

Standardization of Skin Care Cosmetics in India

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Cosmetic regulations in India



- Cosmetics definition : Section 3 (aaa) of Drugs & 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

- Cosmetic Rules, 2020 :

- Manufacturing License – Prior permission from State Licensing Authority Form COS 8 / 9
- GMP – Seventh Schedule
- Cosmetics Mandatory BIS compliance – Ninth Schedule
- List of colourants – Tenth Schedule (IS 4707 part I + additional for soaps)
- Some safety aspects already built in Rules – e.g. Mercury < 1ppm
- Labelling – Rule 34
- New Cosmetic – definition and requirements on safety and efficacy as per Rule 32
- False or misleading claims – prohibited under rule 36



Objectives of the Regulations



Skin Care Cosmetics in India



- Beauty and personal care : market valued at **INR 129.76 B** in 2020 and growing at approx. 8-9 % annually.
- Ever evolving category and fast moving products
- Categorised as **Face, body, sun and other skin care** products
- Consumer trends : **seasonal, festive, sensorial, fashion** etc. drive the innovations
 - **Traditional products** : skin powders, skin cream, lipsticks etc.
 - **New age products** : lotions, gels, facewashes, sunscreens, serums, patches etc.
 - **Global trends** : Personalisation / Customisation
 - **Ongoing developments****newer formats**
- Quality and safety : Compliance to regulations of land + Manufacturers own responsibility

Skin care Cosmetic Products



Skin cream,
Moisturizers,
Skin Powders,
Depilatories

Cologne,
Shaving cream,
After-shave lotion,
Men care cosmetics



Foundation,
Face packs,
Facewashes, Kajal,
Eyeliners.....

Global
Harmonization
Imports / Export ...
Many new formats
evolving

Products then
&
Now



Face serums,
Sheet masks
Essences,
Skin patches

Skin gels,
Body lotions,
Sunscreens,
Gel-cremes,.....

Colour Cosmetics -
Lipsticks, Lip salve
Cosmetic pencils, Eye
shadow, Blushers,
Rouge, Mascara.....



Ninth Schedule – BIS Standard compliance

Ninth Schedule

(See rules 34(7), 39(1), 48)

Standards for cosmetics

Standards for cosmetics in finished form.— The following cosmetics in finished form shall conform to the Indian Standards specifications laid down from time to time by the Bureau of Indian Standards (BIS).

1. Skin Powders IS :3959

2. Skin Powder for infants IS :5339

3. Tooth Powder IS :5383

4. Toothpaste IS :6356

5. Skin Creams IS :6608

6. Hair Oils IS :7123

7. Shampoo, Soap – based IS :7669

8. Shampoo Specification IS : 7884

9. Hair Creams IS :7679

10. Oxidation hair dyes, Liquid IS :8481

11. Cologne IS :8482

12. Nail Polish (Nail Enamel) IS :9245

13. Aftershave Lotion IS :9255

14. Pomades and Brilliantines IS :9339

15. Depilatories Chemicals IS :9636

16. Shaving Creams IS :9740

17. Cosmetic Pencils IS :9832

18. Lipstick IS :9875

19. Toilet Soap IS :2888

20. Liquid Toilet Soap IS : 4199

21. Baby Toilet Soap IS : 10523

22. Shaving Soap IS :5784

23. Transparent Toilet Soap IS :11303

24. Lipsalve IS: 10284

25. Powder Hair Dye IS: 10350

26. Bindi (Liquid) IS : 10998

27. KumKum Powder IS: 10999

28. Henna Powder IS : 11142

29. Bathing Bars IS:13498

30. Sindoor IS: 14649

31. Liquid foundation make-up IS 14318

32. Coldwax-Hair remover IS : 15152

33. Face pack IS: 15153

34. Kajal IS : 15154

35. Oxidation Hair Dyes (Emulsion type) IS: 15205

36. Cream Bleach IS:15608

37. Hair Shampoo for Babies- Specification IS:17117

Note.—In case of any new or amended standards published by the Bureau of Indian Standards, the new or amended standards shall be mandatory to the cosmetics after six months from the date of publication.



Standards – Safety and Quality

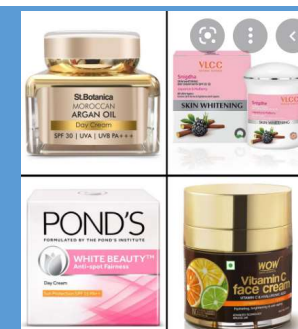
BIS Standards



- [IS 4707 Part 1](#) – Colourants, dyes and Pigments – GRAS Positive List
- [IS 4707 Part 2](#) – Other Cosmetic Ingredients (Prohibited and Restricted list) – GNRAS list
 - Annex A – List of Prohibited ingredients – not to be intentionally added.
 - Annex B – List of ingredients allowed with restrictions
 - Annex C – List of permitted Preservatives, with restrictions
 - Annex D – List of permitted UV filters, with restrictions
- [IS 4011](#) – Safety Standard (Animal testing prohibited, Non-animal alternates included, open for other approaches to be amended)
- [IS 14648](#) – Methods of Test for Microbiological Examination of Cosmetics And Cosmetic Raw Materials
- [IS 16913](#) – Heavy metals – newer techniques AAS etc.....
- RM standards and FG standards
- ISO standards and adoption EU updates / global updates

Skin cream BIS standard : IS 6608

Moisturisers, lightening, glow, anti-aging, anti-acne, sunscreen, anti-spots, beautification, BB, CC ...



IS 6608 : 2004

Table 1 Requirements for Skin Creams
(Clause 3.3)

Sl No.	Characteristics	Requirement	Method of Test, Ref to	
			Annex	IS No.
(1)	(2)	(3)	(4)	(5)
i)	Thermal stability	To pass the test	A	
ii)	pH ¹⁾	4.0 to 9.0	B	
iii)	Total Fatty substance content, percent by mass, <i>Min</i>	5.0	C	
iv)	Total residue, percent by mass, <i>Min</i>	10	D	
v)	Heavy metals ²⁾ (as Pb), parts per million, <i>Max</i>	20	E	
vi)	Arsenic ²⁾ (as As ₂ O ₃), parts per million, <i>Max</i>	2	F	
vii)	Microbial content/limit			
	a) Total viable count cfu/g	Not more than 1 000		14648
	b) Gram Negative pathogens	Less than 10		14648

¹⁾ For creams based on beeswax and borax, the pH shall be between 5.0-10.0

²⁾ If all the raw materials requiring test for heavy metals and arsenic have been so tested and comply with the requirements, then the manufacturer may not test the finished cosmetic for heavy metals and arsenic.

3.1 Description

The skin cream shall be in the form of a thick emulsion or unctuous mass with a pleasant odour. It shall be white or pigmented or of uniform colour.

Safety – HM, As, Microbiology

- A1 Jan 2015 : Foot note 2 deleted
- A2 Nov 2017 : Inclusion of 3.2.3

For safety evaluation of novel ingredients used in formulation of skin creams, the skin cream shall comply to IS 4011

Quality – Thermal stability, pH, TFM, Total residue Revised in due course, but still is restrictive

Skin cream BIS standard : IS 6608



Additional requirements for ECO mark

- Ingredient compliance as per IS 4707 Part 1 and 2
- List of key ingredients declared in descending order on product pack
- Product shall not be manufactured from carcinogenic ingredients
- Manufacturer to submit environmental consent clearance from SPCB – water, air , environment
- Specific requirements – safety as per IS 4011, Heavy metals – Total <20ppm (as pb), As < 2ppm

Lipstick BIS standard : IS 9875



Table 1 Requirements for Lipstick
(Clause 3.3)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Softening point, <i>Min</i>	55°C	B-2
ii)	Microbiological content/limit total viable count, cfu/g	Not more than 1 000	IS 14648
iii)	Gram negative pathogens	Absent	do
iv)	Rancidity (peroxide number), <i>Max</i>	10	B-3
v)	Breaking load value, g, <i>Min</i> ¹⁾	200	B-4
vi)	Freedom from grittiness	Pass the test	B-5
vii)	Pay off test, g/cm ²	0.01–0.25	B-6
viii)	Arsenic (as As ₂ O ₃), parts per million, <i>Max</i>	2	B-7
ix)	Heavy metals (as Pb) parts per million, <i>Max</i>	20	B-8

¹⁾ The breaking load value of 200 g (*Min*) may not applicable for finner lipsticks for which the values range can be as agreed to between the supplier and the buyer.

3.1 Description

The lipstick shall be firm but not brittle in texture. It shall have an attractive appearance, pleasant taste and feel on the lips and shall be reasonably free from sweating, bloom and rancidity.

Safety – HM, As, Microbiology

For safety evaluation of novel ingredients used in formulation shall comply to IS 4011

Quality – Softening point, rancidity, breaking load, freedom from grittiness, pay-off

Many are subjective parameters and often restrict innovations

Different formats available today ... liquid lipsticks, lip gloss, lip paint, crayons, matte, thin lip colours, chap sticks, roll ons etc.....

WIP BIS standards

Skin gel, Skin lotion, Sunscreen products, Face washes, Face scrub



BIS is constantly adding newer standards :

- Additional vertical standards (as newer formats evolve) (suggest to make voluntary or avoid)
 - New Method of test standards (e.g. For HM- AAS adopted, For Sunscreens, SPF / PA / water immersion - ISO standard is the globally accepted standard and also being adopted by BIS)
 - Updating additional methods in existing BIS
- Time consuming though (suggest alternates to be allowed even if not included in th standard per se)

Safety – HM, As, Microbiology – Need to be applicable for all products

For safety evaluation of novel ingredients used in formulation of skin creams, the skin cream shall comply to IS 4011

Quality – Suggested for manufacturer to define and control, as per consumer needs.

Global Scenario



- Most of countries including EU, US, ASEAN do not have product standards,
- They only have safety requirements / ingredients restrictions etc.
- Hence innovations and technology advancements are easy, faster
- Consumers can be benefitted. 
- Manufacturers are responsible for product quality and consumer safety.

CONSUMERS ARE KING!!!....Quality is best left to them to decide

Standards and Challenges : Horizontal standards Concept

Skin powder
Skin cream
Lipstick
Depilatory...

- Often Archaic (thermal stability / colourimetry...)
- Fast paced Innovations face challenges
- Deprive consumers of advanced technologies
- Restrict the business/Economy
- Performance also evolves, consumer oriented



- **APPLICABLE FOR ALL COSMETICS**
- **ENSURE SAFETY OF CONSUMERS**

Ingredients
Restrictions

Unintended
Traces

Allergen
Declarations

Microbial
Limits

GMP

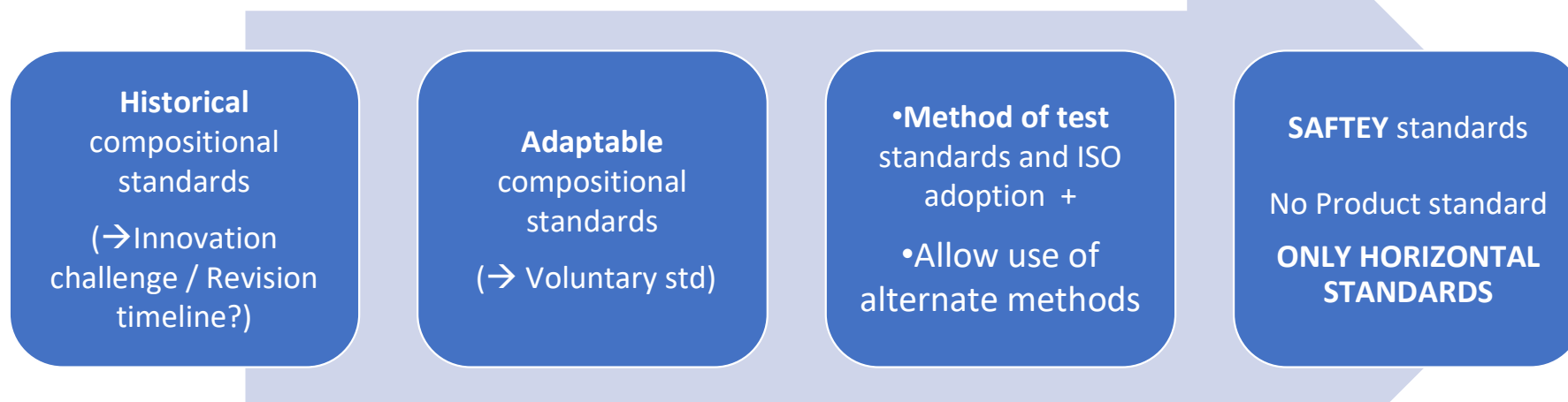
Labeling

Precautions

Evolution of Product standards in Cosmetics



- **CONSUMER SAFETY IS PRIME Safety standards a MUST.**



- Faster revision of BIS standards is highly recommended – Old standards / analytical techniques / formats often outdated.
- Business has to ensure good quality products for the brand to grow.
- “No Vertical Standard” : freedom to innovate = diverse consumer needs, yet safety addressed by Horizontal Standards

Summary

COSMETICS are well REGULATED in India today

Appreciate Authority in supporting updation of regulations and rules over the years

BIS standards are mandated for Finished products through Cosmetic Rules 2020 and cover safety, quality

Horizontal standards / Safety standards already exists under BIS but can increase the same going forward.

Quality – is important, but should be left to consumersneed to move towards next generation approaches

CONSUMERS are KINGS !!! SAFE but variety, innovations MUST

THANKS