SRI LANKA STANDARD 951 : 2001

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SPECIFICATION FOR
EXAMINATION RUBBER GLOVES
(FIRST REVISION)

SRI LANKA STANDARDS INSTITUTION

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SLS 951 : 2001

Gr. 6

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

Sri Lanka Standards are subject to periodical revision in order to accommodate the progress made by industry. Suggestions for improvement will be recorded and brought to the notice of the Committees to which the revisions are entrusted.

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

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FOREWORD

This standard was approved by Sectoral Committee on Chemical and Polymer Technology and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2001-04-17.

This specification was first published in 1992. In this revision, present technological improvements and trade practices in this field had been considered. Methods of test for determination of protein content, powder content and conductivity are included.

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 specification, the assistance derived from the following publications is gratefully acknowledged :

ASTM D 3578 : 1991	American Society for Testing and Materials, Standard Specification for examination rubber gloves.
BS EN 455 : 1994	British Standard Specification for Medical gloves for single use Part 1 - Specification for freedom from holes Part 2 - Specification for physical properties
JIS T 9107 : 1992	Japanese Standard Specification for Surgical rubber gloves
S 90-000 : 1990	French Standard Specification for Non-active medical and surgical equipment specification on single use, sterile or reusable surgical rubber gloves.
S 90-001 : 1990	French Standard Specification for Non-active medical and surgical equipment. Specifications on single - use, sterile or non - sterile rubber gloves
FDA	H. H. S Publication, , U.S Department of Health and Services, Food and Drug Administration 99-4257

1 SCOPE

1.1 This specification prescribes the requirements and methods of test for single use, sterile or non-sterile examination rubber gloves.

1.2 Rubber gloves used in conducting medical and dental examinations, in diagnostic and therapeutic procedures and in the handling contaminated medical materials is covered in this specification.

2 REFERENCES

ISO 11193 Single-use rubber examination gloves
ASTM D 5712 Analysis of Protein in Natural Rubber and its products.
CS 102 Presentation of numerical values
SLS 297 Method of testing vulcanized rubber
Part 5 : Accelerated ageing tests
Part 2 : Tensile stress - strain properties
SLS 359 Surgical rubber gloves
SLS 428 Random sampling methods
SLS 532 House hold rubber gloves
The U.S. pharmacopoeia.

3 DEFINITIONS

For the purpose of this standard following definitions shall apply :

3.1 lubricant : Transferable additive designed to facilitate the donning of the glove.

4 SIZES

The size of examination rubber gloves shall be designated (in words or in numericals) as follows depending on the palm width (see Table **1**).

a) Extra small, small, medium, large and extra large
or
b) 6, 6½, 7, 7½, 8 and 8½

5 MANUFACTURE AND DESIGN

5.1 The gloves shall be made from natural rubber latex or synthetic rubber by a dipping process. The finish of the outer surface may be rough or smooth. The cuff of the glove shall be constructed in such a way that it will resist rolling back during its use.

5.2 The gloves shall be transparent or translucent. Colouring ingredients shall not be used. Lubricant may be present in the gloves.

5.3 The inside and outside surfaces of the gloves shall be free of talc and the maximum powder content allowed for powder free glove is 2 mg per glove. However in powdered gloves, powder content shall not exceed 120 mg per glove.

5.4 The gloves shall not contain or liberate any harmful ingredients or by products such as amines and xanthates.

6 REQUIREMENTS

6.1 Dimensions

6.1.1 *Length*

The length of the glove when measured from the tip of the middle finger to the outer edge of the cuff (see Figure **1**) shall not be less than 240 mm for all sizes.

6.1.2 *Width*

The width of the palm when measured as shown in Figure **1** shall comply with the Table **1.**

TABLE 1 – Palm width of examination rubber gloves

	Size					**Tolerance**
Designation As (a) of Clause 4	extra small	small	medium	large	extra large	
Palm width, mm	70	80	95	111	120	± 10

	Size						**Tolerance**
Designation as (b) Clause 4	**6**	**6½**	**7**	**7½**	**8**	**8½**	
Palm width, mm	75	83	89	95	102	108	± 6

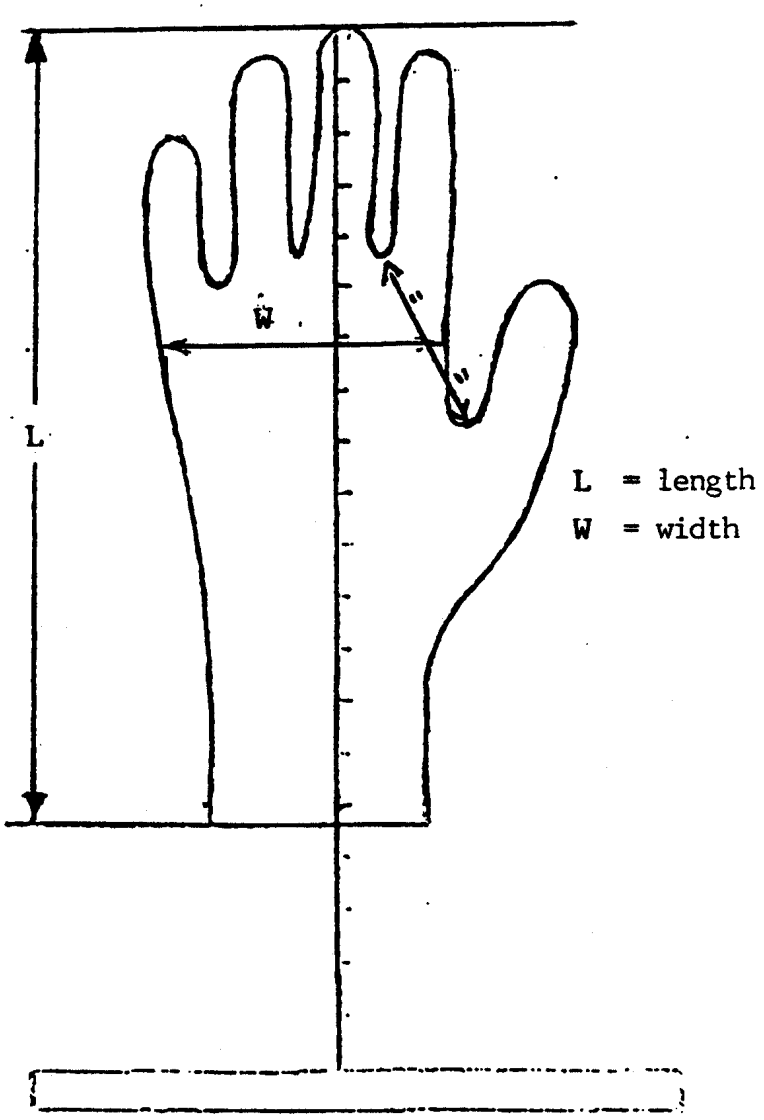


FIGURE 1 - Measurement of length and width of examination rubber gloves

6.1.3 *Thickness*

Single wall thickness of gloves when tested as in **9.2** shall not be less than 0.08 mm.

NOTE

The film thickness shall be determined on a glove from which the lubricating agent has been removed.

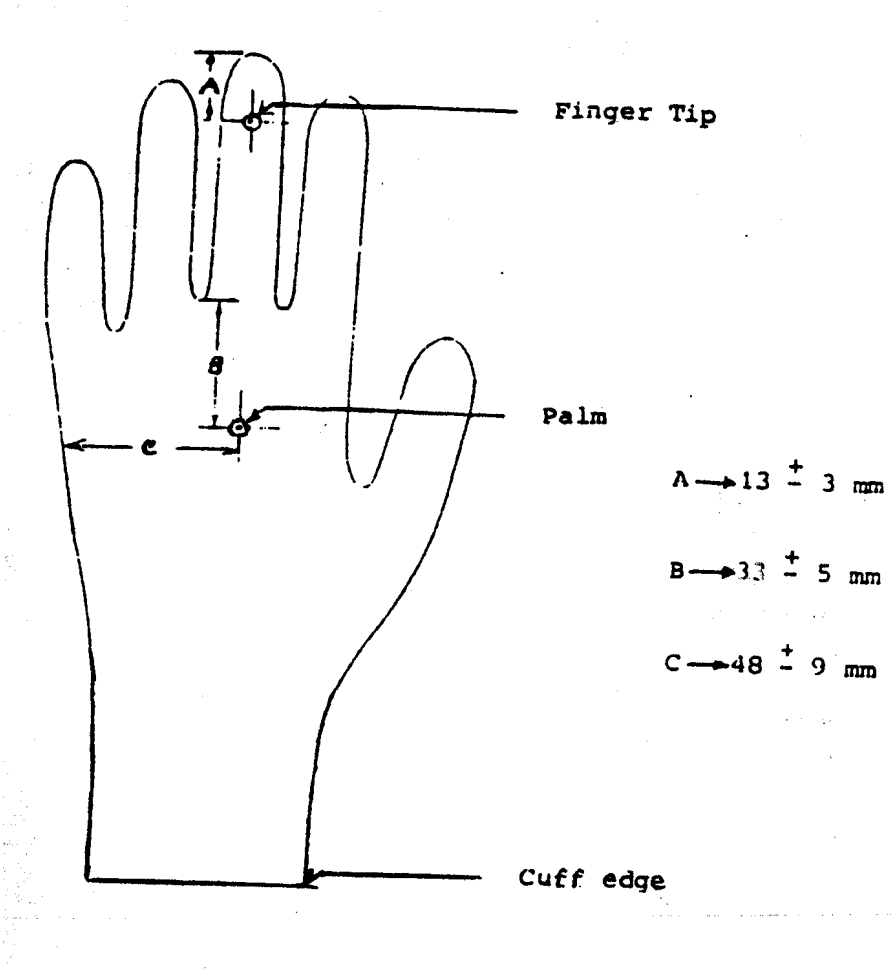


FIGURE 2 - Locations for thickness measurements

6.2 Tensile strength and elongation at break

6.2.1 *Before ageing*

The tensile strength and elongation at break of the material of the glove when tested in accordance with **SLS 297 : Part 2 1974** shall comply with the Table **2.**

6.2.2 *After ageing*

Accelerated ageing in an air - oven shall be in accordance with **SLS 297 : Part 5 1974** at a temperature of 70 $\pm$ 2 ^{o}C for 168 hours. After accelerate ageing tensile strength and elongation at break when tested in accordance with **SLS 297 : Part 2 1974** shall comply with the requirements given in Table **2.**

TABLE 2 - Tensile strength and elongation at break

Sl. No.	Characteristic	Natural rubber		Synthetic rubber
		Unchlorinated	Chlorinated	
(1)	(2)	(3)	(4)	(5)
i)	Tensile strength before ageing MPa, min.	21	18	14
ii)	Elongation at break before ageing per cent, min.	700	700	700
ii)	Tensile strength after accelerated ageing MPa, min.	16	16	14
iv)	Elongation at break after accelerated ageing per cent, min.	500	500	500

6.3 Tear strength of the cuff

The glove shall not show tearing at 300% elongation when tested in accordance with Appendix **B.**

6.4 Leakage test (watertightness test)

The glove shall not exhibit any defects such as tear, rips and holes that will result in leakage, when tested in accordance with ISO 11193 : 1999.

6.5 Conductivity test

The conductivity of the glove shall be not more than 10^{-2} A after 30 minutes when tested in accordance with Appendix **C.**

6.6 Protein level

Maximum total extractable protein (TEP) levels shall be 1200 μg per glove when tested in accordance with the method given in ASTM D 5712 : 1999

6.7 Powder content

The powder content of gloves when tested as in Appendix D shall not be more than,

Powdered gloves - 120 mg/glove
Powder free gloves - 2 mg/glove

6.8 Sterility test

The gloves if sterile shall conform to the sterility test conducted in accordance with the method given in the U.S Pharmacopoeia.

7 PACKAGING

7.1 Sterile gloves

7.1.1 The unit of packaging shall be one glove or one pair of gloves.

7.1.2 A glove or pair of gloves, shall be enclosed in an inner wrapper.

7.1.3 The glove or pair, and accompanying wrapper shall totally be enclosed in an outer package that will allow sterilization of the product.

7.1.4 The outer package shall have a method of closure sufficient to assure the sterility of the product until opened or damaged.

7.1.5 The method of closure of the outer package shall be such that, prior opening will be detectable by the user.

7.1.6 The outer package shall have sufficient strength to withstand normal conditions of transportation and storage.

7.1.7 A number of such packages shall be packed in a suitable carton of sufficient strength to maintain the quality and sterility of the product during normal transportation and storage.

7.2 Non-sterile gloves

7.2.1 The gloves shall be enclosed in an outer package that has sufficient strength to withstand transportation and storage.

7.2.2 A number of such packages shall be packed in a suitable carton of sufficient strength to maintain the quality of the product during normal transportation and storage.

8 MARKING

8.1 Each sterile or non-sterile bulk package shall be legibly and indelibly marked or labelled with the following :

a) Name of the product as "Examination Rubber Gloves";
b) Size in words or numericals as agreed to between buyer and supplier;
c) Name and address of the manufacturer;
d) Batch or code number;
e) The term "Sterile" in the case of sterile gloves with instructions for opening the package;
f) Brand name or trade name/mark if any; and
g) Any other marking as agreed to between buyer and supplier.

8.2 Each carton shall be legibly and indelibly marked or labelled with the following :

a) Size of gloves;
b) Batch or code number;
c) Brand name;
d) The term "Sterile" in the case of sterile gloves with instructions for opening the package; and
g) Any other marking as agreed to between buyer and supplier.

NOTE

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

9 METHODS OF TEST

9.1 Tests shall be carried out in accordance with the methods given in 9.2, ISO 11193 : 1999 ASTM D 5712 : 1999 **SLS 297 : Part 2** and Part **5**, 1974 the U.S. pharmacopoeia and Appendicies **B** to **D** of this specification.

9.2 Measure the thickness of the double wall of the glove by exerting a pressure of 22 kPa $\pm$ 5 kPa on foot of the gauge, at each of the location shown in Figure 2. Half the measured double- wall thickness to obtain single wall thickness.

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 assessed based on manufacturer's control system 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 packages of examination rubber gloves belonging to one batch of supply or manufacture shall constitute a lot.

A.2 GENERAL REQUIREMENTS OF SAMPLING

When drawing samples, the following precautions shall be taken.

A.2.1 Samples shall be kept in clean and dry glass or suitable containers.

A.2.2 The samples shall be protected against adventitious contamination.

A.3 SCALE OF SAMPLING

A.3.1 The samples shall be tested from each lot for ascertaining its conformity to the requirements of this specification.

A.3.2 The number of packages to be selected from a lot shall be in accordance with column (1) and column (2) or column (4) of Table **3.**

TABLE 3 Scale of sampling

Number of packages in a lot	Sterile Gloves		Non - Sterile Gloves	
	Number of packages to be selected	Sub sample size No. of packages	Number of packages to be selected	Sub sample size No. of packages
(1)	(2)	(3)	(3)	(4)
Up to 1 500	15	02	05	05
1 501 to 3 500	20	03	05	06
3 501 to 10 000	25	04	06	06
10 001 to 35 000	30	05	06	07
35 001 to 150 000	32	05	07	08
150 001 and above	40	06	08	10

A.3.3 If the packages are packed in cartons 10 per cent of the cartons subject to a minimum of two (02) cartons shall be selected as far as possible and equal number of packages shall be selected from each carton so selected to form the sample as given in column (2) or column (4) of Table **3**.

A.3.4 The cartons and packages shall be drawn at random. In order to ensure randomness of selection, tables of random numbers as given in **SLS 428** shall be used.

A.4 NUMBER OF TESTS

A.4.1 Each package selected as in **A.3.2** shall be inspected for packaging and marking requirements.

A.4.2 In case of sterile gloves, one glove from each package selected as in **A.3.2** shall be measured for dimensional requirements.

In case of Non-sterile gloves, three gloves from each package selected as in **A.3.2** shall be measured for dimensional requirements.

A.4.3 Five sub samples of size of each as given in column (3) or column (5) of Table **3** as applicable shall be selected from the packages selected as in **A.3.2.**

The sub samples shall be used to carry out the tests given under **A.4.3.1** and **A.4.3.2, A.4.3.3** and **A.4.3.5** separately.

A.4.3.1 In case of sterile gloves, each glove in the sub sample selected as in **A.4.3** , shall be tested for sterility.

A.4.3.2 Each glove in the sub sample selected as in **A.4.3** shall be tested for leakage.

A.4.3.3 Each glove in the sub sample selected as in **A.4.3** shall be tested for tensile strength and elongation at break.

A.4.3.4 Two gloves tested as in **A.4.3.3** shall be tested for accelerating ageing.

A.4.3.5 Each glove in the sub sample selected as in **A.4.3** shall be tested for tear strength of cuff.

A.4.3.6 Each glove tested as in **A.4.3.5** shall be tested for protein level.

NOTE

This test shall be carried out only if requested.

A.4.3.7 Each glove in the sub sample selected as in **A.3.4** shall be tested for conductivity.

A.4.4 Four gloves shall be selected from the packages selected as in **A.3.2** and tested for powder content.

A.5 CRITERIA FOR CONFORMITY

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

A.5.1 Each package inspected as in **A.4.1** satisfies packaging and marking requirements.
A.5.2 Each glove measured as in **A.4.2** satisfies the dimensional requirements.

A.5.3 Each glove tested as in **A.4.3.1, A.4.3.2, A.4.3.3, A.4.3.4, A.4.3.5, A.4.3.6, A.4.3.7** and **A.4.4** satisfies the relevant requirements.

APPENDIX B
DETERMINATION OF TEAR STRENGTH OF THE CUFF

B.1 APPARATUS

B.1.1 Dynamometer

B.1.2 Holding device, consisting of metal plate and a metal rod with diameter 20 mm $\pm$ 1 mm and notch 30 mm from the end as shown in figure 3.

B.2 PROCEDURE

Fit the polished holding device (**B.1.2**) with the glove in position to the jaws of the dynamometer as shown in Figure **3.** The separation of the metal rod should be equal to half of the perimeter of the glove (x cm). Adjust the separation speed of the jaws of dynamometer at 500 mm/min $\pm$ 50 mm/min. Switch on the dynamometer and allow 300 percent elongation. Observe for signs of tearing.

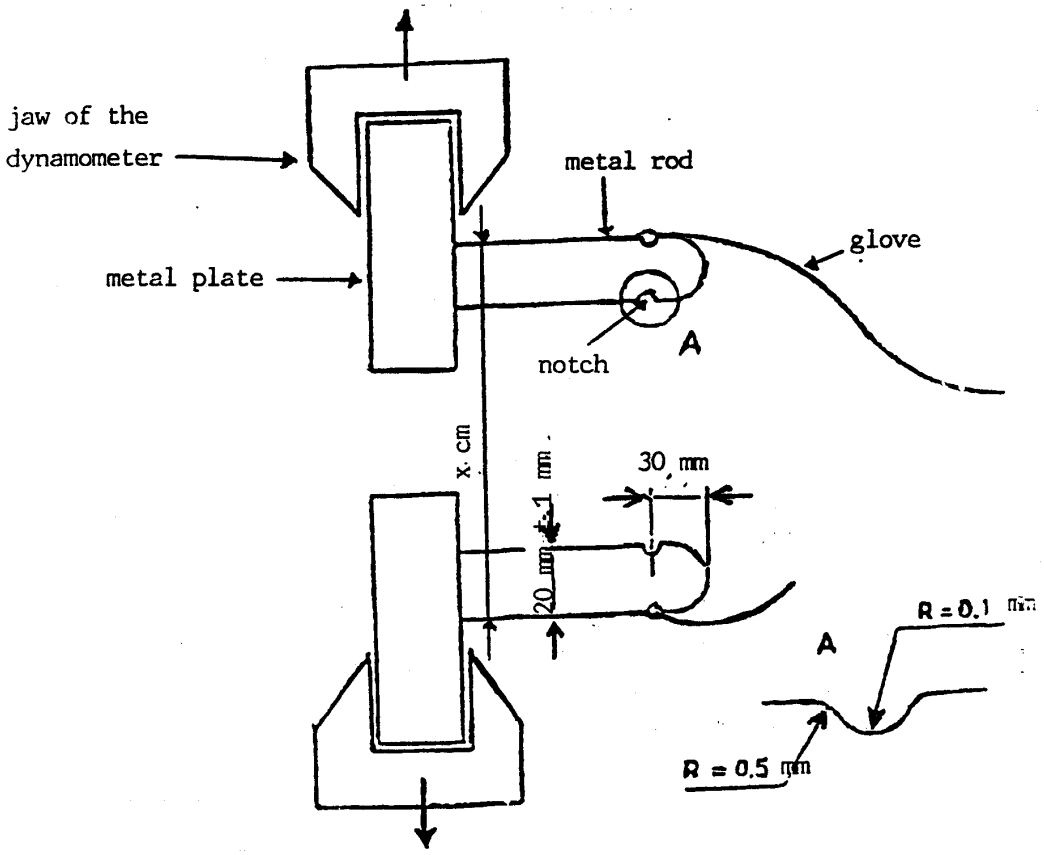


FIGURE 3 - Test device for measuring tear strength of the cuff

APPENDIX C
DETERMINATION OF CONDUCTIVITY

C.1 APPRATUS

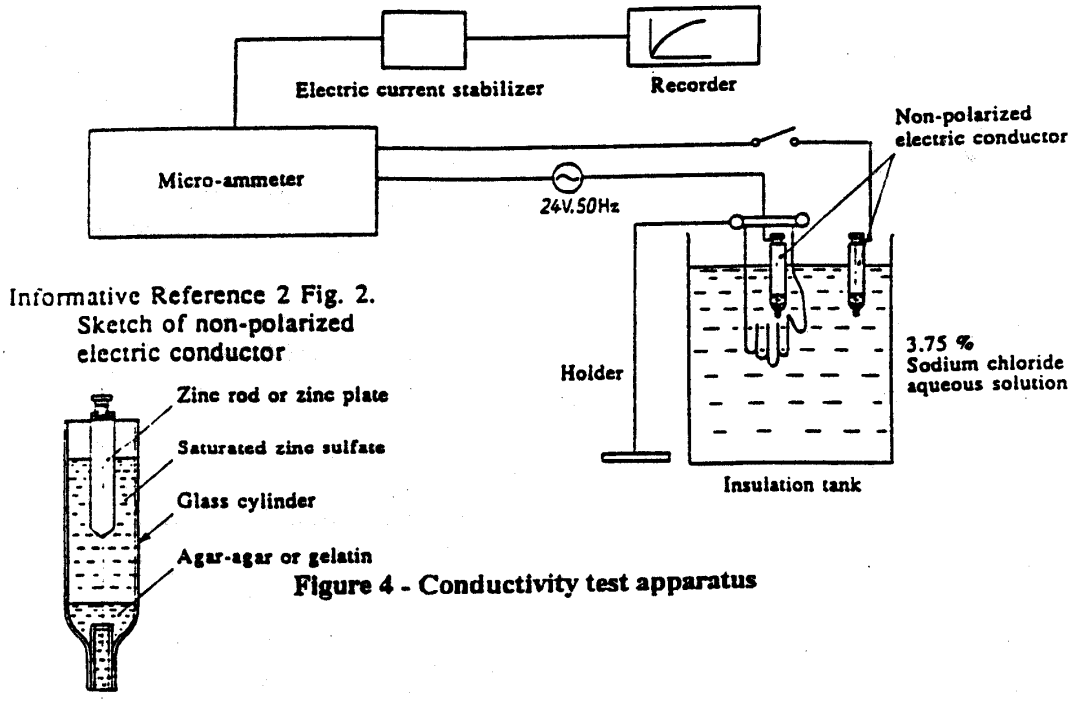
Conductivity test apparatus (see Figure **4**)

C.2 REAGENT

Sodium chloride, 3.75 per cent (V/V) aqueous solution

C.3 PROCEDURE

Mount the glove to be tested to the holder. Inject the sodium chloride aqueous solution into the glove upto the depth of 200 $\pm$ 10 mm. Maintain the temperature of the sodium chloride solution in the tank, and the glove at 37 $\pm$ 2 ^{o}C. Immerse the electrodes as shown in the Figure 4 and connect them to the a.c supply of 24 V, 50 Hz. Read the current indicated by the micro-ammeter after 30 minutes.



Informative Reference 2 Fig. 2. Sketch of non-polarized electric conductor

Figure 4 - Conductivity test apparatus

APPENDIX D
DETERMINATION OF POWDER CONTENT

D.1 PROCEDURE

D.1.1 Weigh, clean and dry petri dish and a filter paper to the nearest 0.001 g.

D.1.2 Wash the glove with 50 ml to 100 ml distilled water by inserting a jet in such a way that it cleans the entire inside of the glove. Hold the end of the cuff so that water do not overflow. Shake the glove to wash sufficiently. Pour the suspension quantitatively into a beaker. Repeat the washing procedure 3 times.

D.1.3 Filter the water/powder suspension, using a suction filter and the weighed filter paper (**D.1.1**). Rinse the beaker twice with distilled water and filter.

D.1.4 Dry the powder and the filter paper **(D.1.3)** in the weighed petri-dish **(D.1.1)** for 15 minutes at a constant temperature of 100 ^{o}C.

D.1.5 Cool in a desiccator for 15 minutes.

D.1.6 Weigh the petri-dish the filter paper and the powder to the nearest 0.001 g.

D.1.7 Repeat the procedure with 4 gloves.

D.2 CALCULATION

D.2.1 Powder content per glove, in milligram $= 1000 \left\{ m_1 - (m_2 + m_3) \right\}$

Where
m_1 is the total mass in grams, of petri-dish, filter paper and powder (**D.1.6**).

m_2 is the mass in grams of the petri-dish (**D.1.1**) and
m_3 is the mass in grams of the filter paper. (**D.1.1**)

D.2.2 Calculate the powder content per glove for four gloves separately and take the average.

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The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI *which includes surveillance inspection of the factory, testing of both factory and market samples.*

Further particulars of the terms and conditions of the permit may be obtained from the Sri *Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08.*

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SRI LANKA STANDARDS INSTITUTION

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The principal objects of the Institution as set out in the Act are to prepare standards and promote their adoption, to provide facilities for examination and testing of products, to operate a Certification Marks Scheme, to certify the quality of products meant for local consumption or exports and to promote standardization and quality control by educational, consultancy and research activity.

The Institution is financed by Government grants, and by the income from the sale of its publications and other services offered for Industry and Business Sector. Financial and administrative control is vested in a Council appointed in accordance with the provisions of the Act.

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