SRI LANKA STANDARD 389 : 2014

UDC 665.584.4

SPECIFICATION FOR
SKIN POWDERS

(*Second Revision*)

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard
SPECIFICATION FOR SKIN POWDERS
(*Second Revision*)

SLS 389 : 2014

(Attached AMD 545)

Gr. 6

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Sri Lanka

Sri Lanka Standards are subject to periodical revision in order to accommodate the progress made by industry. Suggestions for improvement will be recorded and brought to the notice of the Committees to which the revisions are entrusted.

This standard does not purport to include all the necessary provisions of a contract.

Sri Lanka Standard
SPECIFICATION FOR SKIN POWDERS
(*Second Revision*)

FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Chemicals and Polymer Technology and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2014-09-02.

This standard was first published in 1976 and the First Revision was issued in 1984. This Second Revision covers the requirements applicable to any skin powder including make-up powder. The limits for microbiological requirements with relevant test methods and limits for Mercury and Cadmium have been introduced in this Revision. Additional marking requirements have been included.

This standard is subject to the restrictions imposed under the Cosmetics, Devices and Drugs Act No. 27 of 1980 and the regulations framed thereunder.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, measured or computed, expressing the result of a test or an analysis, shall be rounded off in accordance with **SLS 102**. The number of decimal places retained in the rounded off value shall be the same as that of the specified value in this standard.

In the formulation of this standard, the assistance derived from the following publications is gratefully acknowledged :

IS 3959 : 2004	Skin powder - Specification
IS 14648 : 2005	Microbiological examination of cosmetics and cosmetic raw materials
ISO /DIS 17516	Cosmetics – Microbiology – Microbiological limits*

Standards for fragrances published by the International Fragrance Association (IFRA)

* to be published

1 SCOPE

1.1 This standard prescribes the requirements and methods of sampling and test for skin powders (body powders and face powders) with or without herbs/ herbal extracts and medicated skin powder.

1.2 Skin powders for babies are not covered by this standard.

1.3 This standard does not prescribe requirements related to therapeutic/ medicinal properties and claims and efficacy of skin powders.

2 REFERENCES

ISO /TR 17276	Cosmetics - Analytical approach for screening and quantification methods for heavy metals in cosmetics
ISO 18416	Cosmetics - Microbiology - Detection of *Candida albicans*
ISO 21150	Cosmetics - Microbiology - Detection of *Escherichia coli*
SLS 102	Rules for rounding off numerical values
SLS 124	Test sieves
SLS 457	Classification of cosmetic raw materials and adjuncts Part 1 Dyes, colours and pigments recognized as safe Part 2 Raw materials and adjuncts other than dyes, colours and pigments not recognized as safe
SLS 495	Sampling of cosmetics and toilet preparations
SLS 1316	Code of good manufacturing practices for cosmetics industry
SLS 1349	Method for the enumeration and detection of aerobic mesophilic bacteria in cosmetics
SLS 1350	Method for the detection of *Pseudomonas aeruginosa* in cosmetics
SLS 1351	Method for the detection of *Staphylococcus aureus* in cosmetics
SLS 1445	Method for the enumeration of yeast and mould in cosmetics

3 TYPES

Skin powders shall be classified into two types as follows :

3.1 Body powders :

These shall include talcum powders, toilet powders, deodorant powders, and dusting powders.

3.2 Face powders :

These shall include loose powders and compressed powders specially for facial applications.

4 REQUIREMENTS

4.1 General requirements

4.1.1 *Body powders*

These shall consist principally of a finely powdered, free flowing, absorbent, innocuous material. It shall be completely free from grit when tested in accordance with Appendix **G**.

4.1.2 *Face powders*

These shall consist of finer powder with a colour suitable to the complexion of face, free flowing, absorbent and innocuous material.

4.1.3 Skin powder shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS 1316**.

4.1.4 The date of expiry / best before / shelf life of the finished product shall be determined based on the in-vitro studies carried out by the manufacturer for the complete duration of the shelf life.

4.2 Raw materials

4.2.1 The colours and pigments used, if any, shall comply with the provisions of **SLS 457 : Part 1**.

4.2.2 The raw materials and adjuncts other than dyes, colours and pigments shall comply with the provisions of **SLS 457 : Part 2**.

4.2.3 If fragrance is used, it shall comply with the provisions of standards for fragrances published by the International Fragrance Association.

4.3 Free from boric acid

The material shall be free from boric acid when tested by the method prescribed in Appendix **B**.

4.4 Other requirements

4.4.1 The material shall also comply with the requirements given in Table **1**, when tested according to the relevant methods prescribed in Column **5** of the table.

4.4.2 The residue on 125 µm sieve shall be of maximum 1.5 per cent by mass and the residue on 180 µm sieve shall be of maximum 0.1 per cent by mass for skin powder with natural herbal materials when tested by the method prescribed in Appendix **D**.

TABLE 1 – Requirements for skin powder

Sl No. (1)	Characteristic (2)	Requirement		Method of test (5)
		Body powder (3)	Face powder (4)	
i)	Matter insoluble in boiling water, per cent by mass, min.	95.0	95.0	Appendix **C**
ii)	Fineness(see **4.4.2**) :			
	a) Residue on 75-µm sieve, per cent by mass, max.	1.5	0.5	Appendix **D**
	b) Residue on 150- µm sieve, per cent by mass, max.	0.1	0.1	Appendix **D**
iii)	Moisture and volatile matter, per cent by mass, max.	2.0	3.0	Appendix **E**
iv)	pH of aqueous suspension	5.5 to 8.0	5.5 to 8.0	Appendix **F**

4.5 Microbiological limits

The skin powder shall also comply with the microbiological limits given in Table **2** when tested in accordance with the relevant method given in Column **4** of the table.

4.6 Limits for heavy metals

The skin powder shall also comply with the heavy metals limits given in Table **3** when tested in accordance with ISO /TR 17276 **.**

TABLE 2 - Microbiological limits

Sl. No. (1)	Test (2)	Limit (3)	Method of test (4)
i)	Total aerobic mesophilic microorganisms (bacteria , yeast and mould count), per g, max.	500	SLS 1349 SLS 1445
ii)	*Pseudomonas aeruginosa*	Absent in 1 g	SLS 1350
iii)	*Staphylococcus aureus*	Absent in 1 g	SLS 1351
iv)	*E.coli*	Absent in 1 g	ISO 21150
v)	*Candida albicans*	Absent in 1 g	ISO 18416

TABLE 3 – Heavy metal limits

Sl. No. (1)	Test (2)	Limit (3)
i)	Lead (as Pb), mg/kg, max.	10
ii)	Arsenic (as As), mg/kg, max.	3
iii)	Mercury (as Hg), mg/kg, max.	1
iv)	Cadmium (as Cd), mg/kg, max.	3

5 PACKAGING

The material shall be packed in suitable, well closed containers. Glass shall not be used as containers. Proper identification method shall be maintained when many number of containers of same variety and different varieties are in a package.

6 MARKING

6.1 The containers shall be marked legibly and indelibly with the following:

a) Name of the product as registered with the Regulatory Authority in Sri Lanka;
b) Name and address of the manufacturer for locally manufactured products;

c) Name and address of the distributor in Sri Lanka / importer including the country of origin, in the case of imported products;
d) Registered trade mark, if any ;
e) Brand name, if any ;
f) Net content, in grams, of the material ;
g) Batch or code or lot identification number ;
h) Date of manufacture ;
j) Best before / shelf life ;
k) List of ingredients;
m) Instructions for use where necessary ;
n) Special precautions to be observed in use , if required ; and
p) Specific warning statement necessary or appropriate to prevent health hazard.

7 METHODS OF TEST

Tests shall be carried out as prescribed in Appendix **B** to Appendix **G, ISO/TR 17276** and the relevant methods indicated in Column **4** of Table **1** and Table **2**.

APPENDIX A
COMPLIANCE OF A LOT

The sampling scheme given in this Appendix should apply where compliance of a lot to the requirements of this standard has to be assessed based on statistical sampling and inspection.

Where compliance with this standard is to be assured based on manufacturer's control systems, appropriate schemes of sampling and inspection coupled with type, testing and check tests or any other procedure, an appropriate scheme of sampling and inspection should be adopted.

A.1 LOT

In any consignment packages / containers of the same type and capacity belonging to one batch of manufacture or supply shall constitute as a lot.

A.2 SCALE OF SAMPLING

A.2.1 Representative samples of the material shall be drawn according to the relevant clauses of **SLS 495**.

A.3 NUMBER OF TESTS

A.3.1 Each container selected as in **6.2** and **6.3.1** of **SLS 495** shall be examined for packaging and marking requirements.

A.3.2 Test for detection of boric acid and grit shall be carried out on each individual sample obtained as in **6.4.2** of **SLS 495**.

A.3.3 Tests for determination of other requirements of the standard shall be conducted on the composite sample obtained as in **6.4.1** of **SLS 495**.

A.4 CRITERIA FOR CONFORMITY

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

A.4.1 Each container examined as in **A.3.1** satisfies the relevant requirements.

A.4.2 Each container examined as in **A.3.2** satisfies the relevant requirement.

A.4.3 The composite samples tested as in **A.3.3** satisfies the relevant requirements.

APPENDIX B
DETECTION OF BORIC ACID

B.1 PROCEDURE

Weigh, to the nearest mg, about 1 g of the powder material and place it in a boiling tube (20 mm x 3 mm). Add about 2 ml of concentrated sulphuric acid and about 5 ml of methyl alcohol. Stopper the tube with a cork carrying two bent tubes as shown in Figure **1**. Boil the contents in the test tube. Blow in air through one tube and light the vapours that come off the other bent tube (outlet tube). A green flame is obtained if boric acid is present.

The test is considered as “pass” if the green flame is not obtained.

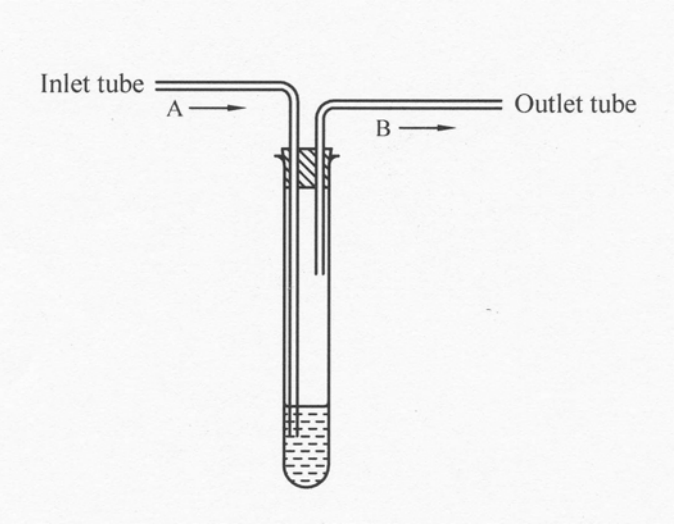

FIGURE 1 – Boiling tube arrangement for Detection of boric acid

APPENDIX C
DETERMINATION OF MATTER INSOLUBLE IN BOILING WATER

C.1 REAGENT

Rectified spirit

C.2 PROCEDURE

Weigh, to the nearest mg, about 1 g of the material and transfer to a 500-ml beaker. If necessary, wet the material with a little rectified spirit. Add to beaker about 200 ml of water and boil. Allow to settle and filter the supernatant liquid through a Gooch crucible. Wash the residue in the beaker with water and transfer completely to the filter. Dry the residue in the crucible at 105 ± 2 °C, cool in a desiccator and weigh. Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 5 mg.

C.3 CALCULATION

$$Matter\ insoluble\ in\ boiling\ water,\ per\ cent\ by\ mass = \frac{m_1}{m}\ \text{X}\ 100$$

where,

m_1 is the mass, in g, of the dried residue; and
m is the mass, in g, of the material taken for the test.

APPENDIX D
DETERMINATION OF FINENESS

D.1 REAGENT

Denatured spirit, filtered

D.2 PROCEDURE

Place about 10 g of the material, weighed to the nearest gram, in a 75-µm sieve and sieve to 150-µm sieve, conforming to **SLS 124,** (see Note) and wash by means of a slow stream of running tap water and finally with a fine stream from a wash bottle until all the material that can pass through the sieve has passed. In case, the material is not easily wetted by water, the washing could be started with a slow stream of filtered denatured spirit.

Let the water drain from the sieve and then dry the sieve containing the residue shall be transfered to a tared watch glass and dry it at 105 ± 2 °C in an oven. Cool in a desiccator and weigh (m_1). Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 10 mg.

NOTE : *For skin powder with natural herbal materials, use 75-µm sieve and sieve 150-µm sieve, conforming to* **SLS 124.**

D.3 CALCULATION

$$\textit{Material retained on the specified sieve per cent by mass} = \frac{m_1}{m} \text{ X } 100$$

where,

m_1 is the mass, in g, of the dried residue ; and
m is the mass, in g, of the powder material taken for the test.

APPENDIX E
DETERMINATION OF MOISTURE AND VOLATILE MATTER

E.1 PROCEDURE

Weigh, to the nearest mg, about 5 g of the material in a porcelain or glass dish, about 60-mm to 80-mm in diameter and about 20-mm to 40-mm in depth. Dry in an air oven at a temperature of 105 ± 2 °C. Cool in a desiccator and weigh. Repeat the heating, cooling and weighing operations until the difference in mass between two successive weighings does not exceed 5 mg.

E.2 CALCULATION

$$Moisture\ and\ volatile\ matter,\ per\ cent\ by\ mass = \frac{m_1}{m} \text{ X } 100$$

where,

m_1 is the loss in mass, in g, on drying ; and
m is the mass, in g, of the material taken for the test.

APPENDIX F
DETERMINATION OF pH OF AQUEOUS SUSPENSION

F.1 PROCEDURE

Take 10.0 ± 0.1g of the material in a 150-ml beaker and add 90 ml of freshly boiled and cooled water. Stir well to make a thorough suspension. Using a pH meter, determine the pH of the suspension after 60 ± 5 s of making the suspension at 27 ± 2 °C.

APPENDIX G
DETERMINATION OF GRIT

Take about 20 g of the powder material, weighed to the nearest g, in a beaker, and remove the bulk of the material by overflow under a carefully controlled stream of water. The grit being heavier will remain in the beaker along with some powder. Test the residue in the beaker for the presence of grit by rubbing the residue between the finger and the thumb.

The test is considered as “pass” if grit is not available.

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AMD 545

Amendment No: 01 approved on 2021-04-30 to SLS 389:2014

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FOREWORD

Delete the text given in third paragraph and substitute the following:

"This Specification is subject to the restrictions imposed under the applicable State Legislative requirements. "

2 REFERENCES

Delete the "SLS 457" and "SLS 1316" in the reference list and substitute the followings:

"SLS 457	Cosmetics- Classification of raw materials Part 1: Substances permitted subject to restrictions and permitted colourants, preservatives and UV filters Part 2: Prohibited substances
SLS ISO 22716	Guidelines on good manufacturing practices for cosmetics"
SLS 1587	Cosmetics - Packaging and labelling"

4.1 General requirements

Delete the "**SLS 1316**" and substitute the "**SLS ISO 22716**" at the end of the text given in Clause **4.1.3**"

Insert the following new Clauses:

4.1.5 "It shall be the responsibility of the manufacturer to provide evidence for assessment of safety on human health in the final product formulation before releasing the product for sale. Results of safety assessments/such studies shall be produced, whenever required."

4.1.6 "Evidence shall be provided from a recognized body for the talc materials used for manufacture skin powders shall be free from asbestos."

4.2 Raw materials

Delete the Clauses **4.2.1** and **4.2.2** and substitute with the following:

4.2.1 "The raw materials used shall comply with the provisions of Part **1** and Part **2** of **SLS 457**."

AMD 545

6 MARKING

Insert the following new Clause:

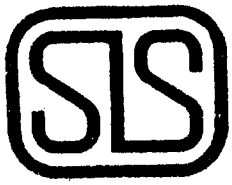
"**6.2** The marking and labelling shall also be in accordance with **SLS 1587**."

……

SLS CERTIFICATION MARK

The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI *which includes surveillance inspection of the factory, testing of both factory and market samples.*

Further particulars of the terms and conditions of the permit may be obtained from the Sri *Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08.*



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SRI LANKA STANDARDS INSTITUTION

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The principal objects of the Institution as set out in the Act are to prepare standards and promote their adoption, to provide facilities for examination and testing of products, to operate a Certification Marks Scheme, to certify the quality of products meant for local consumption or exports and to promote standardization and quality control by educational, consultancy and research activity.

The Institution is financed by Government grants, and by the income from the sale of its publications and other services offered for Industry and Business Sector. Financial and Administrative control is vested in a Council appointed in accordance with the provisions of the Act.

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All members of the Technical and Sectoral Committees render their services in an honorary capacity. In this process the Institution endeavours to ensure adequate representation of all view points.

In the International field the Institution represents Sri Lanka in the International Organization for Standardization (ISO), and participates in such fields of Standardization as are of special interest to Sri Lanka.

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