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PAKISTAN STANDARD SPECIFICATION

FOR

SHAVING CREAM

PAKISTAN STANDARDS AND QUALITY CONTROL AUTHORITY,
STANDARDS DEVELOPMENT CENTRE,
Plot No. ST-7A, Block-3, Scheme 36, Gulistan-e- Johar
Karachi.

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O. FOREWORD

0.1 This Pakistan Standard was adopted by the Pakistan Standards and Quality Control Authority on 30-03-1994. After the draft finalized by the Cosmetic & Toilet Goods Technical Committee had been approved by the National Standard Committee.

0.2 This standard is intended chiefly to cover the technical provision relating to the supply of material & it does not include all the necessary provisions of a contract.

0.3 Shaving creams of lather type are basically soaps composed of sodium and potassium stearates, mixed with water and glycerol to give a creamy soft texture. Non-lather (brushless) shaving creams are as essentially oil-in-water emulsions: They usually consist of mineral oil emulsified in water with a stearate soap containing an excess of stearic acid.

0.4 It is necessary that the raw materials used are such that at concentrations in which they are present in shaving creams and after interaction with the other raw materials, they are free from harmful effects. It shall be the responsibility of the manufacturer to ensure the physiological and dermatological safety of his product.

0.5 For the purpose of deciding whether & 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 PS: 103 – 1991, Rules for rounding of Numerical values. 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 specification prescribes the requirements and methods of sampling and test for shaving creams of both lather type and non-lather type.

1.2 It does not cover aerosols and other types of foams used for shaving.

2. Types

Type 1 Lather (to be used with a brush); and
Type 2 : Non-lather (brushless).

3. REQUIREMENTS

3.1 General requirements

The product shall have a soft texture and a uniform consistency. It shall be white or pigmented and of uniform colour.

3.2 RAW MATERIALS

All raw materials shall be physiologically and dermatologically safe.

3.2.1 The dyes, if used, shall comply with the provisions of F.D.C.

3.2.2 Raw materials other than dyes shall comply with the relevant Pakistan Standard.

3.3 OTHER REQUIREMENTS

The product shall comply with the requirements given in Table 1 when tested according to the relevant method given in Column 5 of the table.

3.4 MICROBIOLOGICAL LIMITS

The product shall also comply with the microbiological limits given in Table 2, when tested according to the relevant method given in Column 4 of the table.

TABLE 1
REQUIREMENTS FOR SHAVING CREAMS

SL.NO.	Characteristic	Requirements for		Method of test
		Type 1	Type 2	
(1)	(2)	(3)	(4)	(5)
i)	Non-volatile matter at 105^0C, per cent by mass. min.	40	25	Appendix – A.
ii)	Lather volume, ml, min.	100	---	Appendix B
iii)	Free caustic alkali	To pass the test	To pass the test	Appendix C
iv)	Stability	To pass the test	To pass the test	Appendix D
v)	Water content, per cent by mass. Max	60	75	Appendix E

TABLE 2
MICRO BIOLOGICAL LIMIT

Sl. No.	Characteristic	Limit	Method of test
(1)	(2)	(3)	(4)
i)	Aerobic plate count per ml, max.	300	F
ii)	Pathogenic bacteria	Nil	F

4. PACKING AND MARKING

4.1 The product shall be packed in collapsible tubes of material which shall not corrode or deteriorate during normal conditions of storage and use. The tubes shall be properly closed and shall have a leak-proof cap. Each tube shall be contained in a suitable package. Each pack (tube and package) shall be legibly and indelibly marked with the following:

a) Name and type of the product;
b) Name and address of the manufacturer, (including country of origin);
c) Registered trade mark, if any
d) Brand name if any;
e) Net mass, in grams, or net volume in milliliters, which ever is relevant;
f) Batch or code number; and
g) Instructions for use, where necessary.

4.2 A number or such packs, as agreed to between the purchaser and the supplier, shall be suitably packed in a carton. Each carton shall be legibly and indelibly marked with the following:

a) Name and type of the product;
b) Name and address of the manufacturer, (including country of origin);
c) Registered trade mark, if any and
d) The number of packs.

5. SAMPLING;

5.1 Lot
In any consignment all the tubes of the same type and size and belonging to one batch of manufacture or supply shall constitute a lot.

5.2 Scale of sampling

5.2.1 Sample shall be tested from ea 3 lot for ascertaining its conformity to the requirements of this specification.

5.2.2 The number of tube to be selected from each lot shall be in accordance with Table 3.

TABLE- 3
SCALE OF SAMPLING

No. of tubes in the lot	No. of tubes to be selected
Up to 3 200	15
3201 to 10,000	20
10001 and above.	30

5.2.3 Tubes shell be taken from the carton for this purpose 10 per cent of the cartons subject to a minimum to five (05) cartons shall be selected from the

lot and as far as possible an equal number of tubes shall be drawn from each carton so selected, to form a sample as given in the table.

5.2.4 The cartons and tubes shall be selected at random.

5.3 NUMBER OF TEST

5.3.1 Each carton selected as in 5.2.3. shall be inspected for marking requirements.

5.3.2 Each tube selected as in 5.2.3 shall be inspected for packaging and marking requirements.

5.3.3 Two tubes shall be crown from the tubes selected as in and tested for stability.

5.3.4 A sufficient amount of material shall be taken under aseptic conditions from each tube selected as in 5.2.3 and mixed to form a composite sample. The composite sample thus obtained shall be tested f or microbiological requirements given in 3.4 of this specification.

5.3.5 A sufficient amount of material shall be taken from each tube selected as in 5.2.3 and mixed to form a composite sample. The composite sample thus obtained shall be tested for non-volatile matter, water content, lather volume and free caustic alkali.

6. METHODS OF TESTS

6.1 Tests shall be carried out as 4 :cified in Appendixes A to F of this specification.

6.2 During the analysis, unless otherwise stated, reagents of recognized analytical grade and only distilled water or water of equivalent purity shall be used.

7. CRITERIA FOR CONFORMITY:

A lot shall be declared as conformity to the requirements of this specification, if the following, conditions are satisfied:

7.1 Each carton inspected as in 5.3.1 satisfies the relevant requirements.
7.2 Each tube inspected as in 5.3.2 satisfies the relevant requirements.
7.3 The tubes tested as in 5.3.3. Satisfy the relevant requirements.
7.4 The test results on the composite samples satisfy the relevant requirements.

APPENDIX – A

DETERMINATION OF NON-VOLATILE MATER AT 105 ^{O}C

A.1 PROCEDURE

Weigh, to the nearest 1 mg, a proximately 5 g of the material in a tared evaporating dish and heat on a steam bath until most of the volatile matter

has escaped. Continue heating at 105 ± 2 ^{0}C in an oven for 2 hours. Cool in a desiccator and weigh. Repeat heating, cooling and weighing until the difference in mass between two successive weighings does not exceed 1 mg.

A-2. CALCULATION:

Non-volatile matter at 105^{0}C, percent by mass = $\frac{m_2 - m_3}{m_1 - m_3} \times 100$

Where

m_1 = mass, in grams, of the dish with the sample;
m_2 = mass in grams of the dish after heating; and
m_3 = mass, in grams of the empty dish.

APPENDIX B
DETERMINATION OF LATHER VOLUME

B.0 APPARATUS

B.1 Stoppered cylinder, of 250-ml capacity.

B.2. PROCEDURE

B.2.1. Weigh, to the nearest 1 mg,. approximately 5 g of the material in a 100 ml glass beaker. Add 10 ml of water, cover the beaker with a watch glass and allow to stand for 30 minutes (see Note).

NOTE – Ensure that the material is completely dispersed. Warm the aqueous suspension, if necessary.

B-2.2 Stir the contents of the beaker with a glass rod and transfer slurry to the 250-ml stopper cylinder, ensuring that no lather (more than 2 ml) is produced and no lumpy paste goes into the cylinder.

Repeat the transfer of the residue left in the beaker with further portions of 5-ml to 6-ml of water ensuring that all the matter in the beaker is transferred to the cylinder. As soon as the temperature of the contents of the cylinder reaches 30 ^{0}C, stopper the cylinder and give it 12 complete shakes, each shake comprising movements shown in Figure 1 in a vertical plane upside down and vice versa. After the 12 shakes have been given, allow the cylinder to stand for 5 minutes and read the volumes as shown in Figure 2.

B.3 CALCULATION

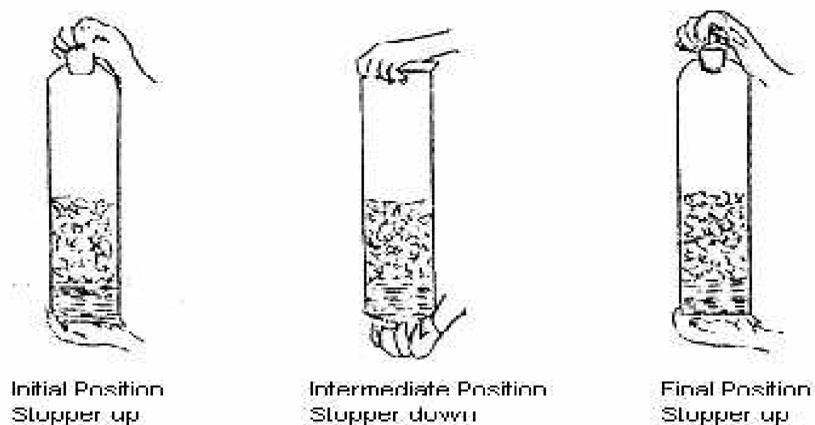
Lather volume, in milliliters = $V_1 - V_2$

Where

V1 = Volume, in Millilitres, of lather (foam) plus water; and

V2 = Volume, in milliliters, of water

Figure 1: One Complete shake of cylinder



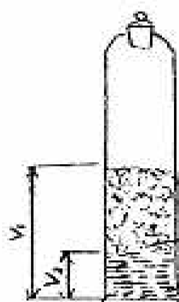


Figure 2 ; Measurement of foam

APPENDIX C
TEST FOR FREE CAUSTIC ALKALI

C-1. REAGENTS

C-1.1 Rectified spirit,

C-.1.2 Phenolphthalein indicator solution, dissolve 1 g of phenolphthalein in 100 ml of rectified spirit.

C.2 PROCEDURE

Dissolve 1 g of the material in 100 ml of rectified spirit by warming, if necessary, Cool and add a few drops of phenolphthalein indicator (C.1.2) and observe the colour of the solution. The material shall be taken to have passed the test if no pink colouration in developed.

APPENDIX - D
TEST FOR STABILITY

D.1 Keep the tube at 37 ± 1^{0} C for 24 hours, Press the tube and take about 10 g of the cream. On visual examination, the cream shall not show any separation of water or oil phase.

D.2 Keep the tube at 10 ± 1 ^{0} C for 24 hours. Press the tube. The cream shall be found extrudable from the tube.

APPENDIX - E
WATER CONTENT

E. 1 Apparatus:

The apparatus shown in Fig. consists of the following

a) Flask, 500-ml capacity, made of hard resistant glass;

b) Trap, the cylindrical portion of the receiving tube is 146 mm to 156 mm in length, graduated to contain a volume of
10 ml end is sub-divided into 0.1 ml divisions; and

c) Condenser, approximately 400 mm in length and the bore diameter of the inner tube is 16 mm to 17 mm. The condenser is connected to the trap as shown in the figure.

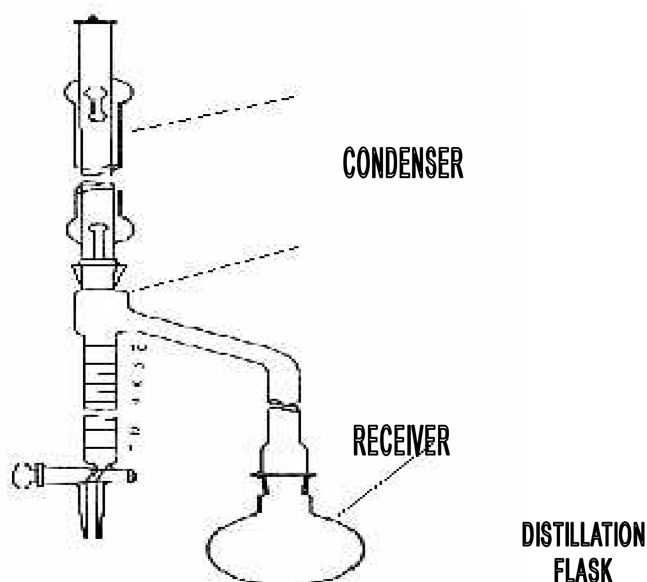


FIG 3: Entrainment Distillation of Water

E – 2 REAGENTS

E – 2.1 Toluene, treated with excess water and distilled.

E – 2.2 Heptene; and

E – 2.3 Xylene,

E – 3. PROCEDURE

Weigh to the nearest 0.1 g approximately 10 g of the material into the flask. Add about 200 ml of the solvent and a few pieces of dry pumice stone. Connect the apparatus and fill the receiving end of the trap with the solvent, poured through the top of the condenser,. Heat the flask gently for 15 min. and then the solvent begins to boil, reflux at a rate of 2 drops per second until most of the water has passed. Increase the rate to about 4 drops per second. When the water has apparently all distilled, rinse the inside of the condenser tube with solvent while brushing down the tube with a tube brush attached to a copper wire and saturated with the solvent. Continue the distillation for 5 min, then remove the source of heat, and allow the receiving tube to cool to room temperature. If any droplets. of water are seen adhering to the wall of the receiving tube, scrub down with a brush consisting a of a rubber bend wrapped around a copper wire and dipped with the solvent. When the water and solvent have separated, read the volume of water.

E – 4. CALCULATION

$$\text{Water content, per cent by mass} = \frac{V \times d \times 100}{m}$$

where

V = volume of water, in ml, at room temperature collected in the receiving tube;

d = density of water, at room temperature; and
m = mass, in grams, of the test portion.

F. 0 MICROBIOLOGICAL EXAMINATION

F.1. APPARATUS

F.1.1 Forceps, scissors, spatula and scalpel, sterile instruments for preparation of sample.

F.1.2 Gauze pads, sterile, 100 mm x 100 mm.

F.1.3 Balance, with weights sensitivity of 0.01 g.

F.1.4 Mechanical blender, with glass or metal jars fitted with lids and resistant to the conditions of sterilization.

F.1.5. Water bath, controlled at 45 ± 2 ^{0}C.

F.1.6 Incubators, controlled at 36 ± 1^{0}C , 30 ± 2 ^{0}C and 42 ± 1^{0}C.

F.1.7 Petri dishes, sterile, diameter 90 mm or 100 mm.

F.1.8 Pipettes sterile, graduated, capacity 1, 5 and 10 ml.

F.1.9 Dilution bottles, wide mouth.

F.2 Culture Media And Solutions.

Dehydrated media of any brand equivalent to the formulations may be used.

F.2.1. Diluent

F.2.1.1 Phosphate buffer pH 7.2

Dissolve 34 g of monobasic potassium phosphate in 500 ml of water in a 1 000-ml volumetric flask. Adjust to pH 7.2 by the addition of 1 N NaoH (about 175 ml), and water to volume and mix.Store under refrigeration. For use, dilute the stock solution with water in the ratio of 1:800. Sterilize at 121^{0}C for 20 min.

F.2.1.2 Modified letheen broth

Prepared from Difco or BBL commercially available medium with the same supplementation as for modified letheen agar (see below). Dispense in appropriate amounts into dilution bottles.

F.2.1.3 Modified letheen agar.

a) Latheen agar (Difco or / 11 om BBL) 32 g.
b) Trypticase peptone 5 g.
c) Thiotone peptone 10 g
d) Yeast extract 2 g
e) NaCl 5 g
f) Sodium bisculphate 0.1 g and
g) Distilled water 1 000 ml

Dissolve ingredients boiling.
Autoclave for 15 minute at 121 ^{0}C and dispense into 15 mm x 100 mm Petri dishes.

F. 2.2. Plate count agar

a) Dehydrated yeast extract 2.5 g
b) Tryptone 5.0 g

c) Anhydrous D-glucose (anhydrous dextrose). 1.0 g
d) Agar 9 g to 18 g and
e) Distilled water. 1000 ml.

Dissolve all ingredients in water by boiling. Sterilize by autoclaving at 121^{0}C for 20 min. Final pH 7.0 ± 0.2.

F.2.3 Trypticase soy agar

a) Trypticase or tryptone 15 g
b) Phytone 5 g
c) NaCl 5 g
d) Agar 15 g and,
e) Water 1 000 ml.

Suspend and mix thoroughly. Heat with frequent agitation and boil for about 1 min to dissolve completely. Autoclave for 15 min at 121^{0}C. Final pH 7.3. ± 0.1.

F.2.4 Malt extract agar

a) Maltose 12.75 g
b) Dextrose 2.75 g
c) Glycerol 2.35 g
d) Peptone 0.78 g
e) Agar 15 g and
f) Water 1000 ml

Suspended all ingredients and mix until homogenous. Heat with frequent agitation and boil for 1 min. Dispense and sterilize by, autoclaving at 121^{0}C for 15 min. Malt extract a 12 [illegible]ld be supplemented with 40 mg / Kg of filter sterilized chlortetracy[illegible] acidified to PH 3.5 with sterile 10 percent citric acid or tartaric acid.

F.2.5 Vogel-Johnson (VJ) agar.

F.2.6 Cetrimide agar.

F.2.7 Fluid soybean casein digest medium.

a) USP pancreatic digest of casein 15.0 g
b) USP soy peptone 5.0 g
c) Sodium chloride 5.0 g
d) Lecithin 0.7 g
e) Tween 80 5.0 g
f) Agar (dried) 15.0 g and
g) Distilled water 1000 ml.

Sterilize at 118^{0}C to 121 ^{0}C for 15 min. Final PH should be 7.3 ± 0.2.

F.2.8. Motility test medium

a) Beef extract 3 g

b) Peptone 10 g
c) Agar 4 g
d) Nacl 5 g and
e) Distilled water 1 000 ml.

Adjust pH to 7.4 dispense in 8 ml portions in tubes sterilized for 15 min at 121^{0}C.

F.2.9 Cytochrome oxidase reagent.

a) N, -N, -N^{1}, N^{1}- tetramethyl- p-phenylene diamine 3.0 g
b) Distilled water 100 ml.

Store in a dark glass bottle at 5^{0}C to 10^{0}C. Storage life is 15 days.

F.2.10 Brain heart infusion broth or nutrient broth.

F.2.11 Rabbit coagulass plasma (with EDTA).

F. .2.11 Tween 80.

F.2.13 Solution of 1 per cent HCL 13 rcent alcohol (aqueous).

F.3. PROCEDURE

F.3.1. Preparation of test sample.

F.3.1.,1 Analyses the samples as soon as possible after arrival in the laboratory. If storage is necessary, the samples should be stored at room temperature.

F.3.1.2 Disinfect the surface of the sample container with an aqueous mixture of 80 per cent alcohol (v/v) and 1 percent HCL (v/v) . Dry the surface with sterile gauze before opening and removing contents.

F.3.1.3 Transfer by means of a spatula, using aseptic techniques, 10 g of the product into a wide mouth dilution bottle containing 10 ml of Tween 80 and disperse the product within the Tween 80 with a spatula. Bring volume up to 100 ml with either diluent given in F.2.1. to obtain a 1:10 dilution.

F.3.1.4 Prepare decimal dilution from 10^{-1} to 10^{-4} by adding 1 ml of a previous dilution to 10 ml of diluent. Shake all dilutions by rotating tube or with a mechanical shaker.

F.3.1.5 Using sterile pipette transfer 1 ml of each dilution into each of duplicate, Petri dishes.

F.4 AEROBIC PLATE COUNT

F.4.1. Pour about 15 ml of plate count agar or ISA previously cooled to 45^{0}C into each Petri dish. (see F.3.1.5). Rotate the plates carefully to mix the inoculum with the medium. Allow to solidity.

F.4.2 Invert the dishes and incubate at 36 ± 1^{0}C in 48 hours.

F.4.3 Count colonies on plates containing 30 to 300 colonies and record the results per dilution counted.

If plates do not contain 30 to 300 colonies, record the dilution counted and note the number of colonies found.

F.4.4. Average the counts obtained and multiply by the appropriate dilution factor to obtain the number of bacteria / g or sample.

F.5 MOULD AND YEAST COUNT

F.5..1 Pour about 15 ml of malt extract agar into a second series of Petri dishes containing 1 ml aliquots of the 10^{-1} to 10^{-4} dilutions.

F.5.2. Mix, allow to solidify and incubate plates at 25 ± 1^{0}C for 5 days. Check plates daily for growth.

F.5.3 Average the counts of duplicate plates containing 30 to 300 colonies, and multiply by dilution factor to obtain the number of fungi and yeast/g sample.

F.5.4 The total number of microorganisms per gram is the sum of bacteria, fungi and yeast per gram of sample.

F.6 DETECTION OF STAPHLOCOCCUS. AUREUS AND PSEDOMONAS AERUGINOSA

F.6.1. Enrichment culture.

Incubate all dilution bottles prepared as in F.3.1.3 and F.3.1.4 at 30 ± 2 ^{0}C for a minimum of 7 days, examining the broths daily for growth. If growth is suspected, as well as at the 7 days. Incubation period, subculture all bottles on to VJ and cetrimide agar plates. Incubate plates at 30 ± 2^{0}C for 24 hours. Prepare a gram stain of all morphologically dissimilar colonial types. If characteristic colonies develop which have the gram staining reactions of S. aureus and P. aeruginosa (see Table 4), the preparation has a presumptive content of these organisms.

TABLE -4
PRESUMPTIVE TESTS.

Medium	Staphlococcus. Aureus	Psedomonas. Aeruginosa
(1)	(2)	(3)
Vogel-Johnson agar	Convex, shiny black colonies with or without yellow zone surrounding the colony.	--
Cetrimide agar	--	Generally greenish fluorescence.

F.6.2 Confirmation of Staphlococcus. aureus

With the aid of an inoculating loop, transfer each suspect colony from the agar surfaces of the VJ medium to individual tubes each containing 0.2 ml brain heart infusion broth or nutrient broth. Incubate for 18 to 24 h at 35 ± 2 ^{0}C, then add 0.5 ml reconstituted rabbit coagulase plasma (with EDTA) and mix thoroughly. Incubate at 35 ± 2^{0}C, examining at every 3 hour interval up to 24 hours. If coagulation in any degree is observed, staphylococcus aureus is present.

F.6.3 Confirmation of Psedomonas aeruginosa:

F.6.3.1 Perform cytochrome oxidase test on presumtive Pseudomonas colonies by placing a few drops of the cytochrome oxide reagent "see F..2.9) on suspect colonies. If the organisms produce oxidase, colonies will turn pink, red, and then black. Discard plates after 20 min. On all oxidase positive colonies perform either a microscopic motility test or stab and incubate motility agar for 24 hours.

F.6.3.2 Transfer oxidase and motility positive colonies to soybean casein digest medium and incubate at 42^{0}C for 24 h to 48 h. Growth at 42^{0}C indicates the presence of pseudomonas aeruginosa.