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DRAFT EAST AFRICAN STANDARD

Skincare creams, lotions and gels — Specification

EAST AFRICAN COMMUNITY

2nd Edition 2021

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing. 071, *Cosmetics and related products*.

This third edition cancels and replaces the first edition (EAS 876:2013), which has been technically revised.

Skincare creams, lotions and gels — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for creams, lotions and gels for skincare.

This standard does not apply to skincare products, for which therapeutic claims are made.

This standard does not apply to anti-aging, anti-wrinkle, sun protection products, aromatherapy substances and Alpha Hydroxy Acids (AHA)

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 346, *Labelling of cosmetics — General requirements*

EAS 377 (all parts), *Cosmetics and cosmetic products*

EAS 846 Glossary of terms relating to the cosmetic industry

EAS 847-1, *Cosmetics Analytical methods Part 1: Glossary of terms*

EAS 847-16, Cosmetics —Analytical methods —Part 16: Determination of lead, mercury and arsenic content

EAS 847-17, *Cosmetics —Analytical methods —Part 17: Determination of pH*

EAS 847-18, *Cosmetics —Analytical methods —Part 18: Determination of thermal stability*

ISO 18416, *Cosmetics —Microbiology —Detection of Candida albicans*

ISO 21149, *Cosmetics --Microbiology --Enumeration and detection of aerobic mesophilic bacteria*

ISO 22717, *Cosmetics —Microbiology —Detection of Pseudomonas aeruginosa*

ISO 22718, *Cosmetics —Microbiology —Detection of Staphylococcus aureus*

ISO 24153, *Random sampling and randomization procedures*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EAS 846 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
cream
semi-solid emulsion which contain mixtures of oil and water as a cosmetic preparation applied to the skin. Examples include vanishing creams, foundation creams, cold creams, night creams, moisturizer creams, hand creams, face creams, body creams, toning creams, emollient creams, purifier creams, nourisher creams, facial scrub creams, facial mask creams, facial wash creams and such products among others.

3.2
lotion
thick, smooth liquid preparation designed to be applied to the skin for cosmetic purposes. Examples include vanishing lotions, foundation lotions, cold lotions, night lotions, moisturizers, cleanser lotions, hands lotions, face lotions, body lotions, toner lotions, emollients, purifiers, and nourishers and such products among others.

3.3
gel
semi-solid colloidal suspension of a solid dispersed in a liquid to be applied to the skin for cosmetic purposes

4 Requirements

4.1 Ingredients

All ingredients used including dyes, pigments and colours shall comply with all parts of EAS 377.

4.2 General requirements

4.2.1 The preparation shall be clear or of uniform colour.

4.2.2 The cream, lotion or gel shall be free from visible impurities.

4.3 Specific requirements

4.3.1 The skincare creams and lotions, shall comply with the specific requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Specific requirements for skincare creams and lotions

S/No.	Characteristic	Requirement		Test Method
i)	Thermal stability	To pass test		EAS 847-18
ii)	pH range	Adult products	4.5 - 8.5	EAS 847-17
		Baby products	5.0 - 8.5	
		Skin lightening products	3.5 – 8.5	
iii)	Total fatty substance content, % by mass, min	5		Annex A
iv)	Hydroquinone content	Not detected		Annex B

4.3.2 Non-emulsified products and gels shall comply with the specific requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Specific requirements for non-emulsified products and gels

S/No.	Characteristic	Requirement		Test Method
i	pH range	Non skin lightening products	4.5 - 8.5	EAS 847-17
		Skin lightening products	3.5 - 8.5	
ii	Hydroquinone content	Not detected		Annex B

4.4 Microbiological limits

The skincare creams, lotions and gels shall comply with the microbiological limits given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — Microbiological limits for skincare creams, lotions and gels

S.No.	Micro-organisms	Limits	Test methods
i)	Total viable count for aerobic mesophyllic microorganisms CFU/g or CFU/ml, max.	100	ISO 21149
ii)	*Pseudomonas aeruginosa*	Not detectable in 1 ml or 1g of cosmetic product	ISO 22717
iii)	*Staphylococcus aureus*		ISO 22718
iv)	*Candida albicans*		ISO 18416
v)	*Escherichia coli*	Not detected in 1 g of cosmetic product	ISO 21150

4.5 Heavy metal contaminants

The skincare creams, lotions and gels shall comply with the heavy metal limits given in Table 4 when tested in accordance with the test methods specified therein.

Table 4 — Heavy metal limits for skincare creams, lotions and gels

S/No.	**Heavy metal**	**Limit[a], mg/kg, max**	**Test method**
i)	Lead	10	EAS 847-16
ii)	Arsenic	2	
iii)	Mercury	2	
[a]The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product shall not exceed 10 mg/kg.			

5 Packaging

The product shall be packaged in suitable well-sealed containers that shall protect the contents and shall not cause any contamination or react with the product.

6 Labelling

In addition to the labelling requirements given in EAS 346, each package shall be legibly and indelibly marked with the following

a) product name as “cream”,” lotion” or “gel”; and

b) an indication on whether the product is skin lightening.

7 Sampling

Sampling shall be carried in accordance with ISO 24153.

Annex A
(normative)

Determination of total fatty substance content

A.1 Outline 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.

A.2 Reagents

A.2.1 Dilute hydrochloric acid 1:1 (v/v)

A.2.2 Petroleum ether, B.P. 40 °C to 60 °C

A.2.3 Methyl orange indicator solution — Dissolve 0.1 g of methyl orange in 100 mL of water.

A.2.4 Sodium sulphate, desiccated

A.3 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 separation funnel and allow it to cool to 20 °C. Rinse the conical flask with 50 mL of petroleum ether in portions of 10 mL. Pour the ether rinsings into the separation funnel shake the separation funnel well and leave until the layers separate. Separate out the aqueous phase and shake it out with 50 mL portions of 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 ether extracts through a filter paper containing sodium sulphate into a conical flask which has been previously dried at a temperature of 60 °C ± 2 °C and then weighed. Wash the sodium sulphate on the filter with ether and combine the washings with the filtrate. Distil off the ether and dry the material remaining in the flask at a temperature of 60 °C ± 2 °C to constant mass.

C.4 Calculation

The total fatty substance shall be calculated as follows

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

where:

m_1 mass, in grams, of the residue, and

m_2 mass, in grams, of the material taken for the test.

Annex B
(normative)

Determination of hydroquinone content

B.1 Principle

Hydroquinone is extracted from the cosmetic product using a mixture of water and methanol in the ratio of 20:80 in an ultrasonic bath for 20 minutes. Determination of the analyte in the resulting solution is performed by reverse phase HPLC equipped with UV/VIS detector at a wavelength of 295nm.

B.2 Reagents

B.2.1 HPLC grade water.

B.2.2 HPLC grade methanol

B.2.3 Hydroquinone standard, purity 99.9+%

B.2.4 HPLC grade acetonitrile

B.2.5 Mobile phase Methanol/Water (80/20).

B.3 Apparatus

B.3.1 HPLC equipped with UV/VIS detector

B.3.2 Analytical balance with accuracy of ±0.0001g

B.3.3 Ultrasonic bath

B.3.4 Amber volumetric flasks, 10 mL, 1000 mL.

B.3.5 10 mL and 100 mL beaker

B.3.6 250 mL measuring cylinder

B.3.7 0.45 µm Teflon syringe filters.

B.3.8 Aluminium foil paper.

B.3.9 10 mL glass syringe

B.3.10 Stainless steel column, length 150 mm, internal diameter 4.6 mm, C18, particles size of 5 µm or equivalent.

B.3.11 Wash-bottle.

B.4 Sample preparation

B.4.1 Preparation of the solvent mixture

Prepare the solvent mixture by measuring about 200 mL of HPLC grade water using 250 mL measuring cylinder and transfer into a 1000 mL volumetric flask. Fill the 1000 mL volumetric flask to the mark with HPLC grade methanol using a wash bottle. Cap the flask and shake well to ensure a homogeneous solution is obtained. Label the flask appropriately (Methanol/Water 80/20) and allow the resultant solution to settle.

B.4.2 Preparation of Calibration Standard Solutions

Calibration standard solutions are prepared as per Work Instruction TES/04/WI/13.

B.4.3 Sample preparation

Weigh 100 mL beaker and record the mass (S1). Weigh approximately 0.5 g of sample into the pre-weighed beaker and record the mass (S2). Disperse the sample in about 8 mL solvent mixture (7.1.1). Cover the beaker with aluminium foil paper (6.2.8) and place it in a ultrasonic bath (6.2.3) for 10 min. Weigh 10 mL amber volumetric flask and record the mass (S3). Transfer the sample solution into the volumetric flask and top to the mark with the solvent mixture. Weigh the volumetric flask containing sample mixture and record the mass (S4). Transfer sample into appropriately labelled amber autosampler vials for HPLC determination. Test samples within 24 hr of preparation.

B.5 Environmental control

The analysis should be carried out in a well-ventilated air-conditioned room maintained at 20 C±2ºC since the retention time of hydroquinone fluctuates with temperature changes.

B.6 Quality control

The stability of the retention time shall be ensured when the relative standard deviation (RSD) of successive injections do not vary one from the other by more than 2%. If the linearity is below the acceptable limit, repeat the calibration exercise.

The linearity of the calibration curve should be above 0.999XX. If the linearity is below the acceptable limit, repeat the calibration exercise.

B.7 Procedure: High Performance Liquid Chromatography (HPLC) Setup.

B.7.1 Degas mobile phase solvents in a sonicator for 10 minutes and then connect solvent reservoirs to instrument. Turn on the instrument and load the method of test in the software.

B.7.2 Download the method into the instrument. Allow software to connect to instrument and then open the pump valve.

B.7.3 Press the purge button to prime the pump before use. Once purging is complete, close the valve and check if pressure is building up. Check for any air bubbles in the plumbing and purge the system if necessary. Install the appropriate column and check for any leaks. If leaks are detected, tighten the connectors.

B.7.4 Allow the equipment to run for 20 min to equilibrate, with a different solvent other than the mobile phase flowing through; in this case the solvent is Acetonitrile). After the equipment has stabilized, switch off the pump and switch to the mobile phase and allow the equipment to run for about 10 minutes. Ensure that the oven temperature of 40°C has been attained and any signals arising from the noise and drift of the equipment has been reduced.

B.7.5 Adjust the flow rate of the mobile phase to 1.5 mL/min, set runtime at 5 minutes, the pump mode to isocratic mode, the lamp to D2, and detector wavelength set at 295 nm.

B.8 HPLC Calibration Curve

To obtain a calibration curve, inject 1 µL of calibration standard solutions starting with the blank and then standards starting with the lowest concentration. Record the peak areas/heights for each corresponding concentration level. Ensure at least five replicate injections are made for each calibration standard. Prepare the calibration curve by plotting the peak areas/heights against hydroquinone concentration, in mg/Kg. Ensure that the results meet the acceptance criteria stipulated in clause B.6.

B.9 HPLC Determination

Inject 1 µL of the samples and record the peak area/heights. Using the peak areas/heights of the sample calculate the concentration of the sample using the Microsoft® Excel spreadsheet calibration curve. Ensure that at least three injections are made and the average is reported as the result if it passes the QC checks stipulated in clause B.6.

B.10 Results

B.10.1 Determination of Hydroquinone concentration

Hydroquinone concentration is determined using the following formula:

$$\text{Conc (mg/kg)} = \frac{\text{Peak}_{Area} - \text{Intercept}}{\text{Scope}} \times \frac{S_4 - S_3}{S_2 - S_1}$$

Where:

S1 mass in grams of empty beaker

S2 mass in grams of beaker with sample

S3 mass in grams of empty volumetric flask

S4 mass in grams of volumetric flask with sample solution

B.10.2 Expression of Results

Levels ≥ 10 mg/Kg but < 100 mg/Kg to the nearest three significant figures

Levels ≥ 100 mg/Kg to the nearest whole number

Levels > 0.1 mg/Kg < 10mg/Kg to the nearest two significant figures.

Bibliography

[1] EAS 786: 2013, *Skin care creams, lotions and gels — Specification*

[2] IS 6608: 2004, *Specification for skin creams*

[3] IS 4011: 1982, *Methods for dermatological tests for cosmetics*

[4] Official Journal of the European Communities N. L26217