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Metaraminol Bitartrate Injection

» Metaraminol Bitartrate Injection is a sterile solution of Metaraminol Bitartrate in Water for Injection. It contains, in each mL, an amount of metaraminol bitartrate equivalent to not less than 9.0 mg and not more than 11.0 mg of metaraminol ($C_9H_{13}NO_2$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—
USP Metaraminol Bitartrate RS

Identification—

A: Evaporate a 1-mL portion to dryness: the residue so obtained meets the requirements for *Identification* test *A* under *Metaraminol Bitartrate*.

B: It meets the requirements for *Identification* tests *B* and *C* under *Metaraminol Bitartrate*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 3.5 USP Endotoxin Units per mg of metaraminol.

pH ⟨791⟩**:** between 3.2 and 4.5.

Particulate Matter in Injections ⟨788⟩**:** meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

0.0032 M Hexanesulfonate buffer—Mix 600 mg of sodium 1-hexanesulfonate with water to obtain 1000 mL of solution, adjust with phosphoric acid to a pH of 3.0 ± 0.05, and filter.

Mobile phase—Prepare a suitable degassed and filtered mixture of methanol and *0.0032 M Hexanesulfonate buffer* (7:3). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Metaraminol Bitartrate RS in water to obtain a solution having a known concentration of about 0.2 mg of metaraminol per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 20 mg of metaraminol, to a 100-mL volumetric flask, dilute with water to volume, and mix.

System suitability preparation—Prepare a solution of propylparaben in alcohol containing 0.4 mg per mL. Mix 1 volume of this solution with 99 volumes of the *Standard preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 264-nm detector and a 4-mm × 25-cm column that contains packing L7. The flow rate is about 1 mL per minute. Chromatograph the *System suitability preparation* and the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 2600 theoretical plates, the resolution, *R,* between the metaraminol bitartrate and propylparaben peaks is not less than 3.0 with propylparaben eluting first, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of metaraminol ($C_9H_{13}NO_2$) in each mL of the Injection taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of metaraminol represented by the USP Metaraminol Bitartrate RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METARAMINOL BITARTRATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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