

Analytical cosmetics

BIS specification and analytical methods for shampoo, skincream and toothpaste.

Why are Cosmetics regulated?

- To ensure that the cosmetics sold in India are **safe, effective and conform** to state quality standards.

Cosmetics Regulation in India

- Cosmetic Legislation is driven through **Drugs and Cosmetics Act**, and the legislative body is CDSCO (Central Drugs Standards Control Organization) headed by **Drugs controller general of India**.



Cosmetics Regulations

Cosmetics products in **India** are regulated under the Drugs and **cosmetics** Act 1940 and Rules 1945 and **Labelling Declarations** by **Bureau of Indian Standards (BIS)**.

BIS sets the **standards** for **cosmetics** for the products which are under Schedule 'S' of the Drugs and **Cosmetics** Rules 1945.

BIS specification



BUREAU OF INDIAN STANDARDS

BIS –The National Standards Body Of India Functioning Under **Ministry Of Consumer Affairs** and leaders in all matters concerning standardization, certification & quality.

- ✓ Indian Standards Institution (ISI) in 1947
- ✓ Bureau of Indian Standards(BIS) Act 1986
- ✓ Bureau of Indian Standards 1 April 1987



Objectives of BIS specifications



- Main objective is harmonious development of activities of standardization, marking and quality certification
- Providing new thrust to standardization and quality control
- Evolving the national strategy for according recognition to standards and integrating them with growth and development of industrial production and exports
- Product specification, method of test, codes of practices, terminologies, basic standards (17000 standards)



Main activities of BIS specifications



- Standards Formulation
- Certification
 - ✓ Product
 - ✓ Hallmarking of Gold Jewelry
 - ✓ Quality Management System
 - ✓ Environmental Management Systems
 - ✓ Occupational Health and Safety Management System
 - ✓ Hazard Analysis and Critical Control Points
 - ✓ Imported Products FMCS
- Laboratory Management
- International Activities
- Training Services
- Others
 - ✓ Information Services
 - ✓ Consumer Affairs & Standards Promotion
 - ✓ Sale of Standards



Indian Standards on Cosmetics



30 Indian Standards on finished cosmetics are listed in Schedule 'S' of the Drugs and Cosmetics Act 1940 and Rules, 1945 as per which the cosmetics in their finished form (manufactured or imported) need to conform to these Specifications.



List of Indian Standards referred in Schedule S of the Drugs and Cosmetics Rules, 1945



1. Skin powders (IS 3959)
2. Skin powders for infants (IS 5339)
3. Tooth Powder (IS 5383)
4. Tooth paste (IS 6356)
5. Skin Creams (IS 6608)
6. Hair Oils (IS 7123)
7. Shampoo, Soap-based (IS 7669)
8. Shampoo, Synthetic-Detergent based (IS 7884)
9. Hair Creams (IS 7679)
10. Oxidation hair dyes, Liquid (IS 8481)
11. Cologne (IS 8482)
12. Nail polish (IS 9245)
13. After shave 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. Lipsalve (IS 10284)
20. Powder hair dyes (IS 10350)
21. Bindi (Liquid) (IS 10998)
22. Kum kum powder (IS 10999)
23. Henna powder (IS 11142)
24. Sindoor (IS 14649)
25. Liquid foundation make-up (IS 14318)
26. Cold Wax-Hair remover (IS 15152)
27. Face pack (IS 15153)
28. Kajal (IS 15154)
29. Oxidation Hair Dyes (Emulsion type) (IS 15205)
30. Cream Bleach (IS 15608)



IS 7884 : 2004

Shampoo Surfactant Based- Specification

This standard prescribes the requirements and methods of sampling and test for shampoo based on surfactants.



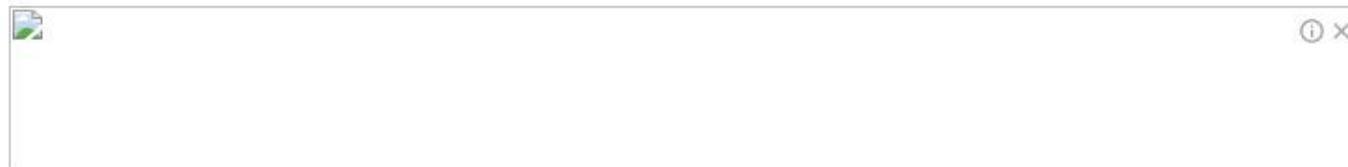
<i>IS No.</i>	<i>Title</i>
321 : 1964	Absolute alcohol (<i>revised</i>)
1070 : 1992	Reagent grade water (<i>third revision</i>)
3958 : 1984	Methods of sampling cosmetics (<i>first revision</i>)
4011 : 1997	Methods of test for safety evaluation of cosmetics (<i>second revision</i>)
4707	Classification of cosmetic raw materials and adjuncts:
(Part 1) : 2001	Dyes, colours and pigments (<i>second revision</i>)
(Part 2) : 2001	List of raw materials generally not recognized as safe for use in cosmetics (<i>second revision</i>)

Shampoo Surfactant Based- Specification

Sr. No.	Requirements	
1	Description	The Shampoo shall be in a form liquid, emulsion or a paste . It may be colored and perfumed.
2	Physical Characteristics	Shampoo when visually examined shall be free from any sediments . If it is in the form of any emulsion, it should be stable. Shampoo in the form of paste shall be free from any agglomerated particles.
3	Ingredients	Raw Material should conform to the requirements prescribed in the relevant Indian standards, where such standards exist.
3.1	Dyes	The Dyes used shall comply with the provisions of IS 4707 (Part 1), subject to the provision of Schedule Q of the Drugs and Cosmetics Act, issued by the Government of India.
3.2	Other Ingredients	Other Ingredients shall comply with the provisions of IS 4707 (Part 2)
3.3.	List of Ingredients used conventionally in formulation of Shampoo	Annexure A
3.4	Compliance with Table 1 When tested in accordance with the method prescribed.	Annex

Shampoo Surfactant Based- Specification

Sr. No.	Requirements
3.5	Additional Requirements for ECO Marks
3.5.1.1	The product shall conform to the requirements for quality, safety and performance.
3.5.1.2	All the ingredients that goes into formulation of cosmetics shall comply with the provisions of IS 4707 Part 1 and IS 4707 Part 2.
3.5.1.3	The product package shall display a list of key ingredients in descending order of the quantity present.
3.5.1.4	The product shall not be manufactured from any carcinogenic ingredients





3.5.1.5 Additional Requirements for ECO Marks

3.5.1.5 The manufacturer shall produce to BIS environmental consent clearance from the concerned State Pollution Control Board as per the provisions of the *Water (Prevention and Control of Pollution) Cess Act, 1977* and the *Air (Prevention and Control of Pollution) Act, 1981* along with the authorization, if required under the *Environment (Protection) Act, 1986* and the Rules made there under, while applying for ECO Mark. Additionally, provisions of the *Drugs and Cosmetics Act, 1940* and the Rules thereunder shall also be complied with.



3.6 Specific Requirements

3.6 Specific Requirements

3.6.1 Product shall be dermatologically safe when tested as per IS 4011.

3.6.2 Biodegradable agents wherever used in cosmetic formulations shall be as per their limit finalized for synthetic detergents for ECO Mark by the technical committee.

3.6.3 Heavy metals calculated as lead (Pb) and arsenic (As_2O_3) shall not exceed 20 and 2 ppm, respectively when tested by the respective method prescribed in relevant Indian Standards.

3.6.4 The material for product packaging shall meet the parameters evolved under the scheme of labelling environment friendly packaging/packaging materials.



4. PACKING AND MARKING

4.1 Shampoo shall be packed in glass or plastic containers or any other suitable containers.

4.2 The containers shall be legibly marked with the following information:

- a) Name of the material,
- b) Manufacturer's name and/or his recognized trade-mark, if any;
- c) Net content in volume for liquids and emulsions and in mass for pastes;
- d) Month and year of manufacturing/packing;
- e) Batch or Lot number, in code or otherwise.
- f) 'Best use before. . . .' (month and year to be declared by the manufacturer);

NOTES — This requirement is exempted:



4.2.1. BIS Certification Marking

4.2.1 *BIS Certification Marking*

The containers may also be marked with the Standard Mark.

4.2.1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

4.2.2 If the product is covered under ECO Mark (optional), it shall be suitably marked with ECO Mark logo besides Standard Mark. The label may clearly specify that ECO Mark is applicable to the contents or the package or both, as case may be. If the product package is not separately covered under ECO Mark Scheme, it shall be clearly mentioned on the product that ECO Mark label is applicable to contents only.



5. SAMPLING

5.1 Representative samples of the material shall be drawn as prescribed in IS 3958.

5.2 Tests for all the requirements shall be carried out on a composite sample.

5.3 The shampoo shall be taken to have conformed to this standard if the composite sample passes all the tests.

Annexure A :List of Raw Material Used in the formulation of surfactant based Shampoo

A-1 DETERGENTS

- a) Sodium or potassium or ethanolamine salts of lauryl sulphonic acid,
- b) Lauryl ether sulphates,
- c) Sulphated monoglycerides,
- d) Sodium alkyl sulfo-acetate,
- e) Alkyl benzene polyoxyethyl sulphonates,
- f) Sodium n-lauryl sarcosinate,
- g) Sodium alpha olefin sulphonates, and
- h) Other synthetic detergents.

A-2 FOAM STABILIZERS

- a) Ethanolamides or isopropanolamides of fatty acids,
- b) Amine oxides,
- c) Cocobetaines, and
- d) Cocoamidopropyl betaines.

Annexure A :List of Raw Material Used in the formulation of surfactant based Shampoo

A-3 CHELATING AGENTS

- a) Sodium polyphosphates, and
- b) Sodium salts of ethylenediamine tetra-acetic acid.

A-4 SOLUBILIZING AGENTS

- a) Urea,
- b) Aliphatic alcohols,
- c) Sodium toluene sulphonate, and
- d) Sodium xylene sulphonate.

A-5 PRESERVATIVES

- a) Alcohols,
- b) Formaldehyde,
- c) Esters of phydroxybenzoic acid,
- d) Sorbic acid, and
- e) Imidozolidinyl urea.

A-6 OPACIFYING AGENTS

- a) Higher fatty alcohols,
- b) Ethylene/Propylene glycol stearates,
- c) Mono and di-stearates of glycerol,
- d) Zinc, calcium and magnesium salts of fatty acids,
- e) PEG-distearate 6000, and
- f) Polyacrylates.

A-7 INORGANIC SALTS

- a) Sodium chloride,
- b) Sodium sulphate,
- c) Sodium phosphate,
- d) Ammonium sulphate,
- e) Ammonium phosphate, and
- f) Ammonium chloride.

Annexure A :List of Raw Material Used in the formulation of surfactant based Shampoo

A-10 OTHER GROUPS OF INGREDIENTS

- a) Perfumes,
- b) Dyes,
- c) Conditioning agents,
- d) Quaternary compounds,
- e) Vitamins,
- f) Vegetable oils,
- g) Silicones,
- h) Proteins, and
- j) Sunscreens, etc.

A-8 EMOLLIENTS

Lanolin and its derivatives.

A-9 THICKENING AGENTS

- a) Sodium carboxymethyl cellulose,
- b) Methyl cellulose,
- c) Methyl isopropyl cellulose, and
- d) Guar gum.

ANNEX B

[Table 1, Sl No. (i)]

DETERMINATION OF NON-VOLATILE ALCOHOL SOLUBLE MATTER

B-1 GENERAL

This method determines the amount of non-volatile alcohol soluble matter in surfactant based shampoos.

B-2 REAGENTS

B-2.1 Ethyl Alcohol — Neutral, conforming to IS 321.

B-2.2 Methyl Red Indicator Solution — Dissolve 0.1 g of methyl red in 300 ml of ethyl alcohol and 200 ml of water.

B-2.3 Potassium Chromate Solution — 10 percent solution.

B-2.4 Nitric Acid Dilute — 1 : 4 (v/v).

B-2.5 Silver Nitrate Solution — 0.1 M.

B-3 PROCEDURE

B-3.1 Weigh accurately about 10 g of the sample into a 150 ml beaker. Evaporate on a steam-bath to almost complete dryness. Digest with 50 ml of 96 percent ethyl alcohol by heating on a steam bath for about 2 min. Filter the hot alcoholic solution through a sintered glass filter funnel fitted to a Buchner flask to which suction is applied. Wash the beaker and the residue in the sintered glass funnel 5 times with 30 ml portions of hot ethyl alcohol.

B-3.2 Transfer the filtrate in the Buchner flask to a

Mass, percent
of residue (Y) =
$$\frac{\text{Mass of residue obtained} \times 100}{\text{Mass, in g, of the material taken for tes}}$$

B-3.3 Dissolve the residue in 50 ml of distilled water and add to it 2 drops of methyl red indicator solution. If the solution is yellow in colour, neutralize it by adding dilute nitric acid drop by drop to get pink colour. Titrate the solution with silver nitrate solution using 2.5 ml of potassium chromate solution as indicator, till a brown colour is obtained. Carry out a blank determination using the same quantity of all reagents except the sample.

B-3.4 Calculate the chloride content in shampoo in terms of molecular mass of sodium chloride (X) in percent by the formula:

$$\text{Sodium chloride in percent (X)} = \frac{V \times 0.5844}{M}$$

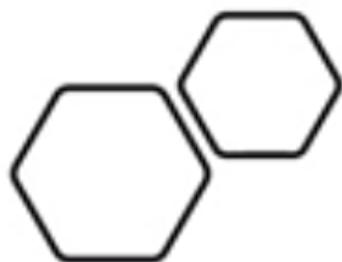
where

V = volume, in ml, of standard silver nitrate solution required for the material minus volume, in ml, of standard silver nitrate solution required for the blank; and

M = mass, in g, of the material taken for test.

B-3.5 Calculation

Annexure C



Determination of pH

pH meter equipped with glass rod. Determination of pH to be done at 27°C



Annexure D

Determination of Foam Height

- Requirements of Shampoos Surfactants based.

Table 1 Requirements for Shampoo, Surfactant Based

Sl No.	Characteristic	Requirement	Method of Test, Ref to Annex
(1)	(2)	(3)	(4)
i)	Non-volatile alcohol soluble matter; percent by mass, <i>Min</i>	10	B
ii)	<i>pH</i>	4.0 to 9.0	C
iii)	Foam height for two percent solution, <i>Min</i>	150 mm	D

Annexure E

Ideal Properties of a Shampoo

- Ease of Application
- Rinsing
- Easy Wet Combing
- Manageability
- Luster
- Body
- Fragrance
- Low Level of Irritation
- Well Preserved
- Good Stability
- Economical

BIS requirements of Shampoos

Characteristics	Requirements
The pH of shampoo should be	Between 4.0 to 9.0
The maximum heavy metals (lead) permitted in shampoos	20 ppm
The maximum arsenic (As_2O_3) permitted in shampoos is	2 ppm
List of dyes, colours and pigments permitted to be used in cosmetics is under	Schedule Q of Drug and Cosmetics Act
Non-volatile alcohol soluble matter, percent by mass, Min	10
Foam height for 2 % solution, Min	150 mm

