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Hydralazine Hydrochloride Injection

DEFINITION

Hydralazine Hydrochloride Injection is a sterile solution of Hydralazine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of hydralazine hydrochloride ($C_8H_8N_4 \cdot HCl$).

IDENTIFICATION

- **A. INFRARED ABSORPTION**

Sample: A volume of Injection, equivalent to 60 mg of hydralazine hydrochloride. Mix the *Sample* with a quantity of 1 N hydrochloric acid sufficient to prepare 25 mL of solution. Place 20 mL of this solution in a separator, wash with 10 mL of methylene chloride, and discard the methylene chloride washing. Mix the aqueous solution in the separator with 2 mL of sodium nitrite solution (14 mg/mL). Add 10 mL of methylene chloride, shake by mechanical means for 5 min, and allow the layers to separate. Pass the methylene chloride layer through a filter of anhydrous sodium sulfate, previously washed with methylene chloride, and collect the solution in a 50-mL beaker. Evaporate to dryness with the aid of gentle heat and a stream of dry nitrogen.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of [USP Hydralazine Hydrochloride RS](#) similarly treated and prepared.

ASSAY

- **PROCEDURE**

Sample solution: Transfer an amount equivalent to 100 mg of hydralazine hydrochloride from a suitable volume of Injection in a 250-mL iodine flask. Add 20 mL of hydrochloric acid, cool to room temperature, and add 5 mL of chloroform.

Analysis: Titrate with 0.02 M potassium iodate VS until the purple color of iodine disappears from the chloroform, adding the last portion of the potassium iodate solution dropwise and agitating the mixture vigorously and continuously. Each mL of 0.02 M potassium iodate is equivalent to 3.933 mg of hydralazine hydrochloride ($C_8H_8N_4 \cdot HCl$).

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- [pH \(791\)](#): 3.4–4.4
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 1.45 USP Endotoxin Units/mg
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements for small-volume injections
- **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#)

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Hydralazine Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
HYDRALAZINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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