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Aminohippurate Sodium Injection

 $C_9H_9N_2NaO_3$

216.17

Glycine, N-(4-aminobenzoyl)-, monosodium salt;

Monosodium p-aminohippurate CAS RN®: 94-16-6; UNII: SUO3KVS109.

DEFINITION

Aminohippurate Sodium Injection is a sterile solution of Aminohippuric Acid in Water for Injection prepared with the aid of Sodium Hydroxide. It contains NLT 95.0% and NMT 105.0% of the labeled amount of aminohippurate sodium (C_oH_oN₂NaO₂).

IDENTIFICATION

٠A.

Sample solution: A volume of Injection equivalent to 100 mg of aminohippuric acid

Analysis: Dilute the *Sample solution* with water to 50 mL. To 5 mL of this solution add 0.5 mL of 3 N <u>hydrochloric acid</u>, 0.5 mL of <u>sodium nitrite</u> solution (1 in 10), and a solution of 0.20 g of <u>2-naphthol</u> in 10 mL of <u>6 N ammonium hydroxide</u>.

Acceptance criteria: A red color is produced.

• B.

Sample solution: A volume of Injection equivalent to about 200 mg of aminohippurate sodium

Analysis: In the order named, add to the *Sample solution* 2 mL of <u>potassium iodide TS</u>, 10 mL of water, and 5 mL of <u>sodium hypochlorite TS</u>. **Acceptance criteria:** A red color is produced.

• C. A sample imparts an intense yellow color to a nonluminous flame.

ASSAY

• Procedure

Sample solution: A volume of Injection equivalent to 1 g of aminohippurate sodium

Analysis: Transfer the *Sample solution* to a 200-mL volumetric flask, and dilute with water to volume. Transfer 50.0 mL of the solution to a suitable container, and add 5 mL of hydrochloric acid. Proceed as directed in Nitrite Titration (451), beginning with "cool to about 15°". Each mL of 0.1 M sodium nitrite is equivalent to 21.62 mg of aminohippurate sodium (C_oH_oN₂NaO₃).

Acceptance criteria: 95.0%-105.0%

SPECIFIC TESTS

- <u>PH (791)</u>: 6.7-7.6
- BACTERIAL ENDOTOXINS TEST (85): NMT 0.04 USP Endotoxin Units/mg of aminohippurate sodium
- OTHER REQUIREMENTS: Meets the requirements in <u>Injections and Implanted Drug Products (1)</u>

ADDITIONAL REQUIREMENTS

• Packaging and Storage: Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

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

Topic/Question	Contact	Expert Committee
AMINOHIPPURATE SODIUM INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

https://trungtamthuoc.com/

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