



Edition: BP 2025 (Ph. Eur. 11.6 update)

Water for Diluting Concentrated Haemodialysis Solutions



[General Notices](#)

(Haemodialysis Solutions, Concentrated, Water for Diluting, Ph. Eur. monograph 1167)

Ph Eur

The following monograph is given for information.

The analytical methods described and the limits proposed are intended to be used for validating the procedure for obtaining the water.

DEFINITION

Water for diluting concentrated haemodialysis solutions is obtained from potable water by distillation, by reverse osmosis, by ion exchange or by any other suitable method. The conditions of preparation, transfer and storage are designed to minimise the risk of chemical and microbial contamination.

When water obtained by one of the methods described above is not available, potable water may be used for home dialysis. Because the chemical composition of potable water varies considerably from one locality to another, consideration must be given to its chemical composition to enable adjustments to be made to the content of ions so that the concentrations in the diluted solution correspond to the intended use.

Attention has also to be paid to the possible presence of residues from water treatment (for example, chloramines) and volatile halogenated hydrocarbons.

For the surveillance of the quality of water for diluting concentrated haemodialysis solutions, the following methods may be used to determine the chemical composition and/or to detect the presence of possible contaminants together with suggested limits to be obtained.

CHARACTERS

Clear, colourless, liquid.

TESTS

Acidity or alkalinity

To 10 mL of the water to be examined, freshly boiled and cooled in a borosilicate glass flask, add 0.05 mL of [methyl red solution R](#). The solution is not red. To 10 mL of the water to be examined add 0.1 mL of [bromothymol blue solution R1](#). The solution is not blue.

Oxidisable substances

To 100 mL of the water to be examined add 10 mL of [dilute sulfuric acid R](#) and 0.1 mL of [0.02 M potassium permanganate](#) and boil for 5 min. The solution remains faintly pink.

Total available chlorine

Maximum 0.1 ppm.

In a 125 mL test-tube (A), place successively 5 mL of [buffer solution pH 6.5 R](#), 5 mL of [diethylphenylenediamine sulfate solution R](#) and 1 g of [potassium iodide R](#). In a second 125 mL test-tube (B), place successively 5 mL of [buffer solution pH 6.5 R](#) and 5 mL of [diethylphenylenediamine sulfate solution R](#). Add as simultaneously as possible to tube A 100 mL of the water to be examined and to tube B a reference solution prepared as follows: to 1 mL of a 10 mg/L solution of [potassium iodate R](#), add 1 g of [potassium iodide R](#) and 1 mL of [dilute sulfuric acid R](#); allow to stand for 1 min, add 1 mL of [dilute sodium hydroxide solution R](#) and dilute to 100 mL with [water R](#). Any colour in the mixture obtained with the water to be examined is not more intense than that in the mixture obtained with the reference solution.

Chlorides (2.4.4)

Maximum 50 ppm.

Dilute 1 mL of the water to be examined to 15 mL with [water R](#).

Fluorides

Maximum 0.2 ppm.

Potentiometry ([2.2.36, Method I](#)): use as indicator electrode a fluoride-selective solid-membrane electrode and as reference electrode a silver-silver chloride electrode.

Test solution The water to be examined.

Reference solutions Dilute 2.0 mL, 4.0 mL and 10.0 mL of [fluoride standard solution \(1 ppm F\) R](#) respectively to 20.0 mL with [total-ionic-strength-adjustment buffer R1](#).

Carry out the measurement of each solution.

Nitrates

Maximum 2 ppm.

Dilute 2 mL of the water to be examined to 100 mL with [nitrate-free water R](#). Place 5 mL of the dilution in a test-tube immersed in iced water, add 0.4 mL of a 100 g/L solution of [potassium chloride R](#) and 0.1 mL of [diphenylamine solution R](#) and then, dropwise and with shaking, 5 mL of [sulfuric acid R](#). Transfer the tube to a water-bath at 50 °C. Allow to stand for 15 min. Any blue colour in the solution is not more intense than that in a standard prepared at the same time and in the same manner using a mixture of 0.1 mL of [nitrate standard solution \(2 ppm NO₃\) R](#) and 4.9 mL of [nitrate-free water R](#).

Sulfates (2.4.13)

Maximum 50 ppm.

Dilute 3 mL of the water to be examined to 15 mL with [distilled water R](#).

Aluminium (2.4.17)

Maximum 10 µg/L.

Prescribed solution To 400 mL of the water to be examined add 10 mL of [acetate buffer solution pH 6.0 R](#) and 100 mL of [water R](#).

Reference solution Mix 2 mL of [aluminium standard solution \(2 ppm Al\) R](#), 10 mL of [acetate buffer solution pH 6.0 R](#) and 98 mL of [water R](#).

Blank solution Mix 10 mL of [acetate buffer solution pH 6.0 R](#) and 100 mL of [water R](#).

Ammonium

Maximum 0.2 ppm.

To 20 mL of the water to be examined in a flat-bottomed and transparent tube, add 1 mL of [alkaline potassium tetraiodomercurate solution R](#). Allow to stand for 5 min. The solution is not more intensely coloured than a standard prepared at the same time and in the same manner using a mixture of 4 mL of [ammonium standard solution \(1 ppm NH₄\) R](#) and 16 mL of [ammonium-free water R](#). Examine the solutions along the vertical axis of the tube.

Calcium

Maximum 2 ppm.

Atomic absorption spectrometry ([2.2.23, Method I](#)).

Test solution The water to be examined.

Reference solutions Prepare reference solutions (1 ppm to 5 ppm) using [calcium standard solution \(400 ppm Ca\) R](#).

Source Calcium hollow-cathode lamp.

Wavelength 422.7 nm.

Atomisation device Oxidising air-acetylene flame.

Magnesium

Maximum 2 ppm.

Atomic absorption spectrometry ([2.2.23, Method I](#)).

Test solution Dilute 10 mL of the water to be examined to 100 mL with [distilled water R](#).

Reference solutions Prepare reference solutions (0.1 ppm to 0.5 ppm) using [magnesium standard solution \(100 ppm Mg\) R](#).

Source Magnesium hollow-cathode lamp.

Wavelength 285.2 nm.

Atomisation device Oxidising air-acetylene flame.

Mercury

Maximum 0.001 ppm.

Atomic absorption spectrometry ([2.2.23, Method I](#)).

Test solution Add 5 mL of [nitric acid R](#) per litre of the water to be examined. In a 50 mL borosilicate glass flask with a ground-glass-stopper, place 20 mL of the water to be examined and add 1 mL of [dilute nitric acid R](#) and shake. Add 0.3 mL of [bromine water R1](#). Stopper the flask, shake and heat the stoppered flask at 45 °C for 4 h. Allow to cool. If the solution does not become yellow, add 0.3 mL of [bromine water R1](#) and re-heat at 45 °C for 4 h. Add 0.5 mL of a freshly prepared 10 g/L solution of [hydroxylamine hydrochloride R](#). Shake. Allow to stand for 20 min.

Reference solutions Use freshly prepared reference solutions (0.0005 ppm to 0.002 ppm) obtained by diluting [mercury standard solution \(1000 ppm Hg\) R](#) with a 5 per cent V/V solution of [dilute nitric acid R](#) and treat as described for the test solution.

To a volume of solution suitable for the instrument to be used, add [stannous chloride solution R2](#) equal to 1/5 of this volume. Fit immediately the device for the entrainment of the mercury vapour. Wait 20 s and pass through the device a stream of [nitrogen R](#) as the carrier gas.

Source Mercury hollow-cathode tube or a discharge lamp.

Wavelength 253.7 nm.

Atomisation device Flameless system whereby the mercury can be entrained in the form of cold vapour.

Potassium

Maximum 2 ppm.

Atomic emission spectrometry ([2.2.22, Method I](#)).

Test solution (a) Dilute 50.0 mL of the water to be examined to 100 mL with [distilled water R](#). Carry out a determination using this solution. If the potassium content is more than 0.75 mg/L, further dilute the water to be examined with [distilled water R](#).

Test solution (b) Take 50.0 mL of the water to be examined or, if necessary, the water to be examined diluted as described in the preparation of test solution (a). Add 1.25 mL of [potassium standard solution \(20 ppm K\) R](#) and dilute to 100.0 mL with [distilled water R](#).

Reference solutions Prepare reference solutions (0 ppm; 0.25 ppm; 0.50 ppm; 0.75 ppm; 1 ppm) using [potassium standard solution \(20 ppm K\) R](#).

Wavelength 766.5 nm.

Calculate the potassium content of the water to be examined in parts per million from the expression:

$$\frac{p \times n_1 \times 0.5}{n_2 - n_1}$$

p = dilution factor used for the preparation of test solution (a);

n_1 = measured value of test solution (a);

n_2 = measured value of test solution (b).

Sodium

Maximum 50 ppm.

Atomic emission spectrometry ([2.2.22, Method I](#)).

Test solution The water to be examined. If the sodium content is more than 10 mg/L, dilute with [distilled water R](#) to obtain a concentration suitable for the apparatus used.

Reference solutions Prepare reference solutions (0 ppm; 2.5 ppm; 5.0 ppm; 7.5 ppm; 10 ppm) using [sodium standard solution \(200 ppm Na\) R](#).

Wavelength 589 nm.

Zinc

Maximum 0.1 ppm.

Atomic absorption spectrometry ([2.2.23, Method I](#)): use sampling and analytical equipment free from zinc or not liable to yield zinc under the conditions of use.

Test solution The water to be examined.

Reference solutions Prepare reference solutions (0.05 ppm to 0.15 ppm) using [zinc standard solution \(100 ppm Zn\) R](#).

Source Zinc hollow-cathode lamp.

Wavelength 213.9 nm.

Atomisation device Oxidising air-acetylene flame.

Heavy metals (2.4.8)

Maximum 0.1 ppm.

Heat 200 mL of the water to be examined in a glass evaporating dish on a water-bath until the volume is reduced to 20 mL. 12 mL of the solution complies with test A. Prepare the reference solution using [lead standard solution \(1 ppm Pb\) R](#).

Microbial contamination

TAMC: acceptance criterion 10^2 CFU/g ([2.6.12](#)).

Bacterial endotoxins ([2.6.14](#))

Less than 0.25 IU/mL.

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