

Key principles and features of INDIA's cosmetic regulations



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What is AIM of this Regulation



- The present contribution gives insight into the important cosmetics regulations in areas of premarket approval, ingredient control, and labelling and warnings with a special focus on cosmetics regulatory environments in the INDIA.

INTRODUCTION

Drugs and cosmetics acts, 1945

- The rules amend the existing Drugs and Cosmetics Rules, 1945, were first published (as draft rules) way back in February 2007. Subsequently after few amendments these were finalized as 'Drugs and Cosmetics (4th Amendment) Rules, 2010' on 19th May, 2010.
- Effective, April 1, 2013, India introduced a compulsory registration system for imported cosmetics products.

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Cosmetics Rule 2020

- The Cosmetics Rules, 2020 for the first time introduce the concept of a 'new cosmetic' which has been defined to mean 'a cosmetic that contains a novel ingredient that has not been used anywhere in the world or is not recognized for use in cosmetics in any national or international literature'
- Cosmetic Rules 2020 have been modified vide notification No. G.S.R. 763 (E) Dated 15-12-2020
 - These new rules mandate importers/ manufactures of a 'new cosmetics' to make an application and seek an approval from the Central Licensing Authority (CLA) before such a 'new cosmetics'
 - The manufacturer must comply with IS 4011:2018 standards for testing the safety of the 'new cosmetic'.



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What is COSMETICS

Definition of cosmetics according to Regulation:

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.

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Applicable Rules



Rule 129 :Registration of Cosmetics Products Imported into the Country

Rule 129 A: Form and manner of application for Registration certificate

Rule 129 B: Registration certificate for the import of Cosmetics manufactured by one Manufacturer

Rule 129 C:Grant of Registration Certificate

Rule 129 D:Duration of Registration certificate

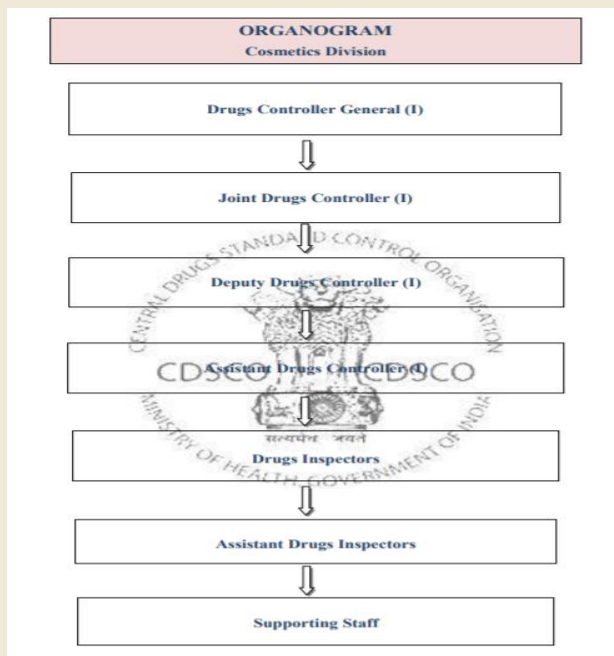
Rule 129 E:Suspension and Cancellation of Registration Certificate

Rule 129 F:Prohibition of Import of Certain Cosmetics

Rule 129 G:Standard for Cosmetics

Rule 129 H:Labeling and Packaging of Cosmetics

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Who can apply for Registration

- ✓ The Manufacturer himself having registered office in India
- ✓ The Authorized agent of Manufacturer
- ✓ The Subsidiary of Manufacturer
- ✓ Importer



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What is Authorized agent and process of appointing Authorized agent

- An "Authorized Agent" means a person or entity in India authorized by the manufacturer.
- The authorized agent will be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act in all respects.

Process of appointing Authorized agent:

- The authorization by a manufacturer to his authorized agent in India has to be documented by a Power of Attorney.
- The power of attorney shall be executed and authenticated either in India before a magistrate; or in the country of origin of the manufacturer before an equivalent authority or attested by the Indian Embassy in the manufacturer's country.

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Manufacture of Cosmetics

How to Obtain License:

Regulated under a system of inspection & licensing by State licensing Authority appointed by State Govt.
According to Drugs and Cosmetics Rules 1945 Schedule M II classifies cosmetics into 11 broad categories:

Powders	Preparation used for eye
Creams,Lotions,Emulsions,Pastes,cleansing milks,Shampoos,Shaving creams,hair oils etc	Aerosol
Nail Polishes and Nail lacquers	Alcoholic,Fragrance solutions
Lip Stick and Lip gloss Etc	Hair dyes
Depilatories	Tooth powder and Tooth pastes
	Toilet Soaps

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Manufacture of Cosmetics

How to Obtain License:

- Application has to be submitted in form 31 along with a license fee of Rs.2500 and an inspection fee of Rs 1000
- The manufacturer has to ensure that production is done in the presence of a competent and qualified staff
- Before granting license ,the licensing authority is required to order inspection of whole premises where the operations are to be carried out.
- Schedule M(II) mentions requirement of factory premises for manufacture of cosmetics

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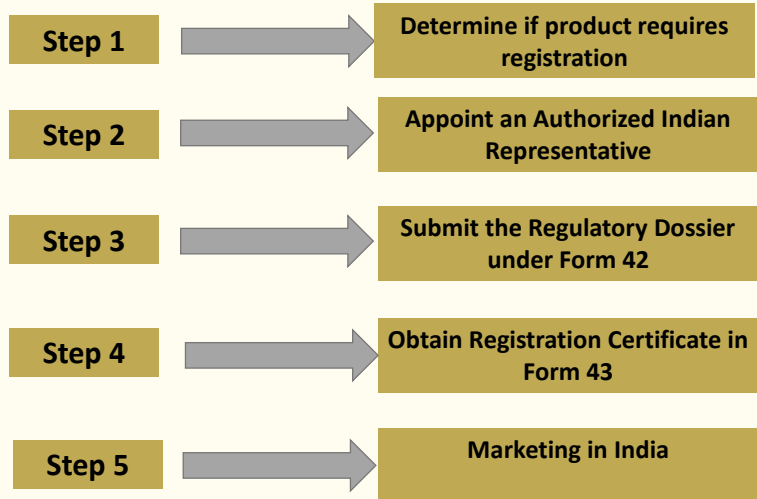
Import of Cosmetics:

Regulated under a system of registration by Central licensing Authority appointed by Central Government

The Drugs Controller General (India) functions as the Central Licensing Authority who grants the Import Registration Certificate and regulates the import of cosmetics into India vide Gazette notification G.S.R 763(E) under the provisions of Drugs and Cosmetics Act, 1940.

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Step by Step Process to register import of cosmetics:



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Requirements for import of Cosmetics in India:

- i. Covering letter by the applicant
- ii. Form 42
- iii. Treasury Challan
- iv. Power of Attorney
- v. Schedule D III
- vi. Original or a copy of the Label.
- vii. Free Sale Certificate (FSC)/Marketing Authorization letter/Manufacturing License, if any
- viii. Product specification and testing protocol.
- ix. List of countries where Market Authorization or import permission or registration was granted.
- x. Pack insert, if any
- xi. Soft copies of the information about the brands, products and manufacturer



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Cosmetics under mandatory List for Import

Product category with applicable BIS standards	
1. Skin Powder: IS 3959	8. Shampoos synthetic detergent based: IS 7884
2. Skin Powder for Infants: IS 5339	9. Hair creams: IS 7679
3. Tooth Powders: IS 5383	10. Oxidation hair dyes, liquid: IS 8481
4. Toothpastes: IS6356:2001	11. Cologne: IS 8482
5. Skin Creams: IS 6608:2004	12. Nail Polish: IS 9245
6. Hair oils: IS 7123	13. Aftershave Lotion: IS 9255
7. Shampoos soap based: IS 7669	14. Pomades and Brillinatine's: IS 9339

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Cosmetics under mandatory List for Import

Product category with applicable BIS Standards	
15. Depilatories: IS 9636	22. Transparent toilet soap: IS 11303
16. Shaving creams: IS 9740	23. Shaving soap: IS 9740
17. Cosmetic Pencils: IS 9832	24. Lip slave: IS 10284
18. Lipstick: IS 9875:1990	25. Powder Hair dye: IS 10250-26
19. Toilet soap: IS 2888	26. Bindi: IS 10998
20. Liquid Toilet soap: IS 4199	27. Kumkum Powder: IS 10999-28
21. Baby Toilet soap: IS 10523	28. Henna Powder: IS 11142

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Registration Cases-I

A) Registration Certificate (RC): Following documents are required to be submitted for grant of registration certificate:

Covering Letter	Pack insert
Power of Attorney	Manufacturing Licenses
Schedule D III	Free sale Certificate
List of Ingredients	Non-Animal Testing Declaration
Labels of proposed products in pdf form	Declaration for Heavy Meatal and
Specifications	Hexachlorophene content
Other documents (if any)	Application (Form-42)
Online Payment Receipt	

Note: The applicant has to provide the English translated version (from qualified translator) of all documents which are in any other foreign language.

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Registration Cases-II

B) Endorsement under issued Registration Certificate: Under issued RC of manufacturer, applicant can apply for adding Product categories, Product Variant, Manufacturing facility by means of endorsement. List of documents for Endorsement Certificate:

Issued RC	Original or a copy of the label
Power of Attorney	Free Sale certificate (FSC)/Marketing
Schedule D III	Authorization letter/ manufacturing License, if any
List of Ingredients	Product specification and testing protocol
Labels of proposed products in pdf form	List of countries where Market Authorization or import permission or registration was Granted
Specifications	Pack insert, if any
Soft copies of the information about the brands, products	

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Registration Cases-III

A) Re-registration/Renewal of RC: Renewal needs to be applied 6 months prior to the expiry of RC. List of documents for Re-registration/ Renewal certificate:

Power of Attorney in original	Copies of original RC and endorsement certificates that were granted earlier
Treasury Challan/ Online payment proof	Undertaking/ Self-declaration stating that there are no changes in the earlier shared information with respect to product details (like composition, test methods, specifications, label (complying Rule 148 of D&C Rules 1945) etc., constitution of the firm and sourcing location/site of the products
Dully filed and signed Form 42 along with the list of products to be renewed	
Certificate of the free sale/marketing Authorization Letter/Manufacturing License, if any	

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Labelling Requirement

Labelling requirements on Primary & Secondary Packaging:

1. Brand holder/Legal Exporter name and address as per registration certificate.
2. Manufacturer name and address as per registration certificate.
3. Complete Product name including brand name, description, variant/shade name and pack size such as 50 ml/100gm etc. as per registration certificate
4. Ingredients Mandatory in case pack size is more than 60 ml or 30grams
5. Directions to use if any
6. Batch No, Manufactured on [mm/yy] and use before date [mm/yy]



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Government Fee Structure

Fresh Registration:

From December'2018, Ministry of Health has increased the fees of Registration of Cosmetics from USD 250 to USD 2000 per category along with USD 50 each variant and Kit Name.

Endorsement:

New Product Category (each): USD 2000 each

Variant & Kit Name under registered product category (each additional): USD 50

Re-registration:

Each Product category getting Renewed*- USD 2000

Each additional variant & Kit Name getting Renewed- USD 50

* It depends on applicant if they want to Renew all Products/Variants or not.

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Validity & other key points

- Validity of Registration Certificate- 3 years from date of issue.
- Registration is Non- Transferable. Any change in the Name & address of the Registered Brand holder or Indian Importer means Fresh Registration
- Single application can be made in Form for any number of brands manufactured at one or more locations by a single manufacturer.
- Single registration certificate in Form 43 to be issued for any number of brands manufactured at one or more locations by a single manufacturer.

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Timeline required

- After Applicant filing 6-10 weeks: Under normal circumstances CDSCO processing time varies depending on the ongoing backlog of processing of the application.
- The notified/ published timeline by the Government under the Drugs and Cosmetics Act is 6 months

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Animal Testing:



Cosmetics that have been tested on animals are prohibited from import into India

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Restricted ingredients



The permitted Synthetic Organic Colors and Natural Organic Colors used in the Cosmetic shall not contain more than:

- 2 ppm (parts per million) of Arsenic calculated as Arsenic Trioxide.
- 20 ppm of lead calculated as lead.
- 100 ppm of heavy metals other than lead calculated as the total of the respective metals.

- Rule 145 of the Drugs and Cosmetics Rules prohibits use of lead and arsenic compounds in cosmetics for the purpose of coloring.
- Rule 135 prohibits import of cosmetics in which a lead or arsenic compound has been used for the coloring purpose.
- Rule 145 D and 135 A prohibits manufacture and import respectively of cosmetics containing mercury compounds

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Offences and Penalties

Contravention	Penalties
Import of spurious cosmetics or cosmetic containing any ingredient which is harmful to use	Imprisonment of term of 3 years which may extend to 5 years with fine of five thousand Rupees
Import of cosmetic whose import is prohibited	Imprisonment of term of 3 years which may extend to 5 years with fine of five thousand Rupees
Repeated offence of above two	Imprisonment of term of 5 years and fine which may extend upto 10 thousand years
Sale/manufacture of cosmetic which is not of standard or misbranded cosmetic	Imprisonment of term of 3 years which may extend to 5 years with fine of five thousand Rupees

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Conclusion

- All cosmetic products that are manufactured/imported for sale in India now need to be registered with the **Central Drugs Standard Control Organization (CDSCO)** which has been appointed as the licensing authority for the purpose of these rules
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- If not then product will be banned for its sale in Indian Market



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Thank you for your attention



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