DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Monitoring of Recovery addition	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for monitoring of Reprocessing of product.

2.0 RESPONSIBILITY

2.1 Production Officer shall be responsible for recovery addition as per SOP.

2.2 Quality Assurance Officer shall be responsible for counterchecking that the entire process of recovery addition is done as per SOP.

3.0 ACCOUNTABILITY

Quality Assurance Manager

4.0 PROCEDURE

4.1 Procedure of recovery addition is applicable to products for domestic market. No recovery addition shall be carried for export market.

4.2 If the recovery is more than 3 months old, get it tested for assay in QC. If the assay conforms to release specifications the recovery may be used.

4.3 If the recovery is less than 3 months old, it can be added without testing.

4.4 Ensure that the total recovery added is not more than 10 % of original batch size.

4.5 Ensure that process of recovery addition is mentioned and recorded in BMR in detail.

4.4 Ensure that the batch wise recovery to be added to the fresh recovery batch is the same as recovered and reconciled primarily batch wise.

4.4 Ensure that manufacturing date of the batch is given the month in which the fresh batch is taken for production.

4.5 The expiry of the batch shall be given as shortest as of the batch holding shortest expiry.

4.6 Ensure that the total calculated quantity of recovered blend is correct

4.7 Carry out line clearance at startup and at each stage of processing as per SOP.

4.8 Ensure that the correct integrated sieve is being used for sifting of the granule as specified in BMR.

4.9 Collect the samples of the blended granules and submit it to quality control for analysis along with BMR.

4.10 Check the result of analysis and follow the recommendation of quality control for further processing of the batch.

4.11 If the result of analysis is approved by quality control then affix "Approved" label to product bin for clearance. If any addition of active ingredient is recommended then allow to production for addition of the same and collect the sample after addition of the required material and blending.

4.12 Again submit the sample to quality control for analysis and follow pt. n. 4.10 & 4.11.

4.13 If the recovery in carried for the product first time , evaluate the stability of the product at accelerated stability study condition of 40 °C and 75 % RH.

4.14 The product shall remain in hold till one month accelerated stability data is found well within the acceptance criteria of accelerated stability studies.

4.15 The new recovery product shall be released only after completion of one month of accelerated stability study , but the study shall be continued for duration as per stability protocol.

4.16 Ensure that leftover of the recovery batch is destroyed and neither stored as recoverable nor added to any other batch

5.0 REASION FOR REVISION

5.1 Harmonization of format

6.0 TRAINING:

Trainer	--	Head – Quality Assurance
Trainees	--	Head – Oral Dosage Form/ Head-Injection / Quality Assurance Officers
Period	--	One day

7.0 DISTRIBUTION:

Certified Copy No.	1	: Head of Department – Quality Control
Certified Copy No.	2	: Head of Department- Oral Dosage Form
Certified Copy No.	3	: Head of Department- Injection
Original Copy :		Head – Quality Assurance

8.0 ANNEXURES:

None

9.0 REFERENCES:

In house