

ISO 23500-4:2024-04 (E)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies

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.....	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
6	Labelling.....	11
6.1	General.....	11
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