SRI LANKA STANDARD 688:1985
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SPECIFICATION FOR
DISINFECTANTS

SRI LANKA STANDARDS INSTITUTION

SPECIFICATION FOR DISINFECTANTS

SLS 688:1985

(Attached AMD 167)

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SRI LANKA STANDARDS INSTITUTION

53, Dharmapala Mawatha,

Colombo 3

Sri Lanka

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SRI LANKA STANDARD

SPECIFICATION FOR DISINFECTANTS

FOREWORD

This Sri Lanka Standard was authorized for adoption and publication by the Council of the Sri Lanka Standards Institution on 1985-04-02, after the draft, finalized by the Drafting Committee on Disinfectants had been approved by the Chemicals Divisional Committee.

This specification covers two types of disinfectants. Type 1, for all-purposes, is for use in public places such as hospitals, factories and restaurants. Type 2 is for household purposes.

All standard values given in this specification are in SI units.

In the preparation of this specification, valuable assistance derived from the relevant publications of the British Standards Institution and the Standards Association of New Zealand is gratefully acknowledged.

1 SCOPE

1.1 This specification prescribes the requirements, and methods of sampling and test for disinfectants.

2 REFERENCES

CS 124 Test sieves

SLS 428 Random sampling methods

SLS 516 Microbiological test methods

Part 1 - General guidance for enumeration of micro-organisms -aerobic plate count at 36 ± 1 ^{o}C

3 TYPES

Disinfectants covered under this specification shall be of the following two types.

Type 1 : All-purpose disinfectants

Type 2 : Household disinfectants

4 REQUIREMENTS

4.1 General requirements

4.1.1 The disinfectant shall be either a clear solution or a homogeneous suspension containing phenolic compounds, quaternary ammonium compounds or any other active ingredient(s) or a mixture of active ingredients which permits the disinfectant to comply with the requirements of this specification. It may contain pine oil, related terpenes or other compatible odour-enhancing compounds. It may also contain non-ionic surfactants or other builders and solubilizers, which if used shall also be compatible.

NOTE - By 'compatible' is meant, materials that do not affect adversely either the activity of the disinfectant or the packaging.

4.2 Stability on storage

4.2.1 The disinfectant shall remain stable for a period of at least three months from the date of manufacture, when stored between 15 °C and 40 °C, and shall not show more than one per cent total separation at the top and bottom, when tested by the method prescribed in Appendix A.

4.3 Stability after dilution

4.3.1 When tested by the method prescribed in Appendix B, the disinfectant shall be miscible with artificial sea-water and shall give a stable dilution in concentrations between one per cent and five per cent by volume of disinfectant, and shall pass the test.

4.4 Disinfecting efficacy

4.4.1 The disinfectants of Type 1 and Type 2, when tested at the 'use-dilution' recommended by the manufacturer, which shall be not less than 1 : 20, shall pass the test prescribed in Appendix C and Appendix D respectively.

5 PACKAGING

5.1 The disinfectant shall be supplied in acceptable containers, that are such that neither the container nor its closure interacts chemically or physically with the disinfectant. The containers shall protect the product adequately during normal storage and transportation. These containers may be further packed in bulk containers as agreed to between the buyer and seller.

6 MARKING

6.1 The containers shall be legibly and indelibly marked with the following details:

a) Name and Type of the material as 'All-purpose disinfectant' or 'Household disinfectant';

b) Manufacturer's name and address;

c) Registered trade mark/trade name (if any);

d) Month and year of manufacture and batch number;

e) Volume in millilitres, of the contents;

f) Recommended 'use-dilution' and specific instructions for use; and

g) A statement specifying active ingredients.

6.2 The containers may also be marked with the Certification Mark of the Sri Lanka Standards Institution illustrated below on permission being granted for such marking by the Sri Lanka Standards Institution.

NOTE - The use of the Sri Lanka Standards Institution Certification Mark (SLS Mark) is governed by the provisions of the Sri Lanka Standards Institution Act and the regulations framed thereunder. The SLS mark on products covered by a Sri Lanka Standard is an assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control, which is devised and supervised by the Institution and operated by the producer. SLS marked products are also continuously checked by the Institution for conformity to that standard as a further safeguard. Details of conditions under which a permit for the use of the Certification Mark may be granted to manufacturers or processors may be obtained from the Sri Lanka Standards Institution.

7 SAMPLING

7.1 Representative samples of the material for ascertaining conformity to the requirements of this specification shall be drawn as prescribed in Appendix E.

8 METHODS OF TEST

8.1 Tests for the requirements laid down in 4.2, 4.3 and 4.4 shall be carried out as prescribed in Appendices A, B, C and D.

9 CONFORMITY TO STANDARD

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

9.1.1 Each container examined as in E.5.1 satisfies the relevant requirements.

9.1.2 The composite sample tested as in E.5.2 satisfies the relevant requirements.

9.1.3 Each individual sample tested as in E.5.3 satisfies the relevant requirement.

APPENDIX A

TEST FOR STABILITY ON STORAGE

A.1 OUTLINE OF THE METHOD

Samples of the disinfectant are kept at the upper and lower limits of the temperature range specified for the stipulated period, and examined.

A.2 PROCEDURE

Transfer 250 ml portions each of the disinfectant under test, separately to two 250-ml stoppered measuring cylinders with an ullage of not more than 5 per cent and store one at 15 ± 1 °C and the other at 40 ± 1 °C for three months. After the stipulated period of three months examine the samples.

A.3 REPORT

The disinfectant shall be taken to have passed the test if it does not show more than one per cent of total separation at the top and the bottom. A small amount of float, which may be restored to a homogeneous condition on shaking, is permitted.

APPENDIX B

TEST FOR STABILITY AFTER DILUTION

B.1 OUTLINE OF THE METHOD

One per cent and five per cent dilutions of the disinfectant with artificial sea-water are prepared. These dilutions are maintained at the upper and lower limits of the temperature range specified for the stipulated period and examined.

B.2 APPARATUS

B.2.1 Facility to maintain 15 ± 1 °C.

B.2.2 Facility to maintain 40 ± 1 °C.

B.2.3 *Measuring cylinders*, with stoppers, 100-ml capacity.

B.3 REAGENT

Artificial sea-water. Dissolve 27.0 g of sodium chloride (purity not less than 99.5 per cent) and 5.0 g of magnesium sulfate heptahydrate ($MgSO_4 . 7H_2O$) in water and make upto 1 000 ml. Filter the solution before use.

B.4 PROCEDURE

B.4.1 Take separately 95 ml of artificial sea-water (B.3) in two 100-ml stoppered measuring cylinders and maintain the temperature of one of these at 15 ± 1 °C and the other at 40 ± 1 °C. Add 5 ml of the disinfectant, adjusted to the corresponding temperature, to each of these cylinders and mix well by inverting the stoppered cylinder five times.

B.4.2 Similarly, take separately 99 ml of artificial sea-water (B.3) in two 100-ml stoppered measuring cylinders and maintain the temperature of one of these at 15 ± 1 °C and the other at 40 ± 1 °C. Add 1 ml of the disinfectant, adjusted to the corresponding temperature, to each of these cylinders and mix well as before.

B.4.3 Store these cylinders at the specified temperatures (two cylinders at 15 ± 1 °C and the other two at 40 ± 1 °C) for six hours and then examine the contents by reflected light to determine whether any separation of layers has occurred.

B.5 REPORT

The disinfectant shall be considered to have satisfied the test if it does not show more than one per cent total separation at the top and the bottom. A small amount of creaming, which may be restored to a homogeneous condition on shaking, is permitted.

APPENDIX C

DETERMINATION OF DISINFECTING EFFICACY OF TYPE 1 DISINFECTANTS

C.1 OUTLINE OF THE METHOD

C.1.1 The disinfectant is tested at the recommended 'use-dilution' and concurrently at 0.5 and 1.5 times that dilution. The test consists of challenging the diluted disinfectant with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixture is again challenged by a second inoculum and after a second interval is again sampled for culturing. This process is then repeated to provide a third challenge.

C.1.2 The sample is considered to have passed or failed the test according to the extent of growth shown in the first two cultured samples.

C.2 APPARATUS

C.2.1 Facility, for incubation at 37 ± 1 °C.

C.2.2 Facility, for incubation at 27 ± 1 °C.

C.2.3 *Stopclock*, indicating in seconds.

C.2.4 Facility, for refrigeration at 4 ± 1 °C.

C.2.5 *Universal containers*, made of glass and having metal tops with rubber liners. Plastic containers or glass containers with plastic tops shall not be used.

C.2.6 *Test tubes*, not less than 19 mm x 150 mm.

C.2.7 *Filter paper*, No. 4 Whatman (sterile) or equivalent.

C.2.8 Facility, for autoclaving at 121 ± 1 °C.

C.2.9 *Pipette*, capable of dispensing 0.02 ± 0.005 ml.

C.2.10 *pH meter*

C.2.11 Facility, to sterilize by filtration

C.2.12 *150-µm test sieve*, conforming to CS 124

C.2.13 *Oven*, capable of maintaining temperature at 100 ± 1 °C.

C.3 MEDIA

C.3.1 *Growth media for test organisms*. Wright and Mundy Broth with Dextrose (WMBD).

C.3.1.1 Dispense 10 ml and 6 ml quantities of the Wright and Mundy Broth into universal bottles, and autoclave at 121 ± 1 °C for 12 minutes.

C.3.1.2 Add to this medium, 10 per cent (*m/V*) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 per cent (*m/V*), (i.e. to 10 ml broth add 0.1 ml dextrose solution and to 6.0 ml broth add 0.06 ml dextrose solution).

C.3.2 Recovery medium

A nutrient broth prepared as follows:

C.3.2.1 *Composition*

Beef extract	10 g
Peptone	10 g
Sodium chloride	5 g
Polyoxyethylene sorbitan mono-oleate	30 g

C.3.2.2 *Preparation*

Add the ingredients to 1 000 ml of water. Mix well. Dispense 10 ml quantities into test tubes and autoclave at 121 ± 1 °C for 15 minutes.

C.3.3 *Hard water*, conforming to World Health Organization Standards 342 mg/l hardness prepared as follows:

Dissolve 0.304 g of anhydrous calcium chloride ($CaCl_2$) and 0.139 g of magnesium chloride hexahydrate ($MgCl_2.6H_2O$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at 121 ± 1 °C for 15 minutes. Allow this to reach room temperature before use.

C.3.4 **Yeast suspension**

C.3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (C.3.3) using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more hard water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains, and 500 ml of hard water has been used.

C.3.4.2 Shake the contents of the flask vigorously and strain through a 150-µm sieve (C.2.12) breaking down any remaining lumps.

C.3.4.3 Add 500 ml sterile hard water, shake vigorously.

C.3.4.4 Transfer 50 ml or 100 ml portions into screw-capped bottles, screw the caps tightly and autoclave at 121 ± 1 °C for 15 minutes. Allow the autoclave to cool without releasing the pressure. Store cold but not freezing.

C.3.4.5 Dry two glass petri dishes to constant mass. Into each of these dishes, pipette 25 ml of sterilized yeast suspension and dry to constant mass at 100 °C. Calculate the average solids content of the suspension.

C.3.4.6 Before use, pipette 25 ml of the sterilized yeast suspension into a beaker. Determine the pH using a glass electrode, and determine the volume of 40 g/l sodium hydroxide solution needed to adjust the pH to 7.0 ± 0.1.

C.3.4.7 Immediately before use, add to each bottle of sterilized yeast suspension a volume of sterile hard water and a volume of 40 g/l sodium hydroxide calculated to adjust the concentration of dry yeast to 5 per cent (*m/V*) and the pH to 7.0 ± 0.1. Discard prepared yeast, two weeks after preparation.

C.3.5 *Ringer's solution*, 25 per cent (*V/V*)

Dissolve 9.00 g of sodium chloride, 0.42 g of potassium chloride, 0.24 g of anhydrous calcium chloride and 0.20 g of sodium bicarbonate in water and dilute to 1 000 ml.

Add 1 volume of this solution to 3 volumes of water to give a 25 per cent solution. Dispense into test tubes fitted with suitable closures and sterilize by autoclaving at 121 ± 1 °C for 15 minutes.

C.4 SELECTION OF THE MOST RESISTANT ORGANISM BY THE MINIMUM INHIBITORY CONCENTRATION TEST

C.4.1 The following organisms shall be used for the test:

Pseudomonas aeruginosa	(NCTC 6749 or equivalent)
Proteus vulgaris	(NCTC 4635 or equivalent)
Staphylococcus aureus	(NCTC 4163 or equivalent)

These organisms may be obtained as freeze dried cultures. Once sub-cultured, the organisms shall be maintained on agar slopes of suitable nutrient medium at 4 ± 1 °C.

C.4.2 Sub-culture each organism daily into a universal bottle containing 6 ml of growth medium (C.3.1) and incubate for 24 ± 2 hours at 37 ± 1 °C.

C.4.3 Dilute one part of freshly grown sub-culture of each organism, which is at least a fifth sub-culture and not more than a fourteenth, with ten parts of the growth medium (C.3.1). Before dilution, the *P. aeruginosa*, culture shall be filtered using a Whatman No. 4 filter paper.

C.4.4 Prepare three sets of ten, doubling dilutions of the disinfectant in universal containers (C.2.6). For this purpose dilute the neat disinfectant in the growth medium (C.3.1) or the recovery medium (C.3.2) to give a final volume of 5 ml of the diluted disinfectant for each dilution.

C.4.5 Inoculate each dilution in one set with 0.02 ml of a diluted culture of one organism (see C.4.3).

C.4.6 Incubate all the three sets of inoculated dilutions at 37 ± 1 °C for 72 hours, and examine to determine the organisms most resistant to the disinfectant, that is the organism for which the minimum inhibitory concentration is highest.

C.5 PREPARATION OF THE INOCULUM

C.5.1 Daily sub cultures of the test organism selected as in C.4.6 shall be grown in 6 ml quantities of the growth medium (C.3.1) and incubated at 37 ± 1 °C for 24 ± 2 hours.

C.5.2 The day before the test, inoculate 10 ml of the growth medium (C.3.1) with the test organism from a daily sub-culture which shall be at least a fifth sub culture and not more than a fourteenth. Incubate the inoculated broth at 37 ± 1 °C for 24 ± 2 hours.

C.5.3 Add 6 ml of the test organism culture (C.5.1 and C.5.2) to 4 ml of the yeast suspension (C.3.4) thus making a final concentration of 2 per cent (*m/V*) of yeast in the yeast/organism suspension. If a culture of *P. aeruginosa* is used, it shall be filtered using a Whatman No. 4 filter paper before addition.

C.5.4 Shake the yeast/organism suspension for one minute with a few sterile glass beads. Immediately before the test, count the number of viable organisms in the inoculum by decimal dilutions in 25 per cent Ringer's solution (see C.3.5) and by the drop plate method (7.2.1 of SLS 516 Part 1). The viable count shall be not less than 10^8 organisms/ml or more than 10^{10} organisms/ml or the test results are considered invalid.

C.6 PREPARATION OF THE DISINFECTANT DILUTIONS

Prepare three dilutions of the disinfectant in hard water (C.3.3), based on the recommended 'use-dilution' of the disinfectant, as follows:

A = 0.5 times the recommended 'use-dilution'

B = 1.0 times the recommended 'use-dilution'

C = 1.5 times the recommended 'use-dilution'

The disinfectant dilutions shall be prepared and tested on the same day.

C.7 TEST PROCEDURE

C.7.1 The test shall be carried out at 27 ± 1 °C.

C.7.2 Dispense 3 ml of each dilution of disinfectant (C.6) into separate universal bottles labelled A, B and C, then allow to equilibrate to 27 ± 1 °C.

C.7.3 Add 1 ml of the inoculum to A, B and C at 0, 1 and 5 minutes respectively and mix by swirling gently.

NOTE - Although Clauses C.7.4 *to* C.7.9 *inclusive relate to a single sample, in practice all three dilutions are tested concurrently and a protocol for this is given in* C.9. *It is recommended that before commencing the test universal containers holding the disinfectant dilutions are arranged in a rack together with a fourth container holding the inoculum. The tubes of the recovery broth, labelled A1, A2 and A3; B1, B2 and B3: C1, C2 and C3 are placed nearby and using a copy of the test protocol, each step is ticked off as it is completed.*

C.7.4 Eight minutes after the addition of the inoculum, remove a sample of the inoculum/disinfectant mixture and place 0.02 ml into each of the first group of five tubes of recovery broths. Return the remainder of the mixture in the pipette to the universal container.

C.7.5 Ten minutes after the first addition of the inoculum, add another 1 ml of the inoculum to each of the disinfectant dilutions and mix by swirling gently.

C.7.6 Eight minutes later, remove a sample of the mixture as before (C.7.4) and place 0.02 ml into each of the second group of five tubes of recovery broths.

C.7.7 Twenty minutes after the first addition of the inoculum, add a further 1 ml of inoculum to each of the disinfectant dilutions and mix by swirling gently.

C.7.8 Eight minutes later, remove a sample of the mixture as before and place 0.02 ml into each of the third group of five tubes of recovery broths.

The three additions of inoculum to A and three transfers of samples to recovery broths A1, A2 and A3 are shown diagrammatically in Figure 1.

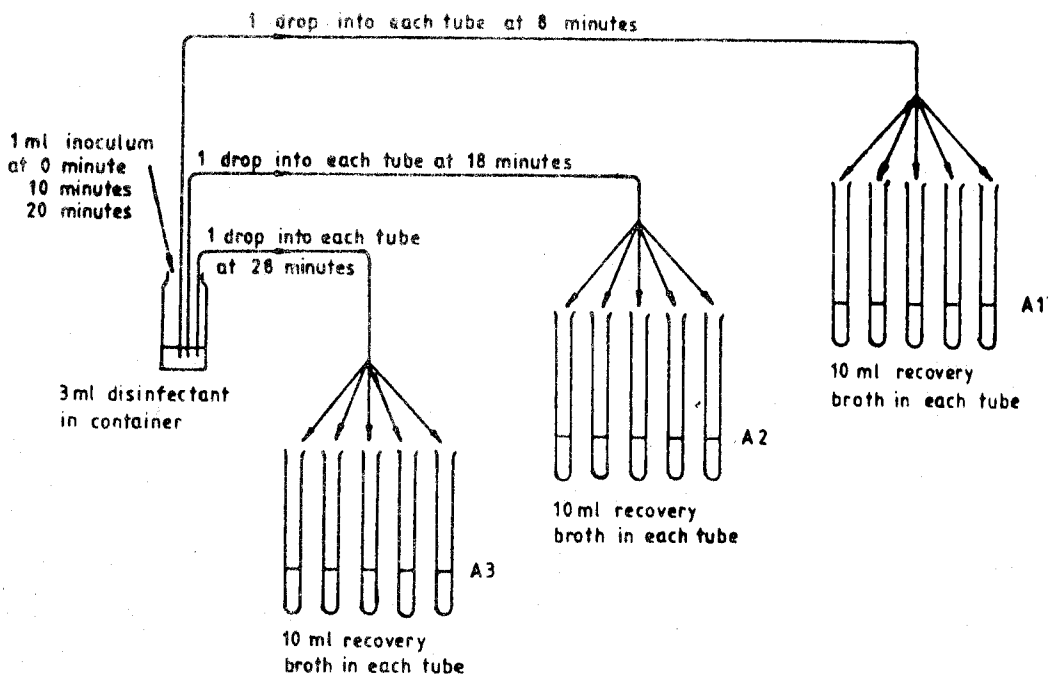

FIGURE 1 - Method of testing for one dilution shown diagrammatically

C.7.9 Swirl the recovery broths and incubate at 37 ± 1 °C for 48 ± 2 hours. Examine the growth and record the results.

C.8 INTERPRETATION OF RESULTS

C.8.1 The disinfectant, shall be regarded as having passed the test at the recommended 'use dilution' if there is no growth in at least two of the five recovery broths for the first and second additions of the inoculum. A model set of test results is given in C.10.

C.8.2 To be acceptable, a disinfectant shall pass the test on three separate occasions using freshly prepared disinfectant and freshly prepared inoculum on each occasion.

C.9 PROTOCOL FOR THE TEST

Disinfectant dilution A		Disinfectant dilution B		Disinfectant dilution C	
Time (minutes)	Action	Time (minutes)	Action	Time (minutes)	Action
0	Add 1 ml of inoculum	01	Add 1 ml of inoculum	05	Add 1 ml of inoculum
08	Transfer 0.02 ml of sample to recovery broths A1.	09	Transfer 0.02 ml of sample to recovery broths B1.	13	Transfer 0.02 ml of sample to recovery broths C1.
10	Add another 1 ml of inoculum	11	Add another 1 ml of inoculum.	15	Add another 1 ml of inoculum.
18	Transfer 0.02 ml of sample to recovery broths A2.	19	Transfer 0.02 ml of sample to recovery broths B2	23	Tansfer 0.02 ml of sample to recovery broths C2.
20	Add another 1 ml of inoculum.	21	Add another 1 ml of inoculum.	25	Add another 1 ml of inoculum.
28	Transfer 0.02 ml of sample to recovery broths A3.	29	Transfer 0.02 ml of sample to recovery broths B3.	33	Transfer 0.02 ml of sample to recovery broths C3.

C.10 MODEL TEST RESULTS

Disinfectant X

Test organism : *Pseudomonas aeruginosa* NCTC 6749

\+ = growth in one recovery broth,

\- = no growth in one recovery broth

Test Number	Date	Concentration per cent (*V/V*)	Count (organisms/ml)	Recovery Broths			Results
				First	Second	Third	
1A	May 3	0.6	3.6×10^9	+++++	+++++	+++++	Fail
1B	May 3	1.2	3.6×10^9	-----	--+-+	+++++	Pass
1C	May 3	1.8	3.6×10^9	-----	-----	-----	Pass
2A	May 7	0.6	7.2×10^8	++-++	+--++	+++++	Fail
2B	May 7	1.2	7.2×10^8	-----	--+++	+++++	Pass
2C	May 7	1.8	7.2×10^8	-----	-----	----+	Pass
3A	May 9	0.6	5.5×10^8	--+++	+++++	+++++	Fail
3B	May 9	1.2	5.5×10^8	-----	-----	+++++	Pass
3C	May 9	1.8	5.5×10^8	-----	-----	-----	Pass

X has passed the test at 1.2 per cent and at 1.8 per cent

X may be recommended for use at 1.2 per cent

APPENDIX D

DETERMINATION OF DISINFECTING EFFICACY OF TYPE 2 DISINFECTANTS

Carry out the method prescribed in Appendix C but using only the following organisms in place of the organisms given in C.4.1 ;

Proteus vulgaris (NCTC 4635 or equivalent)
Staphylococcus aureus (NCTC 4163 or equivalent)

APPENDIX E

SAMPLING

E.1 LOT

In a single consignment, all the containers of the same type of material and drawn from a single batch of manufacture shall constitute a lot.

E.2 GENERAL REQUIREMENTS OF SAMPLING

In drawing, preparing, storing and handling samples, the following precautions and directions shall be observed:

E.2.1 Samples shall not be taken in an exposed place.

E.2.2 The sampling instrument shall be clean, dry and sterile when used.

E.2.3 The sample shall be placed in suitable clean, dry and sterile air-tight glass containers.

E.2.4 The sample containers shall be of such a size that an ullage of at least 10 per cent is left after pouring in the sample.

E.2.5 The samples shall be drawn from freshly opened containers.

E.2.6 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

E.2.7 The sampling instrument and the container for samples shall be rinsed with the material prior to drawing the sample.

E.2.8 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the container for samples from adventitious contamination.

E.2.9 Each sample container shall be sealed air-tight with a stopper after filling and marked with the necessary details of sampling.

E.3 SCALE OF SAMPLING

E.3.1 Samples shall be tested from each lot separately for ascertaining the conformity of the lot to the requirements of this specification.

E.3.2 The number of containers to be selected from a lot shall be in accordance with Table 1.

TABLE 1 - Scale of sampling

Number of containers in the lot	Number of containers to be selected
Upto 100	2
101 to 300	3
301 to 1 000	4
Over 1 000	5

E.3.3 The containers shall be drawn at random. In order to ensure randomness of selection, random number tables as given in SLS 428 shall be used.

E.4 PREPARATION OF TEST SAMPLES

E.4.1 Small quantities of material shall be drawn from top, middle and bottom parts of each container selected as in **E.3.2**, using an appropriate sampling instrument. The material so obtained shall be mixed to form an individual sample of not less than 75 ml to represent the container selected and transferred to a sample container and sealed air-tight.

E.4.2 Small quantities of material shall be drawn from top, middle and bottom parts of each container selected as in E.3.2, using an appropriate sampling instrument. The material so obtained shall be mixed to form a composite sample of not more than 500 ml and transferred to a sample container and sealed air-tight.

E.5 NUMBER OF TESTS

E.5.1 Each container selected as in E.3.2 shall be examined for packaging (5) and marking (6).

E.5.2 The composite sample prepared as in E.4.2 shall be tested for stability on storage (4.2) and stability after dilution (4.3).

E.5.3 Each individual sample prepared as in E.4.1 shall be tested for disinfecting efficacy (4.4).

AMENDMENT NO. 01 APPROVED ON 1994-12-22

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Clause 4.4.1

Delete the words "which shall be not less than 1 : 20", from the text.

SRI LANKA STANDARDS INSTITUTION

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