



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

Paraldehyde Injection

[General Notices](#)

DEFINITION

Paraldehyde Injection is Paraldehyde that has been sterilised. It does not contain any added antimicrobial preservatives.

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

IDENTIFICATION

- A. A 10.0% v/v solution in [carbon dioxide-free water](#) (solution A) is *clear*, [Appendix IV A](#), but becomes turbid on warming.
- B. Heat 5 mL with 0.1 mL of 1M [sulfuric acid](#). Acetaldehyde is evolved.
- C. To 5 mL of solution A in a test tube add 5 mL of ammoniacal [silver nitrate solution](#) and heat on a water bath. Silver is deposited as a mirror on the side of the tube.

TESTS

Acidity

Titrate 50 mL of solution A with [0.1M sodium hydroxide VS](#) using 0.05 mL of [phenolphthalein solution](#) as indicator. Not more than 1.5 mL of [0.1M sodium hydroxide VS](#) is required to change the colour of the solution.

[Distillation range](#)

Not more than 10% distils below 123° and not less than 95% distils below 126°, [Appendix V C](#).

[Freezing point](#)

10° to 13°, [Appendix V B](#).

[Refractive index](#)

1.403 to 1.406, [Appendix V E](#).

[Relative density](#)

0.991 to 0.996, [Appendix V G](#).

[Acetaldehyde](#)

Shake 5 mL with a mixture of 5 mL of [ethanol](#) (60%), 5 mL of [alcoholic hydroxylamine solution](#) and 0.2 mL of [methyl orange solution](#). Not more than 0.8 mL of [0.5M sodium hydroxide VS](#) is required to change the colour of the solution to

Peroxides

To 50 mL of solution A in a ground-glass-stoppered flask add 5 mL of 1M [sulfuric acid](#) and 10 mL of [potassium iodide solution](#), close the flask and allow to stand in the dark for 15 minutes. Titrate with 0.1M [sodium thiosulfate VS](#) using 1 mL of [starch solution](#) as indicator; allow to stand for 5 minutes and, if necessary, complete the titration. Not more than 2.0 mL of 0.1M [sodium thiosulfate VS](#) is required.

STORAGE

Paraldehyde Injection should be supplied in single-dose glass ampoules sealed by fusion of the glass. It should be kept in complete darkness.