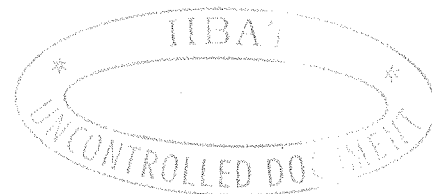


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SOP APPROVAL

Responsible	Name	Signature	Date
Author	A.Vijayakumar, M.Sc., M.Phil.		19.05.2020
Quality Assurance	A.Vijayalakshmi, Ph.D.		19.05.2020
Test Facility Manager	A.Ramesh, D.Sc.		19.05.2020

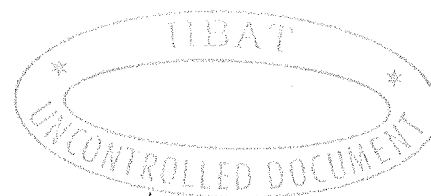
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### 1. Introduction

Hand sanitizer, also called hand antiseptic, or hand rub, agent applied to the hands for the purpose of removing common pathogens (disease-causing organisms). It is employed as a simple means of infection control in place. WHO, considering logistic, economic and safety factors has identified certain formulations worldwide to be used as Hand sanitizers.

### 2. Scope

This SOP is applicable for those who are preparing and using hand sanitizer. This SOP is prepared based on following references.

- WHO Guidelines on Hand Hygiene in Health Care 2009
- European Pharmacopeia
- Textbook of Quantitative Chemical analysis by Vogel 5<sup>th</sup> edition.

### 3. Abbreviations

WHO - World health organization

IPA-Isopropyl alcohol

H<sub>2</sub>O<sub>2</sub> - Hydrogen peroxide

### 4. Procedure

#### 4.1 In-house/local production

##### Ingredients:

Ethanol

Isopropyl alcohol

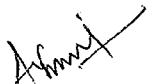
Glycerol

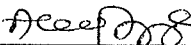
Hydrogen Per oxide

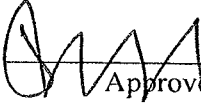
Sterile water / cold boiled water

#### 4.1.1 Stepwise Preparation (1000 mL) – Formulation 1

- Ethanol (Minimum 96%) 833.3 mL is poured into the large bottle with marking of 1000 mL
- Hydrogen peroxide (3%) 41.7 mL is added using the measuring cylinder to the ethanol in 1000 mL bottle.
- Glycerol (Minimum 98%) 14.5 mL is added to the above using a measuring cylinder. As glycerol is very viscous and sticks to the wall of the measuring cylinder,

  
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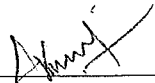
it will be rinsed with some sterile distilled or cold boiled water and then emptied into the bottle.

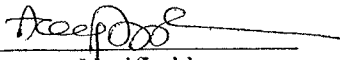
- The bottle is then topped remaining volume up to the mark with sterile distilled or cold boiled water

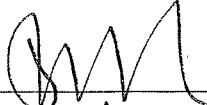
#### 4.1.2 Stepwise Preparation (1000 mL) – Formulation 2

- Isopropyl Alcohol (Minimum 99.8%) 751.5 mL is poured into the large bottle with marking of 1000 mL
- Hydrogen peroxide (3%) 41.7 mL is added using the measuring cylinder to the alcohol in 1000 mL bottle.
  - Glycerol (Minimum 98%) 14.5 mL is added to the above using a measuring cylinder. As glycerol is very viscous and sticks to the wall of the measuring cylinder, it will be rinsed with some sterile distilled or cold boiled water and then emptied into the bottle.
- The bottle is then topped remaining volume up to the mark with sterile distilled or cold boiled water
- The lid or the screw cap is placed on the bottle as soon as possible after preparation, in order to prevent evaporation.
- The above solutions (Formulation 1 / Formulation 2) solution is mixed by shaking gently or a paddle is used to mix the solution.
- After preparation, solution is divided into smaller volumes appropriately based on the requirement.
- Bottles are quarantined for about 72 hours before use.

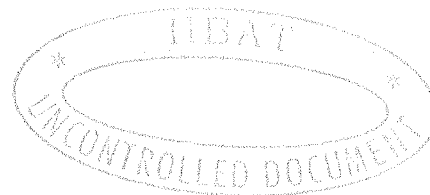
pharmacopoeial quality reagents are used (e.g. The International Pharmacopoeia) . Technical grade products are not used in the preparation of hand sanitisers.

  
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Final Products

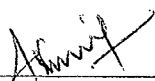
Formulation 1	Formulation 2
Final Concentrations: <ul style="list-style-type: none"><li>Ethanol 80% (v/v),</li><li>Glycerol 1.45% (v/v),</li><li>Hydrogen peroxide 0.125% (v/v)</li><li>Sterile distilled 18.425 % (v/v)</li></ul>	Final Concentrations: <ul style="list-style-type: none"><li>Isopropyl alcohol 75% (v/v),</li><li>Glycerol 1.45% (v/v),</li><li>Hydrogen peroxide 0.125% (v/v)</li><li>Sterile distilled 23.275 % (v/v)</li></ul>

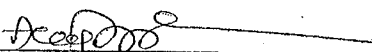
4.2 Safety Precautions

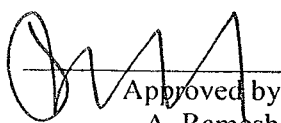
The person who is preparing hand sanitizer wears the hand gloves, laboratory over coat and goggles.

4.3 Quality control

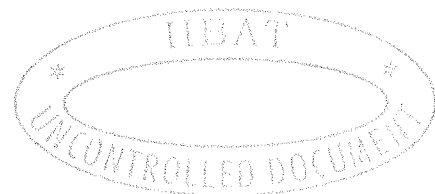
- As a part of Quality control, pre-production analysis will be made every time if an analysis certificate is not available to guarantee the titration of alcohol (i.e. local production).
- Alcohol concentration is verified using an alcoholmeter and necessary adjustments in volume to arrive at the required alcohol concentration.
- Post-production analysis is mandatory if either ethanol or an isopropanol solution is used. The alcohol concentration of the final use solution is carried out using an alcoholmeter to reconfirm the alcohol concentration.
- The accepted limit for alcohol concentration in the final solution is  $\pm 5\%$  of the target concentration (75%–85% for ethanol).
- If an alcoholmeter is used to check the final concentration of the solution prepared using isopropyl alcohol, a deviation of  $\pm 1\%$  is acceptable for the final concentration of isopropyl alcohol (e.g: an isopropanol 75% solution will show 77% ( $\pm 1\%$ ) on the scale at 25°C).

  
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- In the locally prepared Hand sanitisers, Hydrogen Per oxide (H<sub>2</sub>O<sub>2</sub>) concentration can be measured by titrimetry (oxydo-reduction reaction by iodine in acidic conditions).
- Alternatively a titrimetric method to quantify the alcohol and the hydrogen peroxide content shall be used.

Note: A higher level quality control can be performed using a Gas chromatography method.

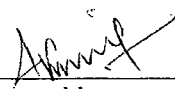
#### 4.4 Labeling Procedure in accordance with National guidelines:

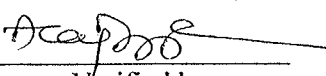
The label contains the following but no limited to:

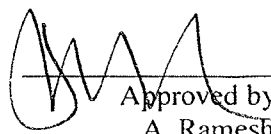
- Name of institution
- WHO-recommended Handrub formulation
- For external use only
- Avoid contact with eyes
- Caution (Such as Flammable /Keep out of the reach of children)
- Date of production
- Directions to use
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide.
- Flammable: keep away from flame and heat

#### 4.5 Storage facilities

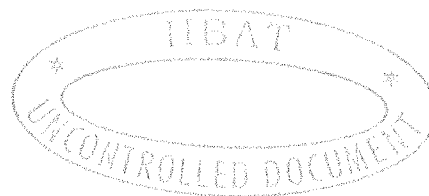
- Production and storage facilities are air conditioned or cool rooms with adequate ventilation.
- No naked flames or smoking is permitted in the area if production.
- Maximum quantity of production is 50-litres as per WHO-for Handrub formulations

  
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- Since undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities shall directly dilute it to the required concentration.

#### 4.7 Cleansing and disinfection process for reusable Handrub bottles.

- Wash bottles thoroughly with detergent and tap water to eliminate any residual liquid;
- If heat-resistant, thermally disinfect bottles by boiling in water. Whenever possible, thermal disinfection will be chosen in preference to chemical disinfection. The chemical disinfection may increase costs and introduces an extra step to flush out the remains of the disinfectant. Chemical disinfection will include soaking the bottles in a solution containing 1000 ppm of chlorine for a minimum of 15 minutes and then rinsing with sterile/cooled boiled water;
- After thermal or chemical disinfection, leave bottles to dry completely upside-down in a bottle rack. Dry bottles will be closed with a lid and stored, protected from dust, until use.

#### 4.8 Directions to Use

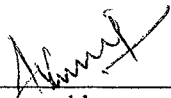
Apply a palmful of alcohol-based Handrub and cover all surfaces of the hands. Rub hands until dry.

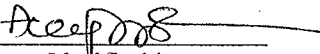
#### 5 Appendices

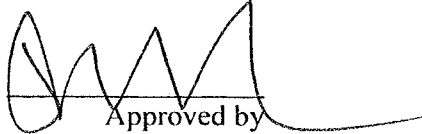
Nil

#### 6 History

This is a newly prepared SOP.

  
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