AYD 03 (26746)
September, 2024

भारतीय मानक
पॉलीप्रोपाइलीन एनीमा कैन – विशिष्टि

Indian Standard
Polypropylene Enema Can - Specification

Naturopathy Sectional Committee - AYD 03 **Last Date of Comments: 31 October, 2024**

FOREWORD

(Formal clause shall be added later on)

Naturopathy is a form of medicine that employs therapeutic qualities of natural resources namely soil, water, sunlight, air, space (emptiness), diet, rest and exercise enabling the body to heal itself. It is helpful in treating and preventing diseases as well as in promoting overall well-being. The therapeutic techniques involved in naturopathy are based on the customs and culture of the Indian sub-continent documented in the *Upanishads*, *Purāṇās* and other ancient Indian Scriptures.

A branch of naturopathy, Hydrotherapy (or) Water-therapy involves external and internal therapeutic applicationof water in any of its three states namely ice, water or steam for addressing and averting illness while fostering holistic health.

Enema is a water-based therapy in which water and water-based solutions are passed into the rectum by way of the anus to empty the part of large intestine. It is used in treating various disease conditions and also to maintain the health of the human. It is prescribed in combination with other naturopathy treatment modalities. Enema is very useful in treating conditions like constipation, hyperacidity, digestive disorders etc. in Naturopathy.

As available Enema Cans in the market are neither standardized nor of the required quality, there is a need for standardization of Enema Can for quality, safety, and advantage of the users and stakeholders.

This document is the Standard Document stipulating the standardized specification for Polypropylene Enema can.

The inputs for formulation of this standard have been derived from the information available in the public domain in print and electronic media including authoritative books of Naturopathy and related Indian standards. Technical inputs from subject matter experts have also been used to formulate the standard.

CAUTION — The treatment should be given under the supervision of a Naturopathy physician by a Naturopathy therapist.

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Indian Standard
POLYPROPYLENE ENEMA CAN — SPECIFICATIONS

1 SCOPE

This standard specifies the dimensional specification of the Polypropylene Enema Can and its accessories. Enema Can comprise of 4 components a) Can b) Connecting tube c) Nozzle and d) Stopper or Pinch Clamp, sterilization or disinfection procedures, packaging, storage and marking.

This Draft Indian Standards covers minimum requirements and dimensional details for an Enema Can made of Polypropylene. IS 10910 – 1984 This standard for both disposable and reusable Enema Can fall under the scope of this document.

2 REFERENCES

The standards mentioned below contains provisions which, through reference in this text, constitute provisions of this standard. 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 listed below:

Standard No.	***Title***
AYD 3 (24752)	Glossary of Naturopathy Terminology
IS 4033 : 1968 (Reviewed): 2021	General Requirements for Hospital Furniture
IS 10910 - 1984	Specification for Propylene and its copolymers for its safe use in contact with food stuffs, pharmaceuticals and drinking water
IS 10951:2002	Polypropylene Materials for Moulding and Extrusion
IS/ISO 11137-1 : 2006	Sterilization of Health Care Products — Radiation Part 1 Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
IS/ISO 11607-1 : 2006	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 and Routine Control of a Sterilization Process for Medical Devices
IS/ISO 15223-1 : 2016	Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements
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 18319 (Part 1) : 2023 ISO 17665-1 : 2006	Sterilization of health care products Moist heat Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

3 TERMINOLOGY

For the purpose of this standard, the definitions given in AYD 3 (24752) shall apply.

4 MATERIALS

The materials from which the Enema Can is made shall not have undesirable effect on the person.

4.1 Can

4.1.1 The can shall conform to the requirements of Table 1.

4.1.2 The shape, size and nominal capacity of the can shall be as agreed between the purchaser and the Manufacturer.

TABLE 1 REQUIREMENTS FOR ENEMA CAN

SI No.	Characteristics	Requirements
1)	Height of the can	165 mm
2)	Height of the lid	20 mm
3)	Top Diameter	110 mm
4)	Bottom Diameter	75 mm
5)	Outlet Diameter	9 mm
6)	Length of the Nipple	12.5 mm
7)	Maximum marking of water	750 ml
8)	Connecting Tube - Diameter	9 mm
9)	Connecting Tube - Length	1000 – 1500 mm
10)	Nozzle Inner Diameter	4 mm
11)	Nozzle length	90 mm

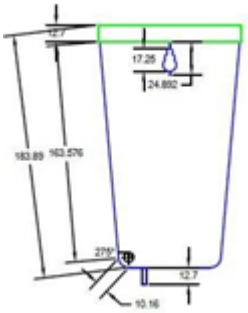

FIG 1A BACK VIEW

FIG 1B TOP VIEW

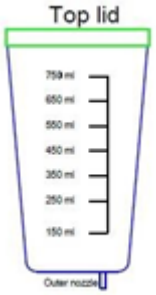

FIG 1C FRONT VIEW

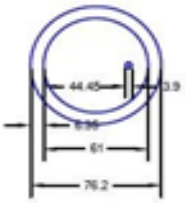

FIG 1D BOTTOM VIEW

All dimensions in mm

FIG. 1 Diagrammatic Shape of Emena Can

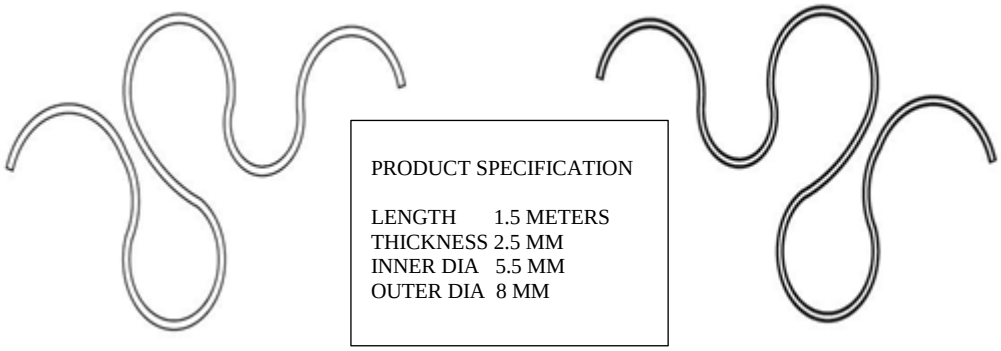

FIG 2A PRODUCT ELEVATION FIG 2B PRODUCT SPECIFICATION

FIG 2 DIAGRAMMATIC SHAPE OF ENEMA CAN HOSE

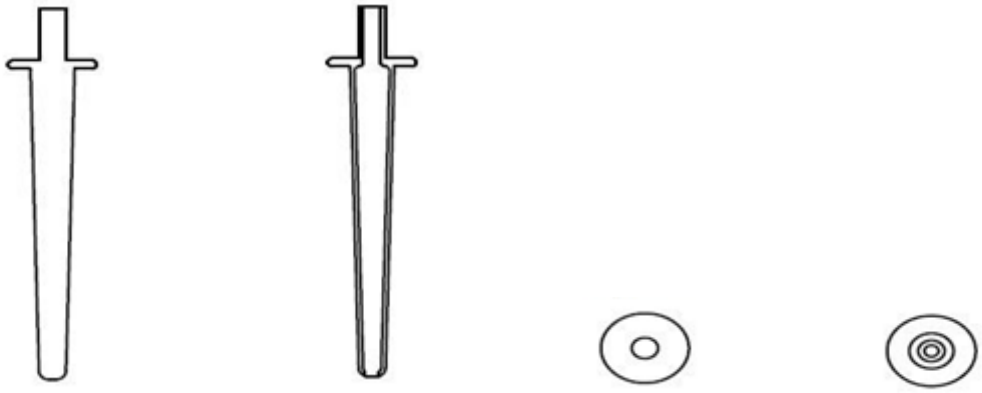

FIG 3A OUTER VIEW FIG 3B INNER VIEW FIG 3C TOP VIEW FIG 3D BOTTOM VIEW

FIG 3 DIAGRAMMATIC SHAPE OF ENEMA CAN NOZZLE

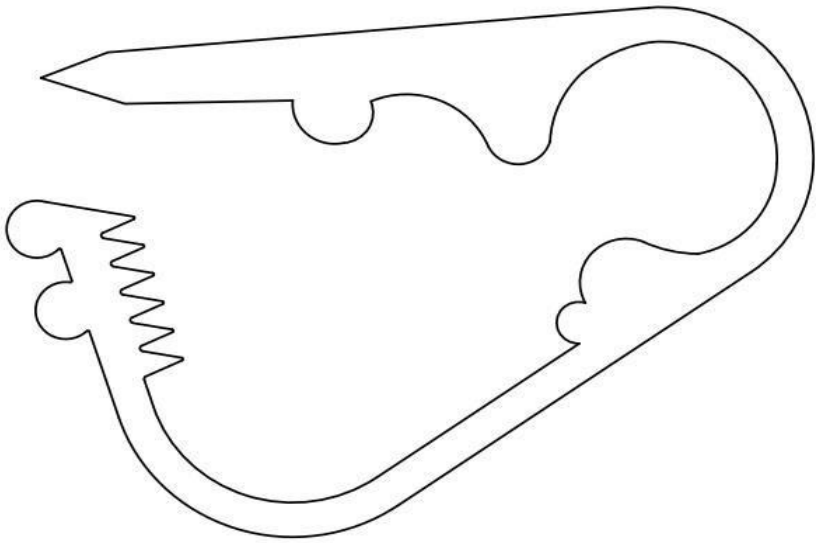

FIG 4 DIAGRAMMATIC SHAPE OF STOPPER OR PINCH CLAMP

4.2 Connecting tube

4.2.1 The length of the connecting tube shall be between 0.75 m to 1.5 m.

4.2.2 The tube shall be of flexible Polyvinyl Chloride (PVC).

4.3 Nozzle

4.3.1 The nozzle shall be made up of Polypropylene & its copolymers.

4.4 Stopper or Pinch Clamp

Stopper or Pinch Clamp shall be made of polypropylene and its copolymers.

5 DIMENSIONS

5.1 The Enema Can shall conform to the requirements of Table 1.

5.2 The Enema Can shall be leakproof.

6 WORKMANSHIP AND FINISH

The Enema Can shall be clean, and reasonably free from distortion, dents, wrinkles, wavy surface, colouring, burrs, scratches, pitting, deep tool marks and other surface defects. The bottle can be designed in such a manner with minimal corners, to clean easily and prevent accumulation of dirt.

7 CONSTRUCTION

7.1 The can being a part of Enema kit will be filled with water, hanged at a particular height in a hook. The connecting tube is fixed at one end to outlet os and the other end is connected to the nozzle.

7.2 The can, connecting tube, nozzle and clamp shall be made up of Polypropylene & its copolymers.

8 PERFORMANCE REQUIREMENTS

The following parameters of Enema can may be analyzed as per IS 10951:2002 needed: Impact resistance, hardness, water absorption, resistance to boiling water, washability etc.

9 STERILIZATION AND DISINFECTION

Sterilization for single-use type devices Single-use type devices shall be sterilized using a validated sterilization procedure that shall comply with IS/ISO 11135 : 2014, IS/ISO 11137-1 : 2006 or IS 18319 (Part 1) : 2023 ISO 17665-1 : 2006

9.1.1 Disinfection for multiple-use type devices Multiple-use type devices shall be disinfected using a validated disinfection procedure that shall comply with IS/ISO 17664 : 2017.

10 MARKINGS

10.1 Each Enema can shall be marked by readings for marking water level. The usable life of the can, connecting tube, nozzle and pinch clamp shall be mentioned on them and easily visible.

10.2 Each enema can shall be marked with:

a) Manufacturer's name/trademark;

b) Name and address of the manufacturer;

c) Name and address of the marketer;

d) Month and year of manufacture;

e) Unique Device Identification / Serial Number and

11 MANUFACTURER'S INSTRUCTIONS

The manufacturer shall furnish with each Enema Can, the suitable instructions for cleaning and maintenance of the enema can.

12 Package

12.1 Primary package

The Enema Can 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 IS/ISO 11607-1 : 2006.

12.2 *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.

13 Labelling

13.1 *General*

The symbols used on the package shall comply with IS/ISO 15223-1 : 2016.

13.2 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 **4.1.2**
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 4.1.2
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.

13.3 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,(see 10).

m) information for handling, storage and transportation;

n) a warning to check the integrity of each secondary package before use, such as "Do not use if package is damaged" or symbol;

13.4 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.