

# Cosmetics Rules, 2020

**Presentation by**

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# Definition of Cosmetic:

- ▶ Cosmetic is defined under section 3(aaa) of the Drugs & Cosmetics Act, 1940.

# Ingredients of Definition:

- 1. An article.
- 2. Specific method applications.
  - (i) Rubbed.
  - (ii) Poured.
  - (iii) Sprinkled.
  - (iv) Spray.

# Purpose of Cosmetics:

1. Cleansing.
2. Beautification.
3. Promoting attractiveness.
4. Altering the appearances.

For Human Beings.

# **Status of Cosmetics Mfg. licenses Before 15.12.2020**

- License was issued on Form-32.

- The Cosmetics Rules, 2020 have been enforced w.e.f. 15.12.2020 vide GSR no. 763 dated 15.12.2020.

# Status of Old Cosmetics Licenses issued on Form-32

- Old license will remain valid till the expiry of that license.
- Before the expiry of license, firm should have to apply conversion of licenses from Form-32 to COS-8.

# Mandatory documents for applying for grant of new Cosmetics Mfg. License

- Form COS-5.
- Form COS-7.
- Challan of Rs. 10,000/- must be deposited (with every new cosmetic mfg. license upto 10 items in each cosmetic category can be applied without fee).



# List of documents required for issue of Additional items

- Application.
- Challan of Rs-500/- per applied item.
- Brand name proof or Non-resemblance undertaking.
- Agreement, if third party is involved.

# Data to be mentioned in the application of additional items

- Proper & correct name & address of the firm.
- Mfg. license number with its validity.
- Cosmetic Categories for which firm is licensed.

- Brief manufacturing process shall be mentioned.
- Use of the cosmetic must be mentioned.
- Direction of use must be mentioned.

# Proper format for applying additional items

Sr. No.	Name of Cosmetic	Name of Ingredients	Specifications or standards or Grade of ingredients	Percentage of Ingredients	Function of Ingredients

## **Requirement of format for additional items**

1. All columns should be filled properly.
2. The font used to fill the format should be legible. (It should not be too small).
3. There should be only one item on one page.
4. Each page of format should be signed by  
Authorised Signatory.

# Points to be considered while naming a Cosmetic

1. Name should not be misleading.
2. Name of cosmetic must not be confusing with the name of a drug.
3. Permission can be given with brand name.
4. The cosmetic shall be only for human use.
5. Cosmetic cannot not be for veterinary use.
6. Cosmetic cannot be intend for surface use (non-living).

# Name of Ingredients & Specifications

1. Specifications as per BIS standards shall be mentioned.
2. If not in BIS, then Inhouse.
3. Drug activity of the ingredients cannot be claimed.
4. All ingredients should be added in descending order of their strength.

# Water used in formulations

- Only 'purified water' can be used in ingredients.
- Following words cannot be used for 'water' in Cosmetics:-
  - a) aqua
  - b) tap water
  - c) for industrial use
- Percentage of water shall not be mentioned. It should be mentioned as sufficient quantity to make it 100%.



## Use of v/v and w/w

- For fluid measures final packing shall be volume i.e. ml.
- For solid measures final packaging shall be in grams.

# Format of Additional Items is below

List of additional items under the Mfg. licence No. ~~XXXXXXXXXX~~

S.No.	Name of Cosmetics	Name of Ingredients	Specifications or Standards or Grade of Ingredients	Percentage of Ingredients	Function of Ingredients
1	ONIOLIM SHAMPOO 10ml, 20ml, 50ml, 100ml, 150ml, 200ml, 250ml, 300ml, 500ml, 1000ml.	Sodium lauryl sarcosinate	In House	13%w/v	Thickner
		Decyl Glucoside	BIS 1165:2002	11%w/v	Cleanser
		Cocoglucoside	In House	11%w/v	Cleanser
		Polyquaternium 7	In House	4% w/v	Hair conditioner
		Glycerin	BIS : 1796 - 1986	2%w/v	Humectant
		Polyquaternium 73	In House	2% w/v	Hair conditioner
		Silicone Emulsion	BIS 14742:1999	2%w/v	Conditioner
		Onion Extract	In House	2%w/v	Astringent
		Aloe Vera Extract	In House	1%w/v	Moisturizer
		Ethylene Glycol Monostearate	BIS 5295:1985	1%w/v	Purifying
		Guar hydroxypropyltrimonium chloride	In House	0.5% w/v	Thickner
		Xanthan Gum	BIS 6356:2001	0.5%w/v	Thickner
		Polyquaternium 10	BIS 6608:2004	0.4% w/v	Hair conditioner
		Ethylenediamine tetra Acetate	BIS7220:1974	0.2%w/v	Chelating agent
		Perfume	In House	0.2%w/v	Fragrance
		Kathon CG	In House	0.1%w/v	Preservative
		Milk Protein	BIS 1165:2002	0.1%w/v	Conditioner
Lanolin Anhydrous	BIS 5340:1901	0.05%w/v	Lubricant		
Sodium hyaluronate	In House	0.05%w/v	Moisturizer		
Purified Water	BIS 13268(1992)	q.s.	Base		

BIS Number/Specification - BIS:7884:2004

USE: Revitalizing Cleanser of Hair & scalp.

Direction of use: Massage slowly into wet hair and lather on hair, rinse with water.

Manufacturing Process:

**Water Phase:**

Heat Purified Water to 80°C in main mixture & mix ingredient Glycerin, Ethylene Glycol Monostearate into it at the same temperature.

**Mixing Phase:**

Under slow stirring mix ingredients Sodium Lauryl Sarcosinate, Decyl Glucoside, Cocoglucoside, Polyquaternium 7, Polyquaternium 73, Guar hydroxypropyltrimonium chloride, Xanthan Gum, Polyquaternium 10, Kathon CG, Lanolin, Sodium Hyaluronate, and Milk Protein into it in same sequence.

Start cooling under slow stirring till 45°C add ingredients Onion Extract, Silicone Emulsion, Aloe Vera Extract, Ethylenediamine Tetra Acetate and Perfume into it.

After proper mixing give the sample to Quality Control Department for bulk testing.

After approval From Quality Control Department. Transfer the bulk for filling.

# claims not allowed while applying for items

- Bacteriostatic.
- Bactericidal.
- Antiseptic.
- Anti-aging.
- Anti-inflammatory.
- Drug claim.
- Disinfectant.
- Gold.
- Diamond.
- Fairness.
- Anti-microbial.
- Anti-acne.
- Medicinal property.
- Treatment of ailment.

# Preservatives are allowed as per BIS 4707 Part-I

**Few examples are as follows:**

- Methanol allowed up to 5%.
- Benzoic Acid up to 0.5%.
- Salicylic Acid up to 0.5%.
- Benzyl Alcohol up to 1%.
- Chlorhexidine up to 0.3%
- Phenoxyethanol up to 1%.
- Paraben up to 0.4%.
- Triclosan up to 0.3%.
- Benzalkonium chloride up to 0.1%.
- Oxalic acid, used in hair care upto 5%

## Hydrogen Peroxide:

- Hair 12<sup>0</sup>%
- Skin 04<sup>0</sup>%
- Nails 02<sup>0</sup>%
- Oral 0.1<sup>0</sup>%
- BKC – 3<sup>0</sup>% for hair & 0.1<sup>0</sup>% as preservative
- Picramic acid, picramate – hair care products - 0.6 percent
- Phenylenediamine – 6<sup>0</sup>% (for hair dye).

# Ethyl Alcohol

- It should be in de-natured form.
- All cosmetic products must use only denatured Ethyl Alcohol.
- Permission with Ethyl alcohol is not allowed.
- Hand sanitizer is not allowed as cosmetic, only hand wash is allowed under Cosmetics Rules.

# Colours to be used in Cosmetics

- Approved colour as per 10<sup>th</sup> Schedule Part-I will be used.
- Colour should not be mentioned in the composition list or in percentage.

- Mention of word Schedule Q is wrong as this has been deleted.
- For soap, colour can be used as per Part-II of 10<sup>th</sup> Schedule of Cosmetics Rules, 2020.
- No need of mentioning name and strength of the colour.



# Major changes in factory premises by Cosmetics Rules, 2020

- Coving in the manufacturing area.
- Calibration record of all the instruments.
- Bio waste management agreement.

# Banned Combination for Cosmetics

- **Sugam at 3462**
  - **Octinoxate+ Avobenzzone+ Oxybenzone**
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- **Sugam at 3621**
- **Octinoxate+Avobenzzone+Oxybenzone+Octocrylene**

# Testing of Cosmetics

- Every raw material and all finished goods should be tested.
- Testing can be done from outside labs (NABL accredited) is also permitted.

# Dog Shampoo

- No Cosmetics License can be issued on the above said product by FDA or any veterinary product.

# Manufacturing Record

- It should be maintained for 03 years.

# Categories of Cosmetics

## List of categories of cosmetics :

(A)	Powders
(B)	Skin Powder for Infants
(C)	Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.
(D)	Nail Polishes and Nail Lacquers.
(E)	Lipsticks and Lipgloss.
(F)	Depilatories
(G)	Preparations used for Eyes 1. Eyebrows, Eyelashes, Eyeliners. 2. Kajal and surma.
(H)	Aerosol
(I)	Alcoholic Fragrance solutions
(J)	Hair Dyes
(K)	Tooth-powders and toothpastes, etc. 1. Tooth-powder in General. 2. Toothpastes. 3. Tooth — Powder (Black).
(L)	Toilet Soaps

# Conversion of Cosmetics Manufacturing License from Form-32 to COS-8

**Subject:** Conversion of cosmetic manufacturing license from Form-32 to COS 8.

**1. List of documents for conversion of license:**

- a) Forwarding letter
- b) Challan form
- c) Undertaking
- d) Total number of items retained by the firm. (     ).
- e) Old license i.e. Form-32.

**2. Forwarding letter:-**

- a) Firm will apply for conversion of license after 15.12.2020.
- b) Challan form calculation:-
  - i) License fee =
  - ii) Item fee =
  - iii) Total Fee =

**3. Challan form:-**

- a) Submission of challan Online

**4. Undertaking:-**

- a) Firm will inform about any change in constitution.
- b) Firm will inform about any change in premises or shifting of section / area.
- c) Name of technical person of the firm.

Sr. No.	Name of the chemist
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**5. Cosmetics:-**

One consolidated list of items to be retained.

Sr. No.	Name of the product	Approval date
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# Areas required for different categories

## CATEGORIES

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	10
G.	Preparations used for eyes: Eyebrows, Eyelashes, Eyeliners, Kajal & surma	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



# Ayurvedic Cosmetics

- There is no provision for ayurvedic cosmetics under Drugs & Cosmetics Act, 1940 and Cosmetics Rules, 2020.

# Retention in Cosmetics license

## Cosmetic Manufacturing (Retention)

Sr. No.	Documents
1.	Request letter (application)
2.	Form Cos 5
3.	Form Cos 7
4.	Affidavit of proprietor/ Partner/ Director
5.	Affidavits of technical person
6.	Name and affidavit of authorized person
7.	Photocopy of previous license
8.	Challan details
9.	List of categories (As per Cosmetics Rules, 2020).
10.	Updated Fire NOC
11.	List of items to be retained.

## Details Of Firm (in application)

Sr. No.	Details
1.	Name of the firm
2.	Address
3.	Retention fee
4.	Item fee
5.	Total fee
6.	License no.
7.	License validity
8.	Whether any change in premises
9.	Whether any change in constitution

# Fee details Example

Sr. No.	Category	Total no. of items	Number of Free items	Fee Paid for items	Total fee paid
1	C	16	10	04	04 X 500
2	J	12	10	02	02 X 500

# Retention of cosmetics mfg. licenses

- Valid only for 05 years.

## Fee for additional section

- Rs. 10,000/-

**Note:** At one time as many as sections can be applied.

# No testing of cosmetics on animals

- As per Rule 37 (7).
- No person shall use any animal for testing of cosmetics.

# Voluntary indication of red/brown or green dot

- No such rule.
- Only voluntary declaration.
- As advisory notice issued by DCGI office on 10.09.2021.

# Neutral Code

- State Licensing Authority will issue neutral code as per rule 34 (10).



# Change in constitution

- Fresh license is required.
- Within 06 months.

# Requirement for GMP

- Mentioned in 7<sup>th</sup> Schedule of Cosmetics Rules, 2020.
- Now, schedule M2 has been deleted.

# Qualification of technical person

- Mentioned in Rule 26 of Cosmetics Rules, 2020.
- At least 01 person who is full time employee.
- Competent technical staff.
- Diploma in Pharmacy or Registered in Pharmacy Act or Passed intermediate examination with chemistry or hold bachelor degree in cosmetics technology.

# Provisions of loan license

- Apply on Form-Cos 6.

# Legal metrology (Packaged Commodities Rules, 2011)

- Provision of above said Rules are applicable for cosmetics.
- Cosmetics including creams, shampoo, lotions and perfumes (weight or measure).

Volume will be replaced by Weight.

# Sections for various Cosmetics

1. Misbranded: Section 17 C.
2. Adulterated: Section 17 E.
3. Spurious: Section 17 D.
4. Without license: Section 18 C.

# Penalties under Cosmetics

## **Section 27 A:**

Spurious or adulterated shall be punishable with imprisonment for a term which may extent to 3 years and fine.

## **Misbranded:**

Imprisonment for a term which may extent to 1 year or fine.

# Home made soaps

- Manufacturing license is required.



# Import of Cosmetics

- Import registration of cosmetics will be issued by CDSCO office.
- Import registration number shall be mentioned on the label on the unit pack as RC or RC number or Reg-Cert no along with the name of the importer.

- Stickering of imported cosmetics is allowed on the unit pack at the bonded warehouse.

# Labelling of Cosmetics

- Batch number:  
Batch No.  
B. No.  
Batch  
Lot No.  
Lot

# Labelling of Cosmetics

- Manufacturing license number:  
M. L. No.  
Mfg. Lic. No.

# Labelling of Cosmetics

- Expiry Date:  
Use before  
Date of Expiry (Month & Year)

# Room Fresheners

- Is not a cosmetic.

# Parametric released of cosmetics

Except:

1. Eye products.
2. Lipsticks.
3. Dental products.

# Testing of Cosmetics for microbiology

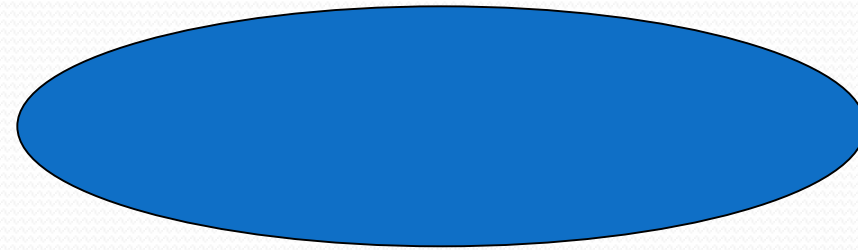
Following cosmetics shall be tested for microbiology limits:

1. Lipstic.
2. Tooth powder.
3. Tooth paste.
4. Skin Creams.
5. Hair creams.
6. Skin powder.
7. Skin Powder for infants.
8. Hair oils.



# Free Sale Certificate

- Issued by SLA.
- No FSC issued against NOC.



Thank You !!!