

ICS 11.040.40

CCS C45

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0793.2-2023

Replacing YY 0572-2015

**Preparation and quality management of fluids for
haemodialysis and related therapies - Part 2: Water for
haemodialysis and related therapies**

血液透析和相关治疗用液体的制备和质量管理 第2部分：血液透析和相关治疗用
水

Issued on: November 22, 2023

Implemented on: December 1, 2026

Issued by: National Medical Products Administration

Table of Contents

1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Requirements	1
6 Reference	11

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document is Part 2 of the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapeutic Uses. Preparation and Quality Management of Liquids has been published in the following sections.

1. Water treatment equipment for hemodialysis and related treatments (YY/T 0793.1-2022);

2. Water for hemodialysis and related treatments (YY 0793.2-2023);

4. Quality of dialysate for hemodialysis and related therapies (YY/T 0793.4-2022). This document replaces YY 0572-2015 "Water for Hemodialysis and Related Treatments". Compared with YY 0572-2015, in addition to structural adjustments and In addition to editorial changes, the main technical changes are as follows:

--- Changed the scope (see Chapter 1, Chapter 1 of YY 0572-2015);

--- Deleted the terms and definitions of "intervention level", "total chlorine" and "dialysis water" (see

3.3 of YY 0572-2015);

--- Added quality requirements for dialysis water (see 4.1);

--- Added fungi requirements (see 4.2);

--- Deleted the requirements for dialysis water in hemodialysis machine reprocessing (see 4.2 of YY 0572-2015);

--- Added the maximum allowable amount and total chlorine explanation in Table 1 (see 4.3);

--- Deleted the verification and monitoring of dialysis water (see

1 Scope

YY 0793.2 sets the minimum quality of the water used to make dialysis concentrate and dialysis fluid for haemodialysis, haemodiafiltration and haemofiltration. A dialysis patient is exposed to hundreds of litres of water a week across a membrane, so contamination that would be harmless in drinking water becomes a clinical hazard here: this is the standard that fixes the chemical and microbiological limits and the monitoring that keeps a water treatment plant within them. Being a YY standard without the /T suffix, compliance is compulsory in China. It is the document a dialysis unit is inspected against and the specification a water treatment supplier has to design to. The 2023 edition takes effect in December 2026 and supersedes YY 0572-2015, the standard the sector has worked to for a decade.

This document specifies the minimum water concentrations for the preparation of dialysis concentrates and dialysis fluids (for hemodialysis, hemodiafiltration or hemofiltration). Low requirements. This document applies to water used in the preparation of dialysis concentrate and dialysis fluid (for hemodialysis, hemodiafiltration or hemofiltration). This document does not cover the use of water treatment equipment and the mixing of treated water with concentrate to produce the final dialysate. This document does not apply to dialysate regeneration systems.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 43050 General requirements for the preparation and quality management of fluids for hemodialysis and related treatments (GB/T 43050-2023,

ISO 23500-1.2019, MOD) Pharmacopoeia of the People's Republic of China

3 Terms and definitions

The terms and definitions defined in GB/T 43050 apply to this document.

4 Requirements

4.1 Quality requirements for dialysis water After the water treatment system is installed, the quality of the dialysis water should be verified in accordance with the provisions of

4.2 and 4.3. Thereafter, the dialysis water should be monitored regularly. the quality of.
NOTE. This document assumes that the water supply used for treatment is potable water of acceptable quality. If the water supply comes from another source, such as a privately owned borehole or well, the sewage Contaminant levels will not be as tightly controlled.

4.2 Microbiological requirements The total microbial count in dialysis water should be less than 100 CFU/mL. This should be set based on an understanding of the microbial dynamics of the system. An intervention level, which is usually 50% of the maximum permitted level. Endotoxin levels in dialysis water should be less than

0.25 EU/mL. An intervention level should be established, usually 50% of the maximum permissible level. Fungi (yeast and filamentous fungi) can coexist with bacteria and endotoxins in dialysis water, but fungi in hemodialysis water systems are More research is needed into the role of steroids in biofilm formation and their clinical significance, therefore no maximum permissible limits have yet to be established. NOTE See B.4 for the history of these requirements.