**SOP TITLE: CLEANING & OPERATION OF DECARTONING AREA (NON-CEPH)**

1. **Objective:**

The objective of this document is to establish standard procedure for operation and cleaning of decartoning area of Non-Ceph Production.

1. **Scope:**

This procedure shall be applicable to operation and cleaning Decartoning area of Liquid Manufacturing Section in Non-Ceph Production area at PharmEvo factory site.

1. **Reference:**

WHO TRS-986, Annex 2: Good Manufacturing Practice for Pharmaceuticals.

1. **Responsibility:**
   1. Sr. Executive Production/Designee is responsible to prepare, revise and provide the training of SOP.
   2. Operators are responsible for performing the operations mentioned in the SOP.
   3. Senior Manager Production is responsible to check and monitor the implementation of the SOP.
   4. Senior General Manager Production will be responsible to ensure its execution.
   5. QA Department (Documentation) is responsible for controlling and distribution of the SOP.
2. **Definitions:**

N/A

1. **Materials & Equipment:**
   1. **Operation**
      1. Turn Table and Conveyor Belt E-MP-LIQ-02-06-01
      2. Dust Collector E-MP-LIQ-02-DC-01
   2. **Cleaning** 
      1. Lint free Duster
      2. Treated Water 50-60°C
   3. **Personal Protective Equipment (PPEs):**
      1. Goggles
      2. Gloves
      3. Mask
      4. Ear Muff
2. **Precautions:** 
   1. During cleaning of decartoning turn table and conveyer belt disconnect all electrical connections.
   2. Do not clean electrical panel with wet duster.
   3. Use PPE's while using machine.

1. **Procedure:**
   1. **Minor Cleaning (After Batch Change Over):**
      1. Disconnect all the electrical connections.
      2. Clean the surface of turn table, conveyer belt and dust collector with duster soaked in treated water.
      3. Then dry it with dry duster.
      4. Clean the floor and apply Mop.
      5. Affix the “CLEANED” label PRG/5/013 after checking cleanliness.

* 1. **Major Cleaning (After Product Change Over):**
     1. Disconnect all the electrical connections.
     2. Clean surface of turn table, conveyer belt and dust collector with duster soaked in treated water.
     3. Then dry it with dry duster.
     4. Clean the floor, walls, glass and door of area with the duster soaked in treated water.
     5. Clean the floor and apply Mop.
     6. Affix the “CLEANED” label PRG/5/013 after checking cleanliness.
  2. **Operation:**
     1. Receive primary material for filling as per SOP PRP/2/001.
     2. Place all the received bottles in staging area entering through Material air lock (MAL).
     3. Personel will enter through personnel Air Lock (PAL) in decartoning area by wearing dedicated lab coat, shoe cover and head cover.
     4. Check and verify the cleanliness of Decartoning area and dust collector.
     5. Connect all the power connections.
     6. Turn 'ON' the turn table, conveyer belt and dust collector.
     7. Decarton the Bottles and place the bottles on conveyer belt.
     8. Lift the bottles and place them on turn table.
     9. Bottles will pass through turn table to conveyer leading to blowing star wheel.
     10. Then start blowing and filling procedure as per respective SOPs.
  3. Record all activities of the equipment in General Equipment Logbook PRG/5/102.

1. **Training:**

Training will be imparted to the concerned personnel for proper implementation of this SOP and will be recorded on QAG/5/142.

1. **Attachment:**

N/A

1. **Distribution List:**
2. **SOP Review History:**