |
|  | Record Magnehelic gauge reading of intermediate filter (Limit: 3.0 – 6.0 mmwc) | | \_\_\_\_\_\_\_\_\_ |  |  |
|  | Record Magnehelic gauge reading of HEPA filter (Limit: 10-50 mmwc) | | \_\_\_\_\_\_\_\_\_\_ |  |  |

* 1. **LIST OF EQUIPMENT REQUIRED FOR DISPENSING ACTIVITY.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr. No.** | **Name of equipment** | **Equipment Number** | **Cleaning SOP Number** | **Cleaning Status** | **Cleaned By** | **Approved By** |
|  | Weighing Balance | T/RMD/BL/16 T/RMD/BL/17 T/RMD/BL/18 T/RMD/BL/13 T/RMD/BL/14 T/RMD/BL/04  T/RMD/BL/15 | T/RMD (II)/SOP/014 |  |  |  |
|  | Transfer Pump | T/RMD/TP/01  T/RMD/TP/02  T/RMD/TP/03  T/RMD/TP/04  T/RMD/TP/05 | T/RMD (II)/SOP/017 |  |  |  |
|  | Dispensing Booth | T/RMD/LAF/04 | T/RMD (II)/SOP/009 |  |  |  |
|  | Dispensing Booth | T/RMD/LAF/07 | T/RMD (II)/SOP/036 |  |  |  |

1. **STANDARD QUANTITY AS PER BILL OF MATERIAL:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Item Code** | **Item Description** | **Standard quantity** | **UOM\*** |
|  | ININT0001 | TINCTURE IODINE (9.5 -10.5 % w/v) | 40.00 | L |
|  | RMPR00960 | GLYCERINE I.P | 84.000 | KG |
|  | INBLD0002 | PEPTONE | 55.000 # | KG |
|  | -- | PURIFIED WATER TO Q.S. | 215 | L |
| Note: Actual quantity of dispensed material will be generated throughSAP System**.**  # - Quantity of Peptone will be depend on % solid | | | | |

1. **BATCH MANUFACTURING PROCESS:**

|  |  |
| --- | --- |
| * 1. **General Manufacturing Instructions:** | |
| **Sr. No.** | **Instructions** |
|  | Follow current versions of SOPs. |
|  | Ensure personnel involved in manufacturing activity should not be suffering from any sickness, having wound, open lesions or cuts to work in the area. |
|  | Ensure cleaning and sanitization of the area, equipment, utensils, tools etc. as per SOP. |
|  | Before use all manufacturing equipment’s to be checked for ‘Cleaned’ label. |
|  | Rinse all equipment with purified water before use. |
|  | Critical process parameters and Critical quality attributes are defined in italic and underline are required to be verified by supervisor. |
|  | API addition process defined in bold letters are required to be checked by supervisor and verified by IPQA person. |

* 1. **CHECKLIST: MANUFACTURING AREA (LINE CLEARANCE)**

| **Sr. No.** | **Check Point** | | **Observation** | **Verified By** | |
| --- | --- | --- | --- | --- | --- |
| **Production** | **QA** |
|  | Previous Product &  Batch No. |  | |  |  |
|  | To verify the area is clean. | |  |  |  |
|  | To ensure sifter are clean & labeled. | |  |  |  |
|  | To ensure temperature is within limit (NMT 25°C) | | \_\_\_\_\_\_°C |  |  |
|  | To ensure area differential pressure within limit – NLT 0.5 mm WC | |  |  |  |
|  | To ensure the room status updated. | |  |  |  |
|  | To ensure all waste bins are empty & clean. | |  |  |  |
|  | To verify area free from any previous product items. | |  |  |  |
|  | To verify the dispensing sheet complete and appropriate. | |  |  |  |
|  | To ensure equipment logbooks are updated. | |  |  |  |

* 1. **LIST OF EQUIPMENT’S REQUIRED FOR MANUFACTURING OF PEPTONISED IRON:**

| **Sr. No.** | **Name of equipment** | **Equipment Number** | **SOP Number** | **Cleaning Status** | **Cleaned By** | **Checked By** |
| --- | --- | --- | --- | --- | --- | --- |
|  | Manufacturing Tank With Stirrer | TLI2M23 |  |  |  |  |
|  | 50 L S.S.Tank |  |  |  |  |  |
|  | Electronic Weighing Balance | T/RMD/BL/12  TLI1BO1 |  |  |  |  |

* 1. **Process Steps:**

Date of Commencement of sieving: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **S. No.** | **Step** | **Actual Readings** | | **Start Time**  **(hour)** | **End Time (hour)** | **Done by** | **Checked by** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Std. Value** | **Observed Value** |
|  | **PREPARTION OF PEPTONE SOLUTION :** | | | | | | |
| 6.4.1.1 | Ensure bottom outlet valve of tank is closed |  |  |  |  |  |  |
| 6.4.1.2 | Take about 10 L purified water in Tank ID No: TLI2M23 | 10 L | \_\_\_\_\_\_ L |  |  |  |  |
| 6.4.1.3 | **Add 55 kg Peptone in manufacturing tank** | **55 kg** | **\_\_\_\_\_kg**  **(Gr.wt.)**  **\_\_\_\_\_kg**  **(Gr.wt.)** |  |  |  |  |
| 6.4.1.4 | Start the stirrer of tank |  |  |  |  |  |  |
| 6.4.1.5 | Rinse the container of Peptone with about 5-10 L purified water and add rinsing to the manufacturing tank. |  |  |  |  |  |  |
| 6.4.1.6 | Continue the stirring for further 5-10 minutes to form uniform solution of peptone. | 5 – 10 Minutes | \_\_\_\_\_\_ Minutes |  |  |  |  |
|  | **ADDITION OF TINCTURE IODINE IN PEPTONE SOLUTION:** | | | | | | |
| 6.4.2.1 | **Add the Tincture iodine solution prepared for this batch Manufacturing Tank under stirring** | **40 L** | **\_\_\_\_\_\_\_ (Gr.wt.)** |  |  |  |  |
| 6.4.2.2 | Rinse the vessel of Tincture Iodine with about 2 L purified water and add rinsing to the manufacturing tank | 2 L | \_\_\_\_\_ L |  |  |  |  |
| 6.4.2.3 | Continue the stirring for  for completeness of iodization process.  (Initial stirring time NLT 8 hrs) |  |  |  |  |  |  |
| - | **Note: To check the completeness of iodization process, take about 10 ml solution in beaker, dip and take out the starch paper in the solution. If starch paper turns yellow indicates completeness of iodization process. If it is not turns to yellow further more stirring is required to complete the iodization process:** | | | | | | |
| 6.4.2.4 | *Completeness of Iodization processCQA1*  Color of starchpaper : Brown | *Yes* | *Yes /No* |  |  |  |  |
| 6.4.2.5 | **If required**  Continue the stirring for  for completeness of iodization process. |  |  |  |  |  |  |
| 6.4.2.6 | *Completeness of Iodization processCQA1*  Color of starchpaper : Brown | *Yes* | *Yes /No* |  |  |  |  |
|  | **ADDITION OF GLYCERIN:** | | | | | | |
| 6.4.3.1 | Add 84 kg Glycerin to the manufacturing tank under stirring | 84 kg | \_\_\_\_\_\_kg  (Gr.wt.)  \_\_\_\_\_\_kg  (Gr.wt.) |  |  |  |  |
| 6.4.3.2 | Continue the stirring for 5-10 minutes | 5 -10 Minutes | \_\_\_\_\_\_ Minutes |  |  |  |  |
|  | **FINAL VOLUME :** | | | | | | |
| 6.4.4.1 | Stop the stirrer in manufacturing tank. |  |  |  |  |  |  |
| 6.4.4.2 | *Make up the volume of solution up to 215 L with purified water by using calibrated Dip Stick.cpp1* | *215 L* | *\_\_\_\_\_\_ L* |  |  |  |  |
| 6.4.4.3 | *Start the stirrer and stir the content for 20-30 minutescpp2* | *20-30 minutes* | *\_\_\_\_\_\_\_ Minutes* |  |  |  |  |
| 6.4.4.4 | Stop the stirrer |  |  |  |  |  |  |
| 6.4.4.6 | Inform for Sampling of Bulk |  |  |  |  |  |  |
| 6.4.4.7 | Unload the bulk in previously tare Suitable containers and transfer to the RMD | 215 L | 1)\_\_\_\_ kg  2)\_\_\_\_ kg  3)\_\_\_\_ kg  4)\_\_\_\_ kg  5)\_\_\_\_ kg  6)\_\_\_\_ kg  Total =  \_\_\_\_\_\_kg (Net.wt.) |  |  |  |  |

Date of manufacturing completion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Production (Sign/Date): \_\_\_\_\_\_\_\_\_\_\_\_

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| 1. **YIELD RECONCILIATION**: | | |
| A | Standard Batch Size | 215 Lit |
| B | In process check samples during processing | \_\_\_\_\_\_\_\_\_\_\_ |
| C | Validation samples | \_\_\_\_\_\_\_\_\_\_\_ |
| D | Other sample ( ) | \_\_\_\_\_\_\_\_\_\_\_ |
| E | QC sample | \_\_\_\_\_\_\_\_\_\_\_ |
| F | Yield:  F = A - (B + C + D + E) | \_\_\_\_ - (\_\_\_\_ + \_\_\_\_\_ + \_\_\_\_\_ + \_\_\_\_\_)=\_\_\_\_\_ |
| G | % Yield (Fx100/A)  (LIMIT 99-100%) | \_\_\_\_\_\_\_ x 100/\_\_\_\_\_\_\_\_\_ =\_\_\_\_\_\_\_\_% |
| H | Transfer loss / hold up | \_\_\_\_\_\_\_\_ |
| I | Quantity of bulk transferred to RMD | \_\_\_\_\_\_\_\_ kg |

Done By (Production Officer): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Checked By (Production Head): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Verified By (QA): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- |
| Bulk Sampled By (Sign/Date): Sample Qty.:  Results: Bulk is Released / Not released |
| 1. **EXCEPTION LOG:**   Record all interruptions that occur during the entire sieving process. Quality Assurance shall review, classify, initial and date each entry following production, or as required. Deviations and Nonconformance’s require to be documented as per respective SOP. | | |

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| **Sr. No.** | **Exception** | **Documented By / Date** | **Class**  **(E, D, NC)** | **QA Verified By / Date** |
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E = Exception

D = Deviation

NC = Nonconformance