STANDARD OPERATING PROCEDURE	
Department: Production (External Preparation)	**SOP No.:**
Title: Prevention of Contamination and Cross Contamination	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Prevention of Contamination & Cross Contamination.

2.0 SCOPE:

This SOP is applicable for Prevention of Contamination and Cross Contamination in Production department.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

AHU	Air Handling Units
HEPA	High Efficiency Particulate Air
IPQA	In-Process Quality Assurance
No.	Number
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air.

6.0 PROCEDURE:

6.1 CONTAMINATION:

Introduction of undesired dust or dirt into or on to during manufacturing, packing and transportation is called as contamination and contaminant is the unwanted element being introduced in the system. It is any substance which has an adverse effect on the product or process.

TYPES: Contamination is three types depend on mode by which they can damage. They are -

1. Physical Contamination. Eg. Particles, fiber etc.
2. Chemical Contamination. Eg. Moisture, Vapors, Molecule, Gases etc.
3. Biological Contagion. Eg. Bacteria, Virus Fungus etc.

6.2 CROSS CONTAMINATIION:

6.2.1 Unwanted introduction of one drug substance during manufacturing to the other drug substance. **Example for Physical Contamination:** A leakage from oil seal of reactor may contaminate the product being processed inside the reactor.

6.2.2 **Example for Chemical Contamination:** In case the recovered solvent stored in a drum of other solvents, which was not cleaned properly may contaminate the recovered solvent. The contaminated solvent if used in process may spoil the product by giving the additional impurity. In case of product is exposed in an uncontrolled environment of high relative humidity, may increase the moisture content of the product.

6.2.3 Example of Biological Contamination: If powder processing equipment is left untried after cleaning with water proliferate the microbes in the equipment. If same contaminated equipment used for processing, may contaminate the powder microbiologically.

6.2.3.1 BIOLOGICAL CONTAMINATION IS DUE TO

- Improper sanitation of hands.
- Improper gowning.
- Use of biologically contaminated water for cleaning of equipment.
- Open lesions.
- Suffering from infectious diseases.

6.3 PREVANTION OF CONTAMINATION:

- Identify the contaminant.
- Anticipate the contaminant.
- Prevent ingress.
- Facilitate Ingress.
- Minimize the Internal generation.
- Control Residual contamination.

6.4 ELIMINATING SOURCE:

Like Shredding cloth, previously processed material.

6.5 ELEMINATING THE CONTAMINATION TRANSPORTER:

- Reducing human intervention.
- Controlling the use of equipment for different product.
- Controlling the use of air.
- Controlling the use of water.

6.6 TO REDUCE HUMAN AS TRANSPORTER:

- Fallow gowning.
- Proper gowning in clean area where the product is exposed for a longer time.

6.7 TO REDUCE AIR AS TRANSPORTER:

Air as constituent of environment, is prevent universally in work area

6.7.1 Example of air borne contamination

- Particulate contamination –dust, product contamination.
- Biological contamination.

6.7.2 Prevention:

- Control on flow of air through Air Handling Units (AHU's).
- Air locks
- Installing High Efficiency Particulate Air (HEPA)
- Ultra Low Particulate Air (ULPA).

6.8 TIPS TO PREVENTING CONTAMINATION:

- Sample only one material at a time.
- Sampling in a segregated cubicle/booth fitted with suitable air control systems.
- Use of dedicated tools for sampling.
- Dispensing stations must be equipped with suitable dust extraction system.
- All containers packaged must be effectively cleaned before these are admitted to the storage area
- Evolve and follow suitable equipment cleaning procedures. Periodically validate them to confirm the effectiveness.
- Regularly check and confirm the integrity of oil seals.
- Air supply system for the production and dispensing areas must be designed to avoid contamination into the airflow (or) to the manufacturing areas.
- Do not return the samples drawn for in-process control to original containers.
- To the extent possible, material during process should be unidirectional.
- Regularly monitor the quality of water, particularly for microbial contamination.
- Simultaneous charging of raw material for two different batches, two different stage and two different products should be avoided.
- Line clearance must be taken for the product change over.

7.0 ANNEXURES:
Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:
Not Applicable

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By