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भारतीय मानक मसौदा
यूनानी चिकित्सा- ग्लास हिजामा (कपिंग थेरेपी) उपकरण
Draft Indian Standard

Unani medicine— Glass *Ḥijāma* (Cupping therapy) device

ICS 97.140, 81.040.100

Unani Sectional Committee, AYD 04 **Last Date of Comments: 07 December, 2024**

FOREWARD
(Formal Clauses will be added later)

This standard has been adopted by the Bureau of Indian Standards, after modification and following the approval of the Ayush Division Council after the draft was finalized by the Unani Sectional Committee.

Hijāma (Cupping therapy) is a widely practiced regimen throughout the world. It involves applying suction cups to skin to draw out or divert the morbid matters from the body. It is also used to enhance the blood flow and promote detoxification. This therapy has gained popularity due to its rich heritage rooted in traditional healing practices, a strong evidence base supporting its efficacy, and its cost-effectiveness as a method for promoting overall health and well-being. As a minimally invasive procedure, *Hijāma* provides a therapeutic option with low risk and a favorable safety profile for managing diverse health issues.

Ḥijāma works on the principles of *Imala* (diversion) and *Tanqiya* (cleansing) to maintain the balance of the *Akhlāṭ Arba'a* (four bodily humors) in accordance with the basic fundamentals of Unani medicine. It consists of two primary methods: *Ḥijāma bilā Sharṭ* (dry cupping) and *Ḥijāma bi'l Sharṭ* (wet cupping). Dry cupping involves applying suction cups to the skin without any scarification, making it a completely non-invasive technique. This method can be used alone or in conjunction with other therapies for general health maintenance. In contrast, wet cupping entails the application of suction cups followed by small incisions to draw out a controlled amount of blood, providing a more intensive therapeutic effect.

Considering the popularity of this therapy among various stakeholders, including practitioners and healthcare providers, as well as its potential for attracting medical tourists to India, it becomes imperative to define quality requirements. This will ensure the provision of optimal services to meet the expectations. While cupping devices are widely used and manufactured by many companies, there are currently no established Indian standards governing their design and use. Safety is a crucial consideration, as these devices come into direct contact with the skin. In the case of wet cupping, where scarification occurs, the devices come into contact with breached skin, increasing the risk of infection. To mitigate this risk, it is essential to differentiate and develop cupping devices with distinct specifications. Additionally, as medical devices that directly contact blood, the cups must be designed for sterility, allowing for safe reuse and proper disposal.

This document outlines essential performance requirements to ensure safe and effective use of such devices. The standards for glass cupping device have been set in purview of national legal requirements and specific needs of industry.

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.

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Unani medicine— Glass *Ḥijāma* (Cupping therapy) device

1 Scope

This document provides the standards for the glass cupping device that functions through negative pressure. This standard specification for the device's material, pressure levels, sterilization or disinfection procedures, packaging, and the suitable methods for testing.

This document applies to single-use and multiple-use glass cupping devices.

This document does not apply to the suction pump used to create the negative pressure.

2 Normative references

The standards are referred to in the text in such a way that some or all of their content constitutes required of this document. At the time of publication, the editions indicated were valid. All 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.

3 Terms and definitions

3.1 ***ḥijāma*** **(cupping therapy)** mode of regimenal therapy based on the principles of negative air pressure (vacuum) in which cups are applied on skin with or without scarification for diversion or evacuation of morbid matter from blood.

3.2 ***ḥijāma bi'l sharṭ*** (wet cupping): Ḥijāma (3.1) with scarification (3.4) to achieve evacuation of morbid matter.

3.3 ***ḥijāma bilā sharṭ*** **(dry cupping):** a type of ***Ḥijāma*** without scarification; for diversion of morbid matter.

3.4 **scarification (blood-letting):** therapeutic method of withdrawing blood by pricking the skin with a needle/blade/lancet employed in Ḥijāma bi'l Sharṭ (3.2) in order to treat or prevent illness and disease.

3.5 ***ḥijāma bi'l Nār (fire cupping):*** a type of ***Ḥijāma bilā Sharṭ***, where vacuum is created with fire inside the cup.

3.6 **glass cupping device:** device made of glass, which consists of only ***body*** intended for use in ***Ḥijāma bi'l Nār.***

3.7 **body of the device:** main part of the device which maintains vacuum generated by heating and subsequent cooling of the air, which creates the suction effect pulling the skin upward into the cup. It has an internal cavity and an open end to contact the body surface.

3.8 **instantaneous pressure**: pressure produced inside a glass cupping device at the instant moment of ***Ḥijāma.***

3.9 **negative pressure:** air pressure generated in the inner cavity of the body of the cupping devices.

3.10 **single-use type device:** disposable cupping device for *Ḥijāma bi'l Sharṭ* (3.2).

Note 1 to entry: *This type of cupping device is used when contact with blood and body fluids is likely.*

3.12 **multiple-use type device:** reusable cupping device for multiple-use which is used on intact area of skin with *Ḥijāma bilā Sharṭ* (3.3).

Note 1 to entry: This type of cupping device is used when contact with blood and body fluids is not likely.

3.7 Instantaneous pressure

Pressure produced inside a glass cupping device at the instant moment of cupping.

4. Specification

4.1 Configuration: Configuration of cupping device the configuration of the cupping device and the name of each of its parts are shown in Figure 1

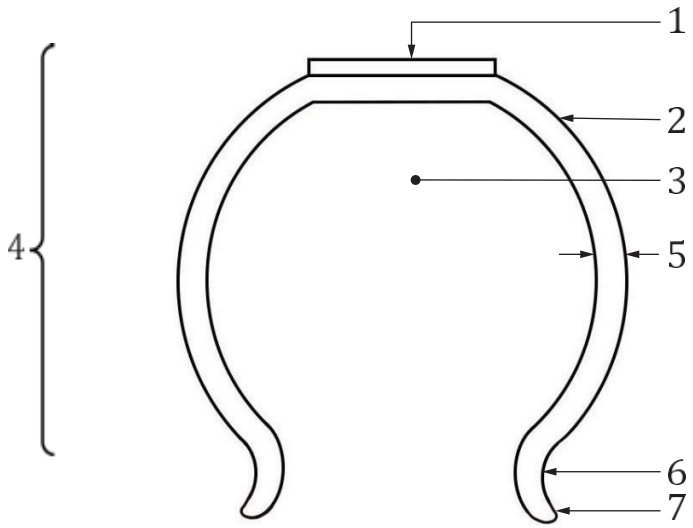


Figure 1: Example of a typical structure of a cupping device

Key
1. Body of cupping device
2. Air outlet
3. Valve unit for air
4. Outlet inner volume

4.2 Dimensions and parameters:

4.2.1 *The glass cupping device should be made in one of five sizes numerically coded from 1 to 5*

4.2.2 Volume of the Inner volume: The volume of the inner cavity for each numerically coded cup shall be specified as shown in Table 1.

Table 1: Inner volume of the cup (Dimensions in millilitres)

Cup number	Inner volume
1	340±17
2	260±13
3	180±9
4	130±6.5
5	95±4.8

4.2.3 Glass thickness: The thickness shall be specified as shown in table 2.

Cup number	Glass thickness δ
1	7.50±0.4
2	6.40±0.3
3	6.30±0.3
4	5.90±0.3
5	4.70±0.2

4.2.4 Material: The glass cupping device shall be made from borosilicate glass that conforms with ISO3585.

5 Requirements

5.1 Biological compatibility: The body of the glass cupping device intended to be exposed to blood during the bloodletting cuppingtechnique shall be assessed and documented according to the guidance and principles given in the ISO 10993-1, ISO 10993-4, ISO 10993-10, ISO 10993-18 and ISO/TS 10993-19.

6. Surface Smoothness

The external surface, the lip and the top of the glass cupping device shall be smooth, without cracks or burrs.

7. Glass quality:

The glass cupping device shall have no more than one impurity with a diameter of ≥ 1.0 mm. There shall be no more than three impurities with a diameter of ≥ 0.5 mm to < 1.0 mm. Cup numbers 1, 2 and 3 shall have no more than two bubbles with a diameter of ≥ 5,0 mm. Cup number 4 and cup number 5 shall have no more than three bubbles with a diameter of ≥ 3.0 mm. No bubble with a diameter of > 5.0 mm is allowed.

8.0 Performance

8.1 Negative pressure resistance

The glass cupping device shall resist the instantaneous pressure of ≥ −91.50 kPa without cracking or breaking.

8.2 Pressure maintenance

Pressure loss between the glass cupping device body and skin shall not be more than 10 % of the instantaneous pressure when being tested for 10 min.

9.0 Test methods (Annex-A)

9.1 *Sterilization and disinfection*

9.1.1 Sterilization for single-use type devices Single-use type devices shall be sterilized using a validated sterilization procedure that shall comply with ISO 11135, ISO 11137-1 or ISO 17665-1.

9.1.2 Disinfection for multiple-use type devices Multiple-use type devices shall be disinfected using a validated disinfection procedure that shall comply with ISO 17664.

10.0 Package

10.1 Primary package

The cupping device shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

The material and design of this primary package shall have no detrimental effects on the contents. The material and design of this primary package shall ensure

a) the maintenance of sterility and disinfection of the contents under dry, clean and adequately ventilated storage conditions;
b) the minimum risk of contamination of the contents during removal from the package;
c) adequate protection of the contents during normal handling, transit and storage, and
d) that once opened, the package cannot be easily resealed without it being evident that it has already been opened.

Note: Requirements of materials, sterile barrier systems and packaging systems for terminally disinfected medical devices are provided in ISO 11607-1.

10.2 *Secondary package*

One or more primary packages shall be packaged in a secondary package.
The secondary package shall be sufficiently robust to protect the contents during handling, transport and storage.
One or more secondary packages may be packaged in storage package, a transit package or both.

11.0 Labelling

11.1 *General*

The symbols used on the package shall comply with ISO 15223-1.

11.2 Primary *package*

The primary package shall be marked with at least the following information:

a) the name or trademark or logo of the manufacturer and/or supplier;
b) product name;
c) product size **4.3.2;**
d) date of manufacture;
e) specification and quantity;
f) product registration number for certification purpose;
g) a description of the contents, including the designated metric size in accordance with 5.1;
h) the lot number, prefixed by the word “LOT” and/or date of manufacture;
i) for single-use type devices, expiry date;
j) for single-use type devices, method of sterilization, the word “STERILE” or symbol;
k) for single-use type devices, the words “For single use” or “Do not reuse” or symbol;
l) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or symbol.

11.3 *Secondary package*

The secondary package shall be marked with at least the following information:
a) the name, address and trademark of the manufacturer and/or supplier;
b) product name;
c) specification and quantity;
d) net weight and gross weight;
e) date of manufacture;
f) product registration number for certification;

g) description of the contents, including the designated metric size in accordance with 5.1, the quantity and the type;
h) the lot number, prefixed by the word "LOT" and/or date of manufacture;
i) for single-use type devices, expiry date;
j) for single-use type devices, method of sterilization, the word "STERILE" or symbol;
k) for single-use type devices, the words "For single use" or "Do not reuse" or symbol;
l) for multiple-use type devices, the maximum number of times the devices can be cleaned and disinfected and the method(s) of cleaning and disinfection recommended by the manufacturer;
m) information for handling, storage and transportation; and
n) a warning to check the integrity of each secondary package before use, such as "Do not use if package is damaged" or symbol;

11.4 Storage and transit package

Storage and transit package shall have the sign "Fragile" and the appropriate symbol. Words and signs shall be legible and durable throughout transportation.

Annex A
LIST OF STANDARDS REFERRED

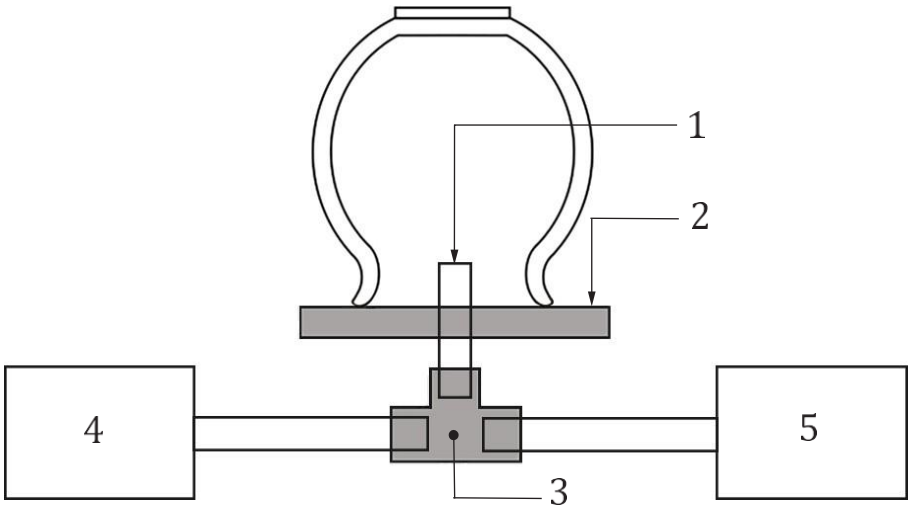
(*Clause* 2)

IS No	*Title*
IS/ISO 15223 : Part 1; ISO 15223-1:2016	Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision) Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose (IS/ISO 11137: Part 2 :2013)
IS/ISO 11607-1 : 2006 ISO 11607-1	Packaging for terminally sterilized medical devices: Part 1 requirements for materials, sterile barrier systems and packaging systems
IS/ISO 11135 :2014	Sterilization of health - Care products - Ethylene oxide - Requirements for the development, validation
IS/ISO 11137 : Part 1 :2006	Sterilization of health care products - Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices
IS 18319 : Part 1 :2023; ISO 17665-1:2006	Sterilization of health care products Moist heat Part 1: Requirements for the development validation
IS 12572 : Part 1 :1994; ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests
IS 12572 : Part 4 :2016; ISO 10993-4 : 2002	Biological evaluation of medical devices: Part 4 selection of tests for interaction with blood
IS/ISO 10993 : Part 10 :2010	Biological evaluation of medical devices Part 10 Tests for irritation and skin sensitization
IS/ISO 10993 : Part 18 :2020	Biological evaluation of medical devices Part18 Chemical characterization of medical device materials
IS/ISO 17664 :2017	Processing of health care products Information to be provided by the medical device manufacturer for
IS/ISO 15223 : Part 1:2016	Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)
IS/ISO 15223 : Part 2:2010	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied: Part 2 symbol development, selection and validation
IS/ISO 17664:2017	Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices
IS 17932 (Part 4) : 2024, IS/IEC/TS 10993 : Part 19 : 2006	Biological Evaluation of Medical Devices Part 4 Physico-chemical morphological and topographical characterization of materials

Annex B
(Clause 9.0)
Test methods for a glass cupping device

A.1 General

To measure internal negative pressure of a glass cupping device, the T-shape valve shall be strongly connected to a suction pump, a manometer and a tube through a silicon plate. The glass cupping device shall be placed on the silicon plate with the tube into the inner cavity at standard atmosphere. The experimental setup is shown in Figure A.1.



Key
1. tube
2. silicon plate (thickness:3mm)
3. T-shape valve
4. suction pump
5. manometer

Figure A.1 — Experimental setup to measure negative pressure

A.2 Negative pressure resistance

Negative pressure resistance of a glass cupping device should be tested by measuring the negative pressure, which is instantaneous maximum pressure (−95.10 kPa), created by a suction pump. The glass cupping device shall maintain the instantaneous maximum pressure for 3s. The performance of the glass cupping device and its appearance shall remain intact after the negative pressure resistance test.

A.3 Pressure maintenance

Pressure maintenance of a glass cupping device should be tested by measuring the negative pressure, which should be within the range of −54.57 kPa to −62.38 kPa, created by a suction pump. Pressure loss between the glass cupping device body and the silicon plate shall not be more than 10 % for 10 min

The performance of the glass cupping device and its appearance shall remain intact after the pressure maintenance test.