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भारतीय मानक मसौदा

क्षारसूत्र (भाग 1) – विशिष्टि

Draft Indian Standard
Ksharasutra (Part-1) - Specification

ICS 11.120.10

Ayurveda Sectional Committee, AYD 01

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FOREWORD

(Formal Clause would be added later)

The *Ksharasutra* therapy is a unique and effective method of drug delivery for the treatment of fistula in ano. It offers an ambulatory and safe alternative to surgical procedures, with promising results in terms of healing and patient outcomes. This therapy is most appropriate for healing the fistulous track and has been widely used in traditional Ayurvedic medicine. *Ksharasutra* therapy provides a non-surgical approach to the treatment of fistula in ano. Its complication-free curative results have earned it an honorable place in the text books of Colorectal surgery.

Ksharasutra therapy involves the use of a medicated thread, which is prepared by coating a thread with a special herbal formulation. As *Ksharasutra* therapy gains recognition as an effective treatment option for anorectal disorders, the standardization of *Ksharasutra* thread becomes increasingly important. Standardization of *Ksharasutra* ensures safety, efficacy and consistent therapeutic outcomes.

In the formulation of this standard, significant assistance has been derived from the Ayurvedic Pharmacopoeia of India, Part II, Vol. II, 2008 published by the Ministry of Ayush, Government of India. Inputs have also been derived from the information available in the public domain in print and electronic media including authoritative books.

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.

Draft Indian Standard
Ksharasutra (Part-1) – Specification

1 SCOPE

This standard prescribes the requirements and methods of test for *Ksharasutra*.

2 REFERENCES

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated:

<i>IS No.</i>	<i>Title</i>
IS 1070 : 1992	Reagent grade water – Specification (<i>third revision</i>)
IS 4905 : 1968	Methods for random sampling
IS 18082 : 2022	<i>Haridra (Curcuma longa L.)</i> Rhizome for use in Traditional Medicine — Specification
IS 18192 : 2023	<i>Apamarga (Achyranthes aspera L.)</i> Whole Plant for use in Traditional Medicine — Specification
AYD/01/23792	<i>Snuhi (Euphorbia neriiifolia Linn.)</i> Stem use in Traditional Medicine – Specification (Under development)

3 DEFINITIONS

3.1 *Kshara*

Alkaline substances obtained from the ash of drugs.

3.2 *Ksharakarma*

A therapeutic measure in which caustic material is applied to tissue.

3.3 *Ksharasutra*

A medicated seton prepared with caustic medicines.

4 MATERIAL

4.1 Linen thread of size 20 No.

4.1.1 The thread used is of linen consisting of processed pericyclic fibres from stems of *Linum usitatissimum L.*

4.1.2 The linen thread shall comply with the Microscopical requirements given in the Annex A.

4.2 *Apamarga Kshara* - *Kshara* prepared from whole plant of *Achyranthes aspera L.* The *Kshara* shall be prepared as per the method given in Annex B.

4.3 Haridra Churna - Powder of *Curcuma longa* L. rhizome.

4.4 Snuhi Ksheera - Latex of *Euphorbia neriifolia* Linn.

4.5 Ksharasutra Cabinet.

5 PREPARATION OF KSHARASUTRA

5.1 Coatings of Snuhi ksheera

Spread the surgical linen thread of size 20 throughout the length and breadth of the hanger of the specially designed cabinet known as *Ksharasutra* Cabinet. Smear the thread with latex uniformly and carefully all around the thread with the help of clean gauze piece soaked in the *Snuhi Ksheera* (4.4). After smearing all the threads on the hanger, place the hanger in the *Ksharasutra* cabinet for drying. Close the cabinet properly and dry at 50° leaving it overnight. Close all the outlets of the *Ksharasutra* cabinet properly in order to prevent the entry of moisture in to the cabinet. Eleven such coatings with *Snuhi Ksheera* (4.4) should be done.

5.2 Coatings of Snuhi ksheera and Apamarga kshara

Next day process for the 12th coat of *Snuhi Ksheera* (4.4) and then pass the wet thread through a heap of finely powdered *Apamarga kshara* (4.2) immediately. After smearing all the threads with *Apamarga kshara* (4.2), shake the hanger gently to allow the excess particles of *kshara* to fall down and place them in *Ksharasutra* Cabinet for drying. Repeat this process till seven coatings of *Snuhi Ksheera* (4.4) and *Apamarga kshara* (4.2) are achieved, thus completing 18 coatings on the thread.

5.3 Coatings of Snuhi Ksheera and Haridra

Perform the remaining 3 coatings with *Snuhi Ksheera* (4.4) and fine powder of *Haridra* (4.3) as per the above said procedure making a total 21 coatings on the thread. Put on the ultraviolet lamp of the *Ksharasutra* cabinet daily for 20 to 30 minutes to maintain sterile atmosphere right from the 1st day of coating.

6 REQUIREMENTS

6.1 Workmanship and Finish

6.1.1 The *Ksharasutra* shall be clean and free from substances liable to cause tendering during storage.

6.1.2 The manufacture and preparation of *Ksharasutra* shall be conducted under proper hygienic conditions.

6.2 Physical and Chemical Requirements

6.2.1 The *Ksharasutra* shall comply with physical requirements given in Table 1 and chemical requirements given in Table 2.

Table 1 Physical requirements for *Ksharasutra*

SI No. (1)	Characteristics (2)	Requirements (3)	Method of Test, Ref to (4)
i).	Length of thread, mm	290 to 310	Annex C
ii).	Weight, g	0.9 to 1	Annex C
iii).	Diameter/Thickness, mm	1.75 to 2.0	Annex C
iv).	Tensile Strength (Breaking load), kg, <i>Min</i>	5	Annex C

Table 2 Chemical requirements for *Ksharasutra*

SI No. (1)	Characteristics (2)	Requirements (3)	Method of Test, Ref to (4)
i).	Loss on drying at 105°, percent, <i>Max</i>	5	Annex C
ii).	Water-soluble extractive, percent, <i>Min</i>	85	Annex C
iii).	Hexane-soluble extractive, percent, <i>Min</i>	6	Annex C
iv).	*pH (1% aqueous solution)	9.3 to 10.5	Annex C
v).	Sodium, percent, <i>Min</i>	1	Annex C
vi).	Potassium, percent, <i>Min</i>	35	Annex C
vii).	*Total alkalies (calculated as carbonates), percent, <i>Min</i>	20% w/w	Annex C
viii).	Turmeric, percent, <i>Min</i>	4	Annex C
ix).	Curcumin, percent, <i>Min</i>	0.05	Annex C
x).	*Sulphated ash, percent	80 to 82	Annex C
xi).	Euphol, percent, <i>Min</i>	3	Annex C

NOTE - * For these tests, collect sufficient quantity of the coated material from a set of *Ksharasutra*, by scraping gently with a spatula.

7 PACKING

7.1 Giving a single fold, keep the thread inside a polythene sachet, pack in a glass tube, and seal it along with a silica bag (as desiccant)

7.2 The *Ksharasutra* shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of packing shall be as agreed to between buyer and seller. Packaging of product shall be such as to maintain the integrity of the product throughout its

shelf life.

8 MARKING

8.1 Each pack of *Ksharsutra* shall be legibly marked or labelled with the following information:

- a) Name of the product;
- b) Batch number;
- c) Manufacturer's name/trademark;
- d) Address of the manufacturer;
- e) Month and year of manufacture;
- f) Instructions for storage; and
- g) Any other information requested by the buyer

8.2 BIS Certification Marking

8.2.1 The product conforming to the requirement of this standard may be marked with the Standard Mark.

8.2.2 The use of 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 license for the use of the standard mark may be granted to manufacturers which can be obtained from the Bureau of Indian Standards.

9 SAMPLING AND CRITERIA FOR CONFORMITY

9.1 Lot

All the *Ksharasutra* of the same grade and material, produced under similar conditions of manufacture shall constitute a lot.

9.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

9.1.2 The *Ksharasutra* shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

9.2 Number of Tests and Criteria for Conformity

9.2.1 All the *Ksharasutra* selected as per column 3 of table 3 shall be examined for physical requirements.

9.2.2 A *Ksharasutra* thread failing to meet one or more of the requirements shall be termed as defective. A lot shall be considered as conforming to the requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of table 3. Otherwise, the lot shall be rejected.

Table 3 Sampling Plan for *Ksharasutra*
(Clauses 9.1 and 9.2)

SI No	Lot Size	Sample size	Permissible Number of Defective Samples	Sub sample size	Permissible No. of Defective Sub-samples
(1)	N (2)	n (3)	a (4)	n_1 (5)	a_1 (6)
i)	Up to 280	13 ¹	1	8	0
ii)	281 – 500	20	2	8	0
iii)	501-1200	32	3	13	0
iv)	1 201 – 3 200	50	5	13	0
v)	3 201-10 000	80	7	20	1

¹ or lot size when less than 13

9.2.3 Out of the samples already found satisfactory according to 9.2.2, a sub sample as per Column 5 of Table 3 shall be taken. The sub sample shall be further tested for chemical requirements.

9.2.4 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective samples is less than or equal to the acceptance number as given in column 6 of Table 3.

10 STORAGE

Ksharasutra shall be stored under conditions that prevent contamination and, as far as possible, deterioration. Storage area shall be clean, well ventilated, protected from light, moisture, insects and rodents.

11 QUALITY OF REAGENTS

11.1 Reagents including pure chemicals used shall be of analytical grade.

11.2 Reagent grade water for laboratory use shall be as per IS 1070.

NOTE– ‘Pure chemicals’ shall mean chemicals that do not contain impurities which effect the results of analysis.

ANNEX A
(Clause 4.1.2)

MICROSCOPICAL EXAMINATION OF LINEN THREAD

A-1 Take a thread, wash thoroughly with chloroform 2 or 3 times followed by hot water 3 times to remove the coated materials. Cut the washed thread into small pieces and digest it by boiling with a 10% aqueous solution of sodium carbonate. Wash to remove sodium carbonate and take small amount of the material on a micro slide and crush it with a glass rod. The material under microscope shows Fibers with very thick cell walls having uniformly narrow lumen and tapering to a very fine point. Fine, oblique or transverse markings present on the walls, sometimes crossing one another.

A-2 Take another small portion of the washed material, mount in Cuoxam (0.5 g of copper carbonate triturated with 10 ml of distilled water, gradually adding strong solution of ammonia, specific gravity 0.88, with continued stirring) and observe. No bulbous swelling is present (distinction from cotton).

ANNEX B
(Clause 4.2)

METHOD OF PREPARATION OF KSHARA

Cut the drug in to small pieces, dry and place in an earthen pot, burn to ashes. Allow the ash to cool down to room temperature, add 6 parts of water and mix well. Allow to settle down and decant the supernatant layers through a piece of clean cloth. Repeat the process of staining two or three times till a clear liquid is obtained. Heat the liquid over a moderate fire till the water evaporates completely, leaving a solid salty white substance at the bottom, which is known as *Kshara*.

ANNEX C
(Table 1, Col. 4)

METHODS OF TEST FOR KSHARASUTRA

This Annex provides the detailed physical and chemical methods of tests for *Ksharasutra*.

C-1 PHYSICAL TESTS

C-1.1 Length

C- 1.1.1 Apparatus

Meter Scale (marked in mm)

C- 1.1.2 Procedure

Fix a standard meter scale on a table. Place the thread with one cut end exactly coinciding with a division on the scale. Applying just enough tension to keep the thread straight, place the other cut end on the scale, and note the division on the scale with which it coincides. Read the length and record it in mm on the meter scale.

C-1.2 Weight

C- 1.2.1 Apparatus

Weighing Balance

C- 1.2.2 Procedure

Record the weight of each thread used in the test C-1.1.2 on a balance of sensitivity 0.1 mg (0.0001 gm) and the average is taken as weight of thread.

C- 1.3 Diameter

C- 1.3.1 Apparatus

Dial Gauge (Sensitivity of 0.0025 mm)

NOTE - Table of the dial gauge should be about 5 cm in diameter, with a pressor foot of about 12.5 mm. The total load applied by the foot when in use shall be $200 \text{ g} \pm 15 \text{ g}$.

C- 1.3.2 Procedure

Take the thread to be measured from its tube and expose it to room temperature for about half an hour. Hold the thread across the gauge table with just the tension required to keep it straight, and allow the pressor foot to touch it. Record the reading on the dial gauge as the thickness of the thread at that point. Three readings are to be taken for each thread, one at mid-point, and two at

equidistance on either side of the midpoint. No point should be within 3 cm of either end of the thread.

C- 1.4 Tensile strength

C- 1.4.1 Apparatus

Tensiometer

C- 1.4.2 Procedure

The thread is tied to a hook suspended from a stand. A weighing pan of 250 g is attached to the other end of the thread, and a weight of 2 kg is placed on the pan. Weights are added to the pan in increments of 50 g, allowing five seconds between such additions. At the time the thread breaks, the total weights in the pan and weight of the pan itself is recorded as the breaking load of the thread. If the breakage occurs within 1 cm from either end, the test should be repeated on a fresh thread.

C- 2 METHODS OF CHEMICAL TEST

C- 2.1 Loss on drying

C- 2.1.1 Apparatus

C- 2.1.1.1 Tared Petri Dish

C- 2.1.1.2 Oven

C- 2.1.1.3 Desiccator

C- 2.1.1.4 Weighing Balance

C- 2.1.2 Procedure

Take a *Ksharasutra* and weigh accurately, place in the form of a coil in a tared petri dish and keep at 105° in an oven for 3 hours. Then cool in a desiccator and, weigh to constant weight and calculate loss on drying using following formula:

$$\text{Percentage of Loss on Drying} = \frac{\text{Weight Loss}}{\text{Weight of Sample}} \times 100$$

C- 2.2 Water soluble extractive

C- 2.2.1 Apparatus

C- 2.2.1.1 Weighing Balance

C- 2.2.1.2 *Reflux apparatus*

C- 2.2.1.3 *Graduated Tube*

C- 2.2.3 *Procedure*

Take a *Ksharasutra* and weigh accurately. Macerate the test material with water (1: 40 w/v) for 5 min at room temperature. Reflux for 5 min on steam bath then cool to room temperature and filter into a graduated tube. Make up the original volume with water, then evaporate a known volume and dry to a constant weight at 100 °C to 105 °C.

C- 2.3 n- Hexane soluble extractive

Carry out the procedure same as given above in C-2.2.3 except using n-hexane instead of water.

C- 2.4 pH (Alkalinity)

C- 2.4.1 *Apparatus*

C- 2.4.1.1 *Vortex mixer*

C- 2.4.1.2 *Digital pH meter*

C- 2.4.2 *Reagents*

Carbon dioxide free water

C- 2.4.3 *Procedure*

Take about 0.1 gm. of coated material of *Ksharasutra* and add 10 ml of carbon dioxide free water. Vortex the mixture for 1 min and set aside for 15 mins. Vortex again for 1 min and filter the mixture. Determine the pH of clear supernatant using digital pH meter.

C- 2.5 Sodium and Potassium

C- 2.5.1 *Apparatus*

C- 2.5.1.1 *Flame photometer*

C- 2.5.1.2 *Volumetric Flask*

C- 2.5.2 *Reagents*

C- 2.5.2.1 *Sodium chloride*

C- 2.5.2.2 *Potassium chloride*

C- 2.5.2.3 Triple Distilled Water

C- 2.5.3 Procedure

Prepare separate stock solution of sodium / potassium (500 mEq) by dissolving 2.9230 g sodium chloride / 3.7280 g potassium chloride in 100 ml triple distilled water. Prepare separate working standard solutions containing 0.5, 1.0, 2.0, 4.0 and 5.0 mEq of sodium/potassium from the respective standard stock solutions.

Using flame photometer with appropriate filters, calibrate the standard solutions and prepare separate calibration plots respectively for sodium/potassium. Take 0.1 gm coated material of *Ksharasutra* and add 15 ml of triple distilled water in 50 ml of volumetric flask and shake vigorously and make the volume up to the mark. Filter the solution and choosing sodium and potassium filter, calculate the content of the sodium/potassium respectively in the coated material of *Ksharasutra* by interpolation from the calibration plot.

C- 2.6 Total alkalies

C- 2.6.1 Apparatus

pH Meter

C- 2.6.2 Reagents

N/25 hydrochloric acid

C- 2.6.3 Procedure

Estimate the total alkalies as carbonate in the coated material of *Ksharasutra* by titrating a known volume of the aqueous solution prepared for determination of pH, with N/25 hydrochloric acid using pH meter to an end point pH of 3.6. Calculate percentage of total alkali as carbonate using the titer value.

C- 2.7 Turmeric

C- 2.7.1 Apparatus

Vortex mixer

C- 2.7.2 Reagents

C- 2.7.2.1 Turmeric

C- 2.7.2.2 Hydrochloric acid

C- 2.7.2.3 Acetone

C- 2.7.3 Procedure

Moisten 0.2 g of coated material of *Ksharasutra* and 0.05 g Turmeric, each separately, with 0.5 ml % v/v hydrochloric acid for 5 min. Extract each separately with 4 x 5 ml acetone by vortexing for 30 seconds, at 0, 5th and 10th min. Pool the respective extracts, filter and make up the volume to 25 ml using acetone. Read the absorbance of each extract after suitable dilution, at 418 nm against acetone Blank.

Calculate the percentage of Turmeric in the coated material of *Ksharasutra* using the absorbance of Reference Turmeric.

C- 2.8 Curcumin

C- 2.8.1 Apparatus

Vortex mixer

C- 2.8.2 Reagents

C- 2.8.2.1 Curcumin

C- 2.8.2.2 Chloroform

C- 2.8.2.3 Methanol

C- 2.8.2.4 Hydrochloric acid

C- 2.8.2.5 Acetone

C- 2.8.3 Procedure

Moisten 0.2 g of coated material of *Ksharasutra* with 0.5 ml % v/v hydrochloric acid for 5 min. Extract the mixture with 4 x 5 ml acetone by vortexing for 30 seconds, each at 0, 5th and 10th minute. Pool the extracts, filter and make up the volume to 25 ml using acetone. Take 10 ml of the solution, evaporate at room temperature to about 0.1 ml. Apply quantitatively 0.1 ml of sample solution, 15 µl (1 mg/ml) solution of Reference Curcumin in acetone and 50 µl of acetone as Blank on a chromatoplate. Develop the Plate in chloroform: methanol (49:1). Mark the yellow coloured Curcumin zone in reference, test sample and blank.

Separate the spots and extract each with 5 x 4 ml methanol and make up the volume to 25 ml in each case.

Read the absorbance of methanol solution of coated material of *Ksharasutra* and Curcumin after suitable dilution against blank at 418 nm. Calculate the percentage of Curcumin in the sample with respect to the Reference Curcumin.

C- 2.9 Sulphated Ash

C- 2.9.1 Apparatus

C- 2.9.1.1 *Silica crucible*

C- 2.9.1.2 *Desiccator*

C- 2.9.1.3 *Weighing Balance*

C- 2.9.2 *Reagents*

Sulphuric acid

C- 2.9.3 *Procedure*

Heat silica crucible to redness for 10 min, allow it to cool in a desiccator and weigh. Take *Ksharasutra* in the crucible and weigh accurately. Ignite gently at first, until the substance is thoroughly charred. Cool, moisten the residue with 1 ml of conc. Sulphuric acid, heat gently until white fumes are no longer evolved and ignite at 8000 until all black particles have disappeared (conduct the ignition in a place protected from air currents). Allow the crucible to cool, add a few drops of conc. sulphuric acid and heat. Ignite as before, allow to cool and weigh to constant weight. Calculate the percentage of Sulphated ash.

C- 2.10 Euphol

C- 2.10.1 *Apparatus*

C- 2.10.1.1 *Vortex mixer*

C- 2.10.1.2 *Chromatogram plate*

C- 2.10.1.3 *Oven*

C- 2.10.1.4 *Water Bath*

C- 2.10.1.5 *Test Tube*

C- 2.10.1.6 *Ice bath*

C- 2.10.2 *Reagents*

C- 2.10.2.1 *n-Hexane*

C- 2.10.2.2 *Chloroform*

C- 2.10.2.3 *Methanol*

C- 2.10.2.4 *Reference- Euphol*

C- 2.10.2.5 *Acetic anhydride*

C- 2.10.2.6 Sulphuric acid

C- 2.10.3 Procedure

Extract 0.2 g of coated material of *Ksharasutra* with 5 x 5 ml n-hexane by vortexing for 30 seconds, each at 0, 5th, 10th, 15th and 20th minute. Pool the extracts, filter and recover the solvent under reduced pressure and re-dissolve the residue in 1 ml chloroform: methanol (3:2). Apply quantitatively 100 µl of the above solution, 100 µl (5 mg /ml) solution of Reference Euphol in n-hexane and 100 µl of n-hexane as Blank on a chromatogram plate. Develop the plate in chloroform: n-hexane (4:1). Mark the Euphol zones in sample, Reference Euphol and Blank by visualizing in iodine chamber. Remove the iodine by vaporizing in an oven at 500 for 20 min. Separate the zones individually, extract each with 5 x 4 ml n-hexane and make up the volume to 25 ml in each case. Take 2 ml from each extract separately in a test tube and dry on a boiling water bath. Cool the residue to the room temperature and add 4 ml of acetic anhydride to each and cool further in an ice bath for 15 minutes. Add 0.05 ml of cold conc. sulphuric acid carefully to each tube and mix thoroughly and set aside in a dark cupboard for exactly 1.5 h and read the absorbance at 281 nm against Blank. Calculate the percentage of Euphol in the coated material of *Ksharasutra* with respect to the Reference Euphol.