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Sodium Nitroprusside for Injection

» Sodium Nitroprusside for Injection is Sodium Nitroprusside suitable for parenteral use. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of sodium nitroprusside ($Na_2[Fe(CN)_5NO] \cdot 2H_2O$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Sodium Nitroprusside RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Identification—To 50 mg contained in a small test tube add 10 mL of ascorbic acid solution (1 in 50), and mix. Add 1 mL of dilute hydrochloric acid (1 in 10), mix, and add dropwise, while mixing, 1 to 2 mL of 1 N sodium hydroxide: a transient blue color is produced.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.05 USP Endotoxin Unit per µg of sodium nitroprusside.

Water Determination, *Method I* ⟨921⟩: not more than 15.0%.

Other requirements—It responds to the *Identification* test *A* under *Sodium Nitroprusside*. It meets also the requirements for *Sterility Tests ⟨71⟩*, *Uniformity of Dosage Units ⟨905⟩*, and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

pH 7.1 buffer—Dissolve 1.36 g of monobasic potassium phosphate and 5.2 mL of a 1 in 4 solution of tetrabutylammonium hydroxide in methanol in water to make 1000 mL, and adjust with phosphoric acid or with the tetrabutylammonium hydroxide solution to a pH of 7.1.

Mobile phase—Prepare a suitable filtered mixture of *pH 7.1 buffer* and acetonitrile (about 70:30).

[Note—Use low-actinic glassware throughout the following sections.]

Standard preparation—Dissolve an accurately weighed quantity of USP Sodium Nitroprusside RS, in *Mobile phase* to obtain a solution having a known concentration of about 0.05 mg per mL.

Assay preparation 1 (where the label states only the total contents of the container)—Transfer the contents of 1 container of Sodium Nitroprusside for Injection to a 100-mL volumetric flask with the aid of *Mobile phase*, dilute with *Mobile phase* to volume, and mix. Dilute an accurately measured volume of this solution quantitatively with *Mobile phase* to obtain a solution containing about 0.05 mg of $Na_2[Fe(CN)_5NO] \cdot 2H_2O$ per mL.

Assay preparation 2 (where the label states the quantity of $Na_2[Fe(CN_5)NO] \cdot 2H_2O$ in a given volume of constituted solution)—Constitute Sodium Nitroprusside for Injection as directed in the labeling. Dilute an accurately measured volume of the constituted solution thus obtained quantitatively and stepwise with *Mobile phase* to obtain a solution containing about 0.05 mg of $Na_2[Fe(CN)_5NO] \cdot 2H_2O$ per mL.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 210-nm detector and a 3.9-mm × 30-cm column that contains 10-µm packing L11. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor for the analyte peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 25 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 $Na_2[Fe(CN)_5NO] \cdot 2H_2O$ in the container or in the portion of constituted solution taken by the formula:

$$L(C/D)(r_U/r_S)$$

in which L is the labeled quantity, in mg of $Na_2[Fe(CN)_5NO] \cdot 2H_2O$ in the container, or in the volume of constituted solution taken; C is the concentration, in mg per mL, of USP Sodium Nitroprusside RS in the *Standard preparation; D* is the concentration, in mg of $Na_2[Fe(CN)_5NO] \cdot 2H_2O$ per mL, of *Assay preparation 1* or of *Assay preparation 2*, on the basis of the labeled quantity in the container, or in the volume of constituted solution taken, respectively, and the extent of dilution; 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
SODIUM NITROPRUSSIDE FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
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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