



ISO 23500-4

**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

**Second edition
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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.....	5
4.3 Systems for bulk mixing concentrate at a dialysis facility.....	5
4.3.1 General.....	5
4.3.2 Materials compatibility.....	5
4.3.3 Disinfection protection.....	5
4.3.4 Safety requirements.....	6
4.3.5 Bulk storage tanks.....	6
4.3.6 Ultraviolet irradiators.....	6
4.3.7 Piping systems.....	6
4.3.8 Electrical safety requirements.....	6
5 Tests	7
5.1 General.....	7
5.2 Concentrates.....	7
5.2.1 Physical state.....	7
5.2.2 Solute concentrations.....	7
5.2.3 Water.....	8
5.2.4 Microbial contaminant test methods for bicarbonate concentrates.....	8
5.2.5 Endotoxin levels.....	8
5.2.6 Fill quantity.....	9
5.2.7 Chemical grade.....	9
5.2.8 Particulates.....	9
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.....	10
5.4 Systems for mixing concentrate at a dialysis facility.....	10
5.4.1 General.....	10
5.4.2 Materials compatibility.....	10
5.4.3 Disinfection protection.....	10
5.4.4 Safety requirements.....	10
5.4.5 Bulk storage tanks.....	10
5.4.6 Ultraviolet irradiators.....	10
5.4.7 Piping systems.....	11
5.4.8 Electrical safety requirements.....	11

This is a preview of ISO 23500-4:2024. [Click here to purchase the full version from the ANSI store.](#)

6.2	General labelling requirements for concentrates.....	11
6.3	Labelling requirements for liquid concentrate.....	12
6.4	Labelling requirements for powder concentrate.....	13
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.....	15
Annex A (informative) Rationale for the development and provisions of this document.....		16
Bibliography.....		22

This is a preview of ISO 23500-4:2024. [Click here to purchase the full version from the ANSI store.](#)

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23500-4:2019), which has been technically revised.

The main changes are as follows:

- alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)] have been incorporated;
- further clarifications on the use of concentrates spikes and containers have been added.

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.

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The requirements established in this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. Haemodialysis 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. In this document, the dialysis fluid made by the end user mixing haemodialysis concentrate and water of the quality given in ISO 23500-3 is discussed to help clarify the requirements for manufacturing concentrates. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

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. 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 are merged.

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. Furthermore, label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

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