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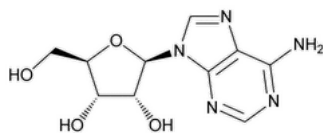
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Adenosine


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

6-Amino-9-β-D-ribofuranosyl-9H-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(1H,3H)-dione.

^b 9-β-D-Ribofuranosylpurine-6(1H)-one.

^c 2-Amino-9-β-D-ribofuranosylpurine-6(1H)-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 \(731\)](#).