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Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders —

Part 2: Test method for determination of the amount of residual acrylate monomers

Aides pour absorption d'urine — Méthodes d'essai pour caractériser les matériaux absorbants à base de polymères —

Partie 2: Détermination de la quantité de monomères résiduels

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

This second edition cancels and replaces the first edition (ISO 17190-2:2001), which has been technically revised. The main changes compared to the previous edition are as follows:

— full text review and new laboratory analysis with statistical evaluation.

A list of all parts in the ISO 17190 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders —

Part 2: Test method for determination of the amount of residual acrylate monomers

WARNING — This document does not claim to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use. It is expected that the person performing this test has been fully trained in all aspects of this procedure.

1 Scope

This document provides a test method for determining the sum of residual monomeric sodium acrylate and acrylic acid present in polyacrylate superabsorbent powders as acrylic acid.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
amount of residual monomers
sum of residual monomeric sodium acrylate and acrylic acid

3.2
sample
product or portion of a product taken from a production lot for testing purposes and identifiable and traceable back to its origin

3.3
specimen
specific portion of the identified *sample* (3.2) upon which a test is performed

4 Principle

Residual monomeric sodium acrylate and acrylic acid are extracted from the polyacrylate superabsorbent powders and the amount determined as residual acrylate monomer by HPLC.

The method described here uses a simple 1 g in 200 ml dilution factor. However, it is equally valid to use different masses and volumes as long as the mass:volume dilution ratio is the same and suitable experimental validation is performed.

5 Reagents and materials

Use only reagents of recognized analytical grade, unless otherwise specified.

5.1 Water.

Grade 1 water according to ISO 3696, for the standard solutions for the calibration and Grade 3 water according to ISO 3696, with the exception that the conductivity can be as high as 30 µS/cm, for the saline solution.

5.2 Sodium chloride solution.

5.2.1 0,9 % mass fraction of sodium chloride solution in water. Weigh (9,00 ± 0,01) g of sodium chloride into a 1 l beaker and add (991,0 ± 0,1) g of deionized water (grade 3). Stir until dissolved.

5.2.2 The conductivity of the solution should be checked prior to each use using properly calibrated measuring equipment. The expected conductivity of a 0,9 % saline solution is of the order of 1600 S/m (depending on temperature). Each testing lab shall determine the correct conductivity for the conditions obtaining in the lab. It is also recommended that the temperature of the solution be maintained at (23 ± 2) °C for the duration of the test. As this matches the required laboratory temperature it is not necessary to record the solution temperature.

5.3 Phosphoric acid.

Concentrated $c(H_3PO_4)$ = 85 % by mass, of HPLC grade or better.

5.4 Phosphoric acid solution.

$c(H_3PO_4)$ = 0,1 % by mass (1 g/l or 0,0087 mol/l). Dilute concentrated H_3PO_4 to volume with deionized water (grade 1). Stir until dissolved.

5.5 Acetonitrile.

HPLC grade or better.

5.6 Acrylic acid.

Greater than 99,5 % purity.

Acrylic acid degrades over time owing to slow polymerization, particularly dimerization, and water uptake. It is important to obtain acrylic acid that meets the purity required for this test method. It is not recommended to obtain the reference substance from a laboratory chemicals distributor as the purity of this material from such a source is likely to be defined inaccurately.