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Medical gloves made from natural rubber latex — Determination of water-extractable protein using the modified Lowry method

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National foreword

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Medical gloves made from natural rubber latex — Determination of water-extractable protein using the modified Lowry method

*Gants médicaux à base de latex de caoutchouc naturel —
Détermination des protéines extractibles par l'eau par la méthode
modifiée de Lowry*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 12243 was prepared by Technical Committee ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 3, *Raw materials (including latex) for use in the rubber industry*.

Introduction

There have been problems of allergic reactions experienced by some users of medical gloves manufactured from natural rubber latex. ISO 12243 specifies a method for the determination of the water-extractable protein in such gloves.

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Medical gloves made from natural rubber latex — Determination of water-extractable protein using the modified Lowry method

WARNING — Persons using this International Standard should be familiar with normal laboratory practice. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

1 Scope

This International Standard specifies a method for the determination of the amount of water-extractable protein in natural rubber (NR) gloves for medical use. The method is potentially suitable for the determination of extractable protein in other articles made from NR latex; however the extraction procedures and times have not been validated and will vary with the type of article to be tested. Other methods for the determination of specific proteins in medical gloves exist (see Annex C) but they are not of general applicability.

This International Standard is concerned solely with the method of assay. It is not concerned with sampling nor does it purport to address the safety implications of the values obtained or requirements for labelling.

2 Principle

Water-soluble proteins are extracted into a buffer solution and then precipitated to concentrate them and separate them from other water-soluble substances which may interfere with the determination (see Annexes A and D). The precipitated protein is redissolved and quantified colorimetrically by the modified Lowry method using a protein standard (for a general review of the method, see reference [1] in the Bibliography).

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

concentration factor

F

extent to which a protein extract is concentrated by precipitation followed by redissolution in a smaller volume of sodium hydroxide solution

NOTE Thus if the protein in 4 cm³ of solution is precipitated and redissolved in 0,8 cm³, then the concentration factor *F* would be 4/0,8 (= 5).

3.2

protein

proteins and protein-like substances (e.g. polypeptides) occurring in articles made from NR latex and which are extractable with water

3.3

modified Lowry method

modification of the original Lowry assay method, which involves the precipitation and isolation of the proteins to reduce the level of other water-extractable substances that may interfere in the determination