

**Documents to be furnished by the manufacturer for the grant of manufacturing license or loan license for cosmetics.**

- 1) Application Form - in Form COS-5/COS-6 (for loan licence)
- 2) Receipt for the fees paid (**e-challan remitted in favour of Drugs Controller, Office of the Drugs Controller, Thiruvananthapuram only**) (the fees are as given in Third Schedule) as the case may be or their attested copies. (Rs.10000/- per category of products upto 10 items and Rs. 500/- for additional items above 10)
- 3) Copy of Approved layout plan of the manufacturing area. Specify the area of each section in m<sup>2</sup>.

<b>Category</b>	<b>Production Area Requirement as stipulated in Rule</b>
Powders - face powder/ cake make up/ compact/ face pack/ face mask/ rouge	15 sq.m
Skin powder for infants	15 sq.m
Cream/Lotions/Emulsions/paste/cleansing milk/shampoo/pomade and brilliantine/shaving cream/hair oil/face wash/hand wash/shower gel/body wash/hair conditioner/hair serum/hair mask	25 sq.m
Nail polish/nail lacquers	15 sq.m
Lipstick/lip gloss/ lip balm	15 sq.m
Depilatories(hair removing cream)	10 sq.m
Eye brow, eye lashes, eyeliners	10 sq.m
Kajal and suruma	10 sq.m + separate area of 5 sq.m for base sterilization
Aerosol	15 sq.m
Alcoholic fragrance solutions	15 sq.m
Hair dye	15 sq.m
Tooth powder	15 sq.m
Tooth paste	15 sq.m
Tooth powder- black	15 sq.m
Toilet soap	100 sq.m

**In addition to production area, separate adequate space for storage of raw materials, finished products, packing materials shall be provided in factory premises.**

- 4) Copy of Aadhar / voter's ID card of the applicant.
- 5) Documents viz. rent receipt, purchase documents or its attested copies showing lawful possession of the premises.
  1. Ownership certificate pertaining to the building.
  2. Rent agreement / lease deed
  3. Building layout with each area demarcated in terms of m<sup>2</sup>.
- 6) List of machinery and equipment - **Details of equipments and other requirements recommended for the manufacture of different categories of Cosmetics are specified in Seventh Schedule, Part II of Cosmetic Rules 2020.**
- 7) Documents relating to the constitution of the firm viz. partnership-deed, memorandum and article of association etc.
- 8) Full particulars of the competent technical staff employed for manufacturing and testing of cosmetics along with copies of their educational qualifications and experience certificates approval letter as competent staff. The competent technical staff is required to furnish consent letter for full time employment with the applicant firm. (Declaration format enclosed as Annexure III)
- 9) List of Cosmetics along with their composition formula, manner of labeling in triplicate along with their composition formula, manner of labeling in triplicate along -with undertaking to be submitted.
- 10) Documents relating to the ownership of the brand of cosmetic whether it is registered or under trademark, if any.
- 11) Full name of the proprietor or the partners, as the case may be shall be provided in the application. In case of private or public limited concerns, full name of the Directors who sign the application or the Authorized signatory, if any, shall be provided in the application.
- 12) Self-certificate of compliance of Good Manufacturing Practices (GMP) for manufacture of cosmetics as specified in Form COS-7.(enclosed as Annexure- II)
- 13) No Objection Certificate from Fire force department for nail polish /nail lacquers/ aerosol /alcoholic fragrances

**14)** Form of undertaking (enclosed)

**Undertaking to declare that-**

- a) I/We shall comply with all the conditions imposed on the license or loan license for the manufacture of cosmetics as required under the provisions of the Cosmetics Rules, 2020.
- b) I/We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on.
- c) I/We shall comply with the provisions of Chapter IV of the Cosmetics Rules, 2020.
- d) Every cosmetic manufactured by us for sale or for distribution in India shall conform to the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
- e) I/We declare that no cosmetic manufactured by us has been tested on animals.
- f) I/We shall inform to Licensing Authority, in case of any change in respect of labeling or composition or testing of licensed product or its specifications within thirty days along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
- g) I/We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made there under.
- h) I/We shall allow the Licensing Authority or any person authorized by him in that behalf to take samples of the cosmetics for testing of considered necessary by the Licensing Authority.
- i) I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good Manufacturing Practice in the said premises in respect of the

above said cosmetics. Further I will not claim any damages, etc.  
 for any action of the State Licensing Authority in this regard.  
 The information submitted above is true to the best of my or  
 our knowledge and belief.

Place: \_\_\_\_\_  
 Date: \_\_\_\_\_ Signature \_\_\_\_\_ of \_\_\_\_\_ the  
 manufacturer/applicant  
 Name and Designation  
 Seal/Stamp

**Annexure -I  
 Form COS-5  
 [See rule 23 (2)]**

Application for grant of a license to manufacture cosmetics for  
 sale or for distribution

1. **I/We**.....  
**residing at**...(residential address of applicant along with  
*mobile number and email id*)  
 .....**of**  
*(firm name)*.....  
**hereby apply for the grant of a License to manufacture**  
**on the premises situated at** *(firm's full address)*  
 ..... **the following**  
**cosmetics:**

2. Details of cosmetic products:

Sl. No.	Name of Cosmetic	Name of Ingredients	Specifications or Standards or Grade of Ingredients	Percentage of Ingredients	Function of Ingredients

*(Specifications / standards/ grade of raw material are specified in website, www.bis.gov.in)*

3. Names, qualifications and experience of technical staff employed for **Manufacture** :.....

**Testing** : .....

4. A fee of rupees ..... has been credited to Government under the head of account .....

Date .....

Signature .....

Note: The application should be accompanied by a plan of the premises.

**Annexure-I**  
**Form COS-6**  
**[See rule 23 (2)]**

Application for grant of a loan license to manufacture cosmetics for sale or for distribution

1. I/We .....of ..... hereby apply for the grant of a loan license to manufacture cosmetics, for sale, on the premises situated at .....C/o ..... the following cosmetics:

2. Details of cosmetic products:

Sl. No.	Name of Cosmetic	Name of Ingredients	Specifications or Standards or Grade of Ingredients	Percentage of Ingredients	Function of Ingredients

3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

4. (a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.  
 (b) A true copy of a letter from – the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and they will analyse every batch of and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.
5. A fee of rupees ..... has been credited to  
 Government under the head of Account  
 .....

**Date.....**

**Signature**

.....

*Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also their license number:*

**Annexure - II  
 Form COS-7**

**[See rule 23 (4) and 23 (7)]**

Self-certificate of compliance of Good Manufacturing Practices (GMP) for manufacture of cosmetics

(To be given by the applicant along with Form COS-5 or Form COS-6 at the time of application for manufacturing license or loan license)

1. I/We ..... of ..... hereby applied for the grant of a License to manufacture at premises situated at ..... the following cosmetics.
  - 1.
  - 2.
  - 3.
2. I/We hereby declare that the above premises having facilities of good manufacturing practices, requirements of premises,

- plants and equipment for manufacture of above cosmetics as per the Seventh Schedule of the Cosmetics Rules, 2020.
3. I/We undertake to provide facility to inspect the above premises as per the Cosmetics Rules, 2020 to the State Licensing Authority or any officer appointed by the authority.
  4. I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good Manufacturing Practice in the said premises in respect of the above said cosmetics. Further I will not claim any damages, etc. for any action of the State Licensing Authority in this regard.

Date :  
Place:

Name:  
Signature :  
Designation:

### **Annexure- III**

#### Declaration format of Technical Staff - (Manufacturing / Testing)

I ..... aged ..... residing at.....  
 Holder of..... do hereby declare that I shall work as manufacturing chemist / analytical chemist as per Rule 26 of the Cosmetic Rules 2020.....  
 situated ..... at  
 .....  
 ..... with effect from .....

I declare that I am working as a full time employee in this concern and shall supervise the manufacturing / testing of cosmetics as envisaged under the provisions of Cosmetic Rules 2020.

Place:  
Date:

Name:  
Signature:

### Third Schedule

[See rules 12(5), 12(9), 13(5), 23(2), 23(10), 28, 30(1), 32(1), 55(3),  
55(4), 59, 60(1) and 60(2)]

Fee payable for license, permission and registration certificate.

<b>Serial Number</b>	<b>Subject</b>	<b>In rupees (INR) except where specified in dollars (\$)</b>
1	Registration Certificate	
	(a) Fee for the grant or retention of registration certificate for each category of cosmetic	\$1000
	(b) Fee for the grant or retention of registration certificate for additional category of cosmetic.	\$1000
	(c) Fee for each variant of cosmetic for the	\$50



	grant or retention of registration certificate	
	(d) Fee for each manufacturing site for the grant or retention of registration certificate	\$500
	(e) Fee for grant of permission for new cosmetics	\$500
	(f) Fee for issue of duplicate copy of the registration certificate, if the original is defaced, damaged or lost	\$200
	(g) Fee for inspection of each overseas manufacturing site of cosmetics	&5000
2	Manufacturing License	
	(a) Fee for grant of license in Form COS-8 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(b) Fee for grant of license in Form COS-8 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic	500
	(c) Fee for grant of license in Form COS-8 for manufacture of cosmetics for sale or for distribution of ten items of each additional category of cosmetic.	10000
	(d) Fee for grant of loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(e) Fee for grant of loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic	500
	(f) Fee for grant of loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(g) Fee for issue of duplicate copy of the license in Form COS-8 or loan license in Form COS-9, if the original is defaced, damaged or lost	500
	(h) Fee for further application after rejection	1000
	(i) Retention fee for license in Form COS-8 for manufacture or cosmetics for sale or for distribution of each additional items of the category of cosmetic.	10000
	(j) Retention fee for license in Form COS-8 for manufacture of cosmetics for sale or for distribution of each additional items of the	500

	category of cosmetic.	
	(k) Retention fee for license in Form COS-8 for manufacture of cosmetics for sale or for distribution of ten items of each additional category of cosmetic	10000
	(l) Retention fee for loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(m) Retention fee for loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic	500
	(n) Retention fee for loan license in Form COS-9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
3	Fee for approval of laboratory carrying out test on cosmetics and their raw materials	
	(a) Fee for approval of laboratory in Form COS-23 for test and analysis of cosmetics	1000
	(b) Fee for issue of duplicate copy of the approval, if the original is defaced, damaged or lost	100
	(c) Fee for inspection of laboratory for further inspection after rejection of the application	500
	(d) Fee for retention of approval granted in Form COS-23 for laboratory carrying out test and analysis of cosmetics	1000

B/