



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Good Manufacturing Practices in Aseptic Processing Area

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

**1.0 OBJECTIVE:**

To lay down a Procedure for Good Manufacturing Practices in Aseptic Processing Area.

**2.0 SCOPE:**

This SOP is applicable for Good Manufacturing Practices in Aseptic Processing Area.

**3.0 RESPONSIBILITY:**

Officer / Executive Production

**4.0 ACCOUNTABILITY:**

Head Production

**5.0 ABBREVIATIONS:**

Ltd.	Limited
SOP	Standard Operating Procedure
No.	Number
QA	Quality Assurance
IPA	Isopropyl Alcohol
UV	Ultra Violet
SS	Stainless Steel
Mfg.	Manufacturing
etc.	Etcetera
IPQA	In-Process Quality Assurance
PVT	Privet

**6.0 PROCEDURE:**

- 6.1** Access to the Aseptic Processing Area shall be restricted to Authorize Personnel only.
- 6.2** Before entering any aseptic environment, personnel must understand the responsibilities of their positions and must know the clean room techniques and system / operations are executed.
- 6.3** All personnel entering the aseptic processing area shall follow gowning and de-gowning procedure.
- 6.4** They shall follow the Personnel Hygiene guidelines in terms of health, personnel cleanliness and hygienic behaviors.
- 6.5** The personnel movement in the area shall be minimum, slow and rhythmic.
- 6.6** All verbal communication with the people outside the Aseptic Area shall be done through the intercom, and never through Air Locks or Pass Boxes.
- 6.7** Loud, unnecessary talk through the mask shall be not allowed. Laughing, whistling, singing and shouting shall not be allowed.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Good Manufacturing Practices in Aseptic Processing Area

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	2 of 3

- 6.8** Open the doors by pushing with the help of elbow and pulling with the wrist. Ensure that two adjacent doors will not be opened simultaneously.
- 6.9** At a time, the in process checks shall be done by either a Production Chemist or an IPQA Chemist. The two shall avoid being in a room together, unless required (as in manufacturing area), to reduce man movement in that particular area.
- 6.10** At the time of Shift changeover the personnel in the outgoing Shift shall leave the area, prior to the entry of the next Shift personnel (If required).
- 6.11** Eating and drinking will not be allowed inside the aseptic processing area.
- 6.12** Pencil, erasers are not permitted inside the clean room. Instead ball pens to be used for all purpose.
- 6.13** Corrugated boxes, wooden piece, bricks etc. will not be allowed inside the aseptic processing area.
- 6.14** It has to be ensured that no skin is exposed between the gloved hands and garments part. In the same way, head gear must be tucked completely inside the uniform and hair to be covered at all times.
- 6.15** Any equipment, part of equipment if taken inside the clean room must be disinfected with 70% IPA before they are taken in.
- 6.16** No one who is physically ill or especially with respiratory or stomach disorders will enter the clean room.
- 6.17** Personnel items like jewelry and things like watch, keys, coins, combs etc. are not allowed to take inside the clean room.
- 6.18** Before entering the clean environment, personnel must understand the responsibilities of the work as well as aseptic technique / sterile behavior.
- 6.19** Once inside the clean room, personnel shall remain till the end of the work / shift and unnecessary or frequent opening of doors of either mixing or filling area or air locks shall be avoided.
- 6.20** Nervous relief-type manners such as head scratching or rubbing hands face or parts of the body must be consciously avoided.
- 6.21** Clean room garments must be discarded while leaving the aseptic area. Fresh, clean sterilized garments shall be worn when returning to work.
- 6.22** No flaking or corrosive material shall be allowed in the area.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Good Manufacturing Practices in Aseptic Processing Area

<b>SOP No.:</b>		<b>Department:</b>	Production	
		<b>Effective Date:</b>		
<b>Revision No.:</b>	00	<b>Revision Date:</b>		
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	3 of 3	

**6.23** Unnecessary storage of articles like files, papers and wooden articles in aseptic processing area are not allowed and it should be used minimum in manufacturing and washing area after prior exposure to UV light through pass box.

**6.24** During operation, personnel movement in aseptic processing area must be minimized.

**6.25** All materials, containers, equipments etc. intended for use of aseptic operation must be labeled for identification.

**6.26** Used articles, hardware etc. shall be sent out through a Pass Box.

**6.27** All equipment, SS tables, Doors, floors, walls and ceilings shall be subjected to a regular mopping/spraying and disinfection on rotational basis, using approved disinfectants schedule.

**6.28** Once the actual power supply is resumed, the area should be sanitized using 70 % IPA.

**7.0 ANNEXURES:**

Not Applicable

**ENCLOSURES:** SOP Training Record

**8.0 DISTRIBUTION:**

- Controlled Copy No.1      Quality Assurance Department
- Controlled Copy No.2      Production Department
- Master Copy                  Quality Assurance Department

**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