



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

Mannitol Infusion

[General Notices](#)

Mannitol Intravenous Infusion

DEFINITION

Mannitol Infusion is a sterile solution containing Mannitol. It is supplied as a ready-to-use solution.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of mannitol, $C_6H_{14}O_6$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

- A. Evaporate to dryness on a water bath a volume containing 0.2 g of Mannitol. The [melting point](#) of the residue, [Appendix V A](#), is about 167°.
- B. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.
- (1) Dilute a volume of the infusion with [water](#) to contain 0.25% w/v of Mannitol.
 - (2) 0.25% w/v of [mannitol EPCRS](#) in [water](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel G](#).
- (b) Use the mobile phase as described below.
- (c) Apply 2 µL of each solution.
- (d) Develop the plate to 17 cm.
- (e) After removal of the plate, dry in air and spray with a 0.2% w/v solution of [sodium periodate](#). Allow the plate to dry in air for 15 minutes and spray with a 2% w/v solution of 4,4'-methylenebis-N,N-dimethylaniline in a mixture of 1 volume of [glacial acetic acid](#) and 4 volumes of [acetone](#).

MOBILE PHASE

10 volumes of [water](#), 20 volumes of [ethyl acetate](#) and 70 volumes of [propan-1-ol](#).

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) is similar in position, colour and size to that in the chromatogram obtained with solution (2).

- C. Add 0.3 mL of a solution containing 10% w/v of Mannitol to 3 mL of a cooled mixture prepared by adding 6 mL of [sulfuric acid](#) to 3 mL of a freshly prepared 10% w/v solution of [catechol](#) while cooling in ice. Heat gently over a naked flame

TESTS

Acidity or alkalinity

pH, 4.5 to 7.0, [Appendix V L](#), when determined on solutions diluted, if necessary, with [water for injections](#) to contain 10% w/v of Mannitol and to which 0.30 mL of a saturated solution of [potassium chloride](#) has been added for each 100 mL of solution.

Reducing sugars

Add 20 mL of [cupri-citric solution](#) and a few glass beads to a volume of the infusion containing 5 g of Mannitol. Heat so that boiling begins after 4 minutes and continue boiling for 3 minutes. Cool rapidly and add 100 mL of a 2.4% v/v solution of [glacial acetic acid](#) and 20 mL of 0.025M [iodine VS](#). With continuous shaking add 25 mL of a mixture of 6 volumes of [hydrochloric acid](#) and 94 volumes of [water](#) and, when the precipitate has dissolved, titrate the excess of iodine with 0.05M [sodium thiosulfate VS](#) using 1 mL of [starch solution](#), added towards the end of the titration, as indicator. Not less than 12.8 mL of 0.05M [sodium thiosulfate VS](#) is required.

Bacterial endotoxins

The endotoxin limit concentration is 0.5 IU per mL, [Appendix XIV C](#). Dilute infusions containing more than 10% w/v (100 g/L) of Mannitol with [water BET](#) to contain 10% w/v.

ASSAY

Dilute a quantity containing 0.4 g of Mannitol to 100 mL with [water](#), transfer 10 mL to a stoppered flask, add 20 mL of 0.1M [sodium periodate](#) and 2 mL of 1M [sulfuric acid](#) and heat on a water bath for 15 minutes. Cool, add 3 g of [sodium hydrogen carbonate](#) and 25 mL of 0.1M [sodium arsenite VS](#), mix, add 5 mL of a 20% w/v solution of [potassium iodide](#), allow to stand for 15 minutes and titrate with 0.05M [iodine VS](#) until the first trace of yellow colour appears. Repeat the operation without the substance being examined. The difference between the titrations represents the amount of iodine required. Each mL of 0.05M [iodine VS](#) is equivalent to 1.822 mg of $C_6H_{14}O_6$.

STORAGE

Mannitol Infusion should be stored at a temperature of 20° to 30°. Exposure to lower temperatures may cause the deposition of crystals, which should be dissolved by warming before use.