 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-035-01	Effective Date:	01.01.2018
	Supersedes:	SOP-QA-035-00	Next Review Date:	31.12.2020
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TITLE: TECHNOLOGY TRANSFER				

1.0 PURPOSE:

To lay down the procedure for technology transfer of an Active Pharmaceutical Ingredient (API) or intermediate from R&D to manufacturing site.

2.0 SCOPE:

The procedure is applicable to technology transfer of an API or Intermediate produced at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

It is responsibility of the R&D personnel shall be prepare the technology transfer documents and production, Quality Assurance, Quality control, Warehouse to follow the procedure defined in the SOP and ensures the successful technology transfer of process.

4.0 DEFINITIONS:

4.1 Technology Transfer:

Transfer to technology is defined as a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between intra-and inter-sites.

5.0 PROCEDURE:


5.1 The manufacturing process of drug substance from R&D to manufacturing site for commercial production shall be executed through following procedure.

5.1.1 Head-R&D shall communicate to Head-QA for technology transfer of process.

5.1.2 Head-QA shall form a cross functional team in consultation with Plant-Head. The team consists of representatives from Production, Warehouse, Engineering & Maintenance, Quality Control and Quality Assurance.

5.1.3 Concerned personnel from R&D shall arrange the documents as per the technology transfer checklist (QA035-FM161).

	Prepared by	Reviewed by	Approved by
Sign & Date			
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Department	Quality Assurance	Quality Assurance	Quality Assurance

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- 5.1.4 Head-QA and cross functional team shall verify the received documents as per the technology transfer checklist. If any clarifications or additional documents are needed, Head-QA shall inform to Head-R&D.
- 5.1.5 Based on the development report/ technology transfer documents shall be prepare the Batch Production and Control Records (BPCRs) for initial batches (trial/ Validation).
- 5.1.6 Production and R&D departments shall review the BPCRs and finally approved by Head-QA.
- 5.1.7 Before execution of batches, personnel from R&D shall give a technical presentation to cross functional team at manufacturing site to adequately transfer process knowledge.
- 5.1.8 The technical presentation shall contain, but not limited to brief description about process parameters, critical quality parameters, critical test procedures, precautions, safety instructions etc.
- 5.1.9 Training shall be imparted to the concerned personnel before effective of documents.
- 5.1.10 The data of trail/ validation batches shall be reviewed, after completion with respect to optimization of process during scale-up.
- 5.1.11 Three successive batches of validation shall be manufactures in the plant, after successful completion of manufacturing trial batches (if required).
- 5.1.12 Material from the validation batches shall be subjected for stability studies.


6.0 FORMATS / ANNEXURE(S):

- 6.1 Technology transfer checklist: QA035-FM161

7.0 CHANGE HISTORY:

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Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.04.2017	New SOP Introduced	--
01	01.01.2018	SOP Format changed make to inline with SOP-QA-01-05	CCF/GEN/ 17037

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