SLOVENSKI STANDARD
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Smernice za pripravo in vodenje kakovosti tekočin za hemodializo in podobne terapije - 4. del: Koncentrati za hemodializo in podobne terapije (ISO/DIS 23500-4:2017)

Guidance for the preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies (ISO/DIS 23500-4:2017)

Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 4: Konzentrate für die Hämodialyse und verwandte Therapien (ISO/DIS 23500-4:2017)

Document d'orientation pour la préparation et le management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 4: Concentrés pour hémodialyse et thérapies apparentées (ISO/DIS 23500-4:2017)

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Guidance for the preparation and quality management of fluids for haemodialysis and related therapies —

Part 4:
Concentrates for haemodialysis and related therapies

Directives concernant la préparation et le management de la qualité des fluides d'hémodialyse et de thérapies annexes —

Partie 4: Concentrés pour hémodialyse et thérapies apparentées

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Foreword

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This document, ISO 23500-4 cancels and replaces ISO 13958, It has been technically revised and renumbered to form part of a new series of standards series dealing with guidance for the preparation and quality management of fluids for haemodialysis and related therapies (ISO 23500-1, previously ISO 23500); water treatment plant, (ISO 23500-2, previously ISO 26722); water used for the preparation of dialysis fluid. (ISO 23500-3, previously ISO 13959) and dialysis fluid quality (ISO 23500-5, previously ISO 11663)

Introduction

The requirements and goals established by this International Standard will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This International Standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and government representatives, to develop a standard for performance levels that could be reasonably achieved at the time of publication. The term "consensus" as applied to the development of voluntary medical device standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests must be merged.

Throughout this International Standard, recommendations are made to use ISO-quality water. Therefore, it is recommended to review ISO 23500-3 along with this International Standard.

This International Standard does not cover the dialysis fluid that is used to clinically dialyse patients. Dialysis fluid is covered in ISO 23500-3. The making of dialysis fluid involves the proportioning of concentrate and water at the bedside or in a central dialysis fluid delivery system. Although the label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

In addition, this International Standard does not cover haemodialysis equipment, which is addressed in IEC 60601-2-16:2012.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this International Standard,

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard, and

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

1 Scope

This International Standard specifies minimum requirements for concentrates used for haemodialysis and related therapies. For the purpose of this International Standard, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, that are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies. This International Standard is addressed to the manufacturer of such concentrates. In several instances in this International Standard, it became necessary to address the dialysis fluid, which is made by the end user, to help clarify the requirements for manufacturing concentrates. Because the manufacturer of the concentrate does not have control over the final dialysis fluid, any reference to dialysis fluid is for clarification and is not a requirement of the manufacturer.

This International Standard includes concentrates in both liquid and powder forms. Also included are additives, also called spikes, which are chemicals that may be added to the concentrate to increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. This International Standard also gives requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Concentrates prepared from pre packaged salts and water at a dialysis facility for use in that facility are excluded from the scope of this International Standard. Although references to dialysis fluid appear herein, this International Standard does not address dialysis fluid as made by the end user. Also excluded from the scope of this International Standard are requirements for the monitoring frequency of water purity used for the making of dialysis fluid by the dialysis facility. Recommendations from the technical committee responsible for this International Standard for monitoring and maintaining water quality are contained in ISO 23500-1. This International Standard does not address bags of sterile dialysis fluid or sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-1 *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements*

ISO 23500-5, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies*

ISO 23500-3, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

3 Terms and definitions

The terms and definitions applicable to this document are given in ISO 23500-1. Except:

3.1
batch system
apparatus in which the dialysis fluid is prepared in bulk before each dialysis session

Note 4 to entry: Dry sodium bicarbonate, without added sodium chloride, is also used in concentrate generators to produce a concentrated solution of sodium bicarbonate used by the dialysis machine to make dialysis fluid.

3.2
bicarbonate dialysis fluid
dialysis fluid containing physiological or higher concentrations of bicarbonate

3. 3
concentrate mixer
mixer for preparation of dialysis concentrate or dialysis fluid at a dialysis facility

4 Requirements

4.1 Concentrates

4.1.1 Physical state

The concentrate for haemodialysis may be supplied in dry or aqueous form. Packaging may be for direct use with a single dialysis machine or for use in systems supplying multiple dialysis machines (bulk use).

4.1.1.1 Liquid solute concentrations

All electrolytes identified on the label shall be present within ± 5 % or ± 0,1 mEq/L (expressed as dialysis fluid concentrations), whichever is greater, of the stated concentration, with the exception of sodium, which shall be present within ± 2,5 % of the labelled concentration, or shall be present according to approved specifications by the local regulations. If used, glucose shall be present within ± 5 % or ± 0,05 g/L (when measured as properly diluted dialysis fluid), whichever is greater, of the labelled concentration, or shall be present according to approved specifications by the local regulations. Where concentrates include non-traditional constituents, such as antioxidants and iron compounds, these constituents shall be present at nominal concentrations with ± 5 % tolerances, or shall be present according to approved specifications by the local regulations. If alternate, locally approved tolerances are used, the tolerances shall be similarly stated and the rationale for their use documented.

Most concentrates are manufactured with standard traditional chemicals such as sodium chloride, potassium chloride, magnesium chloride, calcium chloride, acetic acid, glucose, etc. New concentrates are available in which certain chemicals have been substituted by others; for example, citric acid has been substituted for acetic acid. Where this occurs, the labelling shall correctly reflect this and the substitute chemicals shall be present at nominal concentrations with ± 5 % tolerances, or shall be present according to approved specifications by the local regulations. If alternate, locally approved tolerances are used, the tolerances shall be similarly stated and the rationale for their use documented.