

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDUREDepartment: ProductionSOP No.:Title: Cleaning of RMGEffective Date:Supersedes: NilReview Date:Issue Date:Page No.:

Purpose: To lay down operating procedure for cleaning of RMG.

Scope: This procedure is applicable to

Responsibility: Production Chemist

To supervise the activity

Pre-operating Check: Check no material or residue of previous product is there.

Frequency: At the completion of batch or at the end of shift

Equipment used: RMG (400 liters GMP)

Procedure for product change over:

- 1. Switch ON the RMG.
- 2. Open the lid by pushing the lid knob.
- 3. See that purging air is full ON.
- 4. Remove the adhered material by scrapping with SS Scrapper and scrap it manually through open discharge opening by pulling discharge valve knob.
- 5. Lift the main impeller by lifting mechanism remove any adhered material by ss scrapper and wash it with potable water and wipe with clean cloth. Release the main impellers well
- 1. After releasing main impeller run the blade without power by rotating the gear box pulley by hand to see that the main blade bottom does not touch the vessel bottom.
- 6. Clean the outer area of RMG with potable water and then with DM water and wipe with clean cloth.
- 7. Add adequate amount of potable water inside and start the impellers at slow speed followed by fast speed to rinse out any residue. Drain out the water.
- 8. Repeat the (step 7) procedure first with fresh potable water and then with DM water. Drain out the water then wipe with clean cloth.
- 9. Removes chopper impeller and wash it with potable water and then with DM water and wipe it with clean cloth. Fit the chopper impellers well
- 10. After chopper fitting see that the split pin is fitted properly
- 11. Remove the discharge assembly completely and wash discharge assembly with potable water and then with DM water and then wipe with clean cloth. Fit the discharge assembly. While fixing the discharge assembly ensure that the Silicone gasket is placed properly in the piston groove.
- 12. After fitting discharge assembly, ensure that machine is manually run by rotating the pulley by hand to ensure that their is no accident between the main impeller blades and the discharge piston
- 13. Mention the entire activities in Daily Log Sheet



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Procedure for the same product and at the end of shift:

- 1. Remove the adhered granulation material by scrapping with S.S Scrapper and scrap it manually through open discharge opening.
- 2. Remove the powder materials from inner, outer and surrounding area of RMG.