

COMPANY LOGO AND NAME	BATCH MANUFACTURING RECORD			Page: 1 of 3
Department: Production	TITLE: Wanjiku hand sanitizer			Batch Record: BMR-001
	Name	Signature	Date	Revision: No. 0
Prepared By:	Production Chemist	27/4/2020	28/4/2020	Effective Date: 01/5/2020
Approved By:	Quality Unit Head			
Batch Number: e.g. D120001	Batch Size: 10 liters	Manufacturing Date: May 2020	Expiry Date: April 2021	

Product Details				
Description:	Name: e.g. Wanjiku hand sanitizer Color: e.g. Clear/blue/green			
Batch Quantity in bottles	Batch Size: e.g. Approximately 100 Bottles of 100ml each			
Packaging	Bottles of 100mls/60mls/50mls etc.			
Storage Conditions	Ambient-conditions, Store in tight container protected from light and moisture and away from open flame			
Reference Documents				
SOP-001	SOP for mixing			
SOP-002	SOP for cleaning the production room			
Raw Materials				
Description	Batch No.	Qty Required	Done By/Date	Verified by/Date
Ethanol 96% ¹ or Isopropyl Alcohol 99.8%	enter if available			
Hydrogen Peroxide 3% ²	enter if available			
Glycerol 98% ³	enter if available			
Boiled cold water	enter if available			
Any other additive ⁴	enter if available			
Colorants ⁵	enter if available			
Equipment Description	ID No.	Calibration	Performed By	Verified By
Alcoholometer ⁶	Required	Required		
Container for mixing without overflowing ⁷	enter if available	Not Required		
Wooden, plastic or metal paddles for mixing	enter if available	Not Required		
Measuring cylinders and measuring jugs	enter if available	Not Required		
Plastic or metal funnel	enter if available	Not Required		
Plastic Packaging bottles with leak-proof tops ⁸	enter if available			
Area Clearance				
Room name:		Performed by	Verified by	

¹ Confirm the alcohol content from the the certificate of analysis. If not available verify the alcohol concentration with the alcoholometer and make the necessary adjustments in volume in the preparation formulation to obtain the final recommended concentration.

² Hydrogen peroxide: used to inactivate contaminating bacterial spores in the solution and is not an active substance for hand antiseptics.

³ Glycerol: used as humectant, but other emollients may be used for skin care, provided that they are cheap, widely available and miscible in water and alcohol and do not add to toxicity, or promote allergy.

⁴ Any further additive to both formulations should be clearly labelled and be non-toxic in case of accidental ingestion.

⁵ A colorant may be added to allow differentiation from other fluids, but should not add to toxicity, promote allergy, or interfere with antimicrobial properties. The addition of perfumes or dyes is not recommended due to risk of allergic reactions.

⁶ The temperature scale is at the bottom and the ethanol concentration (percentage v/v) at the top

⁷ 10-litre glass or plastic bottles with screw-threaded stoppers or 50-litre plastic tanks (preferably in polypropylene or high density polyethylene, translucent so as to see the liquid level) or Stainless steel tanks with a capacity of 80–100 liters

⁸ 100 ml or 150ml or 500 ml or any other volume plastic bottles with leak-proof tops

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Review Raw Materials section and ensure that it is complete, accurate, and that all necessary materials are present for the GMP operation.			
Ensure that all Materials are Released, Approved and have sufficient time to the Expiry Date.			
Review Processing Equipment, and ensure that it is complete, accurate, and that all necessary equipment is present, cleaned and calibrated, as appropriate.			
Verify that the Production Area does not contain any items from previous batches or cleaning activities and that no items unrelated to the current batch are present.			
Area Clearance Complete.			
Production Procedure for 10-liter preparation⁹			
Dispensing & Raw Material Preparation			
1. Ensure production room is air conditioned or cool. No naked flames or smoking should be permitted in these areas.			
2. Pour the alcohol for the formula to be used is into the large bottle or tank up to the graduated mark.			
3. Add Hydrogen peroxide using the measuring cylinder.			
4. Add Glycerol using a measuring cylinder.			
5. As glycerol is very viscous and sticks to the wall of the measuring cylinder, it should be rinsed with some sterile distilled or cold boiled water and then emptied into the bottle/tank.			
6. Top up to the 10-litre mark with sterile distilled or cold boiled water.			
7. Place the lid or the screw cap on the tank/bottle as soon as possible after preparation, in order to prevent evaporation.			
Mixing and packing			
8. Mix the solution by shaking gently where appropriate or by using a paddle.			
9. Immediately divide up the solution into its final containers (e.g. 500 or 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.			
Quality control			
Use the alcoholmeter to control the alcohol concentration of the final use solution. The accepted limits should be fixed to $\pm 5\%$ of the target concentration (75%–85% for ethanol).		Obtained concentration _____ % (v/v)	
Ethanol formulation	Isopropyl Alcohol formulation		
1. Ethanol	80% (V/V)	1. Isopropyl Alcohol	75% (v/v)
2. Glycerol	1.45% (v/v)	2. Glycerol	Glycerol 1.45% (v/v)
3. Hydrogen Peroxide	0.125% (v/v)	3. Hydrogen Peroxide	0.125% (v/v)
Finished Product Yield Calculation			

⁹ Multiply the amount by a factor as appropriate e.g. by 10 for 100-liter batch size and by 100 for 1000-liter capacity.

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$$= \frac{\text{No. of good filled \& labelled bottles produced at the end of process}^{10}}{\text{Number of expected batch quantity in bottles}} \times 100\%$$

$$= \text{_____ (Specification: 90 - 100 \%)}$$

Labelling

The labelling on the bottle supplied to customer should contain at least the following:

- Name of Manufacturer
- Physical location of the manufacturer
- WHO-recommended hand sanitiser formulation
- For external use only
- Avoid contact with eyes
- Keep out of the reach of children
- Date of production and batch number
- Use: Apply a palmful of alcohol-based hand sanitizer and cover all surfaces of the hands. Rub hands until dry
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide
- Flammable: keep away from flame and heat

Post-Production Review

The complete Post-Production Batch Record has been reviewed for completeness and accuracy. All pages are complete and all entries conform to Good Documentation Practices.

	Name	Signature	Date
Production			e.g. 30/5/2020
Quality Unit Head			e.g. 30/5/2020

END OF THE DOCUMENT

The template should be used together with the WHO Guide to Local Production of WHO-recommended Sanitizer Formulations available on:

https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

¹⁰ Pack size means the final pack volume as supplied to customer e.g. 150ml, 100mls, 500ml bottle