 Discovery Labs	STANDARD OPERATING PROCEDURE			
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TITLE: LINE CLERANCE WHILE PRODUCT CHANGE OVER				

1.0 PURPOSE:

To lay down a Procedure for Line Clearance

2.0 SCOPE:

This procedure appliance the Line Clearance for the products/stages produced after product/stage changeover cleaning at Discovery Laboratories (P) Ltd.

3.0 RESPONSIBILITY:

- 3.1 Production personnel shall verify and fill the line clearance check list.
- 3.2 QA personnel shall be cross verify and give the clearance.
- 3.3 Head-QA/Designee to monitor compliance of this Procedure


4.0 DEFINITIONS:

- 4.1 **Line Clearance:** The assurance that a production facility (line), and its associated working area is completely cleared of all materials, waste, products, samples, documentation, etc.

5.0 PROCEDURE:

- 5.1 Line clearance procedures shall be carried out for manufacturing/ packing area.
- 5.2 While giving the line clearance previous product/stage to next product/ stage following points to be verified but not limited to;
 - 5.2.1 Remove the following material/tools of pervious product from the area:
 - 5.2.1.1 Raw material
 - 5.2.1.2 Packing material
 - 5.2.1.3 Material containers (Intermediates/finished)
 - 5.2.1.4 Mother liquors
 - 5.2.1.5 Residues
 - 5.2.1.6 Scoops/scrappers/handling tools/transfer lines/sampling devices
 - 5.2.1.7 Filter bags (Centrifuge/leaf filter/nutsche filter/microniser etc.)
 - 5.2.1.8 Filter cartridges (for micro filters)

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5.2.2 Verify adequacy of previous product/stage documentation completion and removal of previous batch documentation if any.

5.2.2.1 Entries in log books.

5.2.2.2 Batch production and control record/packing records.

5.2.2.3 Batch cleaning records. (Equipment).

5.2.2.4 Labels etc,

5.2.3 House Keeping/Area Cleaning/Equipment Cleaning:

5.2.3.1 Ensure the correct cleaning procedures are employed.

5.2.3.2 Ensure that the results are passing as per specification (Acceptance criteria).

5.2.3.3 Check visually and ensure that equipments are cleaned and dry. Ensure the critical areas of equipment (such as inner top dish, anchor, bolts and baffles) are clean.

5.2.3.4 Ensure hosepipes, pipelines, centrifuge MLs pit, samplers, scrappers, handling tools and scoops are clean and dry.

5.2.3.5 Ensure the House keeping Records.

5.2.3.6 Ensure that area cleaning records completion.

5.2.4 Ensure the following in clean rooms:

5.2.4.1 Only one product shall be manufacturing proceed at a time in a clean room.

5.2.4.2 Gowning-clean room garments of previous product replaced and sent for washing


5.2.4.3 Air pressure within the range.

5.2.4.4 Cleaning of exhaust and inlet clean air grills.

5.2.4.5 Ensure no accumulation on the floor, Walls, utilities lines outer surfaces of the equipment, windows and doors.

5.2.4.6 Cleaning/changing of process filters.

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5.2.4.7 Controlling the temperature and relative humidity to pre defined limits

5.2.4.8 Waste collection bins.

5.2.5 Ensure the following in things related to equipment:

5.2.5.1 Cleaning/changing of process filters.

5.2.5.2 Condition of gaskets.

5.2.5.3 Missing of nuts and bolts.

5.2.6 Ensure the following things:

5.2.6.1 Operators are as per authorized list. if not check the training record and get the list amended.

5.2.6.2 Issue of correct Batch production and controlled record for next product/stage execution.

5.2.6.3 Calibration of balance(s).

5.2.6.4 Approval of input material.

5.2.6.5 Tallying of batch number/Quantities mentioned on material release slip and raw material requisition

5.3 Production personal shall fill the line clearance checklist as per format QA008-FM135 and forward it to Quality Assurance for getting clearance.

5.4 Up on the receipt of the Line clearance checklist the Quality Assurance representative shall verify the filled line clearance check list as per format (QA008-FM135) and give clearance for next product process.

5.5 If any abnormalities are found during previous product/stage product change over shall be addressed as per “Handling of Deviation” SOP.


6.0 FORMATS / ANNEXURE(S):

6.1 Line Clearance Check List : QA008-FM135

7.0 CHANGE HISTORY:

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Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.06.2007	New SOP is introduced.	--
01	01.07.2009	SOP format changed and reviewed for more clarity.	--
02	15.06.2014	Revised as per current SOP & more clear and clarity.	--
03	05.07.2014	Line clearance format introduced.	--
04	01.04.2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. Line Clearance Check List format has been rephrased. 3. Altogether procedure has been rephrased for better clarity.	QA-CRF-014/16
05		SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17028

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