

This is a preview of "ISO 23500-4:2019". [Click here to purchase the full version from the ANSI store.](#)

First edition
2019-02

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 4: Concentrates for haemodialysis and related therapies

*Préparation et management de la qualité des liquides d'hémodialyse
et de thérapies annexes —*

Partie 4: Concentrés pour hémodialyse et thérapies apparentées



Reference number
ISO 23500-4:2019(E)

© ISO 2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 23500-4:2019". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	2
4.1 Concentrates.....	2
4.1.1 Physical state.....	2
4.1.2 Water.....	3
4.1.3 Bacteriology of concentrates.....	3
4.1.4 Endotoxin levels.....	3
4.1.5 Fill quantity.....	3
4.1.6 Chemical grade.....	3
4.1.7 Particulates.....	4
4.1.8 Additives — “Spikes”.....	4
4.1.9 Containers.....	4
4.1.10 Bulk-delivered concentrate.....	4
4.1.11 Concentrate generators.....	4
4.2 Manufacturing equipment.....	4
4.3 Systems for bulk mixing concentrate at a dialysis facility.....	4
4.3.1 General.....	4
4.3.2 Materials compatibility.....	5
4.3.3 Disinfection protection.....	5
4.3.4 Safety requirements.....	5
4.3.5 Bulk storage tanks.....	5
4.3.6 Ultraviolet irradiators.....	6
4.3.7 Piping systems.....	6
4.3.8 Electrical safety requirements.....	6
5 Tests	6
5.1 General.....	6
5.2 Concentrates.....	6
5.2.1 Physical state.....	6
5.2.2 Solute concentrations.....	7
5.2.3 Water.....	7
5.2.4 Microbial contaminant test methods for bicarbonate concentrates.....	7
5.2.5 Endotoxin levels.....	8
5.2.6 Fill quantity.....	8
5.2.7 Chemical grade.....	8
5.2.8 Particulates.....	8
5.2.9 Additives — “Spikes”.....	9
5.2.10 Containers.....	9
5.2.11 Bulk delivered concentrate.....	9
5.2.12 Concentrate generators.....	9
5.3 Manufacturing equipment.....	9
5.4 Systems for mixing concentrate at a dialysis facility.....	9
5.4.1 General.....	9
5.4.2 Materials compatibility.....	9
5.4.3 Disinfection protection.....	9
5.4.4 Safety requirements.....	10
5.4.5 Bulk storage tanks.....	10
5.4.6 Ultraviolet irradiators.....	10
5.4.7 Piping systems.....	10

This is a preview of "ISO 23500-4:2019". [Click here to purchase the full version from the ANSI store.](#)

5.4.8	Electrical safety requirements.....	10
6	Labelling.....	10
6.1	General.....	10
6.2	General labelling requirements for concentrates.....	11
6.3	Labelling requirements for liquid concentrate.....	12
6.4	Labelling requirements for powder concentrate.....	12
6.5	Additives.....	13
6.6	Labelling requirements for concentrate generators.....	13
6.7	Labelling for concentrate mixer systems.....	14
6.7.1	General.....	14
6.7.2	Product literature for concentrate mixers.....	14
Annex A (informative) Rationale for the development and provisions of this document.....		16
Bibliography.....		22

This is a preview of "ISO 23500-4:2019". [Click here to purchase the full version from the ANSI store.](#)

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 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition cancels and replaces ISO 13958:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

- The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).

A list of all parts of the ISO 23500 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.

Introduction

The requirements and goals established by this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and regulatory agency 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 shall be merged.

The rationale for the development of this document is given in informative [Annex A](#).

Throughout this document, requirements and recommendations are made to use ISO-quality water. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

For the purpose of this document, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, which are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies.