1. **PURPOSE:**

To provide a procedure for operation of centrifuges in the production of all bulk active substances at Discovery.

1. **SCOPE:**

This SOP is applicable for all centrifuge operations used in manufacturing process.

1. **RESPONSIBILITY:**

It is the responsibility of the person operating to follow this procedure as written in this SOP.

1. **DEFINITIONS:** Nil.
2. **PROCEDURE :**
   1. Ensure the centrifuge is in idle position. Lock the ‘Stop Button”(Red coloured) on the starter.
   2. Open the centrifuge lid.
   3. Centrifuge bag:
      1. Check the bag for its cleanliness & its integrity.
      2. Take out the centrifuge bag.
      3. Check for any particles and holes ( If holes are observed discard the bag & Arrange new one) & enter in the current version of PD012-FM040.
      4. Ensure the bag is free from particle.
      5. Clean the bag as per the relevant cleaning procedure.
      6. Keep the centrifuge bag in centrifuge and set it.
   4. Close the centrifuge lid and lock it.
   5. Remove the stop lock.
   6. Switch on the centrifuge and run for 2 minutes.
   7. Push the stop button and stop the centrifuge.
   8. Lock the ‘Stop Button” (Red coloured) button.
   9. Remove the centrifuge lid locks and lift the lid.
   10. Check whether the bag is adjusted. If it is not adjusted, repeat the above operation and Check it.
   11. Close the centrifuge with its lid, lock it and start after satisfactory adjustments.
   12. Feed the material slowly, from the reactor using a transfer pipe or dedicated containers to the centrifuge.
   13. In case the centrifuging is to done in lots, then the feed from the reactor to the centrifuge should be done so in approximate quantity.
   14. Once the centrifugation is complete, washing of the wet cake with the prescribed Solvent should be carried out.
   15. Wet cake washing shall be carried out through the spray nozzles (if required).
       * 1. Centrifuge washing of liquid materials through charging tank.
         2. Ensure the charging tank is empty and dried.
         3. Charge required quantity of liquid material in charging tank through the flow meter or measuring devise.
         4. Open the valve of the charging tank bottom and transfer the material through gravity.
         5. Once the transfer is completed close both the valves.
   16. Spin-dry the material as per BPR and to ensure the maximum removal of the solvent from the cake.
   17. Stop the centrifuge.
   18. Lock the “Stop Button” (Red button) and open the lid.
   19. unload the material with a clean scoope.
   20. Unload the material in to clean containers containing with polythene bags with the helpof a clean scoop.
   21. Take care that nothing falls in centrifuge while it is opened & material getting unloaded.
   22. Wash the centrifuge bag as described in above procedure and close the centrifuge lid after unloading.
   23. **Unloading of material from centrifuge:**
       1. Get dedicated HDPE /Fiber drums, scoop to the centrifuge site.
       2. The person who unloads the material should wear protective wear like goggles, hand gloves, nose masks and head caps, If applicable.
       3. Place and set polythene bag in the HDPE / Fiber drums.
       4. Open the centrifuge lid.
       5. Unload the material from the centrifuge carefully with a scoop into the HDPE/Fiber drums and tie the bags.
       6. Close the centrifuge lid after completely unloading the material and lock it.
       7. Enter the details in the Batch Production Record
   24. **Warning**:“ Do not open centrifuge lid while it is running. Open the centrifuge lid only when it is stopped’’i.e at Zero RPM
3. **Formats / Annexure(S):**Nil
4. **Change History:**

| **Revision No.** | **Effective Date** | **Details of Revision** | **Ref. CCF No.** |
| --- | --- | --- | --- |
| 00 | 01.01.2009 | New SOP is introduced | ---- |
| 01 | 01.06.2014 | Formats are the part of SOP, So prepared Separately. | ---- |
| 02 | 01.09.2014 | Checking of integrity of centrifuge bag. | ---- |
| 03 | 15.09.2015 | Filter bag’s cleaning changing &checking record changed from PD-F-018-02 to PD-F-040 as per current format. | ----- |
| 04 | 01.01.2017 | Procedure elaborated and SOPs PD-010, was merged in this SOP. | PD-CRF-024/16 |
| 05 | 01.01.2018 | SOP format changed make to inline with SOP-QA-001-05.  Utensils / Filter Bags / Hose pipe / Process Water Usage details (PD012-FM040) format removed. | CCF/GEN/17035 |
| 06 |  | Centrifugation operation is established in 5.16.1 point |  |
| 07 |  | Do not feed centrifuge at high RPM, ON & OFF the centrifuge during feeding the centrifuge. Removed |  |