# HAND SANITIZERS – REGULATORY REQUIREMENTS TO BE MET BY THE APPLICANT FIRMS

1. **LICENCE:** Manufacturers are required to obtain manufacturing licence in **Form-25** for manufacturing of Hand Sanitizers.

2. **COMPOSITION OF THE HAND SANITIZER:**

   The composition of the applied products should be in line with the **DCG(I) approved compositions** indicated in the **Annexure** attached to this document.

3. **DOCUMENTS to be submitted to the Licensing Authority, Drugs Control Administration by the applicant firm for grant of licences in *FORM-25 for Hand Sanitizers (through ODLS portal)***

   a) Application (statutory) in Form-24 (indicating full composition of the applied product)

   duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution.

   b) Declaration of the Proprietor / Partners / Directors etc. in Affidavit (as per the prescribed format - notarized & on non-judicial stamp paper) & List of Directors downloaded from MCA website signed by Company Secretary / Managing Director (In case of company).

   c) Partnership deed *in case of Partnership firms.*

   d) Self attested copy of Aadhar card/Passport/Electoral card as proof of residential address of the responsible person as mentioned in the Affidavit at point No. b.

   e) Rent / Lease deed (registered) in case of Rental premises/ Declaration of the ownership of the premises if premises owned by the applicant firm or company, with the documentary evidence of ownership like Registered sale deed and/or proof of allotment of the site by the local authority along with the latest property tax receipt. *If the applied premises is located in the notified industrial area, the site allocation from the Industrial Area Local Authority also has to be submitted.*

   f) Plan and layout of the premises showing the installation of Machinery and Equipment. preferably a Blue Print duly signed by the applicant who signed in the statutory form.

   g) Detailed list of Manufacturing and Analytical Equipment.

   h) Application for approval of Technical Staff in the prescribed format with enclosures of consent letter, copies of qualification certificates, experience certificates of proposed technical staff along with earlier approvals if any and the appointment order of the Technical staff.

   i) Permission obtained from the Municipal Authorities/ Panchayat authorities/ Industrial Local Authority;

   j) Certificate in conformity with Factories Act for construction and starting the Unit & Permission/Consent from T.S. Pollution Control Board issued to the applicant on the applied premises.

   k) Site Master File as per Para 29 of Part I of Schedule M of Drugs and Cosmetics Act, 1940 and rules made there under. *(Site Master File may be submitted at the time of inspection of the firm for verification)*

**Contd.**

**Product Specific Technical Documents:**

l) Brief Manufacturing procedure of each product

m) Specifications indicating the lists of tests conducted for batch release and the respective acceptance criteria.

n) Standard Test Procedure for the tests indicated by the applicant firm in the Specification document. *(The list of analytical instruments submitted should demonstrate capability of the firm regarding analysis of the product by the analytical procedure submitted)*

o) Specimen label of the proposed product.

p) Undertaking in **Form 51** of Drugs and Cosmetics Rules to the Licensing Authority regarding Brand Names.

**NOTE:**

The application submitted by the firms through ODLS portal should be complete with respect to the documents indicated above and the entries in the respective fields of the online application. The application shall be rejected summarily in case of incomplete applications.

**4. FEES TO BE PAID:**

Applicants are required to pay fees of Rs. 7,500/- for Grant of Form-25 up to 10 products and a fee of Rs. 300/- must be paid for each product thereafter.

**5. FACILITY REQUIREMENTS:**

***Requirements of Premises & Materials:***

The applied premises should meet the requirements of *Schedule-M* of Drugs and Cosmetics Rules with respect to External Preparations. Specific requirements should be as per *Part-ID* of the said schedule for *External Preparations*, as applicable for Hand Sanitizers.

***Requirements of Plant & Equipment:***

The facility should meet the requirements of *Schedule M Part-II 1. External Preparations* with respect to the minimum equipment and minimum area recommended, as applicable for Hand Sanitizers.

**NOTE:** Production and storage facilities should be ideally air-conditioned or cool rooms as the flashpoints of ethanol 80% (v/v) and of isopropyl alcohol 75% (v/v) are 17.5°C and 19°C, respectively.

**ANNEXURE: DCG(I) approved Hand Sanitizer compositions**

## Examples of hand sanitisers/ surgical hand disinfectant approved by CDSCO including the WHO formula for reference purposes

| S.No. | Name | | Date of Approval |
|---|---|---|---|
| 1 | Isopropyl Alcohol IP 45g+n-Propanol 30g+Ethyl-hexadecyl-dimethyl ammonium-ethylsulphate 0.2g liquid each 100gm | | 17.07.15 |
| 2 | Cetrimide15% w/v + Chlorhexidine Gluconate 7.5% v/v + Isopropyl Alcohol 7.5% v/v Concentrate Solution | For cleansing of physically contaminated wounds and for pre-operative disinfection | 09.02.09 |
| 3 | Each 100ml contains:<br>Iso propyl Alcohol IP …75% v/v<br>Hydrogen Peroxide IP 0.125% v/v<br>Glycerol IP…….1.45% v/v<br>Solution | Hand Hygiene | 07.07.2017 |
| 4 | Each ml cutaneous solution contains:<br><br>Chlorhexidine Gluconate Solution IP equivalent to Chlorhexidine gluconate….20 mg<br><br>Isopropyl Alcohol IP…… 0.70 ml | For disinfectant of the skin prior to invasive medical procedures and maintenance of device insertion sites. | 22.03.2018 |
| 5 | Cetrimide15% w/v + Chlorhexidine Gluconate 7.5% v/v + Isopropyl Alcohol 7.5% v/v Concentrate Solution | For cleansing of physically contaminated wounds and for pre-operative disinfection | 09.02.09 |
| 6 | Isopropyl Rubbing Alcohol | | IP 2018 |
| 7 | Ethanol (Denatured with 1% DEP) 10%w/w+2-Propanol IP 9%w/w+1-Propanol BP 6%w/w topical spray | | 17.07.15 |
| 8 | Isopropyl Alcohol IP 45g+n-Propanol 30g+Ethyl-hexadecyl-dimethyl ammonium-ethylsulphate 0.2g liquid each 100gm | | 17.07.15 |
| 9 | Ethanol(95%) IP 72.00%+Propylene Glycol IP 01.000%+Glycerine IP 01.000%+Triclosan 0.3%+Aloes IP 0.007%+Vitamin E 0.007%+Carbopol 0.3%+ 2-Amino, 2-Methyl, 1-Propanol 0.2%+Fragrance 0.3%+purified water q.s. to 100.00% hand sanitizer | | 17.07.15 |
| 10 | 2-Propanol IP 45g + 1-Propanol IP 30g + Ethyl-Hexadecyl-Dimethyl ammonium Ethylsulphate 0.2g per 100gm external liquid | | 17.07.15 |
| 11 | Ethanol (Denatured with 1% DEP) 10%w/w+2-propanol IP 9%w/w+1-propanol BP 6%w/w liquid | | 08.06.2016 |
| 12 | Propanol 50gm+povidone iodine-1gm in 100ml solution | For surgical & hygenic hand disinfection. | 19.11.07 |
| 13 | Propanol-18 gm+Ethenol(100%)-45gm in 100ml solution | For surgical & hygenic hand disinfection. | 19.11.07 |
| 14 | Propanol 1-ol 18gm + Ethanol 100% 45gm/100ml solution | For hygenic and surgical hand disinfection | 18.01.2010 |
| 15 | Industrial Methylated Spirit | | IP 2010 |
| 16 | Surgical Spirit | | IP 2011 |

| S.No. | Name | | Date of Approval |
|---|---|---|---|
| 17 | Povidone Iodine IP 2.0%w/v (eq. to 0.2%w/v available iodine)+Ethyl Alcohol IP 8.38%v/v liquid | | 17.07.15 |
| 18 | Chlorhexidine Gluconate Solution IP 2.5%w/v eq. to Chlorhexidine Gluconate 0.5%w/v+Ethyl Alcohol IP 70%w/v liquid | | 17.07.15 |
| 19 | Chlorhexidine gluconate IP 1%w/v + Ethyl Alcohol IP 61%w/v Solution | Surgical hand scrub & healthcare personnel hand wash | 29.12.2010 |
| 20 | Povidone Iodine USP 4% Scrub | | September-1978 |
| 21 | Sterillium Rub in Disinfectant for Hands. | Disinfectant for hands. | 20-5-1992 |
| 22 | Povidone-Iodine Solution | | IP 10 |
| 23 | Ethanol 70% | | |
| 24 | Each 100ml contains:<br>Ethanol IP……80% v/v<br>Hydrogen Peroxide IP 0.125% v/v<br>Glycerol IP 1.45% v/v<br>Solution | Hand Hygiene | 10.07.2017 |