 Discovery Labs	<b>STANDARD OPERATING PROCEDURE</b>			
	SOP No.:	SOP-PD-020-03	Effective Date:	01.01.2018
	Supersedes:	SOP-PD-020-02	Next Review Date:	31.12.2020
	Department:	Production	Page:	1 of 3
<b>TITLE: ROTARY CONE VACUUM DRYER OPERATION</b>				

#### 1.0 PURPOSE:

To provide a procedure of operations of Rotary Cone Vacuum Drier in the Production of all active substances at Discovery.

#### 2.0 SCOPE:

This procedure is applicable for all Rotary Cone Vacuum Driers operations used in the 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 Check status of the Rotary cone vacuum drier from Equipment status. It should be cleaned.
- 5.2 Update the Equipment status.
- 5.3 Check that discharge valve of the Rotary cone vacuum drier should be closed.
- 5.4 Bring charging port of suitable position of charging of the material.
- 5.5 Open the charging port of Rotary cone vacuum drier.
- 5.6 Check visually, internal surfaces of the Rotary cone vacuum drier for cleanliness.
- 5.7 Check the cleanliness of SS mesh of the dish fitter.
- 5.8 Check the cyclone separator; it should be emptied by opening the valve.
- 5.9 The cyclone separator valve should be closed.
- 5.10 Charge the wet material with a clean SS-Scoop through the charging port.
- 5.11 Close the charging port after placing the gasket at its proper place.
- 5.12 Close the vacuum trap and condenser for condensate by opening the bottom valve.
- 5.13 Start the vacuum pump and apply the vacuum.
- 5.14 After getting the vacuum as per BPR Rotate the Rotary cone vacuum drier by pressing start push bottom.

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- 5.15 Check that no materials spills, while Rotary cone vacuum drier is in operation.
- 5.16 In case the material spillage is observed stop the RCVD immediately and rectify fault
- 5.17 Start the hot water circulation in the jacket of RCVD by switch on the hot water pump.
- 5.18 Sample should be collected as per In process sampling SOP current version (PD-011).
- 5.19 Continue the drying operation till the product till the product attains required content /Loss on drying as per BPR
- 5.20 Switch “OFF” the hot water pump and vacuum pump.
- 5.21 Stop the rotation of RCVD when it is in vertical position with discharge port at the bottom.
- 5.22 Close the vacuum valve and release the vacuum.
- 5.23 Place the container below the discharge valve as per BPR.
- 5.24 Open the discharge valve and unload the material in to the container up to 3/4 th of the volume.
- 5.25 Close the container with lid, seal it with the locking ring and put the respective tag.
- 5.26 After unloading the total material from RCVD, Close the discharge valve.
- 5.27 Verify that there is no material left in RCVD

**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	Revised as per current SOP No system & more clear and clarity	----
02	01.01.2017	Procedure elaborated and SOPs PD-016, PD-022 and PD-026 are merged in this SOP.	PD-CRF-024/16
03	01.01.2018	1. SOP format changed make to inline with SOP-QA-001-05. 2. In Revision No 02 Change History typographical error was rectified	CCF/GEN/17035

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