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

Hydralazine Injection

General Notices

Action and use

Vasodilator; treatment of hypertension.

DEFINITION

Hydralazine Injection is a sterile solution of Hydralazine Hydrochloride in Water for Injections. It is prepared by dissolving Hydralazine Hydrochloride for Injection in the requisite amount of Water for Injections immediately before use. For intravenous infusion, the Hydralazine Hydrochloride for Injection should be dissolved in, and then diluted with, an appropriate volume of a suitable diluent.

The injection complies with the requirements stated under Parenteral Preparations.

STORAGE

Hydralazine Injection deteriorates on storage and should be used immediately after preparation.

HYDRALAZINE HYDROCHLORIDE FOR INJECTION

DEFINITION

Hydralazine Hydrochloride for Injection is a sterile material consisting of Hydralazine Hydrochloride with or without excipients. It is supplied in a sealed container.

The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.

Content of hydralazine hydrochloride, $C_8H_8N_4,HCl$

98.0 to 114.0% of the stated amount.

IDENTIFICATION

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of hydralazine hydrochloride *(RS 177)*.
B. The *light absorption*, Appendix II B, in the range 230 to 350 nm of a 0.002% w/v solution exhibits four maxima, at 240, 260, 305 and 315 nm.
C. Yield the reactions characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH of a 2% w/v solution, 3.5 to 4.2, Appendix V L.

Clarity of solution

A 2.0% w/v solution is not more opalescent than *reference suspension II*, Appendix IV A.

Colour of solution

A 2.0% w/v solution in 0.01M *hydrochloric acid* is not more intensely coloured than *reference solution* GY_6, Appendix IV B, Method II.

Hydrazine

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Dissolve the contents of a sealed container in sufficient 0.1M *methanolic hydrochloric acid* to produce a solution containing 0.5% w/v of Hydralazine Hydrochloride. To 2 mL add 1 mL of a 2% w/v solution of *salicylaldehyde* in *methanol* and 0.1 mL of *hydrochloric acid*, centrifuge and decant the supernatant liquid.
(2) Prepare in the same manner as solution (1), but use 2 mL of a 0.00025% w/v solution of *hydrazine sulfate* in 0.1M *methanolic hydrochloric acid* in place of the solution of the material being examined.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (Merck silica gel 60 plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 40 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and spray with *dimethylaminobenzaldehyde solution R1*.

MOBILE PHASE

The upper layer of the mixture obtained by shaking together 20 volumes of 13.5M *ammonia*, 20 volumes of *ethyl acetate* and 80 volumes of *hexane* and allow to stand.

LIMITS

Any spot corresponding to hydrazine in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2).

Uniformity of content

Sealed containers each containing 20 mg or less of Hydralazine Hydrochloride comply with the requirements stated under Parenteral Preparations, Powders for Injections or Infusions using the following method of analysis. Dissolve the contents of a sealed container in sufficient *water* to produce 100 mL and dilute a volume containing 1 mg of Hydralazine Hydrochloride to 100 mL with *water*. Measure the *absorbance* of the resulting solution at the maximum at 260 nm, Appendix II B. Calculate the content of $C_8H_8N_4$,HCl taking 535 as the value of A(1%, 1 cm) at the maximum at 260 nm.

ASSAY

Determine the weight of the contents of 10 containers described in the test for *uniformity of weight*, Appendix XII C1, Powders for Parenteral Use.

Dissolve 0.1 g of the mixed contents of the 10 containers in a mixture of 25 mL of *water* and 35 mL of *hydrochloric acid* and titrate with *0.025M potassium iodate VS* determining the end point potentiometrically using a platinum indicator electrode and a calomel reference electrode. Each mL of *0.025M potassium iodate VS* is equivalent to 4.916 mg of $C_8H_8N_4$,HCl. Calculate the content of $C_8H_8N_4$,HCl in a container of average content weight.

STORAGE

The sealed container should be protected from light.