

**PROJECT
PROFILE ON
ALCOHOL
BASED
SANITIZER**

1. INTRODUCTION:

Hand sanitizer, also called hand antiseptic hand-rub or hand-rub agent applied to the hands for the purpose of removing common pathogens (disease-causing organisms). Hand sanitizers typically come in foam, gel or liquid form. Their use is recommended when soap and water are not available for hand washing or when repeated hand washing compromises the natural skin barrier (e.g., causing scaling or fissures to develop in the skin). Although the effectiveness of hand sanitizer is variable, it is employed as a simple means of infection control in a wide variety of settings, from day-care centres and schools to hospitals and health care clinics and from supermarkets to cruise ships.

• TYPES OF HAND SANITIZER :

Depending on the active ingredient used, hand sanitizers can be classified as one of two types: *alcohol-based* or *alcohol-free*.

Alcohol-based products typically contain between 60 and 95 percent alcohol, usually in the form of ethanol, isopropanol, or n-propanol. At those concentrations, alcohol immediately denatures proteins, effectively neutralizing certain types of microorganisms.

Alcohol-free products are generally based on disinfectants, such as benzalkonium chloride (BAC), or on antimicrobial agents, such as triclosan. The activity of disinfectants and antimicrobial agents is both immediate and persistent. Many hand sanitizers also contain emollients (e.g., glycerin) that soothe the skin, thickening agents, and fragrance.

• PRODUCT & ITS APPLICATION:

Alcohol-based handrubs (**sanitizers**) are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands. It is used in our houses, Government as well as private hospitals, public places, Offices etc. Being disinfectant and also having germicidal value, it is highly demanded product particularly after the outbreak of COVID 19 pandemic.

2. EFFECTIVENESS OF THE PRODUCT :

The effectiveness of hand sanitizer depends on multiple factors, including the manner in which the product is applied (e.g., quantity used, duration of exposure, frequency of use) and whether the specific infectious agents present on the person's

hands are susceptible to the active ingredient in the product. In general, alcohol-based hand sanitizers, if rubbed thoroughly over finger and hand surfaces for a period of 30 seconds, followed by complete air-drying, can effectively reduce populations of bacteria, fungi, and some enveloped viruses (e.g., influenza A viruses). Similar effects have been reported for certain alcohol-free formulations, such as SAB (surfactant, allantoin, and BAC) hand sanitizer. Most hand sanitizers, however, are relatively ineffective against bacterial spores, nonenveloped viruses (e.g., norovirus), and encysted parasites (e.g., Giardia). They also do not fully cleanse or sanitize the skin when hands are noticeably soiled prior to application.

❖ **WHO recommends alcohol-based handrubs based on the following factors:**

1. Evidence-based, intrinsic advantages of fast-acting and broad-spectrum microbicidal activity with a minimal risk of generating resistance to antimicrobial agents;
2. Suitability for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene (including clean water, towels, etc.);
3. Capacity to promote improved compliance with hand hygiene by making the process faster and more convenient;
4. Economic benefit by reducing annual costs for hand hygiene, representing approximately 1% of extra-costs generated by HCAI
5. Minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products .

❖ **Suggested composition of alcohol-based handrub formulations for local production**

The choice of components for the WHO-recommended handrub formulations takes into account cost constraints and microbicidal activity. The following two formulations are recommended for local production with a maximum of 50 litres per lot to ensure safety in production and storage.

Formulation I

To produce final concentrations of ethanol 80% v/v, glycerol 1.45% v/v, hydrogen peroxide (H₂O₂) 0.125% v/v.

Pour into a 1000 ml graduated flask:

1. Ethanol 96% v/v, 833.3 ml
2. H₂O₂ 3%, 41.7 ml
3. Glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Formulation II

To produce final concentrations of isopropyl alcohol 75% v/v, glycerol 1.45% v/v, hydrogen peroxide 0.125% v/v:

Pour into a 1000 ml graduated flask:

1. Isopropyl alcohol (with a purity of 99.8%), 751.5 ml
2. H₂O₂ 3%, 41.7 ml
3. Glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Only pharmacopoeial quality reagents should be used (e.g. The International Pharmacopoeia) and not technical grade products.

3. RAW MATERIALS (other than Alcohol) :

- **H₂O₂**

While alcohol is the active component in the formulations, certain aspects of other components should be respected. All raw materials used should be preferably free of viable bacterial spores. The low concentration of H₂O₂ is incorporated in the formulations to help eliminate contaminating spores in the bulk solutions and excipients^{501,502} and is not an active substance for hand antisepsis. While the use of H₂O₂ adds an important safety aspect, the use of 3–6% of H₂O₂ for the production might be complicated by its corrosive nature and by difficult procurement in some countries. Further investigation is needed to assess H₂O₂ availability in different countries as well as the possibility of using a stock solution with a lower concentration.

- **Glycerol**

Glycerol is added to the formulation as a humectant to increase the acceptability of the product. Other humectants or emollients may be used for skin care, provided that they are affordable, available locally, miscible (mixable) in water and alcohol, non-toxic, and hypoallergenic. Glycerol has been chosen because it is safe and relatively inexpensive. Lowering the percentage of glycerol may be considered to further reduce stickiness of the handrub.

- **Other additives to the formulations**

It is strongly recommended that no ingredients other than those specified here be added to the formulations. In the case of any additions, full justification must be provided together with documented safety of the additive, its compatibility with the other ingredients, and all relevant details should be given on the product label.

In general, it is not recommended to add any bittering agents to reduce the risk of ingestion of the handrubs. Nevertheless, in exceptional cases where the risk of ingestion might be very high (paediatric or confused patients), substances such as methylethylketone and denatonium benzoate (503) may be added to some household products to make them less palatable and thus reduce the risk of accidental or deliberate ingestion. However, there is no published information on the compatibility and deterrent potential of such chemicals when used in alcohol-based handrubs to discourage their abuse. It is important to note that such additives may make the products toxic and add to production costs. In addition, the bitter taste may be transferred from hands to food being handled by individuals using handrubs containing such agents. Therefore, compatibility and suitability, as well as cost, must be carefully considered before deciding on the use of such bittering agents.

A colorant may be incorporated to differentiate the handrub from other fluids as long as such an additive is safe and compatible with the essential components of the handrubs (see also Part I, Section 11.3). However, the H₂O₂ in the handrubs may tend to fade any colouring agent used and prior testing is recommended.

No data are available to assess the suitability of adding gelling agents to the WHO-recommended liquid formulations, but this could increase potentially both production difficulties and costs, and may compromise antimicrobial efficacy.

The addition of fragrances is not recommended because of the risk of allergic reactions.

All handrub containers must be labelled in accordance with national/international guidelines.

- **Use of proper water for the preparation of the formulations**

While sterile distilled water is preferred for making the formulations, boiled and cooled tap water may also be used as long as it is free of visible particules.

- **Volume of production containers**

- ✓ 10-litre preparations: glass or plastic bottles with screw threaded stoppers can be used.
- ✓ 50-litre preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to 100 litre capacity

should be used to allow for mixing without overflowing.

The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 litres. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

4. METHOD FOR LOCAL PRODUCTION :

- I. The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.
- II. H₂O₂ is added using the measuring cylinder.
- III. Glycerol is added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some sterile distilled or cold boiled water to be added and then emptied into the bottle/tank.
- IV. The bottle/tank is then topped up to the corresponding mark of the volume (10-litre or 50-litre) to be prepared with the remainder of the distilled or cold, boiled water.
- V. The lid or the screw cap is placed on the bottle/tank immediately after mixing to prevent evaporation.
- VI. The solution is mixed by gently shaking the recipient where appropriate (small quantities), or by using a wooden, plastic or metallic paddle. Electric mixers should not be used unless “EX” protected because of the danger of explosion.
- VII. After mixing, the solution is immediately divided into smaller containers (e.g. 1000, 500 or 100 ml plastic bottles). The bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol or the new or re-used bottles to be eliminated by H₂O₂.

5. LABELLING OF THE BOTTLES

The bottles should be labeled in accordance with national guidelines. Labels should include the following:

- Name of institution
- Date of production and batch number
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide (% v/v can also be indicated) and the following statements:
- WHO-recommended handrub formulation

- For external use only
- Avoid contact with eyes
- Keep out of reach of children
- Use: apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry. Flammable: keep away from flame and heat.

6. BASIS AND PRESUMPTIONS :

- The scheme is based on single shift of 8 hours per day and 300 working days per annum.
- The interest rate on the borrowed capital has been taken as 12 % per annum.
- The cost in respect of Raw Materials, Packing Materials, Machinery & Equipment has been taken at the time of preparation of project profile and may vary from place to place and time to time.
- The rental Value of production shed is taken as per the prevailing rates and may vary from place to place.
- The plant capacity utilization has been taken as 50 % for the first year, which may subsequently increase to 60% and 70% in the second and third year respectively.

7. IMPLEMENTATION SCHEDULE :

The project implementation will take about nine months. The break-up of activities with relative time for each activity is as follows:

Sr. No.	Activity	Estimated Time Period (Months)
01.	Scheme preparation & approval	0 – 2
02.	Registration under MSME Act 2006 and sanction of loan	On spot
03.	License from FDA	5 - 6
04.	Placement of Orders for Machines	6 - 7
05.	Power Connection	6 - 7
06.	Installation of Machines	7 - 8
07.	Recruitment of Staff & Trial run	8 – 9
08.	Commercial Production	10 TH onwards.

8. FINANCIAL ASPECTS :

Sr. No.	Description	Quantity	Value (Rs.)
(a)	Land & Building Covered area of 500 Sq. Mtrs. on rent	L.S.	20,000
(b)	Machinery & Equipments		
01.	M.S. Mixing vessel, Cap:250 Ltrs per batch	1 No.	50,000
02.	M.S. Storage tank	4 Nos.	80,000
03.	Automatic Filling Machine	1 No.	1,25,000
04.	Automatic Sealing Machine	1 No.	25,000
05.	Other Misc Equipment	L.S.	50,000
06.	Laboratory Equipment	L.S.	50,000
07.	Installation of Machinery & equipment @ 10% of the cost.		35,000
08.	Preoperative Expenses	L.S.	15,000
		Total	4,50,000

(c) Raw & Packing Materials per Month:

Sr. No.	Description	Rate	Quantity	Value (Rs.)
01.	Isopropyl alcohol (with a purity of 99.8%)	Rs.70/Kg.	15000	10,50,000
02.	Glycerol	Rs.100/Kg	500	50,000
03.	H2O2	Rs.35/Kg.	1750	61,250
06.	Water	L.S.		6000
07.	Packing Materials viz. Bottles, Master Cartons, Bopp Tape etc.	L.S.		50,000
			Total	12,17,250
			Say	12,20,000

(d) Salary & Wages per Month :

Sr. No.	Description	Nos.	Value (Rs.)
01.	Manager	01	12,000
02.	Supervisor / Chemist	01	10,000
03.	Semi – skilled labour	04	32,000
04.	Unskilled labour	08	48,000
		Total	1,02,000

(e) Utilities per Month :

Sr. No.	Description	Rate	Quantity	Value (Rs.)
01.	Power	Rs.5.50/unit	20 HP	12,500
02.	Fuel & Lubricants		L.S.	2,000
03.	Water		L.S.	1,500
			Total	16,000

(f) Other Expenses per Month :

Sr. No.	Description	Quantity	Value (Rs.)
01.	Rent	L.S.	20,000
02.	Postage & Stationery	L.S.	1,500
03.	Telephone	L.S.	1,500
04.	Repair & Maintenance @ Rs.600 per KL		7,500
05.	Insurance @ 2% of Machinery & Equipment Cost		635
06.	Marketing & Traveling Expenses	L.S.	12,000
07.	Other Misc. Expenses	L.S.	5,000
		Total	48,217
		Say	48,000

(g) Working Capital for One Month (c+d+e+f) : Rs. 13,86,000/-

(h) Working Capital for three Months :Rs. 41,58,000/-

(i) Total Capital Investment (b+h) : Rs. 45,88,000/-

9. **FINANCIAL ANALYSIS :**

(a) **Cost of production per Annum :**

Sr. No.	Description	Value (Rs.)
01.	Raw & Packing Materials	1,46,40,000
02.	Salary & Wages	12,24,000
03.	Utilities	1,92,000
04.	Other Expenses	5,76,000
05.	Depreciation on Machinery & Equipments @ 10% p.a.	43,000
06.	Interest on borrowed capital @ 12 % p.a.	
	Total	1,66,75,000

(b) **Turnover per Annum :**

Total sales value of 150 K.L. Alcohol Based Sanitizer : **1,95,00,000**
@ Rs.1,30,000 per K.L.

(c) **Net Profit per Year :**

Net Profit = Total turnover - Total cost of production
= 1,95,00,000 - 1,66,75,000
= **28,25,000**

(d) **Profit Ration on Sales :**

Profit Ratio on Sales = $\frac{\text{Net Profit}}{\text{Total turnover}} \times 100$
= $\frac{28,25,000}{1,95,00,000} \times 100$
= **14.48 %**
Say 14.5 %

(e) **Rate of Return (ROR) on Total Capital Investment:**

$$\begin{aligned} \text{ROR} &= \frac{\text{Net Profit per annum}}{\text{Total Capital Investment}} \times 100 \\ &= \frac{28,25,000}{46,18,000} \times 100 \\ &= \mathbf{61.17 \%} \end{aligned}$$

(f) **Break Even Analysis :**

(i) **Fixed Cost :**

Sr. No.	Description	Amount (Rs.)
01.	Depreciation on Machinery & Equipments @ 10% p.a.	43,000
02.	Interest on Total Capital Investment @ 12 % p.a.	5,54,160
03.	40 % of Salary & Wages	4,89,600
04.	40 % of Other Expenses	2,30,400
	Total	13,17,160
	Or say	13,20,000

(ii) **Break Even Point (B.E.P.) :**

$$\begin{aligned} \text{B.E.P.} &= \frac{\text{Fixed Cost}}{\text{Fixed Cost} + \text{Profit}} \times 100 \\ &= \frac{13,20,000}{13,20,000 + 28,25,000} \times 100 \\ &= \mathbf{21.84 \%} \end{aligned}$$

Name and Addresses of Plant and Machinery Suppliers :

1. M/s.Unique Enterprises, 201, Konarka Mugdha Apartment, Plot No.36, Saraswati Cooperative Housing Society, Deendayal Nagar, Nagpur –22.
Contact Person : Dr. Mukund Moholkar, Mb: 09823116709
Tel No. (0712)2273391, (07104)235675, Fax No. (0712)2224362
E-mail: response@uniquepulveriser.com , uniquepulveriser@mahamail.com
Website: www.uniquepulveriser.com
2. M/s. L & M Automatics
Office : 60 / 7, Old Dal Mandi, kanpur – 208001
Tel. No. (0512) 2352570, Fax No. (0512) 2358287
Factory : H-3, Panki Industrial Area, Site – 1, Kanpur – 208022.
Tel. No.(0512)2692349, 2692658.
3. M/s. National Engraving Works
Registered Office : 90/201, Phoowali Gali, Anwarganj, Kanpur – 208001
Tel. No. (0512) 2368594, E-mail : nationalengg@sify.com
Works : 123 / 796, Opposite Excellent Motors, Factory Area Fazalganj, Kanpur – 208012 (U.P.) Tel. No. (0512) 2242372, 3942808.

Contact Person : Mr. Kazee, Mb:09336118246, 09415486940
4. M/s. Suveja Engineers, U-52, MIDC Hingna Road, Nagpur – 440016.
Contact: Shri J. Ghagre, Tel.No. (07104)236153, Mb: 09422147432.

Name and Addresses of Raw Material Suppliers :

1. M/s. Sandeep Chemicals , Near Reshim Oli, Samarth Gali, Budhwari, Nagpur – 440002. Contact: Shri Sandeep Samarth, Tel. No.(0712)2776930
2. M/s. Shabbir Chemicals, Near Reshim Oli, Samarth Gali, Budhwari, Nagpur – 440002.. Contact Person : Shri Shabbir, Tel. No. (0712)2778388.

-