DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preventing of product and material mix-ups and cross contamination	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for preventing of product mix-ups and cross-contamination.

2.0 SCOPE:

This procedure is applicable to all products and raw material in stores, QC and production department.

3.0 RESPONSIBILITY:

All personnel of concerned Departments and QA

Head – QA

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Raw material procurement, storage and dispensing:

5.1.1 All raw materials, both actives and excepients shall be procured only from approved suppliers.

5.1.2 Stores personnel receiving the material shall follow all steps with respect to handling and storage of raw materials and packing materials as per SOP.

5.1.3 Special attention shall be provided to verify and tally the labels of containers and indented items on receipt.

5.1.4 While storing the materials, care shall be taken to ensure segregation of under test, approved and rejected materials

5.1.5 Any rejected or obsolete materials shall be suitably disposed within the shortest possible time and record shall be maintained accordingly.

5.1.6 Dispensing of the material shall be done only after obtaining line clearance and dedicated cleaned scoops shall be used for dispensing.

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5.2 **Quality control of incoming materials:**

5.2.1 QC shall follow the various steps detailed under specific sampling procedures.

5.2.2 Special precautions shall be taken by QC to ensure that no cross-contamination occurs while sampling.

5.2.3 Dedicated or appropriately cleaned sampling equipment shall only be used for sampling.

5.2.4 During sampling, QC personnel shall critically verify the labels on the containers.

5.2.5 QA Manager shall periodically carryout the review of the laboratory activities and ensure that the laboratory systems and procedures are sufficient to detect any mix-ups or cross-contamination.

5.3 **Manufacturing:**

5.3.1 Production person receiving the materials issued by stores shall carefully verify the labels on the containers and tally them with the indent.

5.3.2 QA person shall crosscheck any weights and addition of materials in manufacturing.

5.3.3 Line clearance procedures shall be strictly followed and documented by production and QA.

5.3.4 Effectiveness of cleaning shall be validated and records shall be maintained.

5.3.5 Adequate in-process checks shall be in place at appropriate stages to ensure that the manufacturing proceeds as per the plan.

5.3.6 QA shall carry out periodic reviews of all manufacturing activities to ensure that there are no potentials for mix-ups or cross contamination.

5.3.7 Care and precaution during product manufacturing, handling of finished products, in-process manufacturing controls, labeling controls, validated cleaning procedures, quality control procedures in addition to general GMP compliance shall be given top priority.

5.3.8 Any OOS or atypical results obtained by QC during the analysis of raw materials, intermediates and finished products shall be investigated in detail before the batch is accepted or released.

5.3.9 QA Head or his personnel shall conduct training program from time to time regarding mix-ups and cross contamination as per given in training module-IV and impact of the same on the product quality. If possible, live examples shall be given to highlight such situations.

6.0 ABBREVIATION(S):

OOS : Out Of Specification.

QA : Quality Assurance

QC : Quality Control

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

NA

9.0 REVISION CARD:

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