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Adenosine Injection

DEFINITION

Adenosine Injection is a sterile solution of Adenosine in Water for Injection. It may contain Sodium Chloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of adenosine ($C_{10}H_{13}N_5O_4$).

IDENTIFICATION

The retention time of the adenosine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Dissolve 2.0 g of monobasic potassium phosphate in 800 mL of water. Add 5 mL of 1.0 M tetrabutylammonium dihydrogen phosphate, dilute with water to 980 mL, and mix. Add 20 mL of acetonitrile.

System suitability solution: 0.03 mg/mL each of USP Adenosine RS and inosine dissolved in warm water (50° to 55°), and diluted with water

Standard solution: 0.03 mg/mL of USP Adenosine RS dissolved in warm water (50° to 55°), and diluted with water to volume. Before addition of the warm water, if sodium chloride is present in the Injection, add 0.01 mL of a solution of sodium chloride (0.9 in 100) per mL of the anticipated final volume of the *Standard solution*.

Sample solution: Nominally 0.03 mg/mL of adenosine, from a suitable volume of Injection in water

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2.5 mL/min

Injection volume: 10 µL

Run time: 2.5 times the retention time of adenosine

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times of inosine and adenosine are 0.43 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6.0 between adenosine and inosine, *System suitability solution*

Tailing factor: NMT 2.0 for the adenosine peak, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of adenosine ($C_{10}H_{13}N_5O_4$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Adenosine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of adenosine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Mobile phase, System suitability solution, Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: Nominally 0.3 mg/mL of adenosine from a volume of Injection, in water

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the volume of Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of the responses of all of the peaks

Acceptance criteria

Any individual impurity: NMT 1.0%

Total impurities: NMT 1.5%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.5–7.5

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

• **Bacterial Endotoxins Test** ⟨85⟩**:** When the product is used for rapid intravenous injection, it contains NMT 11.62 USP Endotoxin Units/mg of adenosine. When the product is used for continuous peripheral intravenous infusion, it contains NMT 5.95 USP Endotoxin Units/mg of adenosine.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, single-dose containers, preferably of Type I glass, and store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Adenosine RS

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

Topic/Question	Contact	Expert Committee
ADENOSINE 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

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