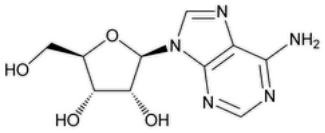
Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Oct-2024
Document Type: USP Monographs
DocId: GUID-C6AF8A22-A530-4F5C-924C-1E13D147F00C_5_en-US
DOI: https://doi.org/10.31003/USPNF_M938_05_01
DOI Ref: rtm6g

Adenosine



$C_{10}H_{13}N_5O_4$ 267.24

6-Amino-9-β-D-ribofuranosyl-9*H*-purine;

9-β-D-Ribofuranosyladenine CAS RN®: 58-61-7; UNII: K72T3FS567.

DEFINITION

Adenosine contains NLT 98.0% and NMT 102.0% of adenosine ($C_{10}H_{13}N_5O_4$), calculated on the dried basis.

IDENTIFICATION

• **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**

• **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Buffer: 6.8 g/L of potassium hydrogen sulfate and 3.4 g/L of tetrabutylammonium hydrogen sulfate in a solution prepared as follows.

Transfer suitable quantities of potassium hydrogen sulfate and ▲tetrabutylammonium▲ (ERR 1-Oct-2024) hydrogen sulfate to an appropriate volumetric flask, and dissolve in 90% of the flask volume of water. Adjust with 2 N potassium hydroxide to a pH of 6.5, and dilute with water to volume.

Mobile phase: *Buffer* and water (60:40)

System suitability solution: 4 µg/mL each of USP Adenine RS and inosine in *Mobile phase*

Standard solution: 0.2 mg/mL of USP Adenosine RS in *Mobile phase*

Sample solution: 0.2 mg/mL of Adenosine in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: NLT 1.5 times the retention time of the adenosine peak

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between adenine and inosine, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.7%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of adenosine ($C_{10}H_{13}N_5O_4$) in the portion of Adenosine 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 = concentration of Adenosine in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

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

Standard solution: 0.001 mg/mL of USP Adenosine RS in *Mobile phase*

Sample solution: 1 mg/mL of Adenosine in *Mobile phase*

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between adenine and inosine, *System suitability solution*

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Adenosine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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 = concentration of Adenosine in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*. Disregard peaks that are less than 0.05% of the adenosine peak.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Uridine[a]	0.29	0.73	0.10
Adenine	0.34	1.6	0.2
Inosine[b]	0.42	0.73	0.1
Guanosine[c]	0.51	0.86	0.10
Adenosine	1.0	—	—
Any individual unspecified impurity	—	1.0	0.10
Total impurities	—	—	0.5

[a] 1-β-D-Ribofuranosylpyrimidine-2,4(1*H*,3*H*)-dione.

[b] 9-β-D-Ribofuranosylpurine-6(1*H*)-one.

[c] 2-Amino-9-β-D-ribofuranosylpurine-6(1*H*)-one.

SPECIFIC TESTS

• **Optical Rotation, *Specific Rotation* ⟨781S⟩:** −68° to −72°

Test solution: 20 mg/mL in sodium hydroxide solution (1 in 20), determined on a sample previously dried at 105° for 2 h

• **Loss on Drying ⟨731⟩**

Analysis: Dry a sample at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Adenine RS

USP Adenosine RS

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

Topic/Question	Contact	Expert Committee
ADENOSINE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(6)

Current DocID: GUID-C6AF8A22-A530-4F5C-924C-1E13D147F00C_5_en-US

DOI: https://doi.org/10.31003/USPNF_M938_05_01

DOI ref: rtm6g