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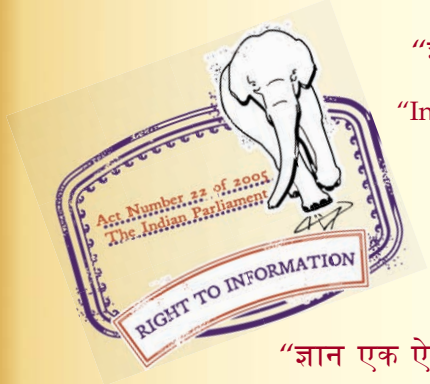
IS 6608 (2004): Skin Creams [PCD 19: Cosmetics]



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"Knowledge is such a treasure which cannot be stolen"

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भारतीय मानक

स्किन क्रीम — विशिष्टि

(दूसरा पुनरीक्षण)

Indian Standard

SKIN CREAMS — SPECIFICATION

(Second Revision)

ICS 71.100.70

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

December 2004

Price Group 4

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was originally issued in 1972 and first revised in 1978. The Sectional Committee responsible for its formulation has decided to revise it in the light of experience gained since its publication. In order to allow new innovations in skin creams, requirement limit of total fatty substance content has been lowered in this revision, since the cosmetic industry has successfully produced acceptable creams with lesser content of fatty matter making it less sticky and oily on skin. Skin creams should not be the cause of bacteriological and fungal contamination. In this revision, a requirement limit for microbial content has been specified, while requirement of *p*H has been modified. Important marking requirements for best use before, list of key ingredients on containers and ECO Mark certification have also been incorporated in this revision.

This standard includes various types of creams, such as vanishing cream, cold cream, cleansing creams, moisturizing cream, sports creams, foundation creams, hand creams, emollient creams and general purpose creams.

Specialized skin creams, such as antiperspirant creams, whitening creams, acne creams, hormone creams etc. which have an effect on the physiological functions of the body or for which therapeutic claims are generally made, are not included in this standard.

No stipulations have been made in this standard regarding the composition of skin creams. However, it is necessary that the raw materials used are such that in the concentrations in which they would be present in the finished skin cream, after interaction with other raw materials used in the formulation, are free from any harmful effects. For determining the dermatological safety of a new formulation, or of a new raw material used in an old formulation, reference may be made to IS 4011 : 1997 'Methods of test for safety evaluation of cosmetics (*second revision*)'. It shall be the responsibility of the manufacturers of skin creams to satisfy themselves of the dermatological safety of their formulation before releasing the product for sale.

A scheme for labelling environment friendly products known as ECO Mark (optional) has been introduced at the instance of the Ministry of Environment and Forests (MEF), Government of India. The ECO Mark is being administered by the *Bureau of Indian Standards Act*, 1986 as per the Resolution No. 71 dated 21 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with ECO logo, it shall also carry the Standard Mark of BIS besides meeting additional environment friendly requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the BIS monogram ISI and the ECO logo. Requirements for the ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

Composition of the Committee responsible for formulation of this standard is given in Annex G.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SKIN CREAMS — SPECIFICATION

(Second Revision)

1 SCOPE

This standard prescribes the requirements and the methods of sampling and test for skin creams.

2 REFERENCES

The following standards are necessary adjuncts to this standard. The standards contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
265 : 1993	Hydrochloric acid (*fourth revision*)
1070 : 1992	Water reagent grade (*third revision*)
2088 : 1983	Methods for determination of arsenic (*second revision*)
3958 : 1984	Methods of sampling cosmetics (*first revision*)
4011 : 1997	Methods of test for safety evaluation of cosmetics (*second revision*)
4707	Classification of cosmetic raw materials and adjuncts:
(Part 1) : 2001	Dyes, colours and pigments (*second revision*)
(Part 2) : 2001	List of raw materials generally not recognized as safe for use in cosmetics (*second revision*)
14648 : 1999	Methods of test for microbiological examinations of cosmetics

3 REQUIREMENTS

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.

3.2 Ingredients

Unless specified otherwise, all the raw materials used in the manufacture of skin creams shall conform to the requirements prescribed in the relevant Indian Standards where such standards exist.

3.2.1 The dyes, colours (pigments, lakes etc) if used in the manufacture of skin creams shall comply with IS 4707 (Part 1) subject to the provision of schedule Q of *Drugs and Cosmetic Act*, issued by the Government of India.

3.2.2 Other ingredients shall comply with the provisions of IS 4707 (Part 2).

3.3 The material shall also comply with the requirements given in Table 1 when tested as prescribed in col 4 of the Table 1.

4 ADDITIONAL REQUIREMENTS FOR ECO MARK (OPTIONAL)

4.1 Requirements for quality, safety and performance prescribed under **4.1.1** to **4.1.4**.

4.1.1 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2).The product shall also meet specific requirements as given in the standard.

4.1.2 The product package shall display a list of key ingredients in descending order of quantity present.

4.1.3 The product shall not be manufactured from any carcinogenic ingredients.

4.1.4 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 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.

4.2 Specific Requirements

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

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

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)	*p*H[1]	4.0 to 9.0	B	
iii)	Total Fatty substance content, percent by mass, *Min*	5.0	C	
iv)	Total residue, percent by mass, *Min*	10	D	
v)	Heavy metals[2] (as Pb), parts per million, *Max*	20	E	
vi)	Arsenic[2] (as As_2O_3), parts per million, *Max*	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 *p*H 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.

5 PACKING AND MARKING

5.1 Packing

The material shall be packed in suitable well-closed containers.

5.2 Marking

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 mass of the material;
d) Month and year of manufacturing/packing;
e) Batch or lot number, in code or otherwise;
f) Expiry date or "Best use before. . . ." (month and year to be declared by the manufacturer);

NOTE — This requirement is exempted:
1 In case of pack sizes of 10 g/25 ml or less, and
2 If the shelf life of the product is more than 24 months.

g) List of key ingredients; and

NOTE — This is exempted in case of pack sizes of 30 g/60 ml or less.

h) Any other information required by statutory authorities.

5.2.1 The containers may also be marked with the Standard Mark.

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 the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5.2.2 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.

6 SAMPLING

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

6.2 Tests for all the characteristics shall be carried out on the composite sample as per methods referred under col 4 and 5 of Table 1.

6.3 The material shall be taken to have conformed to the standard if the composite sample passes all the tests.

7 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

ANNEX A

[*Table* 1 *Sl No.* (i)]

TEST FOR THERMAL STABILITY

A-1 APPARATUS

A-1.1 A humidity chamber/incubator controlled at 60 to 70 percent relative humidity and 45 ± 1°C.

A-1.2 Clear glass bottles of around 30 ml capacity with plug and screw on cap for proper closure.

A-2 PROCEDURE

With the help of spatula, insert the cream into glass bottle and tap it to settle to the bottom. Fill up to two-third capacity of bottle and insert plug and tighten the cap. Keep the filled bottle erect in side the incubator at 45 ± 1 °C for 48 h.

The sample shall be taken to have passed the test, if on removal from the incubator shows no oil separation or any other phase separation.

ANNEX B

[*Table* 1 *Sl No.* (ii)]

DETERMINATION OF *p*H

B-1 APPARATUS

A *p*H meter, preferably equipped with a glass electrode.

B-2 PROCEDURE

B-2.1 For Oil-in-Water Emulsion Creams

Weigh accurately 5±0.01 g of the cream in a 100 ml beaker. Add 45 ml of water and disperse the cream in it. Determine the *p*H of the suspension at 27°C using the *p*H meter.

B-2.2 For Water-in-Oil Emulsion Creams

Weigh 10 g of the cream to the nearest 0.1 g. Add 90 ml of rectified spirit previously adjusted to *p*H 6.5 to 7.0. Warm, if necessary to 45°C and stir thoroughly for 15 min. Filter the alcoholic layer through a filter paper and measure the *p*H of the filtrate at 27°C using the *p*H meter.

ANNEX C

[*Table* 1 *Sl No.* (iii)]

DETERMINATION OF TOTAL FATTY SUBSTANCE CONTENT

C-0 PRINCIPLE OF THE METHOD

The emulsion is broken with dilute mineral acid and the fatty matter is extracted with petroleum ether. It is weighed after removal of the solvent.

C-1 REAGENTS

C-1.1 Dilute Hydrochloric Acid — 1:1 (*v*/*v*).

C-1.2 Petroleum Ether (60-80°C)

C-1.3 Methyl Orange Indicator Solution — Dissolve 0.1 g of methyl orange in 100 ml of water.

C-1.4 Sodium Sulphate — Desiccated.

C-2 PROCEDURE

Weigh accurately about 2 g of the material into a conical flask, add 25 ml of dilute hydrochloric acid, fit a reflux condenser into the flask, and boil the contents until the solution is perfectly clear. Pour the contents of the flask into a 300 ml separating funnel and allow it to cool to room temperature. Rinse the conical flask with 50 ml of petroleum ether in portions of 10 ml. Pour the petroleum ether rinsings into the separating funnel, shake the separating funnel well and leave until the layers separate. Separate out the aqueous phase and shake it out with 50 ml portions of petroleum ether twice. Combine all the ether extracts and wash them with water until free

of acid (when tested with methyl orange indicator solution). Filter the petroleum ether extracts through a filter paper containing sodium sulphate into a conical flask which has been previously dried at a temperature of 90 ± 2°C and then weighed. Wash the sodium sulphate on the filter with petroleum ether and combine the washings with filtrate. Distil off the petroleum ether and dry the material remaining in the flask at a temperature 90 ± 2°C of to constant mass.

C-3 CALCULATION

$$\text{Total fatty substance, percent by mass} = 100\,\frac{M_1}{M_2}$$

where

M_1 = mass in g of the residue, and

M_2 = mass in g of the material taken for the test.

ANNEX D

[*Table* 1 *Sl No.* (iv)]

DETERMINATION OF RESIDUE

D-1 PROCEDURE

D-1.1 Weigh accurately about 5 g of the material in a weighed, clean and dry squat form weighing bottle and dry to constant mass at 105 ± 1°C. Cool in a desiccator and weigh.

D-1.2 Calculation

$$\text{Residue percent by mass} = 100\,\frac{M_1}{M_2}$$

where

M_1 = mass in g of the residue, and

M_2 = mass in g of the material taken for test.

ANNEX E

[*Table* 1, *Sl No.* (v)]

TEST FOR HEAVY METALS

E-1 OUTLINE OF THE METHOD

The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

E-2 APPARATUS

E-2.1 Nessler Cylinders — 50-ml capacity.

E-3 REAGENTS

E-3.1 Dilute Hydrochloric Acid — Approximately 5 N.

E-3.2 Dilute Acetic Acid — Approximately 1 N.

E-3.3 Dilute Ammonium Hydroxide — Approximately 5 N

E-3.4 Hydrogen Sulphide Solution — Standard.

E-3.5 Standard Lead Solution — Dissolve 1.600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and dilute again to 1 000 ml with water. One millilitre of this solution contain 0.01 mg of lead (as Pb).

E-4 PROCEDURE

Weigh about 2.000 g of material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600°C to constant mass. Add 3 ml of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100 ml. Filter the solution. Transfer 25 ml of the filtrate into a Nessler's cylinder. In the second Nessler's cylinder, add 2 ml of dilute acetic acid, 1.0 ml of standard lead solution and make up the volume with water to 25 ml.

Add 10 ml of hydrogen sulphide solution to each Nessler cylinder and make up the volume with water to 50 ml. Mix and allow to stand for 10 min. Compare the colour produced in the two Nessler's cylinders. Blank determination without samples are recommended to avoid errors arising out of reagents.

E-5 RESULTS

The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.

ANNEX F

[*Table* 1, *Sl No.* (vi)]

DETERMINATION OF ARSENIC

F-1 OUTLINE OF THE METHOD

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

F-2 REAGENTS

F-2.1 Mixed Acid — Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

F-2.2 Ferric Ammonium Sulphate Solution

Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to one litre.

F-2.3 Concentrated Hydrochloric Acid — *See* IS 265.

F-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride ($SnCl_2$, $2H_2O$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

F-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of Ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25ml of sample solution as prepared in **E-4**.

For comparison, prepare a stain using 0.001 mg of arsenic trioxide.

ANNEX G

(Foreword)

COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

Organization	*Representative(s)*
Directorate General of Health Services, New Delhi	SHRI ASHWINI KUMAR (***Chairman***)
All India Small Scale Cosmetic Manufacturer's Association, Mumbai	SHRI M. B. DESAI SHRI B. M. CHOPRA (*Alternate* I) SHRI S. CHATTERJEE (*Alternate* II)
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Central Drugs Laboratory, Kolkata	DR M. K. MAZUMDER DR A. C. DAS GUPTA (*Alternate*)
Central India Pharmacopoeia Laboratory, Ghaziabad	DR SANTOSH. K. TALWAR DR SUKOMAL DAS (*Alternate*)
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Dabur Research Foundation, Sahibabad	DR N. M. SUNDER
Food & Drugs Control Admn. Gujarat State, Gandhinagar	DR B. N. PATEL MRS R. B. DESAI (*Alternate*)
Godrej Soaps Ltd, Mumbai	SHRI A. RANGARAJAN DR (MRS) ROHINI THAKKAR (*Alternate*)
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Procter & Gamble, Mumbai	DR ARUN VISWANATH SHRIMATI SHWETA PURANDARE (*Alternate*)
Bajaj Sevashram, Udaipur	SHRI R. F. HINGER DR S. ADHIKARI (*Alternate*)
Shingar Ltd, Mumbai	SHRI V. K. SINGH SHRIMATI SWATI SINGH (*Alternate*)
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Organization	*Representative(s)*
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Member-Secretary
DR (SHRIMATI) VIJAY MALIK
Director (PCD), BIS

Skin Care Products Subcommittee, PCD 19 : 3

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc : No. PCD 19 (2225).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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