SRI LANKA STANDARD 1190 : 1999

UDC 621.798.147 : 666.171 : 615.4

# SPECIFICATION FOR
# GLASS BOTTLES FOR PHARMACEUTICALS

SRI LANKA STANDARDS INSTITUTION

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SLS 1190 : 1999

Gr. 8



SRI LANKA STANDARDS INSTITUTION
No. 17, Victoria Place
Elvitigala Mawatha
Colombo 08.
SRI LANKA

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

# SRI LANKA STANDARD
# SPECIFICATION FOR GLASS BOTTLES FOR PHARMACEUTICALS

## FOREWORD

This standard was approved by the Sectoral Committee on Chemicals and PolymerTechnology and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 1999-08-19.

Guidelines for the determination of compliance of a lot with the requirements of this standard based on statistical sampling and inspection are given in Appendix **A**.

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

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

| | | |
|---|---|---|
| i) | ISO 9058:1992 | Glass containers -Tolerances |
| ii) | BS 1679: Part 6:1994 | Specification for glass medicine bottles |
| (iii) | IS 1108: 1975 | Specification for pharmaceutical glass bottles |

## 1 SCOPE

This standard specification prescribes the requirements and methods of test for glass bottles for pharmaceuticals.

## 2 REFERENCES

**ISO 9008** Glass bottles - Verticality - Test method.
**ISO 9009** Glass containers - Height and non-parallelism of finish with reference to container base test methods.
**CS 102** Presentation of numerical values
**CS 124** Test sieves
**SLS 428** Random sampling methods
**SLS 601** Glass container finishes
Part 1 Thread finishes
**SLS 290** Specification for glass liqour bottles

## 3 DEFINITIONS

For the purpose of this specification the following definitions shall apply :

**3.1 blisters** : An elongated bubble usually near the surface, with a smallest dimension greater than appproximately 2 mm.

**3.2 bloom** : A surface film on glass, resulting from :

a) atmospheric attack
b) deposition of chemical vapours or
c) formation of sulfites and sulfates during the annealing process

**3.3 brimful capacity** : The volume of the contents of a bottle when filled to the brim with water at 27 $\pm$ 2 $^0$C.

**3.4 bubbles** : A cavity in the glass which may be filled or partly filled with gas or may be totally evacuated.

**3.5 cords** : Glassy inclusions at different composition particularly in the form of drawn out lines and possessing optical and other properties differing from those of the surrounding glass.

**3.6 finish** : The top part of the neck of a bottle made to suit the closure.

**3.7 hair lines** : Fine cords on surface of glass.

**3.8 heavy seed** : A group of very small bubbles, less than approximately 0.2 mm in diameter, clustered together.

**3.9 insweep** : An inward curved or tapered portion of a bottle, which joins the lower part of the side to the base.

**3.10 nominal capacity** : The volume normally expected to be filled in the bottle at 27 $\pm$ 2 $^o$C.

**3.11 non-parallelism** : The difference between the maximum and minimum heights of a container.

**3.12 push-up** : The bottom of a bottle shaped to form a concavity.

**3.13 sealing surface** : The portion of the finish which makes contact with the sealing gasket or liner of the closure.

**3.14 seeds** : A bubble between approximately 0.2 mm and 2 mm in diameter.

**3.15 stones** : Imperfections in glass resulting from inclusions from such sources as batch materials, refractories and blow pipes or resulting from devitrification of glass or from any other source.

**3.16. verticality** : The horizontal deviation of the centre of the bore entrance from a vertical line through the centre of the base when the bottle is standing upright on a horizontal surface.

**3.17 wedged bottom (slugged bottom)** : Bottom of a bottle having thick glass on one side and thin glass on the other side.

## 4 NOMINAL CAPACITIES

The bottles shall have 5, 10, 15, 30, 50, 60, 75, 100, 200, 500, 750 or 1000 ml nominal capacities.

## 5 REQUIREMENTS

### 5.1 Shape

The bottle shall be round or flat as agreed to between the manufacturer and the purchaser.

### 5.2 Material and workmanship

The bottles shall be made from amber or white flint soda-lime-silica glass. In the case of amber coloured bottles the colour shall be uniform. The bottles shall be well annealed, free from cords, bubbles, blisters, seeds, stones, hair lines, bloom and any other visible defects that may impair the strength, efficiency or appearance of the bottle.

The bottles shall be well formed with uniform distribution of glass all over the walls, the base and the neck, avoiding any wedged bottom and particulary any uneven thickness in the walls. There shall be no sharp edges inside the neck and the mould seam of the neck finish shall have no protruding edges. The sealing surface of the bottles shall be smooth.

Inner and outer surfaces of the bottle shall be clean and free from ridges, indentations and blemishes which preclude use.

The bottles shall have an insweep at the base of the body and the bottom of the bottles shall have amount of push-up necessary to prevent the bottles rocking on its base. The juncture between side walls and bottom shall be well rounded.

### 5.3 Unevenness of the wall

In any horizontal plane of the bottle the ratio of maximum to minimum thickness of the side wall shall not be more than 2.3 : 1.0 , when meassured as discribed in **7.1**.

### 5.4 Neck finish

The neck finish of the bottles shall conform to the relevant neck finish specified in **SLS 601 : Part 1.**

The neck finish diameter and bore dimensions shall be meassured as described in Appendix **B**.

### 5.5 Brimful capacity and dimensions

The brimful capacity and dimensions of the round bottles shall be as given in Table **1** and that of the flat bottles shall be as given in Table **2.**

**TABLE 1 - Brimful capacities and dimensions of round bottles**

| Sl. No | Nominal capacity ml | Brimful capacity ml | Tolerance on brimful capacity ml. | Dimensions mm | | Neck finish mm |
|---|---|---|---|---|---|---|
| | | | | Overall height | Body diameter | |
| (1) | (2) | (3) | (4) | (5) | (6) | (7) |
| i | 5 | 10.0 | ± 1 | 51.0 ± 1.0 | 30.0 ± 1.0 | 22* |
| ii | 10 | 15.5 | ± 1 | 58.0 ± 1.0 | 32.0 ± 1.0 | 22* |
| iii | 15 | 22 | ± 2 | 64.0 ± 0.8 | 30.0 ± 0.9 | 22* |
| iv | 30 | 38 | ± 2 | 87.0 ± 0.9 | 33.0 ± 0.9 | 22* |
| v | 50 | 55 | ± 2 | 85.0 ± 0.9 | 42.0 ± 1.0 | 28* |
| vi | 60 | 70 | ± 2 | 95.0 ± 1 | 40.0 ± 1.0 | 25* |
| vii | 75 | 81 | ± 2 | 89.9 ± 1.0 | 46.0 ± 1.1 | 28* |
| viii | 100 | 115 | ± 3 | 113.2 ± 1.1 | 49.2 ± 1.1 | 28* |
| ix | 200 | 220 | ± 4 | 140.0 ± 1.2 | 58.0 ± 1.2 | 28* |
| x | 500 | 510 | ± 6 | 185.0 ± 1.3 | 74.5 ± 1.3 | 28* |
| xi | 750 | 770 | ± 7 | 271.4 ± 1.7 | 79.2 ± 1.5 | 31.5** |
| xii | 1000 | 1060 | ± 15 | 219.0 ± 1.5 | 98.3 ± 1.7 | 28* |

* Roll on thread pilferproof (ROPP)
** Standard roll on thread pilferproof (standard ROPP)

**TABLE 2 - Brimful capacities and dimensions of flat bottles**

| Sl No. | Nominal capacity ml | Brimful capacity ml | Tolerance on brimful capacity ml | Dimensions mm | | | Neck finish mm |
|---|---|---|---|---|---|---|---|
| | | | | Overall height | Body width | Body breadth | |
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
| i | 100 | 108 | ± 3 | 133.0 ± 1.2 | 48.0 ± 1.6 | 34.0 ± 1.6 | 28* |
| ii | 200 | 214 | ± 3 | 167.0 ± 1.3 | 57.0 ± 1.6 | 42.5 ± 1.6 | 28* |

* Roll on thread pilferproof (ROPP)
** Standard roll on thread pilferproof (standard ROPP)

### 5.6 Transmission of light

When tested by the method described in Appendix **C**, amber coloured bottles shall transmit not more than 10 per cent of the incident radiation at any wavelength between 290 nm and 450 nm.

### 5.7 Resistance to impact

The resistance of a bottle to impact shall be such that when a bottle is tested in manner described in **7.2**, it shall not break or crack under the impact stress specified therein. Only round glass bottles shall pass the resistance to impact test when tested as described in **7.2**.

### 5.8 Limits of alkalinity

The bottles shall pass the test for alkalinity when tested as described in Appendix **D.**

### 5.9 Resistance to thermal shock

The glass bottles shall pass the thermal shock resistance test when tested as described in Appendix **E.**

### 5.10 Verticality

The verticality of the bottles shall not exceed the value obtained by the expression given in **5.10.1** or **5.10.2,** when measured as prescribed in Appendix **F.**

The dimensional tolerances for verticality of bottles shall be as given below:

**5.10.1** The maximum verticality for a nominal height H < 220 mm
$V = 1.3 + 0.005\ H$

**5.10.2** The maximum verticality for a nominal height H ≥ 220 mm
$V = 0.3 + 0.01\ H$

where,

V is the maximum verticality in mm, of the bottle; and
H is overall height in mm, of the bottle

### 5.11 Waviness of the sealing surface

Waviness of the sealing surface of bottles shall not be greater than 230 µm when determined according to the method given in clause **7.3**.

### 5.12 Non-parallelism of finish

The non-parallelism of finish with reference to container base (or the slope of finish) shall be as in accordance with the values specified in **5.12.1** and **5.12.2**, when measured as prescribed in **ISO 9009.**

**5.12.1** The bottles of 22 mm ROPP and 28 mm ROPP neck finish shall have a maximum non-parallelism of 0.6 mm.

**5.12.2** The bottles of 31.5 mm standard ROPP and 40 mm shallow continuous thread neck finish shall have a maximum non-parallelism of 0.7 mm.

### 5.13 Rocking bottom

A bottle shall be stable, when placed on a flat surface and when lightly tapped with a finger, it shall not sway to and fro.

### 5.14 Mass

The mass of the bottles shall be as agreed to between the purchaser and the supplier.

Permitted tolerance on mass of bottle shall be as given in Table 3.

**TABLE 3 - Tolerances on mass on bottles**

| Sl. No. (1) | Mass of bottle g (2) | Tolerance g (3) |
|---|---|---|
| i | Up to 100 | ± 7.0 |
| ii | 101 to 500 | ± 10.0 |
| iii | 501 and above | ± 15.0 |

## 6 PACKAGING AND MARKING

### 6.1 Packaging

The bottles shall be packed in clean corrugated or solid board trays and each tray shall be individually shrinkwrapped with low density polyethylene having a suitable thickness so as to protect the bottles from dust or it shall be packed as agreed to between the purchaser and the supplier.

### 6.2 Marking

**6.2.1** The following shall be legibly and indelibly marked on the insweep of the bottle :

a) Manufacturer's name or registered trade mark, if any;
b) Mould number; and
c) Production year or identification number.

*NOTE*

*Attention is drawn to certification marking facilities offered by the Sri Lanka Standards Institution. See the inside back cover of the standard.*

## 7 METHOD OF TEST

Test shall be carried out as prescribed in **ISO 9009, 7.1, 7.2** and Appendices **B** to **F** of this specification.

### 7.1 Determination of unevenness of the wall

Cut the bottle in any horizontal plane and measure the thickness of wall at the thinnest and thickest area to the nearest 0.001 mm and determine the ratio of the measurement.

### 7.2 Test for resistance to impact

Strike the bottles at the following points with a hardened spherical steel ball of mass 400 g falling from a height of 100 mm:

a) four different points in the same plane at the belly;
b) on both seams; and
c) at the extremities of a diameter, at right angles to the joining seam.

**7.2.1** A bottle shall be deemed to have passed the test if there is no complete fracture or if no cracks develops in its body

*NOTE*

*A piece of glass falls off from the bottle is considered as a complete fracture.*

### 7.3 Determination of waviness of the sealing surface

Place the bottle vertically on the centre of a rotating table (see Note) place a gauge (having a resolution of 01 μm) on the sealing surface and set it to zero. Rotate the table and observe the maximum and minimum reading of the gauge. Sum of the readings is reported as the waviness.

*NOTE*

*The accuracy of the rotating table shall not be less than 10 μm.*

# APPENDIX A
# COMPLIANCE OF A LOT

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

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

## A.1 LOT

In any consignment all the bottles of same nominal capacity and shape belonging to one batch of manufacture or supply shall constitute a lot.

## A.2 SCALE OF SAMPLING

**A.2.1** Samples shall be tested from each lot for ascertaining conformity of bottles to the requirements of this specification.

**A.2.2** The number of bottles to be selected from a lot shall be in accordance of the following table.

| No. of bottles in the lot<br>(1) | No. of bottles to be selected<br>(2) | Acceptance No.<br>(3) | Sub sample size<br>(4) |
|---|---|---|---|
| Up to 500 | 20 | 2 | 5 |
| 501 to 1200 | 30 | 3 | 8 |
| 1201 to 10000 | 50 | 5 | 10 |
| 10001 to 35000 | 80 | 7 | 12 |
| 35001 and above | 125 | 10 | 15 |

**A.2.3** The bottles shall be selected at random. In order to ensure randomness of selection, random number tables as given in **SLS 428** shall be used.

## A.3 NUMBER OF TESTS

**A.3.1** Each bottle selected as in **A.2.2** shall be examined for packaging and marking requirements and material and workmanship.

**A.3.2** Each bottle selected as in **A.2.2** shall be inspected for the requirements given as in **5.3, 5.4, 5.5, 5.10, 5.12, 5.13** and **5.14.**

**A.3.3** Sub sample of size as given in column **4** of the table shall be tested for the requirements given as in **5.6, 5.7, 5.8, 5.9** and **5.11.**

## A.4 CRITERIA FOR CONFORMITY

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

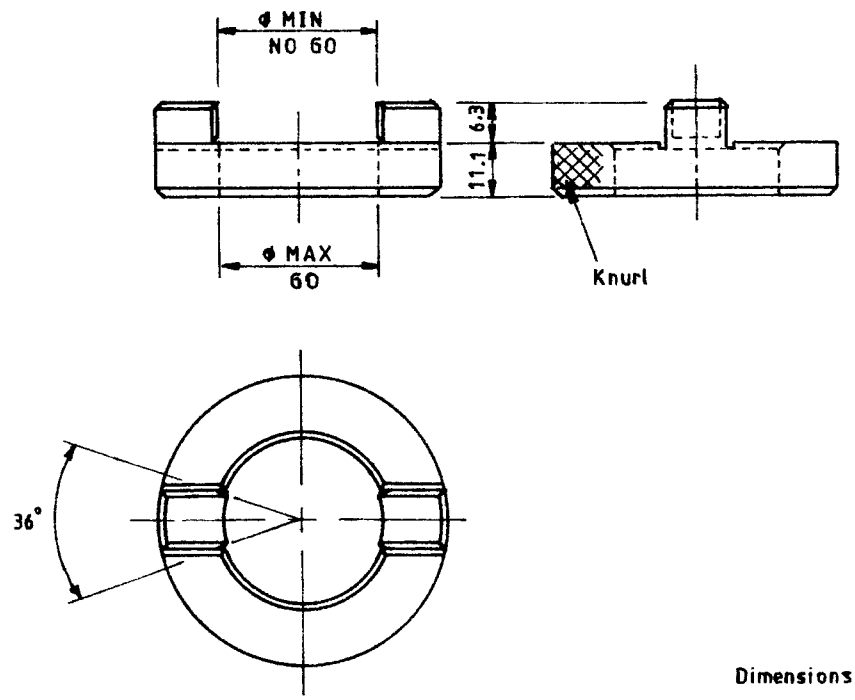
**A.4.1** Each bottle examined and or tested as in **A.3.1** and **A.3.3** satisfies the relevant requirements.

**A.4.2** Number of bottles not conforming to the requirements when taken separately and when inspected as in **A.3.2** is less than or equal to the corresponding acceptance number given as in column **3** of the table.

# APPENDIX B
# METHOD OF MEASURING OF BOTTLE DIMENSIONS

## B.1 NECK FINISH DIAMETER

The diameter of the neck finish shall be measured using a Parnaby gauge as shown in Figure **1**, in which each engaging surface subtends an angle of $36^0$.




NOTE. Harden and grind both GO and NO GO diameters

**FIGURE 1 - Parnaby gauge**

## B.2 BORE DIMENSIONS

Bore dimensions shall be measured using a gauge that enters the neck vertically.

# APPENDIX C
# METHOD OF TEST FOR LIGHT TRANSMISSION

## C.1 PRINCIPLE

A spectrophotometer or similar instrument is used to measure the transmission of light, at the specified wavelengths, of a specimen cut from the side-wall of the bottle.

## C.2 SPECTROPHOTOMETER OR SUITABLE INSTRUMENT

Capable of producing light at wavelengths between 290 nm and 450 nm and of measuring the light transmitted through a test specimen of glass in relation to the intensity of the incident light as percentage transmission or absorbance.

## C.3 PREPARATION OF TEST SPECIMEN

**C.3.1** From the side-wall of the bottle cut test specimens with parallel sides, of a size suitable for the measuring instrument in use.

**C.3.2** Measure the average wall thickness of the bottle in millimetres and select the test specimen whose thickness corresponds most closely to the average wall thickness.

**C.3.3** Wash and dry the selected specimen.

## C.4 PROCEDURE

**C.4.1** Mount the test specimen in the carrier of the measuring instrument using wax or other suitable material, so that the light beam is normal to the surface of the section and reflection losses are minimal.

**C.4.2** Measure the light transmission between 290 nm and 450 nm, either continuously with the appropriate measuring instrument or at suitable intervals with a manual instrument.

## C.5 CALCULATION

**C.5.1** For equipment measuring directly in percentage transmission.

$$\text{Corrected percentage transmission } T = \frac{X}{0.92}$$

*NOTE*

*0.92 is the correction factor for the loss of transmission due to surface reflectance.*

**C.5.2** For equipment measuring absorbance.

$\log_{10} T = \log_{10} 100 - (A + \log_{10} 0.92)$

Where,

A is the measured absorbance
T is the corrected percentage transmission

## APPENDIX D
## TEST FOR ALKALINITY

### D.1 APPRATUS

**D.1.1 Erlenmeyer flask assembly,** of chemically resistant glass, preferably borosilicate, consisting of Erlenmeyer flask of 250-ml capacity with a suitable reflux condenser with ground glass joints.

**D.1.2 Graduated flask,** of chemically resistant glass, preferably borosilicate, 250-ml capacity.

**D.1.3 Mortar,** a suitable mortar made of steel.

**D.1.4 Test sieves**, of aperture size 425 μm and 600 μm conforming to **CS 124.**

### D.2 REAGENTS

**D.2.1 Ethyl alcohol,** 95 per cent (v/v) solution.

**D.2.2 Sodium hydroxide standard solution,** 0.05 mol/l.

**D.2.3 Hydrochloric acid,** standard volumetric solution, c (HCl) = 0.01 mol/l.

### D.2.4 Methyl red indicator

Dissolve 0.04 g of methyl red in 75 ml of ethyl alcohol (**D.2.1**). Add 1.5 ml of standard sodium hydroxide solution (**D.2.2**) or a quantity sufficient to ensure that the colour of the solution corresponds to pH 5.2, and then dilute to 100 ml with water.

### D.2.5 Test solution

Take 1.0 ml of standard hydrochloric acid (**D.2.3**) and 1.0 ml of methyl red indicator (**D.2.4**) in a previously tested (see **D.3**) Erlenmeyer flask and add 240 ml of water. Boil for five minutes. Cool quickly under running water and make up to 250 ml in the graduated flask (**D.1.2**).

## D.3 TESTING OF ERLENMEYER FLASK ASSEMBLY

**D.3.1** Transfer 100 ml of test solution to the Erlenmeyer flask to be tested. Place the flask quickly in a bath of boiling water so that the level of the solution in the flask is below the level of the water in the bath and attach a small reflux condenser. Continue boiling for one hour and at the end of this period observe the colour of the solution. Reject the flask if any change of colour of the test solution has taken place.

**D.3.2** Erlenmeyer flask assemblies which have once passed the test for suitability may fail to do so after prolonged storage. In such a case, they may be re-used by washing with 5 per cent (m/v) solution of glacial acetic acid followed by washing with water until free from acid before use.

## D.4 PROCEDURE

Rinse the bottles selected for this test with distilled water, dry in a stream of dry air and crush them in the mortar such that the glass particles pass through a sieve of aperture size 600 μm, but fail to pass through a sieve of aperture size 425 μm (**D.1.4**). the crushing and sieving should be done in three to four stages to avoid too much fines. Spread the sieved particles weighing more than 5 g on a glazed paper and pass a magnet over them to remove any particles of iron which may have been introduced during crushing. Wash the sieved glass, free from dust in a previously tested Erlenmeyer flask with four successive 30 ml portions of ethyl alcohol (**D.2.1**) and dry the flask and contents at $100 \pm 2\ ^{0}C$. Take two more previously tested Erlenmeyer flasks and transfer 5 g of the sieved, clean, dry glass weighed to the nearest 0.001 g one of the two flasks. Transfer a 100 ml portion of the freshly prepared test solution **(D.2.5)** to both flasks. Place the flasks quickly in a bath of boiling water so that the levels of the contained solutions are below the level of the water in the bath and attach the previously tested reflux condensers. Keep the flasks in the boiling water bath for 30 minutes and then take them out and cool quickly under running water. From the first flask containing the powdered glass sample, decant out the test solution into a third previously tested Erlenmeyer flask. Add 4 ml of water to the powdered glass residue in the first flask, shake a little and decant out into the third flask, taking care to see that transference of the powdered glass is avoided as far as possible. Add 4 ml of water to the second flask containing only the test solution (blank), titrate the solution in the third flask immediately with standard hydrochloric acid **(D.2.3)** to the pink colour of the blank test solution in the second flask.

**D.4.1** The bottles shall be taken to have satisfied the test if not more than 3 ml of hydrochloric acid (**D.2.3**) is required for the titration.

## APPENDIX E
## TEST FOR RESISTANCE TO THERMAL SHOCK

### E.1 APPARATUS

**E.1.1 Wire basket,** suitable for holding the bottles upright.

**E.1.2 Hot water bath,** maintained at 42 $\pm$ 2 $^0$C above the room temperature.

**E.1.3 Cold water bath,** maintained at room temperature with the tolerance of $\pm$ 2 $^0$C.

### E.2 PROCEDURE

Place the empty bottles in the basket (**E.1.1**) vertically with the mouth upwards. When the baths have attained the prescribed temperatures, immerse the basket with the bottles in the hot water bath (**E.1.2**) in such a manner that the bottles become completely filled with the hot water for 15 minutes. Transfer the basket with the bottles filled with hot water to the cold water bath (**E.1.3**) so that the bottles are immersed in water for 5 minutes. The process of transfer from the hot bath to the cold bath shall be completed in 15 $\pm$ 2 seconds. Remove the basket from the cold bath. Inspect each container for cracks or breaks.

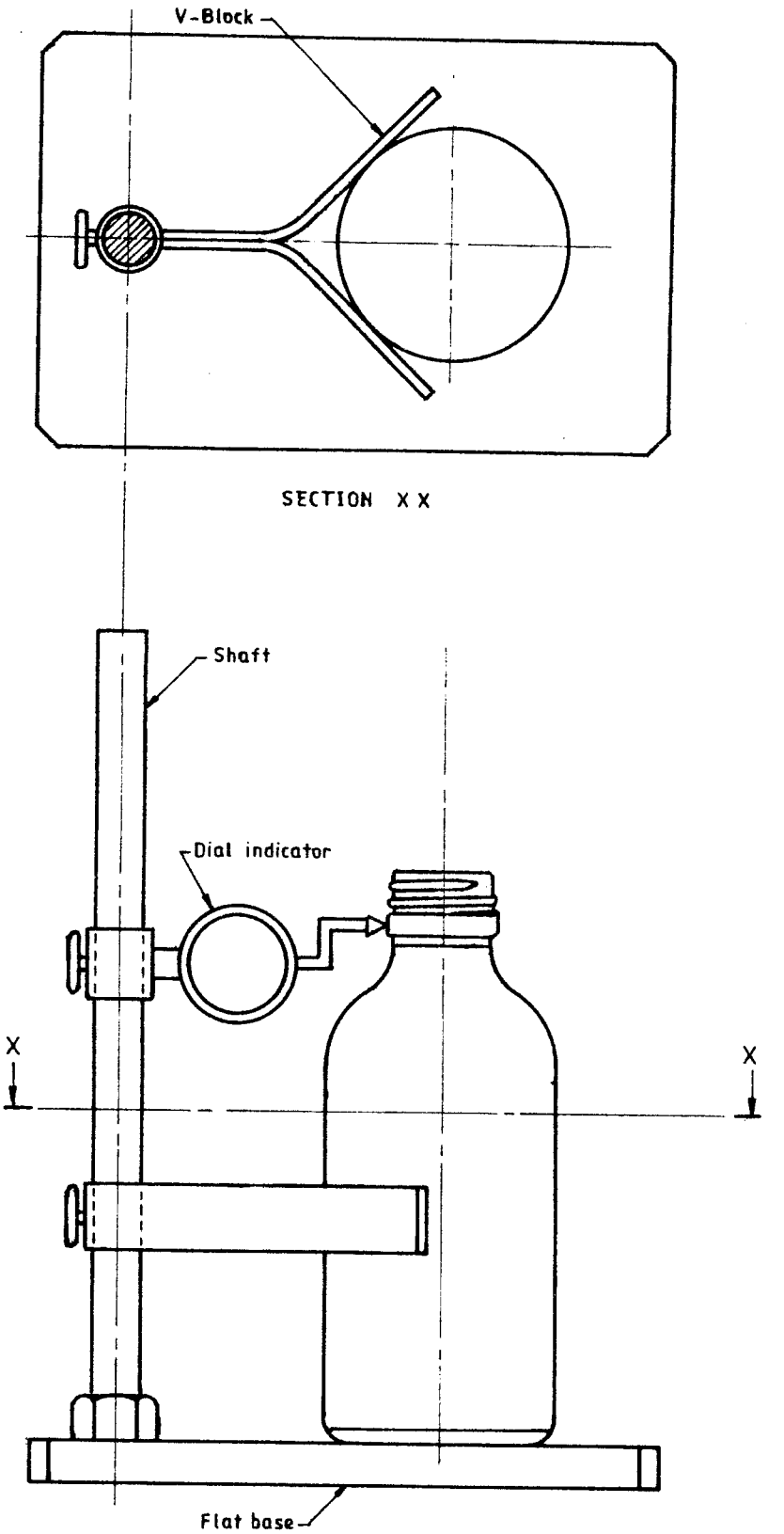



**FIGURE 2 - Assembly for verticality test**

# APPENDIX F
# TEST FOR VERTICALITY

## F.1 ROUND BOTTLES

### F.1.1 Apparatus

A suitable apparatus incorporating a V-block and dial gauge (see Figure **2**).

### F.1.2 Procedure

Assemble the bottle as given in Figure **2** and rotate the bottle through 360°. Record the maximum and minimum reading of the dial gauge. Take care to compensate for any pressure exerted by the dial gauge while turning the bottle in the V-block.

**NOTE**

*Direct pressure inserted to overcome the dial gauge pressure downward towards the V-block.*

## F.2 NON-ROUND BOTTLES

### F.2.1 Apparatus

A suitable device which enables the bottle to be held in the centre of a rotatable plate.

### F.2.2 Procedure

Assemble the bottle in the device (**F.2.1**) and rotate the bottle through 360°. Record to the nearest 0.1 mm, maximum and minimum distance of the outside of the finish from a fixed point on the same horizontal plane.

## F.3 CALCULATION

$$\text{Verticality} = \frac{\text{maximum reading - minimum reading}}{2}$$

*NOTE*

*The measurement obtained includes slight dimensional deviations that may occur in other parts of the bottle such as ring finish ovality, filted finish and rocky bottoms. No correction is made.*

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## SRI LANKA STANDARDS INSTITUTION

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