

New cosmetic Rules 2020 DISCUSSION

DR BAIDYANATH MISHRA, MD, Ph.D(Ay), IPRA
PRESIDENT-NATURAL PRODUCTS, SARVOTHAM CARE LTD, HYDERABAD

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th December 2020

G.S.R. 763(E).—Whereas a draft of the Cosmetics Rules, 2018, was published, with a view to codify separately and to update the rules relating to cosmetics, by the Central Government in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 1153(E), dated the 29th November, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public

Cosmetics Rules, 2020

The Ministry of Health and Family Welfare notified the **Cosmetics Rules, 2020**, on December 15, **2020**, with an *aim to separately codify and update the rules relating to import, manufacture, labelling, sale and distribution of cosmetics in India*, which were earlier set out under the Drugs and **Cosmetics Rules, 1945**

CHAPTERS

Chapter I: PRELIMINARY

Chapter II: AUTHORITIES, OFFICERS AND LABORATORY

Chapter III: IMPORT AND REGISTRATION

Chapter IV: MANUFACTURE OF COSMETICS FOR SALE OR DISTRIBUTION

Chapter V: PERMISSION FOR IMPORT OR MANUFACTURE OF NEW COSMETIC

Chapter VI: LABELLING, PACKING AND STANDARDS FOR SALE OR DISTRIBUTION OF COSMETICS

Chapter VII: PROCEDURE OF SAMPLING FOR TEST OR ANALYSIS, SEIZURE AND REPORT

Chapter VIII: APPROVAL OF LABORATORY FOR CARRYING OUT TESTS ON COSMETICS AND THEIR RAW MATERIAL

Chapter IX: MISCELLANEOUS

Chapter 1: Few critics

New cosmetic: means a cosmetic which contains a novel ingredient which has not been used anywhere in the world or is not recognized for use in cosmetics in any National or International literature.

Manufacturer in relation to import of cosmetics means the actual manufacturer or the legal manufacturer.

The words and expressions used in these rules and not defined herein but defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall have the same meaning as assigned to them in that Act and rules respectively.

Chapter II: Few critics

- Licensing Authorities.: (1) The Central Licensing Authority shall be the competent authority for enforcement of these rules in matters relating to, -(i) import of all categories of cosmetics; (ii) co-ordination with the State Licensing Authorities.
- Controlling officer. any officer not below the rank of Assistant Drugs Controller, by whatever name called, shall be the controlling officer to supervise and give instructions to any officer subordinate to such controlling officer to exercise powers and functions under these rules for areas and purposes specified, by an order, of the Drugs Controller General of India or the Drugs Controller, by whatever name called, of the State respective.
- Government Analyst: As per section 20
- Powers, duties and functions of Inspectors specially Authorized to inspect manufacture and sale of cosmetics: Inspect not less than once in 3 years
- Establishment and functions of the Central Cosmetics Laboratory: headed by a Director who shall be appointed or designated by the Central Government.

Chapter III: Few critics

- Import of cosmetics: No cosmetic shall be imported into India unless the product has been registered in accordance with these rules by the Central Licensing Authority or by any officer to whom such powers may be delegated under sub-rule (1) of rule 5.
- An application for registration, BY Form COS-1 either by the manufacturer himself or by his authorized agent or the importer in India or by the subsidiary in India authorized by the manufacturer.
- The applicant shall pay the fee as specified in the Third Schedule
- Grant of import registration certificate: Form COS- 2, In case of a new cosmetic, the applicant shall obtain prior permission in Form COS- 3

Chapter III: Few critics

- Validity of import registration certificate. five years from the date of its issue, unless it is suspended or cancelled by the Licensing Authority.
- Fresh application in case of change in constitution, within a period of 180 days from the date of such change in constitution:
- In case of change in name or address of a registration holder or overseas manufacturer, after grant of registration need to apply within a period of sixty days from the date of such change.
- Import of cosmetics already registered for import: Form COS-4 with an undertaking as specified in Sixth Schedule.
- Import of cosmetic for personal use Small quantities of cosmetics the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following condition
- Import through points of entry. No cosmetic shall be imported into India except through the points of entry as specified in rule 43A

Chapter IV: Few critics

- Application for grant of license or loan license to manufacture cosmetics for sale or for distribution: Form COS-5 for licence or in Form COS-6 for loan license
- In case of a new cosmetic, the applicant shall obtain prior permission in Form COS- 3 as provided in Chapter V from the CLA, self-declaration in Form COS-7
- Manufacture at more than one premises: Separate license and Separate application
- Form of license or loan license to manufacture cosmetics for sale or distribution: In Cos 8 and 9 with competent technical staff- D.Pharm, B.Sc (Chem), and B. Sc/B.Tech (Cosmetic technology)
- The manufacturer shall inform the Licensing Authority within thirty days, in writing, in the event of change in labelling or composition or testing, or specification or in documentation
- Validity of license: 5 years from the date of its issue, unless it is suspended or cancelled by the State Licensing Authority.

Chapter V: Few critics

- Permission for import or manufacture of new cosmetic shall apply to the Central Licensing Authority in Form COS- 12 along with requisite fee and the data on safety and effectiveness of cosmetic.
- If the Central Licensing Authority, after being satisfied that the cosmetic if permitted to be manufactured or imported shall be safe and effective for use in the country, may issue a prior permission in Form COS-3, subject to the condition specified therein.
- The prior permission obtained in Form COS-3 shall be furnished along with the application for import under Chapter III or manufacture under Chapter IV of such new cosmetics.
- Methods of test or analysis to be employed for safety evaluation of new cosmetic shall be complied by manufacturer as specified in the IS 4011 : 2018 methods of test for safety evaluation of cosmetics, published by the Bureau of Indian Standards as amended from time to time.

Chapter VI: Few critics

- Prohibition of sale or distribution.: Must be as per labelling act
- Prohibition against altering inscription on containers, labels or wrappers of cosmetic
- Prohibition against false or misleading claims
- Labelling of hair dyes containing dyes, colours and pigments Hair dyes containing Para-phenylenediamine or other dyes, colours and pigments shall be labelled with caution
- Special provisions relating to toothpaste containing fluoride Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton
- Standards of cosmetics Raw materials specified in ANNEX A of the Indian Standard IS: 4707 Part 2

Chapter VI: Heavy metals

- Cosmetics imported or manufactured in the country shall contain mercury in the following proportions, namely in cosmetics intended for use only in the area of eye, the level of mercury not exceeding 70% ppm (0.007 per cent.) of mercury, calculated as the metal, as a preservative; 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
- No person shall use any animal for testing of cosmetics.
- The permitted Synthetic Organic colours and Natural Organic Colours used in the Cosmetic shall not contain more than 2 ppm Arsenic calculated as Arsenic Trioxide; 20 ppm of lead calculated as lead.; 100 PPM other than lead calculated as the total of the respective metals., No cosmetic containing hexachlorophene shall be manufactured.
- Provided that in case of soaps, hexachlorophene may be used in concentrations not exceeding 1% w/w, —Contains hexachlorophene - not to be used on babies||.

Chapter VII: SAMPLING

- Testing of Cosmetic from a purchaser shall be made to the Government Analyst in Form COS- 13 and the report of the test or analysis of the cosmetics made on such application shall be supplied to the applicant in Form COS- 14.
- Procedure for sampling exercising powers under section 22 and deliver as per section 23
- Forms of receipts for seized cosmetic, record register, document or any other material object. Shall be given in Form COS-15.
- Manner of certifying copies of seized documents The Inspector shall return the documents, seized by him under clause (cc) or produced before him under clause (cca), of sub-section (1) of section 22 of the Act within a period of twenty days of the date of such seizure or production to the person.
- Form of intimation of purpose of taking samples Form COS- 10 and record in COS 16
- Procedure for dispatch of sample to Government Analyst. Form COS-17
- Form of order not to dispose of stock shall be in Form COS- 18.
- Confiscation of cosmetics, implements, machinery et

Chapter VIII: APPROVAL OF LABORATORY

- Application for grant of approval for testing cosmetics Form COS-22 to the State Licensing Authority, accompanied with the fee as specified in the Third Schedule.
- Approval for carrying out tests on cosmetics on behalf of licensees COS-23
- Inspection before grant of approval ; Procedure of approving authority
- Validity of license : 5 YEARS; Inspection for verification of compliance
- General conditions after approval: Such records shall be retained in case of substances for which an expiry date is assigned for a period of two years from the expiry of such date and in case of other substances, for a period of six years.
- Withdrawal and suspension of approval

Chapter IX: MISC.

- Exemption of cosmetics Cosmetics as may be specified in the Twelfth Schedule shall be exempted from the provisions of Chapter III and Chapter IV of the Act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule.
- Voluntary recall of cosmetics
- Fees for examination of samples under sub-section (1) of section 25 of the Act shall as specified in the Fifth Schedule.
- Mode of payment of fee. paid through challan or by electronic mode, in the Bank of Baroda,
- Debarment of applicant for false documents

Notification

In order to separately codify rules relating to cosmetics for effective compliance, the Union health ministry, through a gazette notification, has notified the Cosmetics Rules, 2020.

The ministry issued the notification in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics (D&C) Act, 1940 (23 of 1940).

These rules shall be applicable to the cosmetic as defined in clause AAA) of Section 3 of the D&C Act, 1940 (23 of 1940).

Brief

In these rules, unless the context otherwise requires,

a) Act means the Drugs and Cosmetics Act, 1940 (23 of 1940);

(b)? Actual manufacturer in relation to import of cosmetics, means a person who manufactures cosmetics at his own manufacturing site in a country other than India approved by National Regulatory Authority or any authorized competent authority in that country for that purpose, by whatever name called for the purpose of this clause, *person includes a company or a unit or a body corporate or any other establishment.*

Authorized agent

As per the notified rules, **authorized agent** means a person in **India authorized by the manufacturer.**

The authorized agent shall be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act and rules made thereunder for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

An authorization by the manufacturer to his agent in India shall be duly authenticated either in India before a first class Magistrate or in the country of origin before the authority competent under the laws of that country or by an authority specified in the First Schedule.

Import

No cosmetic shall be imported into India unless the product has been registered in accordance with these rules by the Central Licensing Authority or by any officer to whom such powers may be delegated under sub-rule (1) of rule 5.

Import

An application for registration of a cosmetic product intended to be imported into India shall be made through the online portal of the Central Government in Form COS-1 either by the manufacturer himself or by his authorized agent or the importer in India or by the subsidiary in India authorized by the manufacturer

Bulk formulation

- The applicant referred to sub-rule (2) above shall furnish along with the application such other information and documents as specified in Part I of the Second Schedule provided also that in the event of application for import of bulk finished formulation ready to fill, the following additional documents shall also required to be furnished.

Registration certificate

A registration certificate granted under rule 13 shall remain valid in perpetuity, subject to payment of registration certificate retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

Registration certificate

If the licensee fails to pay the required registration certificate retention fee on or before the due date as referred to in sub-rule (1), the registration certificate holder shall, in addition to the registration certificate retention fee, be liable to pay a late fee calculated at the rate of two percent of the registration certificate retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

Registration Holder

In case of change in constitution of a registration holder or overseas manufacturer, after grant of registration under sub-rule (1) of rule 13, an application shall be made under sub-rule (2) of rule 12 for grant of fresh registration within a period of one hundred and eighty days from the date of such change in constitution provided that the existing registration shall be deemed to be valid till such time, fresh registration is issued or application is rejected by the Central Licensing Authority.

Labelling change?

In case of any change in respect of labelling or composition or testing of registered product or its specifications, the Central Licensing Authority shall be informed by manufacturer or by the authorized agent or the importer or the subsidiary in India authorized by the manufacturer within fifteen days along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

Full
declaration of
ingredients,
not cosmetic,
made
mandatory

The government has decided to set up the first Central Cosmetics Laboratory and appoint inspectors across states.

It has now become mandatory for manufacturers of cosmetics and make-up products in India to declare all ingredients, even those with concentration of less than 1%, to help buyers make more informed choices. Thus far, there was no Central law mandating them to declare the full composition of their skin and make-up products — though there is such a rule for drugs — and licences were granted without getting detailed information.

Quality control of cosmetic products

- In order to ensure greater quality control of cosmetic products being manufactured, imported and used in India, the government has also decided to set up the first Central Cosmetics Laboratory and appoint inspectors across states.
- Till now, there have been very few instances of crackdown on makers of spurious cosmetics. Under the new cosmetics rules, 2020 notified by the Union ministry of health and family welfare recently following consultations with the drug technical advisory board, hair dyes containing paraphenylenediamine or other dyes, colors and pigments should be labelled with specified warnings. Special provisions have been introduced on fluoride content in toothpaste as well.

Label?

It not be more than 1000 ppm and the fluoride content shall be mentioned on the tube and carton.

According to the new norms, no cosmetic, the manufacture, sale or distribution of which is prohibited in the country of origin, can be imported.

Also on the import ban list are cosmetics containing hexachlorophene — a chemical preservative known for harmful effects on humans. Besides, cosmetics tested on animals cannot be imported. Also, inspectors will be required to inspect at least once in three years all premises licensed to manufacture cosmetics to ensure that the provisions of the Drugs and Cosmetic Act, 1940 and its rules are being fully met.

**From
which date
Cosmetic
Rules 2020
shall come
into force?**

Cosmetic Rules 2020 have been modified vide notification No. **G.S,R. 763 (E) Dated 15-12-2020** and the same have come into force from the date of its notification i.e. 15-12-2020.

What is the status of existing cosmetic manufacturing license issued on form 32?

- As per Rule 72 (Savings) the existing license shall be deemed to be valid for all purposes, **still its expiry or for the period of 18 months** from the date of these rules are notified, whichever is later.

What is the revised license fee under Cosmetic Rules 2020?

Fee is given in 3rd Schedule of the New Cosmetic Rules 2020.

- Fee for the grant of license is Rs. 10,000/- (Free: ten items of each category)
- Retention fee Rs. 10,000/-
- Item fee: Rs. 500/- per item
- Late Fee per month Rs. 2% of the license fee.
- Fee for additional category Rs. 10,000/-
- Fee for duplicate license Rs. 500/-
- Fee for the approval of testing laboratory Rs. 1,000/-

Is inspection required for the grant of cosmetic license?

- As per Cosmetic Rules 2020, no inspection is required before granting the license, but State Licensing Authority (SLA) may verify the documents and fee submitted by the firm as per rule 23 of the Cosmetic Rules 2020.

**On which
form,
cosmetic
license is
granted as
per
Cosmetic
Rules
2020?**

- From Cos-8.

What are the new procedure for getting new cosmetic license as per Cosmetic Rules 2020?

Procedure given in Rule 23 as under:

Firm must apply new cosmetic manufacturing license through online portal on form Cos-5.

- The required fee is mentioned in 3rd schedule of Cosmetics Rules 2020.
- List of documents to be submitted as per 2nd schedule part-2 Cosmetics Rules 2020.
- SLA will issue the license on form Cos-8. If the application was not in complete, then SLA may reject the file and inform the applicant within 45 days.
- After obtaining license, firm must upload the license on website of CDSCO within 30 days.
- SLA within 30 days of grant of license will inspect the premises and verify the information as given by the firm in self-certificate in form Cos-7.

**For how much
time
manufacturing
record is to be
retained?**

- Manufacturing record to be retained for a period of 3 years from the date of expiry of the product.

For how much time the testing record is to be retained?

- The test record is to be retained for a period of 3 years from the date of manufacturing.

**Is there any
change in
qualification of
Technical Staff in
Cosmetics Rules
2020?**

- No. It will be same as previous.

Within how much time the firm has to obtain license due to change in constitution ?

- **Within Six months**

Within how much time the firm has to obtain license due to change in Name of the firm ?

- **Within Two months.**

**What are
the Forms
under
Cosmetic
Rules
2020?**

Purpose	Form
Application to obtain cosmetics manufacturing license	Cos-5
Self- certificate compliance for GMP	Cos-7
Cosmetics Manufacturing license	Cos-8
Form for sampling	Cos-10
Seizure Form	Cos-15
Fair-price Form	Cos-16
Memorandum to Govt. Analyst	Cos-17
Non-Disposal Form	Cos-18
Govt. Analyst Test Report	Cos-19
Application for grant of testing of cosmetics	Cos-22

What are the different categories and area required to manufacture cosmetics under Cosmetic Rules 2020?

Details of categories and area required to manufacture cosmetics under Cosmetic Rules 2020 is as under.

Category	Cosmetics	Area in Sq.Mtrs
A	Powders	15
B	Skin Powder for infants	15
C	Creams, Lotions, Shampoo, Shaving Creams, Hair Oils. Emulsions, Pastes, Cleansing Milk, Pomade	25
D	Nail Polish and Nail Lacquers	15
E	Lipsticks and Lipgloss	15
F	Depilatories used for eyes	10
G	Eyebrows, Eyelashes Eyeliners	10
H	Aerosols	15
I	Alcoholic Fragrance Solutions	15
J	Hair Dyes	15
K	Tooth powders general and toothpastes etc.	15
L	Toilet Soaps	100

**Is definition of
New cosmetic has
been introduced
in Cosmetic Rule
2020?**

- Yes, definition of New cosmetic has been given in Rule-3(f) of Cosmetics Rules 2020.

Which are new schedules introduced in Cosmetics Rules 2020 ?

- Following schedules are introduced:

1	First Schedule	Authorisation from manufacturer
2	Second Schedule Part-I	Information and undertaking required to be furnished by the manufacturer or his authorised importer or distributor or agent with the application form for import registration certificate.
4	Third Schedule	Fee payable for licence, permission and registration certificate.
3	Second Schedule Part-II	Information and undertaking required to be furnished by the manufacturer with the application form for grant of manufacturing licence or loan licence

	5	Fourth Schedule	List of categories of cosmetics for import
6		Fifth Schedule	Fee for test or analysis by the Central cosmetics laboratories or by the state laboratories
7		Sixth Schedule	Undertaking for the import of cosmetics to be submitted by the importer with application form for Import Registration Number
8		Seventh Schedule	Good manufacturing practices and requirements of premises, plants and equipment for manufacture of cosmetics
9		Eighth Schedule	Manufacturing and raw material records
10		Ninth Schedule	Standards for cosmetics (BIS)
11		Tenth Schedule Part-I	List of colourants allowed for use in cosmetic products as given under IS: 4707 (Part 1) of BIS
12		Tenth Schedule Part-II	List of colours permitted to be used in soaps

13	Eleventh Schedule	Good laboratory practices and requirements of premises and equipment
14	Twelfth Schedule	Extent and conditions of exemption of various class of cosmetics
15	Thirteenth Schedule	Word “Cosmetics” is omitted from Drugs and Cosmetics Rules 1945