



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Preparation of Cleaning and Sanitizing Solution in Manufacturing Area	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** Yes

### 1.0 OBJECTIVE:

- 1.1 To lay down the procedure for preparation of cleaning and sanitizing solution in manufacturing area.

### 2.0 SCOPE:

- 2.1 This procedure is applicable to preparation of cleaning and sanitizing solution in manufacturing area.

### 3.0 RESPONSIBILITY:

- 3.1 Housekeeping personnel, Officer, Executive – Production Department  
3.2 Manager – Production Department

### 4.0 DEFINITION(S):

- 4.1 NA

### 5.0 PROCEDURE:

#### 5.1 Safety Precautions

- 5.1.1 Use proper safety apparel such as gowns, rubber hand gloves and safety goggles during preparation and use.

#### 5.2 Cleaning and Disinfectant solutions:

- 2.5 % v/v Dettol  
0.1 % v/v Teepol / 0.1 % v/v SU120  
2.5 % v/v Savlon  
70% v/v Iso-Propyl Alcohol (IPA)  
0.4 % w/v sodium hydroxide  
2 % Sodium lauryl Sulphate Solution

#### 5.2.1 Preparation of disinfectant and cleaning solution:

##### **Solution No. – I: 2.5 % Dettol (For 1 Liter)**

Take 25 ml of Dettol and make-up to 1000 ml with Purified water. Mix well and use within a day.



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**Note:** Destroy the remaining (unused) quantity of solution by pouring in drain point at the end of the working day.

### **Solution No. – II: 0.1% Teepol / 0.1% SU120 (For 10 Liters)**

Take 10 ml of teepol /SU120 and make-up to 10 liters with purified water. Mix well and use within a day.

**Note:** Destroy the remaining (unused) quantity of solution by pouring in drain point at the end of the working day.

### **Solution No.-III: 2.5% Savlon (For 1 Liter)**

Take 25 ml of Savlon and make-up to 1000 ml purified water. Mix well and use within a day.

**Note:** Destroy the remaining (unused) quantity of solution by pouring in drain point at the end of the working day.

### **Solution No.-IV: 70% v/v IPA**

Considering the density of IPA 0.783 M/V, calculate the volume of IPA as per the weight of IPA dispensed.

$D=M/V$ ,  $V=M/D$  (Example:  $D=0.783$ ,  $M=10$  kg (dispensed quantity of IPA))

$V=10/0.783$ ,  $V= 12.771$  liters

And calculate the total volume of disinfectant solution by multiplying the volume of IPA with factor 100 and the dividing it by 70 (i.e. 70%).

Total Volume of disinfectant (T) =  $V \times 100 / 70$

Total Volume of disinfectant (T) =  $12.771 \times 100 / 70 = 18.244$  liters

Now calculate the volume of purified water to be added (i.e. 30% v/v of IPA solution) by subtracting the Total Volume of disinfectant (T) by volume of IPA (V).

Quantity of water (W) =  $T - V$

Quantity of water (W) =  $18.244 - 12.771 = 5.473$  liters.

D=density, M= Mass (weight) of IPA dispensed, V=Volume

**Note:** Pour the remaining (unused) quantity of solution by diluting with excess quantity of Purified water (i.e. 170 mg of IPA / Kg of water) drain point at the end of the working day of weekend or from the week of preparation of 70 % v/v IPA soln .

### **Solution No.-V: 0.4 % Sodium hydroxide (NAOH) (For 1 Litre)**

Take 4 gm of NAOH and make-up to 1000 ml with Purified water. Mix well and use within a day.



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**Note:** Destroy the remaining (unused) quantity of solution by pouring in drain point at the end of the cleaning activity.

### **Solution No. VI: 2 % Sodium lauryl sulphate solution (SLS Solution – For 1 Litre):**

Take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water in the soap holding tank. Fill the required soap solution (2% w/v Sodium Lauryl Sulphate (For 1 liter 2% Sodium Lauryl Sulphate,

Always prefer destruction of 2.5 % Disinfectant solution after destruction of 0.1 % Teepol / SU120 Solution / SLS Solution and 70% v/v IPA Solution.

#### 5.2.2 **Calculation of IPA before drain:**

- 170 mg of IPA/Kg of water.
- or 50 gm of IPA/294 Kg of water.
- or 100 gm of IPA/588 Kg of water.

5.2.3 Maintain record in 'Cleaning and Sanitization Solution Preparation Register' as per Annexure -I, "Cleaning and Sanitization solution utilization record.

### **6.0 ABBREVIATION(S):**

- 6.1 IPA : Iso-Propyl Alcohol
- 6.2 ml : Milliliters
- 6.3 v/v :Volume by Volume
- 6.4 SOP : Standard Operating Procedure

### **7.0 REFERENCE(S):**

- 7.1 OSHA Guideline.

### **8.0 ANNEXURE(S):**

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure I	Cleaning and Sanitization Solution utilization record		Logbook

### **9.0 DISTRIBUTION:**

- 9.1 **Master copy** : Quality Assurance
- 9.2 **Controlled copy( s )** : Production department (02), P & A Department (01),



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Quality Assurance (01)

9.3 **Reference copy (s) :** Production Department (02)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (S) for Revision	Details of Revision	Effective Date



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### Annexure I

#### Cleaning and Sanitization Solution Utilization Record

Date	Name of Disinfectant /Cleaning agent	Concentration of Disinfectant/ Cleaning agent	Quantity of Disinfectant/Cleaning Solution Prepared					Quantity of Disinfectant/ Cleaning Solution Destroyed		
			Quantity of Disinfectant /Cleaning agent	Volume of Purified Water	Total Volume	Used for	Prepared By	Ckd. By	Quantity destroyed	Destroyed by/Date

**Note:** 2.5 % V/V Dettol /Savlon for 1000 ml: 25 ml Dettol / Savlon make up to 1000 ml with Purified water.

0.1 % V/V Teepol /SU 120 for 10 liters: 10 ml Teepol/SU120 and make up to 10 liters with Purified water.

70 % V/V IPA for 15.473 kg: 10 kg IPA (12.771 liters) add purified water 5.473 liter water.

0.4 % W/V NAOH for 1000 ml: 4gm NAOH make up to 1000 ml with purified water.

2.0 % W/V Take Sodium Lauryl Sulphate and dissolve in 1000 ml of purified water.