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MINISTRY OF HEALTH - ETHIOPIA

HEALTH FACILITY ALCOHOL BASED HAND RUB PREPARATION STANDARD OPERATING PROCEDURE

October 2019,
Addis Ababa, Ethiopia

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FOREWORD

Health care-associated infections (HCAI) are infection occurring in a patient with in a hospital or other health-care facility in whom the infection was not present or incubating at the time of admission. It is among the challenges in quality of healthcare deliverance and mainly patient safety in health facilities. No health-care facility, no country, no health-care system in the world can claim to have solved the problem. In order to minimize the risks of HCAI, hand hygiene is recommended. Therefore, alcohol based hand rub solution is evidently recommended as golden method for hand hygiene practice to reduce HCAI and also prevent antimicrobial resistance.

Thus, the adoption of this guideline and procedure manual is essential to address knowledge and skill gaps and standardize the production of the solution at health facilities. Further, it used to promote the weakened hand hygiene practice among healthcare workers through improving the access.

I would like to take this opportunity to thank all who participated in the adoption and development of this procedure manual.

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ABBREVIATIONS

ABHR	Alcohol based hand rub
BUD	Beyond Use Date
EFDA	Ethiopian Food and Drug Administration
EHSTG	Ethiopian Hospital Service Transformation Guideline
FBC	Freshly Boiled and Cooled
HCAI	Health Care Associated Infection
PPE	Personal Protective Equipment
PPM	Parts Per Million
SOP	Standard Operational Procedure
WHO	World Health Organization

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DEFINITION OF TERMS

• **Active Pharmaceutical Ingredient (API)** – means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease.

• **Alcohol based hand rub (ABHR)** – is an alcohol containing liquid preparation that is intended for application of the hands to inactivate micro-organisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol and other active ingredients with excipients.

• **Alcoholmeter** – is an instrument used to measure alcohol content in alcohol containing preparation.

• **Antiseptics** – are antimicrobial substances that are applied to living tissue/skin to stop or slow the growth of microorganisms.

• **Batch** – means a specific quantity of a product or other material that is intended to have a uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

• **Batch number** – means any distinctive combination of letters, numbers, or symbols, or any combination of them from which the complete history of the preparation, processing, packing, holding and distribution of a batch or lot of pharmaceutical product or other material can be determined.

• **Beyond use date (BUD)** – is the date after which a compounded preparation shouldn't longer be used.

• **Distilled water** – is a type of water that has many of its impurities removed through distillation. Distillation involves boiling the water and then condensing the steam into a clean container.

• **Ethanol** – colorless, volatile, flammable solution that is produced by the natural fermentation of sugar and starches or biochemical synthesis with germicidal activity against gram positive, gram negative, vegetative bacteria.

• **Freshly boiled and cooled water (FBC)** – is a water that is used for the preparation of pharmaceutical product after it is boiled and cooled.

• **Glycerol** – is a simple polyol compound. It is colorless, sweet, viscous liquid widely used in pharmaceutical formulations as a solvent, emollient and sweetening agent. It has three hydroxyl groups that are responsible for its solubility in water and its hygroscopic nature.

• **Hydrogen peroxide** – is a strong oxidizing agent. Low concentration of hydrogen peroxide is used in aqueous solution to eliminate and/or inactivate bacterial spores.

• **Isopropyl alcohol** – is a clear, colorless, volatile, flammable water soluble liquid and derived from propylene. It is used specially as a solvent and rubbing alcohol.

• **Label** – a display of written, printed, or graphic matter upon the immediate container of any pharmaceutical product or material.

• **Master formula** – is a master document for any pharmaceutical product that contains all the composition of a formulation with their respective quantity.

• **Personal Protective Equipment (PPE)** – is all garb and accessories, such as mask, gloves, gown and safety goggles, that protect the non-sterile preparation and the worker.

• **Pharmaceutical compounding** – a process of preparation, mixing, assembling, altering, packaging, and labeling of pharmaceutical products in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner–patient–pharmacist–compounder relationship in the course of professional practice.

• **Pharmaceutical Excipient** – are inert substance other than the active pharmaceutical ingredient (API) that have been appropriately evaluated for safety and are intentionally included in drug delivery system.

• **Package** – means the immediate and/or secondary container or wrapping in which any preparation is contained for use or storage.

• **Quality control** – a system for verifying and maintaining a desired level of quality in a product or process by careful planning, use of proper equipment, continued inspection, and corrective action as required.

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1. INTRODUCTION

1.1. OVERVIEW

Health care-associated infections (HCAIs) are a global problem that contribute to and directly result in significant morbidity and mortality. The prevalence of HCAI in developed countries is estimated to vary between 3.5% and 12%. However, in developing countries on average the prevalence ranges from 15% to 20%. The prevalence of HCAIs is relatively higher in sub-Saharan countries (18.9% in Mali, 14.8% in Tanzania, and 14.9% in Ethiopia). HCAIs result in adverse healthcare outcomes as increased hospital stay, economic burden, significant morbidity and mortality. This could be prevented through simple and low-cost infection prevention and control interventions, such as hand hygiene performed at critical moments.

Hand hygiene is an effective strategy to prevent HCAI and limit the transmission of microorganisms, including antibiotic-resistant microorganisms and required practice for all health care providers. It is one of the five key initiatives set out by the World Alliance for Patient Safety's Global Patient Safety Challenge and encompasses the cleansing of hands by using hand washing with soap and water, antiseptic hand washes, antiseptic hand rubs such as alcohol-based hand rub (ABHR).

World Health Organization (WHO) recommends local preparation of different types of antiseptic formulations such as ABHR. Moreover, Ethiopian hospital service transformation guideline (EHSTG) and National Infection Prevention and Control Manual endorsed the preparation of antiseptics such as hand rubs, hydrogen peroxide, and alcohol of different strengths which are needed for patient and health professional care. Among the antiseptic preparations, ABHR is the gold standard and primary choice of care and aseptic procedure in clinical settings. ABHR antiseptic products are mostly prepared from alcohol and its derivative with or without other additives like emollients. Local production of ABHR has been shown to be feasible globally, even in low and middle income countries. Over the past decade, there have been several examples of local production of ABHR as part of multimodal approaches to improve hand hygiene from single hospital pharmacy to national level. In 2011, the Kenya Ministry of Health and the CDC-Kenya adapted the WHO toolkit to train Kenyan pharmacists on production of ABHR.

Despite recommendation of local preparation of different types of antiseptic formulations at hospital level, the practice of the compounding in the low and middle income countries is low. Ethiopian experience of local preparation at hospital level is not different from those countries experiences, i.e., minimal. A few hospitals which were engaged in the preparation of hospital based production are using different standard operating procedures (SOPs) and practices which lack good compounding practice. So, this guideline gives a direction in way of standardizing a practice of ABHR production at hospital level.

Ethiopian Food and Drug Administration (EFDA) standards for the establishment and practice of pharmaceutical compounding laboratory guideline states that the preparation of pharmaceutical product at hospital level should fulfill efficacy, safety, and quality parameters. These can be achieved through employing standards, protocols and procedures that guide the preparation of these products.

1.2. BENEFITS OF USING ALCOHOL BASED HAND-RUBS

Evidence based study showed that proper and regular utilization of ABHR in different health care set up gives the following potential benefits:

- Fast-acting and broad-spectrum antimicrobial activity with a minimal risk of generating resistance to antimicrobial agents.
- More effective at reducing microorganisms on hands, compared with hand washing using soap and water.
- Suitable for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene.
- It has a better capacity to promote improved compliance with hand hygiene by making the process faster, more convenient, and immediately accessible at the point of patient care.
- It can improve the skins condition if formulated with skin moisturizers and emollients like glycerin.

1.3. RATIONALE OF FACILITY BASED PRODUCED ABHR

As ABHR solution has been placed on the WHO Essential Medicines List, its availability in the health care facilities at the point of care is highly recommended. Furthermore, facility based production of ABHR at facility level has the following benefits when compared with commercially available products:

- Secure consistent supply which improves compliance of health-care workers for hand hygiene. This has shown great role in saving lives during emergency situations.
- Provides low cost alternative. Cost per 100 ml of commercially available products is US $2.5 – 8.0; whereas, a cost of local production was only approximately US $0.30. Moreover, literature shows about 85% cost reduction was observed from in-house hand rub solution.
- Enable to ensure the quality of products
- It provides opportunities to implement compounding knowledge and skill which optimizes patient care.
- Strengthen health care finance system through cost saving and income generation

1.4. PURPOSE OF THE DOCUMENT

The purpose of this document is to set the basic requirement for production of ABHR and to standardize the formulation, preparation and storage procedures at national level.

1.5. SCOPE

This guideline covers basic requirement for the small scale production of ABHR at health facility.

2. PREMISES

The premise used for compounding shall be designed, constructed, adapted and maintained to suit the compounding under hygienic conditions. So in order to attain the standards set by EFDA for the establishment and practice of pharmaceutical compounding the premise for compounding unit should fulfill the following;

- The area should be appropriate for the purpose of preparing good quality ABHR product and protect the product from contamination and deterioration.
- The compounding area should be far from areas or premises that can cause contamination to the raw materials or finished products, and equipment, such as medical laboratory, kitchen, waste disposal site and other similar areas.
- There should be NO naked flame or smoking and electric spark in the production and storage areas.
- Compounding unit shall have adequate number of rooms suitable for the purpose of compounding.
- The walls, floor ceilings, and floor of the compounding room shall be smooth, have no cracks or holes.
- The walls, floor and ceilings shall be painted and/or made of washable material.
- The compounding room shall have adequate light and ventilation (ventilator, etc.)
- The compounding room should be protected from direct sunlight.
- The window (s) of the compounding room shall be high enough and sealed.
- The Compounding unit shall have adequate supply of water of acceptable quality for cleaning, preparation, dilution, etc. purposes.
- The compounding unit shall have electricity for the purpose of lighting, distillation, heating, melting and other related activities.
- The compounding unit shall have a drainage system that allows the clearance of dirty water and unwanted solution.
- The compounding unit shall have enough benches on which preparation takes place and should be made from materials easy for cleaning and non-reactive material.
- There shall also be adequate accessory materials like; chairs, shelves, cupboards, fire extinguisher.

3. PERSONNEL

As per the guideline set by EFDA for professionals involved in the compounding services the following conditions should be fulfilled;

- Compounding unit should be headed by a registered pharmacist who will be in charge /control/ of the overall compounding process.
- A compounding unit shall have adequate number of pharmacy professional that will engage in compounding activity and other supporting staff such as trained janitor and porter.
- The personnel involved in compounding activity should take appropriate training in basic compounding skill, garbing and hygiene procedure.
- Any authorized person with an apparent illness or open lesion that may adversely affect the safety or quality of the preparation being compounded should be excluded

3.1. ROLES AND RESPONSIBILITIES

3.1.1. PHARMACY DIRECTORS OR PHARMACY DEPARTMENT HEAD

- The pharmacy manager or pharmacy department head is responsible for developing, organizing, and supervising over all activities related to pharmacy compounding of preparations.
- This person may share or assign these responsibilities to a pharmacist or pharmacy technician, who will be designated as compounding supervisor. He is also responsible for deploying required number of staffs for the compounding unit.

3.1.2. COMPOUNDING UNIT HEAD

The compounding unit head shall have the following minimum responsibilities:

- Ensure that all personnel involved in compounding possess the relevant training and proficiency necessary to properly and safely perform compounding duties
- Assuring that the equipment used in compounding is properly maintained
- Maintaining an appropriate environment in the area where compounding occurs
- Assuring that effective SOP and quality control procedures are developed and followed
- Verify requests for raw materials and monitor their proper utilization
- Monitor daily compounding activities and records and report

3.1.3. COMPOUNDING PHARMACISTS

Pharmacist engaged in compounding of pharmaceutical preparation has the following duties and responsibilities;

- A pharmacist shall inspect and approve all ingredients, containers, closures, labeling and any other material used in the compounding process.

• A pharmacist is responsible for the preparation following a good compounding practice.

• A pharmacist shall ensure all compounding activities are recorded, documented and reported.

• Conduct in-process and final quality checks to assure that basic requirements are met in the compounding process.

• A pharmacist is responsible for ensuring the proper maintenance, cleanliness and use of all equipment used in the compounding process.

3.1.4. PHARMACY TECHNICIANS

• All technicians are engaged in all the compounding activities under supervision of a compounding pharmacist.

4. MATERIALS

4.1. FORMULATION RAW MATERIALS

4.1.1. FORMULATION 1

It is ethanol based formulation and the following ingredients with specified strength are required:

- Ethanol, 96%
- Hydrogen peroxide, 3%
- Glycerol, 98%
- Sterile distilled or freshly boiled and cooled water

4.1.2. FORMULATION 2

It is isopropyl alcohol based formulation which contains the following ingredients:

- Isopropyl alcohol, 99.8%
- Hydrogen peroxide, 3%
- Glycerol, 98%
- Sterile distilled or freshly boiled and cooled water

4.1.3. FUNCTION OF INGREDIENTS

Ethanol or isopropyl alcohol: is used as an active ingredient for its antimicrobial activity.

Glycerol: is used as humectant.

Hydrogen peroxide: is used to inactivate contaminating bacterial spores in the solution and is not an active substance for hand antisepsis.

4.2. EQUIPMENT FOR THE PREPARATION OF ABHR

The minimum compounding equipment required for small scale compounding in a hospital setting are listed below.

a. Plastic tanks with required volume (e.g. 50 liter capacity) preferably in polypropylene or high density polyethylene, translucent so as to see the liquid level for bulk storage and distribution (1)

b. Stainless steel tanks with proper capacity (e.g. 80 liters) for proper mixing without overflowing (2)

c. Mixing device (Wooden, plastic or metal paddles) (3)

d. Measuring cylinders and measuring jugs (4, 5)

e. Funnels (Plastic or metal)

f. Plastic or glass bottles with required volume (e.g. 100 ml) with leak-proof and screw tops (6) (7)

g. An alcoholometer: the temperature scale is at the bottom and the alcohol concentration (percentage v/v) at the top (8)

Figure 1. Equipment used for the preparation of ABHR (World Health Organization, 2010. Guide to local production: WHO-recommended hand rub formulations. Geneva: WHO)

4.3. PERSONAL PROTECTIVE EQUIPMENT

During the Compounding of ABHR, PPE is the "First line of defense" against exposure to hazardous drugs when compounding. Compounding pharmacies need to be familiar with the requirements for PPE and have appropriate policies and procedures to protect workers. The necessary PPE includes:

- Gloves and Gowns
- Head, sleeve, and shoe covers
- Eye and face protection
- Respiratory protection

5. SMALL SCALE PRODUCTION

5.1. MASTER FORMULA FOR 10 LITERS PREPARATION

Table 1: Formulation one ingredients and amount of the hand-rub for 10 liters production

Ingredient	Quantity
Ethanol (96%)	8,333 ml
Hydrogen peroxide (3%)	417 ml
Glycerol (98%)	148 ml
Distilled or FBC water to	10,000 ml

Table 2: Formulation two ingredients and amount of the hand-rub for 10 liters production

Ingredient	Quantity
Isopropyl alcohol (99.8%)	7,515 ml
Hydrogen peroxide (3%)	417 ml
Glycerol (98%)	148 ml
Distilled or FBC water to	10,000 ml

5.2. GENERAL PROCEDURES FOR PREPARATION OF THE ABHR

1. Tare the preparation tank showing the volume level mark for the alcohol and the final preparation.

2. Pour the required quantity of alcohol of chosen formulation into the tank up to the graduated mark (A).

3. Add the hydrogen peroxide using a measuring cylinder (B).

4. Add the glycerol using a measuring cylinder (C). As glycerol is very viscous and sticks to the wall of the measuring cylinder, it should be rinsed with some distilled or boiled and cooled water and then emptied into the tank.

5. Topped up the tank to the marked volume with distilled or freshly boiled and cooled (FBC) water (D).

6. Place the lid or the screw cap on the tank as soon as possible after preparation to prevent evaporation.

7. Mix the solution by shaking gently where appropriate or by using a paddle (E).

8. Immediately divide up the solution into its final containers (e.g. 100 ml plastic bottles), and place the bottles in quarantine for 72 hours before use. This allows time for any spores present in the alcohol or the new/re-used bottles to be destroyed (F).

Figure 2. Procedures used for the preparation of ABHR (World Health Organization, 2010. Guide to local production: WHO-recommended hand rub formulations. Geneva: WHO)

5.3. COMPOSITION OF THE FINAL PRODUCT

Table 3: Formulation one Percentage composition of the final preparation

Ingredient	Quantity (%, v/v)
Ethanol	80%
Glycerol	1.45%
Hydrogen peroxide	0.125%

Table 4: Formulation two percentage of the final preparation

Ingredient	Quantity (%, v/v)
Isopropyl alcohol	75%
Glycerol	1.45%
Hydrogen peroxide	0.125%

6. GENERAL LABELING INFORMATION

The labeling of the product should be in accordance with national guidelines and should include important components including:

- Name of the institution
- Name of the product
- Total volume
- Concentration
- Date of preparation
- Batch number
- Directions for use
- Beyond use date (BUD) / Expiry date
- Precautions

The prototype label for the product is given below.

ALCOHOL BASED HAND-RUB, 20 L

COMPOSITION

- Ethanol 80 % (v/v)
- Glycerol 1.45% (v/v)
- Hydrogen peroxide 0.125% (v/v)

SIG:

- Apply about 2 ml to the palm and rub both hands and fingers until dry

PRECAUTIONS:

- Avoid contact with eyes
- Keep away from flame and heat
- Keep out of the reach of children

Batch No. CHMCT- 001/01/2019

Mfg date: 24/01/2019

BUD: June, 2019

- For external use only

_____ Hospital

Pharmacy Service Directorate

Compounding & Hospital Manufacturing Case Team

Figure 3. An exemplary label for ABHR preparation

7. QUALITY CONTROL

The following steps should be performed before and after the preparation of the product to ensure that its quality is within the acceptable limit.

1. Pre-production analysis should be made for ingredients every time if certificate of analysis is not available to guarantee the concentration:

   1.1. Alcoholmeter to verify the alcohol concentration and make the necessary adjustments in volume in the preparation formulation to obtain the final recommended concentration (i.e. 80% v/v for formulation 1 and 75% v/v for formulation 2)

   1.2. Titrimetry (oxydo-reduction reaction by iodine in acidic conditions) can be used to check concentration of hydrogen peroxide.

2. Post-production analysis is also mandatory. The alcoholmeter should be used to control the alcohol concentration of the final use solution. The accepted limits should be fixed to ± 5% of the target concentration, i.e., the alcohol concentration should be between 75 – 85%.

3. Only quality reagents for the compounding service should be used.

8. PACKAGING AND DISTRIBUTION

• The prepared solution should be packed, labelled, and distributed in a manner that ensures the safety and rational use.

• The batches will be approved by the responsible body (person in charge) for distribution after checking its conformity with the requirements.

• The distribution or dispensing packages at point of care can be using either portable individual small size containers (such as 50, 100, or 130ml) (B) or medium size containers (like 500ml) (A) or wall mounted (C).

• The distribution should be undertaken with regular schedule to each dispensing and service delivery units and the prepared solution should be collected by unit coordinators. Then, the unit coordinators distribute to end users or refill into wall mounted containers.

• The units will be responsible to return the empty dispensing packages to collection site (compounding unit) for refill purpose.

• Each quantity of dispensed solution to each units should be recorded and regular consumption trend should be monitored.

• The distribution of ABHR should be based on consumption and follow first expire first out principle.

• All the documents and records should be maintained and kept for a minimum of two years.

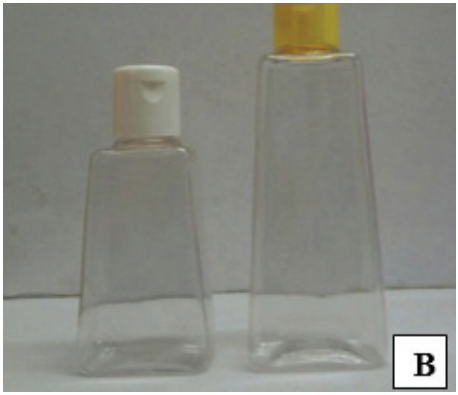

Figure 4. Packaging and distribution materials

9. CLEANSING AND DISINFECTION PROCESS FOR REUSABLE HAND RUB BOTTLES

i. Before use, wash bottles thoroughly with detergent and tap water to eliminate any residual liquid;

ii. If heat-resistant, thermally disinfect bottles by boiling in water. Whenever possible, thermal disinfection should be chosen in preference to chemical disinfection. Chemical disinfection should 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;

iii. After thermal or chemical disinfection, leave bottles to dry completely upside-down in a bottle rack. Dry bottles should be closed with a lid and stored, protected from dust, until use.

10. DOCUMENTATION AND RECORD KEEPING

Documentation and traceability are important aspects of quality assurance and are part of good compounding practice. Pharmacy personnel are required to document relevant information when they perform compounding. The personnel should maintain at least Compounding sheet (see annex

I) AND MASTER FORMULATION RECORD IN THE COMPOUNDING AREA.

The compounding record for ABHR preparations should contain the following information:

- Names and quantities of all ingredients
- Master Formulation Record for the preparation
- Sources, batch numbers and expiry dates of ingredients
- Total quantity compounded
- Name of the person who prepared the preparation, name of the person who performed the quality control
- Steps of Preparation
- Name of the person who approved the preparation
- Date of preparation
- Assigned preparation batch number
- Assigned BUD
- Results of quality control procedures as appropriate (like concentration of alcohol in final solution)
- Documentation of any quality control issues and any adverse reactions or preparation problems

The pharmacist in charge is required to document the following information in a master formulation record when compounding ABHR:

- Name, dosage, and strength of the compounded preparation
- Calculations used
- Ingredients and amounts
- Equipment used
- Step-by-step instructions of how the preparation was compounded
- Labeling information
- Container and package information
- BUD and Storage requirements
- Quality control information

11. SAFETY AND PRECAUTION

A) GENERAL SAFETY ISSUES:

The main safety issues relate to the flammability of alcohol-based hand rubs and the adverse effects associated with accidental or deliberate ingestion. These are summarized in the summary table of risks and mitigation measures concerning the use of alcohol-based hand hygiene preparations (see annex II).

B) FLAMMABILITY – FLASH-POINTS:

The flash points of ethanol 80% (v/v) and isopropyl alcohol 75% (v/v) are 17.5°C and 19°C respectively and special attention should be given to proper storage in tropical climates.

• Production and storage facilities should be ideally air-conditioned or cool rooms.

• Open flames and smoking must be strictly PROHIBITED in production and storage areas.

• Pharmacies and small-scale production centers supplying WHO recommended hand rub formulations are advised not to manufacture locally batches of more than 50 liters at a time.

C) ACCIDENTAL INGESTION:

In general, it is not recommended to add any bitter agents to reduce the risk of ingestion of the hand rubs. If there is an accidental ingestion, an appropriate technical measure should be taken (See annex III).

12. REFERENCE

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13. ANNEX

ANNEX – I: COMPOUNDING PROCESS RECODING FORM (COMPOUNDING SHEET)

Name of the dispensary/health institution _____ Date _____

Batch number/control number_____ Batch quantity _____

Description of ingredients				Name or initials of the person in charge
Name	Source	Batch number	Quantity	
Description of the steps of the preparation				
Results of Quality Control procedures				
Beyond use date: ……..				
Total Quantity Compounded: …… Loss: …… Reason for loss: ……..				
Prepared by: Name _____ Signature _____ date _____				

End control before release of the product	
Parameters	Comment
Approved by: Name _____ Signature _____ date _____	

ANNEX – II: RISKS AND MITIGATION MEASURES FOR ABHR USE AND PREPARATIONS

Risk	Mitigation
Fire – general	▪ Do not produce in quantities exceeding 50 liters locally. If producing in excess of 50 liters, produce only in central pharmacies with specialized air conditioning and ventilation.
	▪ Since undiluted ethanol is highly flammable, production facilities should directly dilute it to the concentrations outlined in this Guide.
	▪ Risk assessment should take into account: – The location of dispensers – The storage of stock – The disposal of used containers/ dispensers and expired stock.
	▪ Store away from high temperatures or flames.
	▪ Water or aqueous (water) film-forming foam should be used in case of fire; other types of extinguishers may be ineffective and may spread the fire over a larger area rather than put it out.
	▪ Health-care workers should be advised to rub hands until dry (once dry – hands are safe).
Fire – Production and storage (central)	▪ Local and central (bulk) storage must comply with fire regulations regarding the type of cabinet and store, respectively.
	▪ Production and storage facilities should ideally be air-conditioned or cool rooms.
	▪ No naked flames or smoking should be permitted in these areas.
	▪ National safety guidelines and local legal requirements must be adhered to for the storage of ingredients and the final product.
	▪ Containers/dispensers should be stored in a cool place and care should be taken regarding the securing of tops/lids.
	▪ A designated 'highly flammables' store will be required for situations where it is necessary to store more than 50 liters.
	▪ Containers and dispenser cartridges containing hand rub should be stored in a cool place away from sources of ignition. This applies also to used containers that have not been rinsed with water
Fire – storage (local)	▪ The quantity of hand rub kept in a ward or department should be as small as is reasonably practicable for day-to-day purposes.
Fire – disposal	▪ Rinse out used containers with copious amounts of cold water to reduce the risk of fire (the containers may then be recycled or disposed of in general waste).

Fire – location of dispensers	▪ Hand rub dispensers should not be placed above or close to potential sources of ignition, such as light switches and electrical outlets, or next to oxygen or other medical gas outlets (because of the increased risk of vapors igniting).
Fire – spillage	▪ Significant spillages should be dealt with immediately by removing all sources of ignition, ventilating the area, and diluting the spillage with water (to at least 10-times the volume).
	▪ The fluid should then be absorbed by an inert material such as dry sand (not a combustible material such as sawdust), which should be disposed of in a chemical waste container.
	▪ Vapors should be dispersed by ventilating the room (or vehicle), and the contaminated item should be put in a plastic bag until it can be washed and/or dried safely.
Ingestion	▪ In areas where there is thought to be a high risk of ingestion, a staff-carried product is advised.
	▪ If a wall-mounted product is used, consideration should be given to small bottles.
	▪ If bottles with a greater capacity than 500 ml are used, consideration should be given to providing them in secured containers.
	Product containers may be labelled with a warning of "dangers associated with ingestion".
Other	▪ Consideration should be given to the risks associated with spillage onto floor coverings, including the risk of pedestrian slips – it is important to deal with spillages immediately.

ANNEX – III: TOOL OF QUALITY ASSURANCE FOR THE COMPOUNDING OF ABHR SOLUTION

Institution	Name of the hospital _____ Compounding unit_____		
Professional	Filled by _____ Date _____		
		Yes	No
PRE-COMPOUNDING			
PPE Availability	Gown		
	Glove		
	Head covers /Hair covers		
	Shoe and sleeve covers		
	Goggles /Face shield / Face shield with goggles		
	Disposable Mask		
Health Conditions Status	Fit to work in the compounding room		
Premises	Is the compounding area appropriately clean and sanitized as SOP?		
	Is there proper ventilation of compounding unit?		
	Is room temperature monitored?		
	Is there functional fire-extinguisher in the compounding room?		
Equipment availability	Is the Equipment are appropriately sanitized and cleaned?		
	Is / are all necessary equipment/s available for ABHR productions?		
	• Plastic tank (for mixing)		
	• Mixing device (paddle)		
	• Measuring cylinders (plastic/glass)		
	• Funnel		
	• Bottles (plastic /glass)		
	• Alcoholmeter		
	• Registry materials and labeling materials		
Raw materials availability	• Ethanol/Isopropyl alcohol		
	• Glycerol		
	• Hydrogen Peroxide		
	• Distilled water /FBC		
Miscellaneous	Is the expiry date of ingredients notified?		
	Is beyond use date to the final preparation assigned?		
	Is proper personal protective equipment wear?		

DURING COMPOUNDING CHECKLIST			
Hand hygiene	Is there proper hand washing?		
Ingredients	Is the strength of alcohol and hydrogen peroxide verified?		
Formulation and procedures	Is the required amount of each ingredient calculated?		
	Is container tare with required volume?		
	Is the ingredients measured and mixed?		
	Is the final volume adjusted with water?		
	Did all procedures are done as of SOP?		
POST COMPOUNDING CHECKLIST /QUALITY ASSURANCE			
Is the strength of alcohol and hydrogen peroxide final preparation Confirmed?			
Is there proper labeling of final preparations done?			
Is the packaging of final products done?			
Is the important information about the product is documented?			
Is line clearance of all equipment and compounding room done after compounding is completed?			

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