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

Isoniazid Injection

General Notices

Action and use

Antituberculosis drug.

DEFINITION

Isoniazid Injection is a sterile solution of Isoniazid in Water for Injections.

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

Content of isoniazid, $C_6H_7N_3O$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Using a rotary evaporator, evaporate a volume of the injection containing 50 mg of Isoniazid to dryness, extract the residue with two 10 mL quantities of *ethanol (96%)*, filter and evaporate the combined ethanol extracts to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of isoniazid *(RS 196)*.
B. To a volume containing 25 mg of Isoniazid add 5 mL of *ethanol (96%)*, 0.1 g of *sodium tetraborate* and 5 mL of a 5.0% w/v solution of *1-chloro-2,4-dinitrobenzene* in *ethanol (96%)*, evaporate to dryness on a water bath, heat for a further 10 minutes and dissolve the residue in 10 mL of *methanol*. A reddish purple colour is produced.

TESTS

Acidity

pH, 5.6 to 6.0, Appendix V L.

ASSAY

Dilute a quantity containing 0.4 g of Isoniazid to 250 mL with *water*. To 25 mL of the solution in a glass-stoppered flask add 25 mL of 0.05M *bromine VS* and 5 mL of *hydrochloric acid*, shake for 1 minute, allow to stand for 15 minutes, add 1 g of *potassium iodide* and titrate with 0.1M *sodium thiosulfate VS* using *starch mucilage* as indicator. Repeat the operation without the injection. The difference between the titrations represents the amount of bromine required. Each mL of 0.05M *bromine VS* is equivalent to 3.429 mg of $C_6H_7N_3O$.

STORAGE

Isoniazid Injection should be protected from light.