

**CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION
Guidance Document
(Cosmetics Division)**

Title: - Guidance Document on Application Submission for obtaining Import Registration Certificate for import of cosmetics into India.

Date:-19.01.2021

Note:

The Guidance Document is aimed only for creating public awareness about regulation on import of Cosmetics by CDSCO and is not meant to be used for any legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act 1940 & Rules made there under, Notifications in the Official Gazette published by the Central Government and Guidelines/Clarifications issued by CDSCO from time to time for all their professional needs.

PREFACE

Cosmetic is defined under section 3(aaa) of the Drugs and Cosmetics Act, 1940 as, 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.

Import of cosmetics into India is regulated through a system of registration by the CDSCO under the provisions of the Drugs and Cosmetics Act, 1940 and the Cosmetics Rules, 2020. Any article falling within the definition of cosmetic is required to be registered along with pack size, variants and manufacturing premises before import into the country.

No cosmetic shall be imported into India unless the product is registered under the rules by the Central Licensing Authority appointed by the Central Government under rule 3(f) or by any person to whom such powers may be delegated under rule 5. [**As per rule 12(1) of the Cosmetic Rules, 2020**]

An application for issue of a Import Registration Certificate for cosmetics intended to be imported into India shall be made online in Form COS-1 on [SUGAM Portal of CDSCO](#) with requisite fee and documents 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 Central Licensing Authority under the Cosmetics Rules, 2020 i.e. Drugs Controller General (I), CDSCO (HQ).

No cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Ninth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case, the cosmetic is not included under the Ninth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin. [**As per rule 39 of the Cosmetic Rules, 2020**]

No cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user. [**As per rule 36 of the Cosmetic Rules, 2020**]

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

Guidance Document for Submission of application in Form COS-1 for grant of Import Registration Certificate in Form COS-2 for import of Cosmetics into India

- 1. PURPOSE:** To provide guidance to stakeholders for submission of application in Form COS-1 to CDSCO for grant of Import Registration Certificate in Form COS-2 for import of cosmetics into India
- 2. SCOPE:** This guidance document is applicable to manufacturer or their authorised agent in India.
- 3. MODE OF SUBMISSION:** Online application submission on SUGAM portal of CDSCO
- 4. GUIDANCE:** An application for issue of a Import Registration Certificate for cosmetics intended to be imported into India shall be made online in Form COS-1 on SUGAM Portal of CDSCO 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 Central Licensing Authority under the Cosmetics Rules, 2020 i.e. Drugs Controller General (I), CDSCO (HQ), New Delhi.

4.1 Covering Letter

- Purpose (Fresh or Endorsement of Products/Manufacturing site/Pack Size/Additional Sourcing Location or Re-Registration) should be clearly mentioned along with the details of earlier issued Import Registration Certificate (if any) and product/ product category (whether already registered or not).

Note: Mention the Section no. of checklist where the correlation charts between Serial number of products in Form COS-1 with Free Sale Certificate and Authorization is uploaded.

4.2 Authorisation from Manufacturer as per First Schedule

- Authorization to accompany an application for issuance of import registration certificate.
 - 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 premises as per Form COS-1.
 - Name and full address of the authorised Indian Agent as per Form COS-1.
 - Name of the Cosmetic product, Variants (if any) along with name and complete address of manufacturing premises of the product to be registered. The categorization of the product should be as per Fourth Schedule of the Cosmetics Rules, 2020.
 - Duly conjointly signed, stamped, and dated with name & designation of the signatory by both authorised Indian agent & the manufacturer.

Note: Authorisation including complete product list duly apostilled and authenticated from the country of origin. All the pages of the authorisation including product list should be signed by both authorised Indian agent and manufacturer before authentication.

Pro forma for Authorisation from manufacturer is enclosed as Annexure-I

4.3 Part-I of Second Schedule - Information and undertaking required to be furnished by the manufacturer or his authorised importer/ distributor/ agent with the application form for import registration certificate.

- The format shall be properly filled in for each application in Form COS- 1.

Pro forma for Part-I of Second Schedule enclosed as Annexure-II

4.4 List of Ingredients/Composition

- Name of the cosmetic and name of Ingredients in the nomenclature of standard reference along with percentage contained in the cosmetic duly signed by competent authorized person with stamp from the manufacturer.
- Raw materials specified in ANNEX A of the Indian Standard IS: 4707 Part 2, as amended from time to time, shall not be added in the cosmetic product.
- No cosmetic shall be imported or manufactured which contains Dyes, Colours and Pigments other than the one specified by the Bureau of Indian Standards (IS: 4707 Part 1 or IS: 4707 Part 2, as amended) and included the Tenth Schedule.
- The permitted Synthetic Organic colours and Natural Organic Colours used in the Cosmetic shall not contain more than:-
 - i. 2 parts per million of Arsenic calculated as Arsenic Trioxide.
 - ii. 20 parts per million of lead calculated as lead.
 - iii. 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.
- No cosmetic containing hexachlorophene shall be manufactured. In case of soaps, hexachlorophene may be used in concentrations not exceeding one per cent weight by weight with cautionary note be printed and shall appear in a conspicuous manner on the wrapper of package of each soap, namely. “**Contains hexachlorophene - not to be used on babies**”.
- Cosmetics imported or manufactured in the country shall contain mercury in the following proportions, namely,-
 - (a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative;
 - (b) in other finished cosmetic products, unintentional mercury shall not exceed one part per million (1 ppm).”.

- The use of lead and arsenic compounds for the purpose of colouring cosmetics is prohibited.

4.5 Labels of proposed products

Legible Original Label for proposed cosmetic product along with their variant (if any) as per the Chapter VI of the Cosmetics Rules, 2020 which includes following:-

- Name of the cosmetics,
- Name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured. If the product has not been manufactured in a factory owned by the manufacturer, the name and address of the actual manufacturer or the name of the country where it has actually been manufactured as "Made in (name of country)" should be there on the label. If the cosmetic is contained in a very small size container as 30gm or less if the cosmetics are in solid or semi-solid state and 60 ml or less if the cosmetics is in liquid state, where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.
- Use before or date of expiry (month and year) or use by or expiry date or expiry XX months from MFD or date of manufacturing or Exp. Dt.
- A distinctive Batch No. or Lot No.,
- Manufacturing licence number, the number being preceded by the letter 'M' or "M. L. No" or "Mfg. Lic. No." shall carry on the inner or outer labels. *In case of imported products, if such provision is not mandatory in country of origin, such cosmetics may be allowed without mentioning manufacturing license number, subject to fulfilment of other import regulations.*
- A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, fluid measure or weight for semi-solids, combined with numerical count if the content is sub-divided. *This statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.*
- **In case of cosmetics; where a hazard exists, every inner label shall clearly indicate adequate directions for safe use, any warning, caution or special direction required to be observed by the consumer, a statement indicating the names and quantities of ingredients that are hazardous or poisonous.**
- In the case of imported cosmetics to be marketed in India, import registration certificate number shall be mentioned on the label of unit pack preceded by letter "RC" or "RC No" or "Reg. Cert. No" along with name & address of the importer;
- **If a package of a cosmetic has only one label, such label shall contain all the information required to be shown on both the inner and the outer labels, under these rules.**
- In all cases, the list of ingredients, present in concentration of more than one percent shall be listed in the descending order of weight or volume at the time they are added,

followed by those in concentration of less than or equal to one percent, in any order, and preceded by the words 'INGREDIENTS'. This statement need not appear for packs of less than or equal to 60 ml of liquid and 30 gm of solid and semi-solids.

- The cosmetic shall comply with labelling requirement, if any, specified in the relevant Indian standard as laid down by the 'Bureau of Indian Standards' for the cosmetics covered under the Ninth Schedule.
- No cosmetic shall be imported unless it is packed and labelled in conformity with these rules and the label of imported cosmetics shall bear registration certificate number of the product and the name and address of the registration certificate holder for marketing the said product in India. Provided that in cases where the imported cosmetics require India specific labelling, the same shall be allowed to be stickered on the unit pack at the bonded warehouses.

4.6 Specification and testing method for testing of cosmetics.

- Cosmetic shall comply with the specifications prescribed under the Ninth Schedule of the Cosmetics Rules, 2020 or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case, the cosmetic is not included under the Ninth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin.
- Each specification and testing method should be signed and stamped by the competent person of the company.

4.7 Pack insert (If any)

4.8 Manufacturing Licenses

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

4.9 Free Sale Certificate

- Original Free sale certificate issued by National Regulatory Authority or other competent associations/organizations from the country of the principal manufacturer or actual manufacturer from country of origin can be considered.
- In case if it is not issued by the 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. or
- In case if free sale certificate is not authenticated from the Indian Embassy of country of origin but authenticated either from the chamber of commerce and apostilled or authenticated from notary public and apostilled, then it may be accepted.
- Product list of free sale certificate should be signed and stamped by issuing authority.

Note:

- Free sale certificate should contain the statement that in which country the applied cosmetic products are freely sold/marketed.
- Correlation chart of the each product with serial number as per Form COS-1 and Authorisation is required to be submitted.

4.10 Non Animal Testing Declaration

- No person shall use any animal for testing of cosmetics.
- No cosmetic that has been tested on animals after the 12th day of November 2014 shall be imported into the country.
- An Undertaking from the manufacturer that the applied cosmetic products to be imported into the country have not been tested on animals needs to be submitted along with application in Form COS-1.

4.11 Declaration for Heavy Metal and Hexachlorophene content.

Test report including result of Pb, As, Hg, other Heavy metals and microbiological test (Wherever applicable) or Undertaking from the manufacturer stating that all raw materials/pigments used, heavy metals (with specified limits) and Hexachlorophene contents in applied products are in compliance with the standards specified in the Cosmetic Rules, 2020.

4.12 Other documents (If any)**4.13 Application in Form COS-1**

- Duly filled, signed & stamped original application in Form COS-1 by the authorised Indian Agent/Manufacturer.
- Name of the Cosmetic product, variants (if any), pack size (in Indian Metric System) along with manufacturing premises of the product to be registered. The categorization of the product should be as per Fourth Schedule of the Cosmetics Rules, 2020.
- Name & full address of Authorized Agent in India.
- Name & full address of Manufacturer & its manufacturing premises.
- All details of Form COS-1 shall be in line with that mentioned in Authorisation and Part-I of Second Schedule.

4.14 Fee: (Bharatkosh Online Payment)

- As per the circular no. CDSCO/IT/2018-(37) dated 09.01.2019 of this directorate and subsequent letter of even number dated 15.02.2019, the fees shall be paid through Bharatkosh only, from 28.02.2019 onwards. The fee shall be paid through Bharatkosh gateway under Head of Account “0210041040000-00-1” Import and Registration and the

acknowledgement receipt shall be submitted along with the application for registration of cosmetics.

- As per the Third Schedule of Cosmetics Rules, 2020, a fee of One Thousand US dollars or its equivalent in Indian Rupees for grant or retention of Registration Certificate for each category of cosmetics, a fee of Five Hundred US dollars for registration of each manufacturing site, a fee of Fifty US dollars for each variant and a fee of One Thousand US dollars for grant or retention of Registration Certificate for additional category of Cosmetic shall be paid along with the application in Form COS-1.

First Schedule
[See rule 12(3)]

Authorization from manufacturer

(To be authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille)

Authorization to accompany an application for issuance of import registration certificate

I working as authorised to sign this authorization on behalf of manufacturer M/s(Legal/Principal manufacturer)..... (Full address/ telephone no., e-mail) having manufacturing site atActual Manufacturing Site(s)..... (Full address, telephone no., e-mail), hereby delegate the authorization to M/s.....(Authorized Indian Agent)....., (full address, with telephone, fax and E-mail address), hereinafter to be known as authorised agent, intends to apply for registration certificate under the provisions of the Cosmetics Rules, 2020 to import into India for the following cosmetics manufactured at below manufacturing site.

Following are the details of cosmetics proposed to be imported (A separate list may be annexed, if required in below given format).

Serial No.	Product/brand of cosmetic	Brand name	Variant name	Pack sizes	Actual manufacturer & its premises
1.					
2.					

(2) Our authorised agent shall act in the following respects:-

a) to act as the official representative for obtaining registration certificate for and on behalf of M/s. _____ (Name and complete address of the overseas manufacturer/brand owner) in India.

b) to submit all necessary documents in the name of _____ (Name and complete address of the overseas manufacturer/brand owner) for the registration certificate of cosmetics manufactured by _____ (manufacturer's name).

(3) I shall comply with all the conditions imposed on the registration certificate and with provisions of the Cosmetics Rules, 2020.

(4) I declare that M/s is carrying on the manufacture of the listed cosmetics at the manufacturing site specified above.

(5) I shall allow the Central Licensing Authority or any person authorized by it in that behalf to enter and inspect the manufacturing premise and to examine the process, procedure and documents in respect of any manufacturing site or to take sample of listed cosmetics for which the application for registration certificate has been made.

(6) In case of any violation of Drugs and Cosmetics Act, 1940 and Rules there under, the authorised agent shall continue to be responsible even after withdraw of this Power of Attorney for the cosmetics imported in India.

(7) I do hereby state and declare that all the photocopies or scanned copies in the application are true copies of the original documents.

(8) I do hereby state and declare that all the documents submitted by the undersigned are true and correct.

Place:

Date:

Signature of the manufacturer

(Name and Designation)

Seal/Stamp

Undertaking from the authorised agent

I, age....., working as at M/s (Full address/ telephone no., e-mail) agrees to act upon the authorization as the authorized agent on behalf of manufacturer M/s (Full address/ telephone no., e-mail) having manufacturing site at (Full address, telephone no., e-mail).

Place:

Date:

Signature of the authorised agent

(Name and Designation)

Seal/Stamp

Second Schedule

[See rules 12(4), 23(2) and 23(4)]

Part-I

Information and undertaking required to be furnished by the manufacturer or his authorised importer/distributor/ agent with the application form for import registration certificate.

The format shall be properly filled in for each application in Form COS- 1.

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 including name(s) and address of its Partners/Directors.
 - d. A brief profile of the manufacturer's business activity, in domestic as well as global market.

Note: In case the brand owner is a company registered in India, the name and registered office address of the company should be given.

2. Particulars of the cosmetics to be registered under registration certificate.
 - 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/product permission /marketing authorizations/free sale certificate / (if any)under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses/ marketing authorization/ free sale certificate /registration issued by the Regulatory Authority or any other competent authorities/associations 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. Specifications and testing method for testing of the cosmetic(s).
 - c. Manner of labelling as per the Cosmetics Rules, 2020.
 - d. Package insert (if any).
4. Undertaking to declare that.-
 - a. I/We shall comply with all the conditions imposed on the registration certificate for the import 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 and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.
- c. I/We shall comply with the provisions of Chapter III of the Cosmetics Rules, 2020.
- d. Every cosmetic manufactured by us for import under the registration certificate into India shall conform to the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
- e. No cosmetic manufactured by us shall be imported into India which has been tested on animals.
- f. I/We shall inform to Licensing Authority, in case of any change in respect of labelling or composition or testing of registered product or its specifications within thirty days along with an undertaking that products comply with the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
- g. I/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.
- h. 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.
- i. I/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

Name and Designation:

Seal/ Stamp

Reference Documents:

1. The Cosmetics Rules, 2020 published in the Official Gazette by the Government of India vide G.S.R. 763(E) dated 15.12.2020 w.e.f. 15.12.2020.