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Draft Indian Standard

SPECIFICATION FOR LIPSALVE

(First Revision of IS 10284)

(ICS No. 71.100.70)

Cosmetics Sectional Committee
PCD 19

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FOREWORD

(Formal clauses will be added later)

Lipsalve consists of a homogeneous suspension of ingredients which are petroleum or vegetable oil based. It is useful in protecting the lips against chapping and cracking in extremes of temperature by forming a thin protective layer.

In this revision, all the previous amendments have been included. The specification table has been revised with respect to melting point range for stick as well as for unctuous form, alternate test methods have been included for estimation of melting point as well as Arsenic. Revision in Marking clause has been included as aligned with latest statutory requirements.

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, 2016* 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.

The composition of the Committee, responsible for the formulation of this standard is given at Annex H (will be added later).

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 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements for lipsalve (lip balm) which are petroleum or vegetable oil based.

1.2 Emulsion types, either oil-in-water or water-in-oil are not included. This standard also does not cover, lipsalve which contain ingredients that have an effect on the physiological functions of the body or lips for which specific therapeutic claims are made and also lipsticks or lipgloss.

2 REFERENCES

The following standards contain provisions which, through reference in text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All the 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.

<i>IS No.</i>	<i>Title</i>
IS 4028 : 1992	Beeswax, bleached for cosmetic industry - Specification (<i>third revision</i>)
IS 4707 (Part 1) : 2020	Classification For Cosmetic Raw Materials and Adjuncts : Part 1 Colourants (<i>fourth revision</i>)
IS 4707 (Part 2) : 2017	Classification For Cosmetic Raw Materials and Adjuncts : Part 2 list of raw materials generally not recognized as safe for use in cosmetics (<i>fourth revision</i>)
IS 7299 : 2021	Light Liquid Paraffin for Cosmetic Industry - Specification (<i>second revision</i>)
IS: 4654 : 2019	Paraffin Wax — Specification (<i>third revision</i>)
IS 4887 : 1980	Specification for petroleum jelly for cosmetic industry (<i>first revision</i>)
IS 4011 : 2018	Methods of test for safety evaluation of cosmetics (<i>third revision</i>)
IS 3958 : 2021	Methods of sampling cosmetics (<i>second revision</i>)
IS 1070 : 1992	Reagent grade water - Specification (<i>third revision</i>)
IS 265 : 2021	Hydrochloric Acid - Specification (<i>fifth revision</i>)
IS 264 : 2005	Nitric acid - Specification (<i>third revision</i>)
IS 2088 : 1983	Methods for determination of arsenic (<i>second revision</i>)

IS 13833 : 2019	Microcrystalline Wax derived from petroleum (<i>first revision</i>)
IS 16913 : 2018	Method of Tests for Cosmetics – Determination of Heavy Metals (Arsenic, Cadmium, Lead and Mercury) by Atomic Absorption Spectrometry (AAS)

2. TYPES

2.1 The material shall be of the following three types in the stick or unctuous form:

2.1.1 Type 1 – The material shall be based on petroleum products, such as white petroleum jelly, microcrystalline wax, liquid paraffin, etc.

2.1.2 Type 2 – This material shall be based on vegetables oils and waxes such as castor oil, coconut oil, groundnut oil, etc. and beeswax (*see* IS 4028 : 1992 (Reaffirmed Year : 2017)

2.1.3 Type 3 -The material shall be based on a mixture of petroleum products, vegetable oils and waxes.

3. REQUIREMENTS

3.1 Description - The lipsalve shall be in the form of solid sticks or soft unctuous mass.

3.2 Ingredients - Unless specified otherwise, all the raw materials used in the manufacture of lipsalve shall conform to the requirements prescribed in the relevant Indian Standards where these exist. Other ingredients shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2), as amended from time to time.

3.2.1 Dyes used in the manufacture of lipsalve shall comply with the provisions of IS 4707 (Part 1) : 2020 .

3.2.2 Ingredients other than dyes shall comply with the provisions of IS 4707 (Part 2) : 2017.

3.2.3 For safety evaluation of novel ingredients used in formulation of a skin powder, the skin powder shall comply to IS 4011 : 2018.

3.2.2.1 *For type 1* - Petroleum products used shall be of the quality specified below:

- a) *Mineral oil* - *see* IS 7299 : 2021.
- b) *Paraffin wax-type 1* - *see* IS 4654 : 2019.
- c) *Soft petroleum jelly* - *see* IS 4887 : 1980
- d) *Microcrystalline wax* - *see* IS 13833 : 2019

3.2.2.2 *For type 2* - Vegetable oils and waxes used shall be of quality specified below:

- a) Coconut oil for cosmetic industry - *see* IS 11470 : 1985

- b) Sesame oil for cosmetic industry – *see* IS 11376 : 2021
- c) Castor oil for cosmetic industry- *see* IS 11486 : 2021
- d) Groundnut oil for cosmetic industry – *see* IS 11375 : 2021
- e) Olive Oil - *see* IS 16311 : 2018
- f) Hydrogenated vegetable oils –
- g) Beeswax - *see* IS 4028 : 1992

3.2.2.3 For type 3 - The petroleum products, vegetable oils and waxes used shall be of quality specified in 3.2.2.1 and 3.2.2.2.

3.3 The raw materials used should not have any harmful effect on the mucous membrane of the skin around lips, and also the interaction of such raw materials in the finished products shall not have any toxic or sensitizing effect For safety evaluation of novel ingredients used in formulation of lipsalve, the lipsalve shall comply to IS 4011 : 2018 ‘Method of test for safety evaluation of cosmetics

3.4 The lipsalve shall also comply with the requirements given in Table 1, when tested as given in col 5 of the table.

TABLE 1 REQUIREMENTS FOR LIPSALVE
(Clause 3.4)

Sl. No.	Characteristics	Requirement		Method of test (Ref to Cl. No in)
		(3)	(4)	
(1)	(2)	(3)	(4)	(5)
		Stick Form	Unctuous Form	
i)	Melting range, °C	48 to 85	35 to 60	Annex A
ii)	Consistency, millimetre per 10	50 to 100	100 to 275	Annex B
iii)	Rancidity*	To pass the test	To pass the test	Annex C
iv)	Stability	To pass the test	To pass the test	Annex D
v)	Arsenic (as As ₂ O ₃), parts per million, <i>Max</i>	2	2	Annex E/ IS 16913 : 2018
vi)	Heavy metals (as Pb), parts per million, <i>Max</i>	20	20	Annex F/ IS 16913 : 2018
vii)	Peroxide Value ¹ , meq/1000 g, <i>Max</i>	10	10	Annex G

NOTE :

¹⁾ Test for peroxide value is not applicable for Type I- petroleum based products.

3.5 ADDITIONAL REQUIREMENTS FOR ECO MARK

3.5.1 General Requirements

3.5.1.1 The product shall conform to the requirements for quality, safety and performance prescribed under clauses 3.1 to 3.4.

3.5.1.2 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1): 2020 'Classification of cosmetic raw materials and adjuncts: Part 1 Dyes, colours and pigments (*fourth revision*)' and IS 4707 (Part 2) : 2017 'Classification for cosmetic raw materials and adjuncts: Part 2 List of raw materials generally not recognized as safe (*fourth revision*)'.

The product shall also meet specific requirements as given in Indian standard.

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

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

3.5.1.5 The manufacturer shall produce to BIS the 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 thereunder, while applying for ECO Mark. Additionally provisions of the *Drugs and Cosmetics Act, 1940* and the Rules thereunder shall also be complied with.

3.5.2 Specific Requirements

3.5.2.1 The Product shall be dermatologically safe when tested as prescribed in IS 4011 : 2008 'Methods of test for safety evaluations of cosmetics (*second revision*)'.

3.5.2.2 Heavy metals calculated as lead (Pb) and arsenic (As₂O₃) shall not exceed 20 and 2 ppm, respectively when tested by the respective method prescribed in Indian Standards.

4. PACKING AND MARKING

4.1 Packing - The lipsalve shall be packed in metallic, plastic or any other container.

4.2 Each container shall be legibly marked with the following information:

- a) Name of the material;
- b) Manufacturer's name and recognized trade-mark, if any;
- c) Net mass of material;

- d) Use before..... or Expiry date as per Statutory requirements
- e) List of ingredients as per statutory requirements.
- f) Batch number in code or otherwise to enable the lot of the manufacture to be traced back from records; and
- g) Any other information as required by the statutory authorities;
- h) For ECO Mark, the product shall be packed in such packages which shall be recyclable/reusable or biodegradable.

4.2.1 The containers may also be marked with the ISI Certification Mark. The product package shall be suitably marked that ECO Mark label is under the ECO Mark scheme.

NOTE - The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

4.3 For ECO Mark the product shall be packed in such packages which shall be recyclable/reusable or biodegradable.

4.3.1 The product package shall be suitably marked that ECO mark label is applicable only to the contents, if the product package is not separately covered under the ECO Mark scheme.

5. SAMPLING

5.1 Representative samples of the material shall be drawn as prescribed in IS 3958 : 2021.

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

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

6. TEST METHODS

6.1 Tests shall be carried out according to the methods prescribed in Appendix A. Reference to relevant clauses of Appendix A is given in col 5 of Table 1.

6.2 Quality of Reagents - Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070 : 1992(Reaffirmed Year : 2019)) shall be used in tests.

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

ANNEX A

(*Table 1 Clause 3.4*)

DETERMINATION OF MELTING RANGE (POINT)

A-1.1 Procedure

A-1.1.1 Melt a quantity of the sample slowly while stirring until it reaches a temperature of 90 to 92°C. Remove the source of heat and allow the molten sample to cool to a temperature of 8 to 10°C above the expected melting point. Chill the bulb of a thermometer (range 1 to 100°C) to 5°C, wipe it dry and while it is still cold, dip it into the molten sample so that approximately half of the bulb is submerged. Withdraw it immediately and hold it vertically away from heat until the wax surface dulls, then dip it for five minutes into a water-bath having a temperature not higher than 16°C.

A-1.1.2 Fix the thermometer prepared in **A-1.1.1** securely in a test-tube so that its lowest tip is about 15 mm above the bottom of the test-tube. Suspend the test-tube in a water-bath adjusted to 16°C and raise the temperature of the bath at a rate of 2°C per minute; up to 30°C. After the temperature of the bath has reached 30°C adjust the rate of rise to 1°C per minute and note the temperature at which the first drop of the melted sample leaves the thermometer. Repeat the determination twice on a freshly melted portion of the sample. If the variation in three determinations is less than 1°C take the average of the three as the melting point. 'If the variation in the three determinations is more than 1°C make two additional determinations and take the average of the five. Report whether the average of the five determinations is within the range specified or not.

A-2 ALTERNATE TEST METHOD

A-2.1 Outline of the method

In this test method, the dropping point is defined as the temperature at which the wax suspended in a cylindrical cup, with a 2.8-mm diameter hole in the bottom, flows downward a distance of 19 mm to interrupt a light beam as the sample is heated at a constant rate in air.

This test method has been found suitable for all types of waxes including paraffin, microcrystalline polyethylene, and natural waxes.

A-2.2 Apparatus

A-2.2.1 Control Unit with a digital temperature recorder – This unit shall provide a continuous linear temperature control from 25 to 250°C at a 2°C/min rate. A digital readout shall record the softening point with an accuracy of 0.1°C.

A-2.2.2 Furnace Unit – This unit shall be capable of heating a sample cup assembly as described in 5.1.3 at 2°C ± 0.3°C/min linear rate from 25 to 250°C. It shall include a sensing system capable of detecting the softening point with an accuracy of 0.1°C.

A-2.2.3 Sample Cup Assembly – A chromium-plated brass cup conforming to the dimensions shown in Test Method D566. It shall be placed in an assembly so that the sample flows down a distance of 19 mm to interrupt a light beam to cause digital display of the softening point.

A-2.3 Preparation of Sample

For waxes heat the sample to 15 to 20°C above its melting point to form a pourable liquid. Place the sample cups on glass slides and pour the melted sample into the cup to a level even with the upper rim of the cup. Allow the sample to stand at room temperature for 2 h before running.

A-2.4 Preparation of Apparatus

Ensure that the furnace unit and the sample cup assembly are clean and bright, since tarnished or dirty apparatus will change the apparent dropping point. After each determination, check to see if the apparatus requires cleaning.

A-2.5 Procedure

A-2.5.1 The procedure for measuring the dropping point of waxes with the Mettler instrument has been developed to duplicate the results obtained by Test Method D566.

A-2.5.2 Preheat or cool the furnace unit to a temperature of 20 to 25°C less than the expected dropping point (Note 2) of the sample and maintain at this temperature. Place the cartridge assembly containing the sample in position in the furnace, taking care that the slits for the light beam are properly positioned. When the ready light becomes steady, indicating the sample and furnace have equilibrated at the present temperature, initiate the 2°C/min heating rate by pressing the START LEVEL. Heating will then continue automatically until the drop point occurs and the dropping point temperature is displayed on the digital readout.

NOTE 2—In the event of a dispute, the purchaser and the seller should agree on the exact starting temperature to be used

A-2.5.3 Immediately remove the cartridge assembly upon completion of the test. Check to determine if the sample has passed the light beam slot and no pretrigger has occurred. Inspect the dropping point apparatus to be sure no dirt, particles, or residue remain.

A-2.5.4 Clean the sample cups by placing them upside down on a hard surface and punching out the residue material. Use a spatula shaped to the contours of the cup, to remove the remaining particles with a gentle twirling motion.

A-2.6 Report

Report the dropping point recorded on the digital readout to the nearest 0.1°C. If converted to degrees Fahrenheit, report to the nearest 0.2°F. Experience has indicated that duplicate runs are not necessary. If a known error in experimental procedure is made, the result should be discarded and a second run should be made.

ANNEX B

(Table 1 Clause 3.4)

DETERMINATION OF CONSISTENCY

B-1 Outline of the Method – Determination of consistency of the material is made by measuring the penetration of a standard cone at $25 \pm 0.5^\circ\text{C}$.

B-2 Apparatus

B-2.2 Penetrometer – Any suitable penetrometer which permits the specified cone to drop vertically without appreciable friction for at least 40 mm and which indicates accurately the depth of penetration to the nearest 0.1 mm. The instrument shall have a table to carry the test sample, which may be adjusted to the horizontal before making the test. A mechanism for releasing and clamping the loaded cone shall be provided.

B-2.3 Cone – Consisting of a conical body of brass or corrosion resistant steel with detachable hardened steel tip, constructed to conform to the dimensions and tolerances shown in Fig. 1. The total moving mass, namely, that of the cone and its movable attachments, shall be 150 ± 0.1 g. The attachments consist of a rigid shaft having a suitable device at its lower end for engaging the cone. The outer surface should be polished to a very smooth finish.

B-2.4 Constant Temperature Bath - A water-bath capable of regulation at $25^\circ\text{C} \pm 0.5$ C and of suitable design for conveniently bringing the sample container to the test temperature. The bath should be provided with a cover to maintain the temperature of the air above the sample at 25°C .

B-2.5 Timing Device - A stop-watch or other suitable instrument capable of measuring an interval of 5 seconds to within 0.2 second.

B-2.6 Sample Container - Flat-bottomed, metal or glass cylinders that are 100 ± 6 mm in diameter and not less than 60 mm in height.

B-3 Procedure - Melt a quantity of the sample at $82.0 \pm 2.5^\circ\text{C}$, pour into one or more of the sample containers, filling to within 6 mm of the brim. Cool at $25.0 \pm 2.5^\circ\text{C}$ over a period of not less than

16 hours protecting from draughts. Two hours before the test, place the containers in a water-bath at $25.0 \pm 0.5\%$. If the room temperature is below 23.5°C or above 26.5°C , adjust the temperature of the cone to $25.0 \pm 0.5^{\circ}\text{C}$ by placing it in the water-bath.

B-3.1 Without disturbing the surface of the sample, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the sample at a spot 25 to 38 mm from the edge of the container. Adjust the zero setting and quickly release the plunger, then hold it free for 5 seconds. Secure the plunger, and read the total penetration from the scale. Make 3 or more trials each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm use a separate container of the sample for each trial. Read the penetration to the nearest 0.1 mm. Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than ± 3 percent.

B-3 Calculation

$$\text{Consistency} = \frac{A}{10}$$

Where,

A = mean of all the values of penetration in mm.

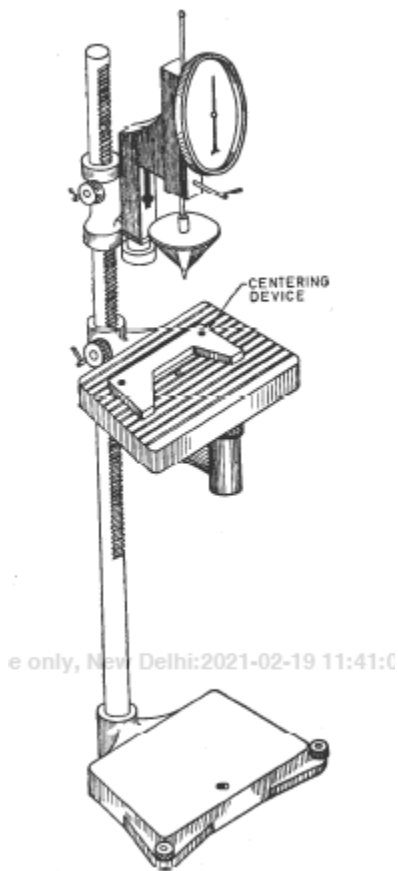


FIG. 1 PENETROMETER

ANNEX C
(Table 1 Clause 3.4)
TEST FOR RANCIDITY

C-1 Reagents

C-1.1 Concentrated Hydrochloric Acid – See IS 265 : 2021 .

C-1.2 Phloroglucinol Solution - Dissolve 0.1 g of phloroglucinol in 100 ml of diethyl ether.

C-2 Procedure - Shake 10 g of the material, melted if necessary, with 10 ml of concentrated hydrochloric acid and 10 ml of phloroglucinol solution. Shake for 1 minute.

C-2.1 The material shall be taken to have passed the test if no pink colour develops.

ANNEX D
(Table 1 Clause 3.4)

TEST FOR STABILITY

D-1 Procedure - Place 50 g of the material in the beaker under the ultra violet lamp and expose it for 6 hours. If the product does not deteriorate after the exposure period, the product shall be taken to have passed the test.

ANNEX E (Table 1 Clause 3.4) DETERMINATION OF ARSENIC

E-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.

E-2 REAGENTS

E-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.

E-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.

E-2.3 Concentrated Hydrochloric acid - See IS 265.

E-2.4 Stannous Chloride Solution - Dissolve 80 g of stannous chloride ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

E-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 25 ml of sample solution as prepared in **F-4**.

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

ANNEX F (Table 1 Clause 3.4) TEST FOR HEAVY METALS

F-1 Apparatus

F-1.1 Nessler Tubes – 50-ml capacity, matched.

F-2 Reagents

F-2.1 Ammonium Acetate Solution – 10 percent.

F-2.3 Ammonium Citrate Solution - Dissolve 8.75 g of citric acid in water, neutralise with ammonia and dilute with water to 100 ml.

F-2.4 Ammonium Hydroxide - 10 percent (*m/m*).

F-2.5 Potassium Cyanide Solution - 10 percent (*m/m*).

F-2.6 Sodium Sulphide Solution - 10 percent (*m/m*).

F-2.7 Standard Lead Solution - Dissolve 1.600 g of lead nitrate in water and 10 ml of concentrated nitric acid and dilute to 1000 ml. Pipette out 10 ml of the solution and dilute it again to 1 000 ml with water. One millilitre of the final solution contains 0.01 mg of lead (as Pb). The solution shall be freshly prepared before use.

F-3 Procedure

F-3.1 Preparation of Sample - Treat 2.000 g of the sample as prescribed in **A-5.2.1**.

F-3.2 Take, the solution prepared in A-6.3.1 in a Nessler tube, add 10 ml of ammonium acetate solution, 5 ml of ammonium citrate solution, 5 ml of ammonium hydroxide and 1 ml of potassium cyanide solution and dilute to 50 ml with water; then add two drops of sodium sulphide solution and mix well. In another Nessler tube, carry out a control test using 4 ml of standard lead solution and the same quantities of other reagents as used in the test with the material.

F-3.3 The material shall be taken as not having exceeded the limit prescribed in Table 1, if intensity of colour produced with the material not greater than that produced in the control test.

Annex G

(Table 1 Clause 3.4)

TEST FOR PEROXIDE VALUE

G 1 REAGENTS

G-1.1 Glacial Acetic Acid

G-1.2 Chloroform

G-1.3 Potassium Iodide Solution — saturated, freshly prepared.

G-1.4 Standard Sodium Thiosulphate Solution — 0.01 N, freshly standardized.

G-1.5 Starch Indication Solution

Triturate 5g of starch and 0.01g of mercuric iodide with 30ml of cold water and slowly pour it with stirring into 1L of boiling water. Boil for 3 minutes. Allow to cool and decant off the supernatant clear liquid.

G- 2 PROCEDURE

Weigh accurately about 5 g of the material in a 250-ml glass stoppered conical flask and dissolve by shaking in 30 ml of a mixed solvent containing 3 parts by volume of glacial acetic acid and 2 parts by volume of chloroform. Add 0.5 ml of freshly prepared saturated potassium iodide solution. Shake and after 2 minutes with occasional shaking, add 30 ml of water and titrate with standard sodium thiosulphate solution. Add the thiosulphate solution until the colour of the titrated solution becomes light yellow. Then add 1 ml of starch indicator solution and continue the titration till the disappearance of the blue colour. Carry out a blank determination without using the sample.

G-3 CALCULATION

$$\text{Peroxide value mEq/1000g} = \frac{1000 (V_1 - V_2)N}{M}$$

Where,

V₁ = volume of ml of standard sodium thiosulphate solution required with the sample;

V₂ = volume in ml of Standard sodium thiosulphate solution required with the blank;

N = normality of standard sodium thiosulphate solution; and

M = mass in g of the sample taken for the test.