

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

(Cosmetics Division)

Guidance Document

Title: Guidance document on Common Submission Format for
Import Registration of Cosmetics in India.



PREFACE

As per section 3(aaa) of the Drugs and Cosmetics Act, 1940

Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

As per Rule 129 of Drugs and Cosmetic Rules, 1945

No cosmetic shall be imported into India unless the product is registered under the rules by the licensing authority appointed by the Central Government under rule 21 or by any person to whom such powers may be delegated under rule 22.

Any substance falling within the definition of cosmetic (Section 3aaa of the Act) required to be registered before import into the country. Not only the cosmetic but the manufacturing site needs to be registered for import.

An application for issue of a Registration Certificate for cosmetics intended to be imported into India shall be made online in Form 42 either by the manufacturer himself or by his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer to the Licensing Authority under the Act i.e. to the Drugs Controller General (I) at Central Drugs Standard Control Organization (CDSCO), FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi.

The purpose of this guidance document is to provide guidance for submission of online application in Form 42 to CDSCO for Import Registration Certificate for cosmetics into India.

Guidance Documents for Submission of application for grant of Registration Certificate to import cosmetics

1. Covering Letter

➤ Purpose should be clearly mentioned along with the details of earlier issued Registration certificate (If any) and product/ product category (whether already registered or not).

Note: Mention the Section no. in which correlation chart of the products with Serial No. as in Form-42 with respect to Free Sale Certificate and Power of Attorney has been uploaded.

2. Power Of Attorney

➤ Executed & authenticated either in India before a First class Magistrate or in the country of origin before such an equivalent Authority or attested by the Indian Embassy of the said country or Apostilled from Hague convention member countries.

➤ Name and full address of the manufacturer & its manufacturing site as per Form-42.

➤ Name and full address of the Indian Agent as per Form-42.

➤ Name of the Cosmetic product, variants (if any) along with actual manufacturer of the product to be registered. The categorization of the product should be as per Column 3 of guidelines on registration of import of cosmetics.

➤ Duly conjointly signed, stamped, and dated with name & designation of the signatory by both Indian agent & the manufacturer.

➤ Time period for which POA is valid must be mentioned in power of attorney.

➤ In case the Brand Owner is located in India and gets its products manufactured from sites located outside India, a Letter of Authorization (LOA) with conditions (Same available in POA performa) of the Brand Owner and acceptance by the overseas manufacturer on Apostilled copy is required.

Note:

- All the pages of Power of Attorney including product list duly apostilled/notarized and authenticated from the country of origin.

- All the pages of Power of attorney including product list should be signed by both Indian agent and legal manufacturer before authentication.

- Correlation chart of the products with serial number as per Form-42 is required to be submitted.

Performa for Power of attorney enclosed as Annexure-I

3. Schedule D III

➤ Duly filled signed and sealed Schedule D III by manufacturer or Indian agent along with undertaking.

Performa for Schedule D-III enclosed as Annexure-II

4. List of Ingredients

➤ Name of the product and List of Ingredients with their name along with exact details of concentration of each ingredient used in the product composition duly signed by competent authorized person with stamp from the manufacturer.

5. Labels of proposed products

➤ Legible Original label for proposed products along with their variants (if any) as per Drugs and Cosmetics Rules, 1945 which includes following:-

- Name of Cosmetics
- Name of Manufacturer and Complete address of premises where the cosmetic is manufactured and correlated with Applied Form-42 and Power of Attorney.
- Use Before.
- Direction for safe use/Caution.
- Batch no.
- Manufacturing License no.(If any)
- Registration Number and Importer name and address.
- Other Information (if any).

6. Specification

➤ Specification and testing method for testing of cosmetics.

➤ Note:-Testing protocol, Specification and Test Report duly signed by competent authorized person with stamp from the manufacturer.

7. Pack insert

If any

8. Manufacturing Licenses

➤ Authenticated copy of manufacturing licenses/registration/marketing authorization in respect of applied products issued by Regulatory Authority from country of origin.

Note: In case there is no provision of manufacturing licenses/marketing authorization in country of origin, an undertaking for the same from the manufacturer is required to be submitted.

9. Free Sale Certificate

Original Free Sale Certificate issued by National Regulatory Authority of Country of origin for the applied products. Product list of Free sale certificate should be signed and stamped by issuing authority.

Note: In case if it is not issued by National Regulatory Authority from the country of origin then from other competent Associations/ organizations duly authenticated from the Indian Embassy of country of origin needs to be submitted.

- Free sale certificate should contain the statement that in which country the applied products are freely sold.
- Correlation chart of the products with serial number as per Form-42 is required to be submitted.

10. Non Animal Testing Declaration

- Undertaking that the applied cosmetic products to be imported in to the country have not been tested on animals (GSR No.718 (E) 13.10.2014).

11. Declaration for Heavy Metal and Hexachlorophene content.

- Test report including result of Pb, As, Hg, other Heavy metals and microbiological test (Wherever applicable) / Undertaking from the manufacturer stating compliance of all raw materials/pigments used, heavy metals (with specified limits) and Hexachlorophene contents in products with Bureau of Indian Standards and Drugs & Cosmetic Rules, 1945.

12. Other documents (If any)

13. Application (Form-42)

- Duly filled, signed & stamped original application by the Indian Agent/ importer/Manufacturer.
- Name of the Cosmetic product, variants (if any) along with actual manufacturer of the product to be registered. The categorization of the product should be as per Column 3 of guidelines of cosmetics.
- Name & full address of Authorized Agent/ importer in India.(Name and address should be correlated with POA)
- Name & full address of Manufacturer & its Factory Premises. (Name and address should be correlated with POA)

14. Fee: TR-6 Challan (In Original)

- Fees paid (250 USD equivalent Indian rupees for each Brand proposed viz. each category of cosmetics as mentioned in Column 3 of the guidelines of cosmetics.
- Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines) adjustable to PAO, DGHS, New Delhi 3.3 Total categories of cosmetics.....TR6 No... ..USD.....INR.....
- TR6 Challan Number, date of challan and Realisation Stamp.
- Note: - The categories of applied products and manufacturer’s name shall be mentioned in TR-6 Challan.
- Payment of fee via payment gateway as available in SUGAM portal through Bharatkosh is also acceptable.

Performa for TR-6 Challan enclosed as Annexure-III

Note*: Coloured scan copies of the above mentioned original documents required to be submitted on SUGAM portal while making an application for Registration Certificate.

Annexure-I

Power of Attorney to accompany an application for issue of Registration Certificate for import of Cosmetics into India, under the Drugs and Cosmetic Rules, 1945.

Whereas,

M/s.-----hereinafter to be known as Authorized Agent of us, intends to apply for a Registration Certificate under the Drugs and Cosmetics Rules, 1945, for the import, use and marketing into India, of the Cosmetics Brand/products marketed by us, we,

M/s. ----- hereinafter to be known as the Principal Manufacturer, having the factory premises at (1)...

Hereby delegate Power of Attorney that for the duration of the said Registration period:-

(1) The said applicant shall be our Authorized Agent for the Registration Certificate of Cosmetics Products imported into India under the brand "-----" only, under rule 129 C of the Drugs and Cosmetics Rules;

(2) We shall comply with all the conditions imposed on the Registration Certificate, for import of Cosmetics as required under the provisions of Drugs and Cosmetics Rules, 1945

(3) We declare that we are carrying on the manufacture of the Cosmetics Products at the premises of the supporting Manufacturers and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(4) We shall comply with the provisions of Part XIII of the Drug and Cosmetics Rules, 1945.

(5) Every Cosmetics products got manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time

(6) We shall inform to the licensing Authority within 30 days in the event of any change in variants or in category or in manufacturing location or in labeling or in documentation of any of the Cosmetics pertaining to the certificate to be granted to us.

(7) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or '**Not of standard quality report**' report of any Cosmetics pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the Product is marketed/sold or distributed. The dispatch and marketing of the Cosmetics in such cases shall be stopped immediately and the licensing authority shall be informed immediately.

(8) 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.

(9) We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the Cosmetics concerned for test, analysis or examination, if considered necessary by the Licensing authority.

Name(s) of the Cosmetic(s)

Signature on behalf of Principal Manufacturer, with name, designation, date and place.

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP

Manufacturing Address(s):

Signature on behalf of Authorized Agent in India with name, designation, date and place.

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP



Annexure-II

SCHEDULE D (III)

INFORMATION AND UNDERTAKING REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORISED IMPORTER/DISTRIBUTOR/AGENT WITH THE APPLICATION FORM FOR A REGISTRATION CERTIFICATE.

(The format shall be properly filled in for each application in form 42)

1. PARTICULARS OF THE MANUFACTURER AND MANUFACTURING PREMISES.-

- (a) Name and address of the manufacturer and manufacturing premises to be registered along with telephone numbers, Fax numbers and e-mail address.
- (b) Name(s) and address of the Partners/Directors.
- (c) Name and address of the authorised importer/distributor/agent in India, responsible for the business of the manufacturer.
- (d) A brief profile of the manufacturer's business activity, in domestic as well as global market.

2. PARTICULARS OF THE COSMETICS TO BE REGISTERED UNDER

- (a) Names of cosmetics along with their brands name, category, pack sizes and variants to be registered and meant for import into and use in India.
- (b) Particulars of the manufacturing licenses/registration/marketing authorizations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses/marketing authorization/registration issued by the Regulatory Authority of that country.
- (c) List of countries where marketing authorization or import permission for the said cosmetic has been granted.

3. CHEMICAL INFORMATION OF COSMETICS.-

- (a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.
- (b) Specification and testing method for testing of the cosmetic(s).
- (c) Manner of labelling as per Drugs and Cosmetics Rules, 1945.
- (d) Package insert (if any).

4. UNDERTAKING TO DECLARE THAT.-

- (a) We shall comply with all the conditions imposed on the Registration Certificate for the import of cosmetics as required under the provisions of Drugs and Cosmetics rules, 1945.
- (b) 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

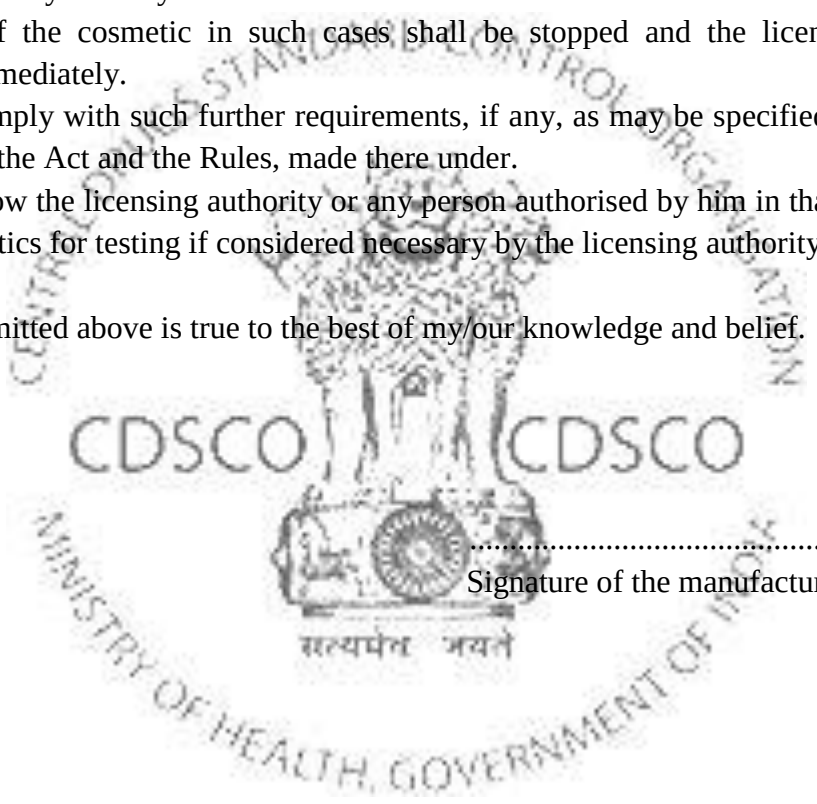
manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

- (c) We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.
- (d) Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time.
- (e) We shall inform to the licensing authority, within 30 days in the event of any change in variants or in category or in manufacturing location or in labelling or in documentation of any of the cosmetic pertaining to the certificate to be granted to us.
- (f) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals/regulatory restriction, or cancellation of authorisation and/or —not of standard quality report of any cosmetic pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the cosmetic is marketed/sold or distributed. The despatch and marketing of the cosmetic in such cases shall be stopped and the licensing authority shall be informed immediately.
- (g) 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) We shall allow the licensing authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the licensing authority.

The information submitted above is true to the best of my/our knowledge and belief.

Place:

Date:



.....
Signature of the manufacturer or his authorized agent

Seal/Stamp

Annexure -III

T.R. - 6.
(See Rule 92)

Challan No.

Please indicate whether	Civil
	Defence
	Railways
	Posts & Telegraphs

Challan of cash paid into Treasury/Sub-Treasury

Bank of Baroda, K.G. Marg, New Delhi

To be filled by the remitter				To be filled by the Department Officer or the Treasury		
By whom Tendered	Name (or designation) and address of the person on whose behalf money is paid	Full particulars of the remittance and/of authority (if any)	Amount	Head of Account	Accounts Officer by whom adjustable	Order to the Bank
Name			Rs. P.			Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total *				
(in words) Rupees				To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.		

Received payment (in words) Rupees

Treasurer

Accountant

Date

Treasury Officer
Agent or Manager

Note

1. In the case of payment at the Treasury, receipts for sums less than Rs. 50,000.00 do not require the Signature of the Treasure Officer but only of the Accountant and the Treasurer. Receipts for cash and cheques paid for service postage stamps should be given in form T.R. 5.
2. Particulars of money tendered should be given below.
3. In case where direct credit at the Bank are permissible the column, "Head of Account" will be filled in by the Treasury Officer or the Accountant General as the case may be on receipt of the Bank's Daily Sheet.

Particulars	Amount	
	Rs	P
Coins		
(Notes with details)		
Cheque (with details)		
Total Rs.		