## Introduction:

This test manual specifies the characteristics of capacity measures and describes the methods by which measuring systems for liquids other than water (hereinafter called "measuring systems") are tested in order to verify that they comply with the relevant metrological requirements.

## Definitions

1.1 Capacity Measure is a container or measuring instrument which can measure a specified volume.
1.2 Maximum Permissible Error(MPE)

Maximum difference, positive or negative, allowed by regulation between the indication of a measure and the corresponding true value, as determined by reference standard volumes or capacities.
2.0 Methods:

There are two methods of Capacity Measure verification
a) Gravimetric method - Determination of Volume by weight (It is recommended for the calibration of standard capacity measure from 0.1 up to 20 liters). This method involves determination of density of liquid by using pycnometer and weighing instrument so that to obtain volume of liquid at a specified temperature, pressure and relative humidity.
b) Volumetric method - liquid transfer from standard capacity measure which has been accurately calibrated to another working capacity measure.
There are two methods of volumetric method:

- Withdrawing Method: This method involves the determination of the volume of water drained by gravity, from the measure being calibrated into one or several, smaller or equally large, standard capacity measure, which have calibrated to an accuracy level significantly higher than that of the measure being calibrated.
- Filling Method: this method consist of filling the standard capacity measure being calibrated with water from a smaller or equally large standard capacity measure that has been calibrated using the gravimetric method.


### 3.0 Metrological Requirement

If the test method is such that the verification capacity measures are used under conditions that differ from their calibration method, the results should be consistent and any systematical difference must be evaluated and necessary correction made.

- Test liquids

A measuring system shall be tested using either the liquid marked on the data plate of the system or a liquid whose viscosity and other flow characteristics are within the ranges of those of the stated liquid.
Any regulation concerning the security for handling the system shall be observed.
A measuring system for milk shall be tested with either milk or potable water (Clean, filtered or drinkable). However, during the test in situ, only milk should be used as test liquid.

## - Preliminary runs

A sufficient number of preliminary runs shall be carried out before the test run in order to eliminate any air that may be contained in the measuring system or the testing equipment, and to ensure that the temperatures of the liquid used for testing, the measuring system and the standard capacity measures are stable.

A leakage test of the measuring system shall be carried out before the test run.

- Temperature and pressure measurement

Temperature measuring devices shall be used to determine the necessary temperature correction for the test liquid, the measuring system and the standard capacity measures being used. These devices shall be mounted at representative positions for the volume on the measuring system and the testing equipment. It is recommended to use temperature measuring devices with an accuracy of $\pm 0.2^{\circ} \mathrm{C}$ or better.
Normally, pressure gauges with an accuracy of $\pm 0.05 \mathrm{MPa}$ ( 0.5 bar ) will be suitable. Pressure gauges should be provided with calibration certificates.

- Measures constructed "to contain" and "to deliver"

The method of calibration should correspond to the manner in which the measure is to be used; e.g. a measure constructed "to deliver" shall be calibrated by determining the volume of the water it discharges, with a specific drainage time, while a measure constructed "to contain" shall be calibrated by determining the volume of the water which is required to fill the dry or pre-wetted measure, a applicable.

- Drainage time and delivery time.

The drainage times for "to deliver" and "pre-wetted" measures have been found to give the required accuracy of measurement for the standard capacity measures, as specified in MPE. However, shorter or longer drainage times in the range of 10-180 seconds may be permitted if the uncertainty requirement can be met.

## Verification for Medical Syringe.

## 1. Definition

1.1 Medical syringe is a simple pump consisting of a plunger that fits tightly in a tube.

The plunger can be pulled and pushed along inside a cylindrical tube (called a barrel), allowing the syringe to take in and expel a liquid or gas through an orifice at the open end of the tube. The open end of the syringe may be fitted with a hypodermic needle, a nozzle, or tubing to help direct the flow into and out of the barrel. Syringes are often used to administer injections, insert intravenous drugs into the bloodstream, apply compounds such as glue or lubricant, and measure liquids.

### 1.2 Testing Procedures:

1.2.1 Visual Examination:

- The total nominal capacity must be: 0.5-1-2-5-10-20-50-100-200 cubic centimeters or milliliters.
- The syringes must be constructed either with or without a scale.
- The total nominal capacity and the capacity between any two scale marks are defined by the volume of water at $+20^{\circ} \mathrm{C}$ delivered by the syringe when the fiducial edge on the piston traverses the whole of the scale or the relevant part of it.


### 1.2.2 Metrological Requirement.

As far as their physical and chemical properties are concerned, the materials used for medical syringes must be suitable for the purpose for which they are to be used.

### 1.2.2.1 Scales.

Only scales with the following scale intervals are permitted:

## Scale intervals

| Nominal | Scale intervals |  |  |  |  |  |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| $\mathrm{cm}^{\mathbf{3}}$ | 0.01 | 0.02 | 0.05 | 0.1 | 0.2 | 0.5 | 1 | 2 | 5 | 10 | 20 | 50 | 100 | $\mathrm{cm}^{3}$ |
| 0.5 | + | + | + | + |  |  |  |  |  |  |  |  |  |  |
| 1 | + | + | + | + | $+$ | + |  |  |  |  |  |  |  |  |
| 2 |  | + | + | + | + | + | + |  |  |  |  |  |  |  |
| 5 |  |  | + | + | + | + | + |  |  |  |  |  |  |  |
| 10 |  |  |  |  | + | + | + | + | + |  |  |  |  |  |
| 20 |  |  |  |  | + | + | + | + | $+$ | + |  |  |  |  |
| 50 |  |  |  |  |  | + | + | + | + | + | + |  |  |  |
| 100 |  |  |  |  |  |  | + | + | + | + | + | + |  |  |
| 200 |  |  |  |  |  |  |  | + | + | + | + | + | + |  |

1.2.2.2 The scale spacing (distance between two consecutive scale marks on the barrel) and the distance corresponding to the maximum permissible error on verification of the total nominal capacity must be at least:
0.8 mm in the case of syringes graduated in 0.01 or $0.02 \mathrm{~cm}^{3}$,
1.0 mm in the case of other syringes.
1.2.2.3 The scale must be regular and uniform*.
1.2.2.4 The difference in length of neighbouring scale divisions must not exceed one tenth of the length of a scale division.
1.2.2.5 The reference marks indicating the total nominal capacity and the scale marks must be made on the barrel.
1.2.2.6 The zero mark must be visible, though part of its thickness may be covered by the tip or its mounting.
1.2.2.7 In the case of scales graduated in:

| 0.01 | 0.1 | 1 | $10 \mathrm{~cm}^{3}$ | every fifth mark | $)^{*}$ |
| :--- | :--- | :--- | :--- | :--- | :--- |
| 0.02 | 0.2 | 2 | $20 \mathrm{~cm}^{3}$ |  |  |

$0.02 \quad 0.2 \quad 2 \quad 20 \mathrm{~cm}^{3} \quad$ every fifth mark $\quad$ )*
$\begin{array}{llll}0.05 & 0.5 & 5 & 50 \mathrm{~cm}^{3}\end{array} \quad$ every alternate mark )*
*must be longer than other un-numbered marks
1.2.2.8 The length of the numbered marks must be at least four tenths of the diameter of the barrel, and the length of the other marks at least two tenths of the barrel diameter, but not less than 2 mm .
1.2.2.9 The marks must lie in planes at right angles to the axis of the barrel.
1.2.3.0 The thickness of the marks may be up to two tenths of the length of a scale division, but may not be more than 0.4 mm nor less than 0.25 mm .

### 1.3. 0 Test method

Only gravimetric method is recommended.

## Equipments:

- Weighing instrument class II
- Thermometer of accuracy $0.2^{\circ} \mathrm{C}$ or better
- Barometer
- Small capacity measure.


## Testing media:

- Distilled water.


## Procedures:

1. Find density of air $\left(\rho_{\mathrm{a}}\right)$ by using the formula:

$$
\rho_{\mathrm{a}}=0.34848 \mathrm{p}-0.009(\mathrm{RH}) \mathrm{e}^{0.061 \mathrm{ta}}
$$

where $\mathrm{p}=$ atmospheric pressure in mmHg
$\mathrm{RH}=$ relative humidity (Recommended 50\%)
$t_{a}=$ atmospheric temperature.
Hint: Density of air with respect to RH, atmospheric pressure and temperature can also be read from reference table
2. Put small capacity measure on the weighing instrument and tare it.
3. Record the air temperature.
4. Record the temperature of distilled water.
5. Suck water with a syringe under test to its maximum marked volume.
6. Withdraw water from the syringe to small tare capacity measure.
7. Record the mass ( m ) of water from the syringe.
8. With mass ( m ) , compute the volume at $20^{\circ} \mathrm{C}\left(\mathrm{V}_{20}\right)$ by the formula:

$$
V_{20}=\frac{m}{\rho_{w}-\rho_{\mathrm{a}}}\left[1-\alpha\left(\mathrm{t}_{\mathrm{w}}-20\right)\right]
$$

where m - mass of distilled water.
$\alpha_{-}$Coefficient of expansion of syringe material ( glass or plastic)
$\rho_{\mathrm{w}}$ - Density of water at surrounding temperature read from reference table.
$\mathrm{t}_{\mathrm{w}}$ - temperature of distilled water
$\rho_{a}$ - density of air.
9. Percentage error by volume of the syringe at $20^{\circ} \mathrm{C}$ is calculated by formula:

$$
E=\underline{v}_{20}-\underline{v}_{\underline{d}} \times 100
$$

where $\mathrm{v}_{\mathrm{d}}$ - maximum marked volume of the syringe
$\mathrm{v}_{20}-$ computed volume at $20^{\circ} \mathrm{C}$
E - Percentage Error by volume of syringe.
NOTE: Take care uniformity of units
Check if $E \leq$ MPE, then the syringe passed

## TEST REPORT FOR MEDICAL SYRINGE

Owner Name and Address $\qquad$
Date: $\qquad$

## Location:

$\qquad$

## General Examination:

Type. Model.

Serial Number Last Verification

Maximum Capacity Minimum Capacity $\qquad$
Visual Examination:
(a) $\qquad$
(b) $\qquad$
(c)


ACCURACY TEST
Value of $R H$ : $\qquad$
$\qquad$
Value of $P_{\text {a }}$ $\qquad$

$$
\begin{aligned}
& \rho_{a}=0.34848 P_{a}-0.009(R H) e^{0.061 t}{ }_{a} \\
& V_{20}=\frac{m}{\rho_{w}-\rho_{a}}[1-\alpha(t-20)] \\
& E=\underline{V}_{20} \frac{-V_{d}}{V_{d}} \times 100
\end{aligned}
$$

| s/no: | $\mathbf{M}$ | $\boldsymbol{\rho}_{\mathbf{a}}$ | $\boldsymbol{\rho}_{\mathbf{w}}$ | $\mathbf{t}_{\mathbf{a}}$ | $\mathbf{t}_{\mathbf{w}}$ | $\mathbf{V}_{\mathbf{2 0}}$ | $\mathbf{V}_{\mathbf{d}}$ | $\mathbf{E}$ | $\mathbf{M P E}$ |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Check if $|\boldsymbol{E}| \leq|\boldsymbol{M P E}|$ Medical syringe Passed.

## $\square_{\text {Failed }}$

Remarks:
$\qquad$
$\qquad$
$\qquad$
$\qquad$
$\qquad$

Name of Inspector:
Name of Owner/Agent:

Signature:
Date:

