 Discovery Labs	STANDARD OPERATING PROCEDURE			
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	Supersedes :	SOP-QA-017-04	Next Review Date:	
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TITLE: REPROCESSING AND REWORKING				

1.0 PURPOSE:

To lay down the procedure for Reprocess or Rework of Intermediate and Active Pharmaceutical Ingredients (APIs).

2.0 SCOPE:

The procedure in this SOP is applicable for Reprocess or Rework of intermediates and APIs, which fails to meet the pre-defined specification at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 Head-Production/ Designee are responsible to carry out the Reprocess or Rework procedure.
- 3.2 Head-R&D/ Designee are responsible to provide the Reprocess or Rework procedure based on the laboratory experiments.
- 3.3 Head – QA/ Designee is responsible for approve the procedure.


4.0 DEFINITIONS:

- 4.1 **Reprocessing:** Introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g.: Distillation, Filtration, Chromatography and Milling) that are part of the established manufacturing process.
- 4.2 **Reworking:** Subjecting an intermediate or API that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or API(e.g.: Re-crystallizing with a different solvent).

5.0 PROCEDURE :


- 5.1 Intermediate or API, which fails to comply with pre-defined specification shall be subjected for Reprocess or Rework.
- 5.2 Material to be Reprocessed or Rework shall be appropriately controlled to prevent unauthorized use.

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- 5.3 If the batch is taken for reprocess or rework, the same shall be investigated thoroughly to find out the root cause for non conformance before reprocess/rework or otherwise justified. The details shall be documented.
- 5.4 With the conclusions drawn from the experiments, R&D shall submit the reprocess / rework procedure along with a report on yield and quality.
- 5.5 Quality Assurance shall review the data generated from the R&D experiments and shall give the clearance to production department for preparation of BPR by addressing through Change Control.
- 5.6 The reprocess or rework shall be carried out as per approved BPR.
- 5.7 If reprocess procedure is used for majority of batches for the similar reason of failure, such reprocessing procedure shall be included as part of the standard manufacturing process.
- 5.8 Quality equivalence shall be evaluated for rework batches and compare with established process. If required, additional tests shall be performed and data shall be compared.
- 5.9 The rework batch may need to be subjected to concurrent validation.
- 5.10 Additional analytical methods shall be followed to characterize the rework batches, if routine methods are inadequate.
- 5.11 The analytical results of Reprocess batches should comply with the established specifications (e.g., Assay, physical attributes, and impurities) and be comparable with the batches manufactured by validated process.
- 5.12 The reprocessed / reworked batches shall be evaluated for stability.
- 5.13 The first reprocessed batch shall be subjected to the stability studies as follows:
- 5.13.1 For final stage of API, stability study shall be initiated at accelerated and long term storage conditions.

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5.13.2 If early stages of the API are subjected for reprocess, the corresponding API batch shall be loaded for stability study at accelerated condition and any other condition based on the investigation report.

5.14 The rework batches shall be subjected to stability studies as follows:

5.14.1 For final stage of API, stability study shall be initiated at accelerated and long term storage conditions.

5.14.2 If early stages of API are subjected to rework, the corresponding API batch shall be loaded for stability at accelerated condition and any other condition based on the investigation report.

5.14.3 After successful completion of six months accelerated stability study, rework batch can be released to market.

5.14.4 In case, further batches manufactured with same rework procedure, these batches can be released based on the first batch stability data.

5.14.5 The details of reprocess and rework shall be reviewed annually as a part of Annual Product Quality Review.

5.14.6 Further Reprocessing / Reworking of Reprocessed / Reworked batch shall not be recommended.


6.0 FORMATS / ANNEXURE(S):

NIL

7.0 CHANGE HISTORY:

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	01-09-2014	1. Requirement of validation for Re work is included.	---
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QA001-FM139-01

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Revision No.	Effective Date	Details of Revision	Ref. CCF No.
		2. Times rework process is allowed included in the SOP. 3. Reprocess /Rework Log book included.	
04	01-03-2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. Reprocess /Rework Log book removed. 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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