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1. **DESCRIPTION:**
   1. **BRAND NAME:** Intermediate Base for Novomix GEN II -65042 and Novomix GEN II-115067
   2. **GENERIC NAME:** BASE HPMC 15cps/Tri/37/8

|  |  |  |
| --- | --- | --- |
| **Abbreviation** | **Full Form** | **Composition in Novomix** |
| HPMC 15cps | Hydroxypropyl Methyl Cellulose 15cps | 37 |
| Tri | Triacetin | 8 |

* 1. **PRODUCT CODE:** Not Applicable
  2. **PHARMACOPOEIA STATUS:** In House
  3. **PACKING CONFIGURATION:**
     1. Food grade LDPE polybags
     2. HDPE drums
  4. **SHELF LIFE:** 6 Months
  5. **STORAGE CONDITION:** Store in dry place, in well closed container, protect against moisture, direct heat and light.
  6. **MFG.LIC.NO./PRODUCT LICENSE NO:** MH/102937/NA
  7. **BATCH SIZE:** As per Requirement.

1. **MASTER FORMULA:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.No.** | **Ingredients** | **Specification** | **Raw Material Code** | **Qty./%** | **Qty./1.00 Kg** |
| 1. | Hypromellose (Hydroxy Propyl Methyl Cellulose 15 cps) | IP/USP/BP | R020020,  R020021,  R020067  R020074  R020082  R020089 | 82.22 | 0.8222 |
| 2. | Triacetin | USP | R073048 | 17.78 | 0.1778 |
|  | Total Weight | - | - | 100.0 % | 1.000 Kg |

1. **MATERIAL DETAILS AND SUPPLIERS:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Ingredients** | **Specification** | **Raw Material Code** | **Manufacturer/Supplier** |
|  | Hypromellose (Hydroxy Propyl Methyl Cellulose 15 cps) | IP/USP/BP | R020020 | G. C. Chemie Pharmie Pvt. Ltd/Novo Excipients Pvt. Ltd. |
| R020021 | Zhongbao Chemicals Co. Ltd./Excigen |
| R020067 | Taian Ruitai Cellulose Co. Ltd./Scope Ingredients Pvt. Ltd. |
| R020074 | Lotte Fine Chemicals/Anshul Lifescience |
| R020082 | Huzhou Zhanwang/Excigen |
| R020089 | Shandong Eton/Amoli Middle East FZE |
| 2 | Triacetin | USP | R073048 | ThomasBaker/Omkar Traders |

1. **FLOW DIAGRAM:**

Requisition to QA for BMR

Requisition to Stores for Raw material and Packing material

Dispensing and Issuance of Raw Material and Packing material

Verification of Raw Material and Packing material

Line Clearance

Raw material transfer to respective room

Pre Manufacturing Operation and Control

Sifting of HPMC 15cps through 20#

In PLM addition of HPMC 15cps and Triacetin and mixing for prescribed time

Unload the material from PLM into doubled LDPE polybags

In RMG/HSM addition of HPMC 15cps and Triacetin and mixing for prescribed time

Continued

Blending the material in suitable blender

Unload the blended material

Intimation to IPQA for sampling

Intimation to QC Department

QC testing and approval

QA Release

BASE Formulation

Use base after 72 hrs. of manufacturing.

1. **PACKING DETAILS:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Items** | **Specification No.** | **Packing Material Code** | **Manufacturer/Supplier** |
| 1. | HDPE Drum  (40” x 30” ) | NA | NA | NA |
| 2. | LDPE bags  (42” x 24”) | PM/SPEC/009-01 | P003001 | Diamond Plastics/Arihant Industries |
| P003002 | Arihant Industries/Arihant Industries |
| P003003 | Avita Polyfilms /Avita Polyfilms |
| LDPE bags  (32” x 20”) | PM/SPEC/012-01 | P002001 | Diamond Plastics/Arihant Industries |
| P002002 | Arihant Industries/Arihant Industries |
| P002003 | Avita Polyfilms /Avita Polyfilms |
| 3. | Nylon string/White seal | NA | NA | NA |

1. **LIST OF EQUIPMENTS:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.No.** | Instrument | Equipment ID | Capacity |
| 1. | Rapid Mixer Granulator | FD-017 | 10 Ltrs. |
| 2. | Vibratory Sifter | FD-019 | 12”diameter |
| 3. | Weighing balance | FD-002,FD-005,FD-003, FD-006 | 600 gms,6 kgs |
| 4. | Octagonal Blender | FD-018 | 10 Ltrs. |
| 5. | Weighing Balance | PR-003,PR-004,PR-008,  PR-009,PR-010,PR-013,PR-014,PR-015,PR-016 | 600gms,6kgs,50kgs |
| 6. | High Speed Mixer | PR-024 | 100 Ltrs. |
| 7. | Rapid Mixer Granulator | PR-025 | 150 Ltrs. |
| 8. | Rapid Mixer Granulator | PR-026 | 250 Ltrs. |
| 9. | Octagonal Blender | PR-027 | 600 Ltrs. |
| 10. | Octagonal Blender | PR-028 | 1200 Ltrs. |
| 11. | Octagonal Blender | PR-029 | 1200 Ltrs. |
| 12. | Vibratory Sifter | PR-035,PR-036,PR-055,PR-057 | 20”diameter,30”diameter |
| 13. | Planetary Mixer | PR-037 | 100 Ltrs. |
| 14. | Air Handling Unit | AHU-07,AHU-08, AHU-09,  AHU-12 | 4600CFM,3000CFM,2000CFM |

**7. MANUFACTURING PROCESS:**

* 1. PROCEDURE -
     1. Production of BASE HPMC15cps/Tri/37/8 is carried out in Intermediate preparation room or respective manufacturing area. The Production department has adequate space into separate cubicles such as Intermediate room, Manufacturing room no. 3, 4 and 5. Material after manufacturing subjected for final blending in the same room. The approved material is then transferred to Intermediate store or use for further manufacturing products.

Note: Use base after 72 hrs. of manufacturing

Adequate lighting and ventilation are provided along with Air Handling Units.

* 1. BATCH MANUFACTURING PROCESS -
     1. Requisition of the raw materials. Issue of the raw materials and verification of the raw materials

issued.

* + 1. Pass HPMC 15 cps through sieve of 20 #.Then load the HPMC 15 cps in Planetary mixer/High speed mixer/RMG.
    2. Add Triacetin in a thin stream to spread over the surface of above material and mix it for 10 mins.at slow speed (65 RPM) in Planetary mixer, 2 mins.in RMG (150 lit) at slow speed (75 RPM) without chopper , 2 mins.in RMG (250 lit) at slow speed (50 RPM) without chopper and 1 min.in High speed mixer at speed of 200 RPM without chopper
    3. Change the speed of the Planetary mixer to fast speed and mix the content of the mixer for 5 mins.at fast speed (130 RPM) and unload the material from Planetary mixer and transfer into doubled LDPE bags of suitable capacity, inserted in HDPE drum and weigh the material
    4. Change the speed of RMG/High Speed Mixer to fast speed and mix for 5 mins at fast speed of 150 RPM without chopper in RMG (150 lit), fast speed (100 rpm) for 5 min without chopper in RMG (250 lit) and 4 mins.in High speed mixer at Fast speed of 350 RPM without chopper.
    5. Transfer the material from RMG/High Speed Mixer to polybags.
    6. Repeat the procedure for other lots of RMG/High Speed Mixer.
    7. Blend all lots of RMG/High Speed Mixer, if there is more than 1 lot, then mixing is carried out in polybag by tumbling, or in appropriate blender in respective manufacturing room.
    8. Transfer all the lots together in a blender of suitable capacity. Close the lid of the blender.
    9. Start the blender. Blend the batch for 20 mins. RPM for octagonal blender set in room no. 3 of

Manufacturing area is 24 RPM and in room no. 4 & 5 is 9 RPM.

7.2.11 Unload the material from octagonal blender into doubled LDPE bags of suitable

capacity, inserted in HDPE drum and weigh the material.

**8. PACKING PROCESS:**

8.1 Collect the material into number of double LDPE bag inserted in HDPE drums.

8.2 Production personnel give the intimation slip and inform IPQA personnel to draw the sample

for testing.

8.3 After sampling, weight of the batch is verified by IPQA person. Inner poly bag is sealed tightly

with nylon string. One Status /In-process label is kept in the outer poly bag followed by sealed

tightly, another Status/ In-process label is stick on HDPE Drum.

8.4 QA personnel affix “Under Test” label on each HDPE drum and then kept in the respective room /

intermediate store room.

8.5 Then Production personnel transfer the material to Intermediate store and make the entry in

Intermediate Stock Register.(F/SOP/PR/011/07-01).

8.6 After material release, QA person paste approved green label on each HDPE Drum.

**9. % YIELD** = Actual Qty. Yield X 100

Standard Qty. Yield

= --------- % (Limit NLT 98%)

**10. STORAGE CONDITION:**

10.1 Store in dry place, in well closed container, protect against moisture, direct heat and light.

**11. GENERAL AND SAFETY INSTRUCTIONS:**

11.1 Personnel instruction to wear the nose mask, head cap, shoe cover, hand gloves and over gown

before entering into manufacturing area and also handling the materials.

11.2 The Room temperature and Humidity during sifting, blending are to be controlled. Room

temperature NLT 30°C and RH NMT 70 %.

**12. REVISION HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No.** | **Revision No.** | **Effective Date** | **Revision Description** |
| 1. | 00 |  | Prepared First Time |