



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Procedure for Cleaning ,Sanitization , Sterilization and Uses of Tools/ Spanners Used In Aseptic Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 2

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Sanitization/Sterilization of tools/Spanners used in aseptic area.

2.0 SCOPE:

This SOP is applicable for cleaning & sanitization/sterilization of various type of tools use in aseptic area for adjustment, change over and repairing of equipments/machineries in Production Department.

3.0 RESPONSIBILITY:

Machine Operator
Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Ltd.	Limited
Pvt.	Private
QC	Quality Control
WFI	Water For Injection
IPA	Isopropyl Alcohol
QA	Quality Assurance
SOP	Standard Operating Procedure
%	Percent

6.0 PROCEDURE:

6.1 CLEANING AND SANITIZATION OF TOOLS / SPANNERS:

- 6.1.1 The tools are primarily clean with WFI to minimized oil or Grease which is accumulated during daily work or maintenance
- 6.1.2 Then scrub with 1% solution .of SLS to get free from oil or grease
- 6.1.3 Finally rinse with WFI and dry with the help of compressed air and check visually , it should be free from any stain
- 6.1.4 After cleaning , cleaned tools / spanners shall be sanitization with filtered 70% IPA solution to avoid possible contamination and finally dry at room temperature
- 6.1.5 Tools shall be cleaned after every operation or whenever used for rectification of machine or equipments

6.2 PROCEDURE FOR USING:

- 6.2.1 Cleaning and sanitized tools shall be taken in aseptic area for daily use or maintenance work via dynamic pass box under UV exposure for 20 minutes



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6.2.2 Tools dedicated for use in aseptic area shall be used in aseptic area to avoid cross contamination. Rusted and damaged tools shall not be used in aseptic area

6.3 PRECAUTIONS:

- The tools which are in aseptic area should be stainless steel .
- Ensure complete dryness of tools after sanitization or sterilization .
- All tools/spanners should be kept in cleaned and sanitized stainless steel tool box and closed when not in used .
- Frequently check for rust and damaged , if found , avoid for further use.
- Tools which are made up of stainless steel shall be sterilized weekly.

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

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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