



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Transfer of Materials / Article from one Grade to Another Grade Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 3	

1.0 OBJECTIVE:

To lay down a procedure for Transfer of Materials / Articles from One Grade to another Grade Area.

2.0 SCOPE:

This SOP is applicable for the Transfer of Materials / Articles from One Grade to another Grade Area in production area.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Report
BFS	Blow Fill Seal
Classified Area	The area having controlled environment condition i.e., Temperature, Humidity, Differential pressure and specific particle count.
EM	Environment Monitoring
IPA	Isopropyl Alcohol
LAF	Laminar Air Flow
Ltd.	Limited
Pvt.	Private
SLS	Sodium Lauryl Sulphate
SS	Stainless Steel
SOP	Standard Operating Procedure
UV	Ultra violet
WFI	Water for Injection

6.0 PROCEDURE:

6.1 Precautions:

6.1.1 Before transfer of material first of all the outer surface of the container with IPA 70%.

6.1.2 Carefully handle the material to avoid the mix up / Mis-handling of material.
(i.e. keeping on floor, touching with hand etc.).

6.1.3 Always use dynamic pass box for transfer of materials from one class to another class.

6.1.4 Open only one door at a time of pass box during transfer of materials (do not open both The doors simultaneously).

6.1.5 Use material transfer trolleys for movement of each material inside Aseptic area and D



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Supersede Revision No.:	Nil	Page No.:	2 of 3

Grade area.

6.2 Procedure:

- 6.2.1** All the materials should be cleaned properly before transferring from one Grade to another Grade area (Low grade to high grade, less clean to more clean i.e., general area to classified area) to avoid contamination. Most common materials transferred crates, dresses, surgical gloves, plastic bags, beakers pressure vessel, filter housing, Mug etc.
- 6.2.2** Clean the crates with mopping pad. Then wipe all the surface with mopping pad dipped in SLS solution and then flush the crates with WFI. Wipe the crates using clean and dry mop. Spray 70% v/v IPA solution before transferring to lower grade area to high grade area.
- 6.2.3** First clean all the dresses with 0.2 % SLS solution in garment washing area, using purified water in garment washing machine. Sterilize washed & dried dresses at 121°C for 30 min in SS sterilization bin in autoclave. After sterilization transfer from Grade D to Grade C. Then transfer the dresses along with SS bin through Mobile LAF to clean area and Store them under LAF in second air lock.
- 6.2.4** Plastics bags used in Aseptic area for removal of plastics scraps & lums generated from BFS m/c. Before transferring these empty bags to Aseptic area mop with 70% IPA solution. Keep the disinfected bags in the dynamic pass box for expose the UV light as per respective SOP before taking in Aseptic area.
- 6.2.5** In case of Log sheet or BMR, expose them in the pass box under UV light as per respective SOP and then transfer to lower grade area to high grade area.
- 6.2.6** Use conveyor belt for transfer of Filled/sealed Bottles from BFS m/c to bottle loading area i.e. from high grade area to lower grade area.
- 6.2.7** In case of Raw materials transfer from low grade to manufacturing area, remove the outer poly bags in Dynamic Pass Box & keep them under UV light, then mop again with 70% IPA solution and transfer the bag to manufacturing area.
- 6.2.8** While transferring the Engineering tool from one class of area to another class i.e., lower to higher grade, clean the tools with 70% IPA and keep under UV light in pass box as per respective SOP and then mop again with 70% IPA solution and transfer to higher grade.
- 6.2.9** Transfer the fogger machine and SS bin containing EM plate after proper sanitization using IPA 70 % & UV light exposer as per respective SOP in Dynamic Pass Box from D Grade to C Grade area.
- 6.2.10** In case of other material not mentioned above should be properly sanitized using 70% IPA and then transfer to lower grade to high grade area.

7.0 ANNEXURES:

Not Applicable.

ENCLOSURES: SOP Training Record.



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Supersede Revision No.:	Nil	Page No.:	3 of 3	

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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