DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Prevention of Contamination and Cross Contamination	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE

To define a procedure for prevention of product mix-ups and cross-contamination.

2.0 SCOPE

2.1 This procedure applies to Warehouse, Engineering, Production, QC and QA Department of …….

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 Schedule M

3.1.2 SOP: “Personal Hygiene”

3.1.3 WHO Technical Report Series 908- Annex 4

3.1.4 In-house

3.2 Attachments

3.2.1 Nil

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Contamination:** The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, in to or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

4.1.2 **Cross Contamination:** Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

4.2 Abbreviations

4.2.1 SOP: Standard operating procedure

4.2.2 QC: Quality Control

4.2.3 QA: Quality Assurance

4.2.4 RM: Raw material

4.2.5 PM: Packing material

4.2.6 OOS: Out of specification

4.2.7 GMP: Good manufacturing Practices

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4.2.8 API: Active pharmaceutical ingredient

4.2.9 etc.: Etcetera

5.0 RESPONSIBILITY:

5.1 Warehouse, Engineering, Production, QC and QA Department:

5.1.1 To follow the procedure as defined in the SOP.

5.2 All Departments Heads:

5.2.1 To ensure that the procedure is being followed as defined in the SOP.

5.3 Quality Assurance Head:

5.3.1 To ensure implementation of the defined procedure.

5.4 Plant Head:

5.4.1 To ensure implementation of the defined procedure.

6.0 Distribution:

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Human Resource and Admin
VII. Environment, Health and Safety

7.0 PROCEDURE:

7.1 Raw material procurement, storage and dispensing

7.1.1 All raw materials, both actives and excipient shall be procured only from approved suppliers.

7.1.2 Warehouse personnel receiving the material shall follow all steps with respect to handling and storage of raw materials and packing materials as per respective SOPs.

7.1.3 Unloading of raw material (API) for respective manufacturing blocks shall be strictly done in their respective blocks.

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

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

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

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

7.2 Quality control

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

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

7.2.3 Dedicated and cleaned sampling equipment shall only be used for sampling.

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

7.2.5 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.

7.2.6 QC Head 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.

7.2.7 Dedicated person shall perform the sampling activities for block wise environmental monitoring.

7.2.8 Cleaning validation of Sampling tools/ Glassware shall be performed.

7.3 Manufacturing

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

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

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

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

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

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

7.3.7 For injectable manufacturing, single product shall be manufactured in the area provided with same air handling unit to prevent cross-contamination.

7.3.8 No RM/PM, in-process/finished product residues, used containers/scrap shall be allowed out for biological products without adequate deactivation (wherever applicable).

7.3.9 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.

7.3.10 QA Head or his personnel shall conduct training program from time to time regarding mix-ups and cross contamination and impact of the same on the product quality.

7.3.11 Dedicated manpower shall be provided for different manufacturing blocks.

7.3.12 Dedicated laundry facility shall be available for different manufacturing blocks.

7.3.13 Gown washing procedure validation shall be in place.

7.3.14 Environmental trace analysis shall be done.

7.3.15 Dedicated RM/PM storage place shall be available.

7.3.16 Individual cleaning validation procedure for different category products.

7.3.17 Person, Material, Equipment, instrument, accessories, gowns, stationaries and etc. once used for biological product shall not be permitted to be used for other products.

7.3.18 There shall be proper air handling system and pressure differential to prevent cross contamination of drug material and drug product.

7.3.19 Manufacturing area shall be fly proof by the use of air curtain, fly-O-cide and proper pest control.

7.3.20 The production area shall be cleaned and sanitized as per defined frequency to prevent accumulation of residual microbial growth or cross contamination. Area housekeeping and sanitization record and drain point sanitization record shall be maintained.

7.3.21 Equipment and accessory cleaning shall be done as per approved SOP and cleaning record shall be maintained to prevent cross contamination.

7.3.22 Personal hygiene shall be maintained as per SOP titled “Personal Hygiene”.

7.3.23 Particulate matter monitoring and filter leakage test shall be performed as per defined frequency to prevent contamination and cross contamination.

8.0 REVISION HISTORY

Version No.	**00**	**Effective Date**	
Details of revision: New SOP Prepared			