STATE OF KUWAIT

MINISTRY OF HEALTH

DRUG AND FOOD CONTROL

Pharmaceutical & Herbal Medicines

Registration & Control Administration

Guidance For Registration And GMP Requirements For Alcohol Hand Sanitizers / Rubs For Local Manufacturers

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1. INTRODUCTION

This document introduce the guidelines for registration of alcohol hand sanitizers/rubs manufactured locally in the State of Kuwait, moreover it includes the good manufacturing practice (GMP) requirements for manufacturers to receive the GMP Certificate.

2. GMP CERTIFICATE REQUIREMENTS FOR ALCOHOL HAND SANITIZERS / RUBS MANUFACTURERS

REQUIREMENTS FOR ISSUING GMP CERTIFICATE:

1. Letter from the company requesting the registration of the factory.
2. Copy of the manufacturing license from the Public Authority for Industry.
3. Copy of the Commercial license from ministry of commerce.
4. Authorized representative with authorized signature

RECOMMENDED FORMULATIONS FOR HAND SANITIZERS/RUBS:

The recommended formulation can include one of the below alcohols:

- Ethanol 80% (v/v)

Or

- Isopropyl alcohol 75% (v/v)

With the addition of

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

And made up to the volume with distilled water.

- If the formulation differs from the recommended, a justification letter must be submitted provided that the concentration of Ethanol is not less than 60% and Isopropyl alcohol 70%
- Product shall not contain Methanol

BASIC GMP REQUIREMENTS

1. Each batch production must be initiated with an approved manufacturing master formula including instructions for each batch to be produced.
2. Standard operating procedure for manufacturing method, cleaning and quality control.
3. Logbook must be implemented with records of all operations where the product has been processed including cleaning and maintenance of the site and equipment. These records must include the dates and signatures of all personals carrying out these operations.
4. Calibration and maintenance of all equipment should be periodically done with retaining of relevant documents.
5. Balance verifications daily.
6. The quality of water used in the production must be monitored in records to chemical and microbiological properties.
7. Water sanitation systems must be regularly maintained assuring the prevention of any risk of microbial growth.
8. The washing, cleaning process and equipment must be selected in a manner that they would not be a source of contamination.
9. Batch manufacturing record must be kept for every batch process including date processed name, batch number with signature of person performing each critical step of the products process.
10. Lab analysis report for each batch produced including physical and chemical analysis.
11. Storage area space should be enough to appropriately store starting, intermediate and finished products.
12. Segregated areas should be implemented for raw materials, intermediate and finished products.
13. Clear identifiable areas for each type of materials.
14. Appropriate ventilation must be installed.
15. Pest and rodent control (Electrical discharge insect control systems should be avoided).
16. Sanitation and cleaning must be kept at high standards.
17. Satisfactory number of personnel should be available with the essential experience and qualifications.
18. Adequate training must be implemented for all personals whose responsibilities would affect the products quality.
19. Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.
20. All individuals accessing the production area should wear adequate protective gowning.

21. Personnel must be enrolled in detailed hygienic programmes coaching on procedures concerning hygiene routines and proper clothing.
22. Unhygienic Practices must be prohibited in areas where it could affect the product including smoking, eating, and drinking.
23. The use of high-quality stainless steel should be used parts that are in direct contact with product, apparatus made of glass should be avoided.
24. The temperature humidity, ventilation and lightning must be adequate and suitable so that they will not impact the product negatively, including manufacturing, and storage areas.
25. A well-ventilated separate room should be designated for weighing out starting materials.
26. Design of containers, tanks, pumps and pipework must be installed in a manner that they can be cleaned, sanitized and maintained efficiently.
27. Adequate and clear labeling of equipment, areas, finished product boxes.

The Pharmaceutical & Herbal Control and medicines Registration & Control Administration has the right to request for further requirements to be applied on the manufacturer.

Special considerations in the production of alcohol hand sanitizers/ rubs:

- Production and storage facilities should ideally be air conditioned or cool rooms. No naked flames or smoking should be permitted in these areas.

- Undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the above-mentioned concentration. The flashpoints of ethanol 80% (v/v) and of isopropyl alcohol 75% (v/v) are 17.5°C and 19°C, respectively.

- Place final product in quarantine after production for 72 Hours before use allowing the destruction of any spores in the container.

Refer to Gulf Health Council GMP Guideline, Scan QR Code below or enter link:

www.ghc.sa → Central Registration → Central Drug Registration → Guidelines → cGMP Guidelines

3. THE BASIC REQUIREMENTS FOR REGISTRATION OF ALCOHOL HAND SANITIZERS AND HAND RUBS

1. Good Manufacturing Practice (GMP) certificate issued from Kuwait Pharmaceutical & Herbal Medicines Registration & Control Administration***.**
2. Detailed Certificate of Composition for active and in-active ingredients quantitatively.
3. Coloured label and outer pack artwork.
4. Shelf life declaration.
5. Safety Data Sheet.
6. Source of raw materials.
7. Free from Methanol Certificate.
8. Certificate of Analysis of finished product.
9. Finished product sample (***for analysis and evaluation)***. The types of information to be provided on the label are shown in the *attached table*. The information shall be in English/or Arabic and shall be printed in a clear and legible manner.
10. A signed commitment to provide Pharmaceutical & Herbal Medicines Registration & Control Administration Post marketing surveillance reports and any safety reports or ADRs report which the company may receive from users or healthcare professionals

***The company must submit a request for an inspection team to visit the plant for assessment, the request must be addressed to the Pharmaceutical & Herbal Control and medicines Registration & Control Administration.**

4. LABEL REQUIERMENTS

Hand Sanitizer / Rub Fact Label must include:

1. Name of the Hand Sanitizer
2. Names and quantities of all the active & Inactive ingredients
3. Product indications/ Intended purpose
4. Pack Size
5. Batch Number
6. Expiry date (or “Use by”, “Use before” or words with similar meaning)
7. Name and address of the manufacturer or MAH
8. Use: Apply a palmful of alcohol-based hand rub and cover all surfaces of the hands Rub hands until dry.
9. Warnings when applicable:
    - For External use only
    - Keep out of reach of children
    - Flammable: Keep away from flame and heat
    - When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water
    - If swallowed, get medical help right away.
    - Do not use:
        - On open skin wounds
        - In children less than 2 months of age
        - Supervise children under 6 years of age when using this product to avoid swallowing