

Quality assurance



Quality management system

A quality management system controls internal processes and defines functions, tasks, responsibilities and methods for achieving, ensuring and improving quality.

Quality assurance in dialysis

An important component of the quality management system in dialysis is the quality assurance of the dialysates used, because the quality of the dialysis treatment is – among other things – directly dependent on the use of a microbiologically and chemically pure dialysing fluid. However, a high-quality dialysate can only be produced if the water used for its production also meets high quality standards.

For this reason, various national and international institutions have defined microbiological and chemical standards for monitoring the quality of water and dialysate.

Since May 2011 the international standard ISO 23 500, “Guidance for the preparation and quality management of fluids for haemodialysis and related therapies” is effective. It describes the monitoring, disinfection strategy, validation and revalidation of systems for the production of fluids for dialysis. As a guideline ISO 23 500 must be seen as a recommendation.

An appropriate monitoring system is the only way of detecting hazards and initiating corresponding countermeasures at an early stage, in order to ensure a high degree of therapeutical safety and quality for the patient.



Quality assurance

Microbiological quality standards

	Medium	Total viable counts (CFU/mL)	Endotoxin content (IU/mL)
European Pharmacopoeia 7.0	Water for dilution of concentrated haemodialysis solutions	≤ 100	< 0.25
	Concentrate	–	< 0.5 after dilution
ISO 13959:2009 – Water for haemodialysis and related therapies	Dialysis Water	< 100 (AL*:50)	< 0.25 (AL*:0.125)
ISO 11663:2009 – Quality of dialysis fluid for haemodialysis and related therapies	Standard Dialysis Fluid**	< 100 (AL*:50)	< 0.5
	Ultrapure Dialysis Fluid**	< 0.1	< 0.03
	Substitution fluid**	sterile	non-pyrogenic

*AL= Action Level, concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels (Typically set at 50% of limit value).

**not required if the haemodialysis system is fitted with bacteria- and endotoxin-retentive filters (e.g. DIASAFE®*plus*) validated by the manufacturer and operated and monitored according to the manufacturer's instructions.

Chemical quality standards¹

Parameter with proven toxicity in dialysis	Limit (mg/L)	Electrolytes	Limit (mg/L)	Trace elements	Limit (mg/L)
Aluminum	0.01	Calcium	2	Antimony	0.006
Lead	0.005	Potassium	8	Arsenic	0.005
Fluoride	0.2	Magnesium	4	Barium	0.1
Total chlorine	0.1	Sodium	70	Beryllium	0.0004
Copper	0.1			Cadmium	0.001
Nitrate (as N)	2			Chromium	0.014
Sulphate	100			Mercury	0.0002
Zinc	0.1			Selenium	0.09
				Silver	0.005
				Thallium	0.002

The total viable counts should be examined on Tryptone Glucose Extract agar (TGE) or Reasoner's 2A (R2A) agar at 17–23 °C with an incubation time of 7 days.^{1,2} The endotoxin concentration is determined by using the LAL test (limulus amoebocyte lysate test).^{1,2}

With regard to standards for chemical parameters, ISO 13959:2009 recommends an at least yearly monitoring of the water used for the production of dialysis fluids (see table to the left).

1 ISO 13959:2009 – Water for haemodialysis and related therapies.

2 ISO 11663:2009 – Quality of dialysis fluid for haemodialysis and related therapies

The recommendations of the European Pharmacopoeia and/or local regulations constitute the “current state of scientific findings” with regard to microbiological criteria and are used for the evaluation of the quality of water and dialysate.



**FRESENIUS
MEDICAL CARE**

Head office: Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg · Germany
Phone: +49 (0) 6172-609-0 · Fax: +49 (0) 6172-609-2191
www.fmc-ag.com