DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Recovery and Reprocessing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for recovery and reprocessing of the products.

2.0 SCOPE:

This SOP is applicable for recovery and re-processing of the tablets/capsules/granules at different stages of manufacturing such as blend, granules, capsules, core tablets and coated tablets that are manufactured at …….

3.0 RESPONSIBILITY:

Executive – QA,

Head – Production

Head-F&D

Head –QA/CQA

4.0 DEFINITION(S):

a) **Recovery is defined as "**the introduction all or part of earlier batches, conforming to the required quality, into a batch of the product at a defined stage of manufacture".

b) **Reprocessing is defined as "s**ubjecting all or part of a batch or a lot of intermediate or a finished product of single batch/lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications.

c) **Reworking is defined as "s**ubjecting an intermediate or finished product of a single batch to an alternate process due to failure to meet the predetermined specifications.

5.0 PROCEDURE:

NOTE: **The non-conforming recovery of the earlier batches into a batch of the product shall not be permitted.**

5.1 Reprocessing is normally a repetition of one of the previous step, already in a manufacturing process".

5.2 Reprocessing of non-conforming all or part of a batch or a lot of intermediate or a finished product of single batch/lot shall be exceptional and shall be authorized by QA.

5.3 It shall be permitted only if the quality of the final product is not affected, if the specifications are met and is done with a defined and authorized procedure after assessment of the risks involved.

5.4 Records shall be kept for the reprocessing, if any.

5.5 Reworking is a new step in manufacturing process, which is not defined in standard manufacturing process".

NOTE: Reworking of the non-conforming intermediate or finished product shall not be permitted.

5.6 Re processing:

5.6.1 Reprocessing of non-conforming all or part of a batch or a lot of intermediate or a finished product of single batch/lot shall be exceptional and shall be permitted after assessment of the risks involved by QA. The reprocessing at different stages of manufacturing shall be done as follows.

5.6.2 Blend/Granules:

5.6.2.1 The product shall be reprocessed if it does not meet

- Assay requirement
- Loss on drying/ moisture content

5.6.3 Capsules:

5.6.3.1 The product shall be reprocessed if it does not comply with any physical parameters as follows:

- Appearance
- Average weight
- Uniformity in weight

5.6.4 Core Tablets:

5.6.4.1 The product shall be reprocessed if it does not comply with any physical parameters as follows:

- Appearance

- Hardness
- Thickness
- Diameter/length
- Average weight
- Uniformity in weight

5.6.5 Coated Tablets

5.6.5.1 The product shall be reprocessed if it does not comply with physical parameters as follows:

- Appearance
- Average weight
- Uniformity in weight

5.7 The batch-reprocessing request (Refer Annexure-I) shall be initiated by Head–Production and then endorsed by R&D giving the details of reprocessing.

5.8 The reprocessing request duly endorsed by R&D, which shall be evaluated by QA head and CQA head for the risk assessment of the reprocessing on the product quality and safety. After assessing the risk involved, the QA/CQA head shall authorize the reprocessing.

5.9 Deviation shall be raised by the production department regarding reprocessing and approved by the QA head.

5.10 In case of reprocessing, put suffix ‘R’ along with the batch number for the identification of reprocess batch.

5.11 Put the reprocess batch under accelerated stability.

6.0 ABBREVIATION(S):

QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I : Batch Reprocessing Request

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Recovery and Reprocessing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Recovery and Reprocessing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure I

BATCH REPROCESSING REQUEST	
Request No.	Date:
Name of the Product: Batch No. : Date of Mfg. : Stage :	Batch size:
Production: 1. Reasons for failure:	
2. Probable causes for failure, if known:	
3. Reprocessing method as suggested by Production: Head – Production Date: (If necessary, attach separate sheets, where required)	
R&D: (To give the detailed reprocessing method with all parameters. If necessary, attach separate sheet) Head – Formulations (R&D) Date:	

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Recovery and Reprocessing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Quality Assurance:

Risk Assessment:

Conclusion

Head – QA (Sign/Date)

Head - CQA (Sign/Date)