 Discovery Labs	<b>STANDARD OPERATING PROCEDURE</b>			
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<b>TITLE: CENTRIFUGE OPERATION</b>				

## 1.0 PURPOSE:

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

## 2.0 SCOPE:

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

## 3.0 RESPONSIBILITY:


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

## 4.0 DEFINITIONS: Nil.

## 5.0 PROCEDURE :


- 5.1 Ensure the centrifuge is in idle position. Lock the 'Stop Button'(Red coloured) on the starter.
- 5.2 Open the centrifuge lid.
- 5.3 Centrifuge bag:
  - 5.3.1 Check the bag for its cleanliness & its integrity.
  - 5.3.2 Take out the centrifuge bag.
  - 5.3.3 Check for any particles and holes ( If holes are observed discard the bag & Arrange new one) & enter in the current version of PD012-FM040.
  - 5.3.4 Ensure the bag is free from particle.
  - 5.3.5 Clean the bag as per the relevant cleaning procedure.
  - 5.3.6 Keep the centrifuge bag in centrifuge and set it.
- 5.4 Close the centrifuge lid and lock it.
- 5.5 Remove the stop lock.
- 5.6 Switch on the centrifuge and run for 2 minutes.
- 5.7 Push the stop button and stop the centrifuge.

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- 5.8 Lock the ‘Stop Button” (Red coloured) button.
- 5.9 Remove the centrifuge lid locks and lift the lid.
- 5.10 Check whether the bag is adjusted. If it is not adjusted, repeat the above operation and Check it.
- 5.11 Close the centrifuge with its lid, lock it and start after satisfactory adjustments.
- 5.12 Feed the material slowly, from the reactor using a transfer pipe or dedicated containers to the centrifuge.
- 5.13 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.
- 5.14 Once the centrifugation is complete, washing of the wet cake with the prescribed Solvent should be carried out.
- 5.15 Wet cake washing shall be carried out through the spray nozzles (if required).
  - 5.15.1.1 Centrifuge washing of liquid materials through charging tank.
  - 5.15.1.2 Ensure the charging tank is empty and dried.
  - 5.15.1.3 Charge required quantity of liquid material in charging tank through the flow meter or measuring devise.
  - 5.15.1.4 Open the valve of the charging tank bottom and transfer the material through gravity.
  - 5.15.1.5 Once the transfer is completed close both the valves.
- 5.16 Spin-dry the material as per BPR and to ensure the maximum removal of the solvent from the cake.
- 5.17 Stop the centrifuge.
- 5.18 Lock the “Stop Button” (Red button) and open the lid.
- 5.19 unload the material with a clean scoope.

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- 5.20 Unload the material in to clean containers containing with polythene bags with the help of a clean scoop.
- 5.21 Take care that nothing falls in centrifuge while it is opened & material getting unloaded.
- 5.22 Wash the centrifuge bag as described in above procedure and close the centrifuge lid after unloading.
- 5.23 **Unloading of material from centrifuge:**
- 5.23.1 Get dedicated HDPE /Fiber drums, scoop to the centrifuge site.
- 5.23.2 The person who unloads the material should wear protective wear like goggles, hand gloves, nose masks and head caps, If applicable.
- 5.23.3 Place and set polythene bag in the HDPE / Fiber drums.
- 5.23.4 Open the centrifuge lid.
- 5.23.5 Unload the material from the centrifuge carefully with a scoop into the HDPE/Fiber drums and tie the bags.
- 5.23.6 Close the centrifuge lid after completely unloading the material and lock it.
- 5.23.7 Enter the details in the Batch Production Record
- 5.24 **Warning:**“ Do not open centrifuge lid while it is running. Open the centrifuge lid only when it is stopped” i.e at Zero RPM

## 6.0 FORMATS / ANNEXURE(S):NIL

## 7.0 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	PD-CRF-024/16

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Revision No.	Effective Date	Details of Revision	Ref. CCF No.
		this SOP.	
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	

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