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Specification for medicine spoon (plastics)

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Specification for medicine spoon (plastics)

1 Scope

This standard specifies the requirements for medicine spoons made from plastics materials and intended for use for the dispensation and oral administration of 2.5 ml and 5 ml volumes of medicines in liquid form.

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.

ARS 1466, General purpose detergent (beads, granules and powders) – Specification

ISO 472, Plastics, definitions and terms

3 Terms and definitions

For the purpose of this standard the ISO 472 applies.

4 Requirements

4.1 Materials

The medicine spoon shall be made of a virgin pharmaceutical grade plastics polymer to which suitable additives may have been added. The additives shall not adversely affect the chemical resistance of the moulding or produce substances which have toxic effects.

4.2 Design and Dimensions

4.2.1 Design

The design of a medicine spoon shall be similar to the typical design shown in Fig. 1 and its shape shall be such as to facilitate oral administration of its contents. The half-full level shall be indicated by a line emboss P-d around the inside face of the bowl (see Fig. 1).

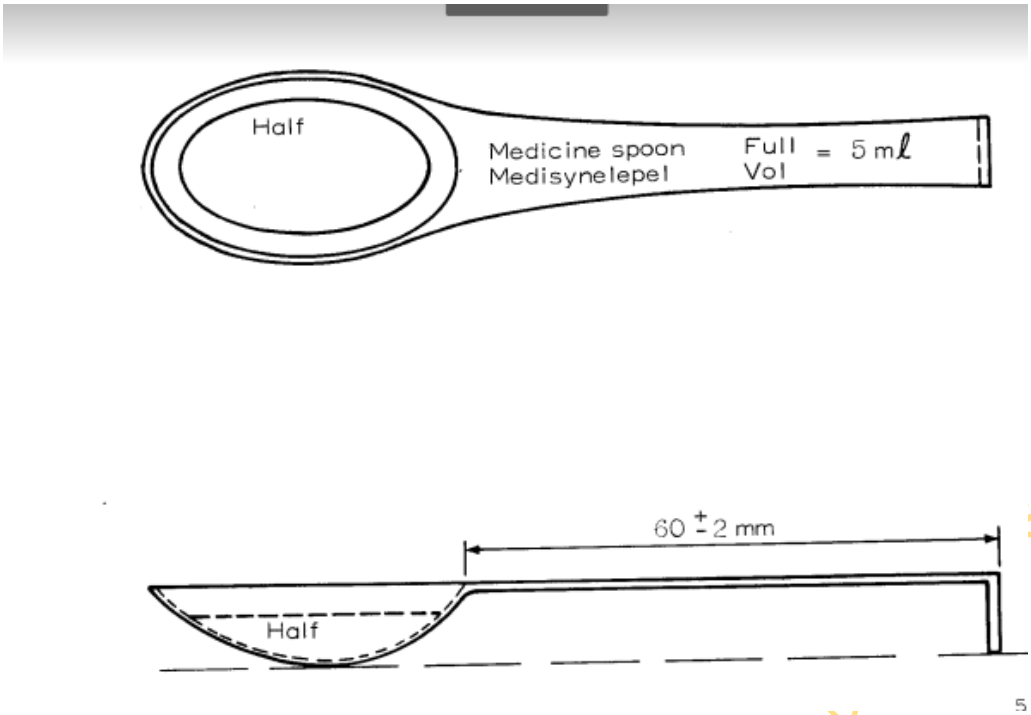

Fig. 1- Typical design of medicine spoon

4.2.2 Bowl

The dimensions of the bowl of a medicine spoon shall be such that, when determined in accordance with A.4,

a) the brim-full capacity of the bowl is 5.0 ± 0.25 ml, and
b) its capacity at the half-full level is 2.5 ± 0.25 ml.

4.2.3 Handle

The handle of the medicine spoon shall enclose the back portion of the bowl, shall have an overall length (measured from the inner edge of the bowl) of 60 ± 2 mm, and the free end shall be turned down for a distance that ensures that when the medicine spoon is placed on a plane horizontal surface, the entire rim of the bowl is horizontal (see Fig. 1).

4.3 Workmanship

A medicine spoon shall be free from blisters, delaminations, and flow lines; its surfaces shall be smooth, homogeneous, and free from all deleterious defects, and all edges of the bowl shall be smooth, and free from flash.

4.4 Colour

Unless medicine spoons of a specific colour are specified by the purchaser, the spoons shall be colourless (i.e. made from a clear resin). The colour of coloured spoons shall be uniform throughout.

4.5 Toxicity

When medicine spoons are tested in accordance with A.2, the aqueous extract shall comply with the requirements given in Table 1, shall have a total hardness (as $CaCO_3$) not exceeding 200 mg/l, and shall have a pH value of 5, 0-9, 0 (inclusive)

Table 1 - Limits for contaminants

Element or compound	Content, mg/l, max.
Lead (Pb)	0,10
Fluorine(F)	1,0
Arsenic (As)	0,10
Hexavalent chromium (Cr)	0,05
Copper (Cu)	1,5
Iron (Fe)	0,7
Manganese (Mn)	0,4
Zinc (Zn)	30
Nitrates (as N)	20
Total dissolved solids*	50
*Dried at 180 °C	

4.6 Resistance to hot detergent solution

When a medicine spoon is tested in accordance with A.3, any change in mass shall not exceed 0. 5 %, the medicine spoon shall show no sign of blisters, delamination, or other surface damage, or of distortion, and the capacity of the bowl shall still comply with the requirements given in 4.2.2.

4.7 Resistance to load

When a medicine spoon is tested in accordance with A.5, any deflection of the medicine spoon shall not exceed 3 mm.

5 Marking

The following information shall appear legibly moulded on each medicine spoon:

a) In the bowl of the medicine spoon and positioned below the embossed line, " 2.5 ml" (see Fig. 1).

b) On the handle of the medicine spoon

i. the words "MEDICINE SPOON"
ii. the lettering "FULL VOL = 5 ml "; and
iii. the manufacturer's name or trade mark.

Annex A
(normative)

Methods of test

A.1 Conditioning

Unless otherwise specified in the method, condition all test specimens for at least 16 h under standard test conditions before testing them, and conduct the test under these conditions.

A.2 Toxicity

A.2.1 Test Sample

From the sample take enough medicine spoons to provide, after granulation, approximately 40 g of granules of particle size 2.8 – 4.0 mm

A.2.2 Preparation of Test Specimens

Granulate and sieve the test sample, using a clean dry granulator. Weigh out 40 ±. 1 g of granules and place in a stoppered flask.

Add 100 ml of distilled or de-ionized water for every 2 g of granulated specimen (see NOTE). Heat the stoppered flask(s) and contents at 70 ±. 1 °c for 24 h; cool, shake the contents, allow the solids to settle, and then decant the clear extract.

NOTE: The extraction is more conveniently carried out with the use of several flasks. Distribute the granulated specimen equally among the flasks and combine the extracts.

A.2.3 Procedure

Use relevant methods to test the extract.

A.3 Resistance to hot detergent solution

A.3.1 Apparatus and Materials

a) Balance. An analytical balance having a sensitivity of 0.1 mg
b) Container. A suitable glass container in which a test specimen can be completely immersed without bending.
c) Absorbent paper. Any suitable absorbent paper such as filter paper or facial tissues.
d) Detergent solution. A 5 % (m/m) aqueous solution of a detergent that complies with the requirements of ARS 1466.

A.3.2 Test Specimen

Use one complete spoon as the test specimen.

A.3.3 Procedure

Weigh the test specimen to the nearest milligram as $\mathbf{m_o}$ and immerse it in the detergent solution in the container. Heat the container and contents at 80 ±: 2 °c for 24 :±: 0, 1 h.

Remove the specimen and place it in distilled water at 23 + 2 °c for 15 :±: 1 min. Using absorbent paper, remove the water adhering to the surface of the specimen and weigh the specimen again as **m** within 1 min of its removal from the water. Visually inspect the specimen, and then test it as described in A.4.

A.3.4 Calculation and Reporting

Calculate the change in mass of the specimen as follows:

$$\text{Change in mass, } \% = \frac{m - m_o}{m_o} \times 100$$

Report the change in mass and the appearance of the specimen.

A.4 Determination of capacity

A.4.1 Apparatus

a. Spirit level, of suitable size
b. Steel needle
c. Calibrated Burette, of capacity 10 ml

A.4.2 Test Specimens

At least one medicine spoon taken at random from the sample, and the medicine spoon used in the test given in A. 3.

A.4.3 Procedure

Level the spoon under test by means of the spirit level. Clamp the steel needle vertically over the centre of the bowl and adjust the height of its point to 1, 7 mm above.

a. the embossed line when determining the half-full capacity, and
b. the edges of the bowl when determining the brim-full capacity

Run distilled water, at approximately 20 °C, from the burette until the meniscus just touches the needle point.
Repeat the test a further two times, and record as the capacities of the spoon the mean of each set of three readings.

A.5 Resistance to load

A.5.5.1 Apparatus and Materials

a) Clamp. A suitable clamp in which the handle of a test specimen can be firmly held
b) Micrometer. A dial-type micrometer having a sensitivity of 0.01 mm .
c) Mercury

A.5.2 Test Specimen

Use one complete spoon as the test specimen.

A.5.3 Procedure

Clamp the handle of the test specimen, 10 mm from the end that the rim of the bowl~~1~~ is in a horizontal plane and the inside of the bowl is facing upwards.

Secure the micrometer below, and with its anvil in contact with, the base of the bowl. Record the micrometer reading. Fill the bowl of the measure to the rim with mercury and after 1 min record the micrometer reading.

A.5.4 Calculation

Calculate the deflection of the measure from the difference between the two readings.

Bibliography

CKS 209- Specification for medicine spoon (plastics)

BS 3221-6, Medicine measure specification for free standing plastic medicine measuring spoons