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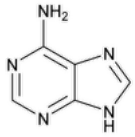
Adenine



$C_5H_5N_5$ 135.13
9*H*-Purin-6-amine;
1,6-Dihydro-6-iminopurine CAS RN®: 73-24-5; UNII: JAC85A2161.

DEFINITION

Adenine contains NLT 98.0% and NMT 102.0% of adenine ($C_5H_5N_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

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

ASSAY

• **Procedure**

Buffer solution: Dissolve 6.90 g of monobasic ammonium phosphate in about 800 mL of water. Adjust with ammonium hydroxide to a pH of 6.2, and dilute with water to 1 L.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Buffer Solution (%)	Acetonitrile (%)	Water (%)
0	5	5	90
20	5	5	90
20.1	10	10	80
30	10	10	80
30.1	5	5	90
40	5	5	90

System suitability solution: 50 µg/mL each of USP Adenine RS and 7-methyladenine in water

Standard solution: 0.1 mg/mL of USP Adenine RS in water. If necessary, sonicate the solution at 30° until the substance is completely dissolved.

Sample solution: 0.1 mg/mL of Adenine in water. If necessary, sonicate the solution at 30° until the substance is completely dissolved.

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 25-cm; 5-µm packing L85

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for 7-methyladenine and adenine are 0.88 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the 7-methyladenine and adenine peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of adenine ($C_5H_5N_5$) in the portion of Adenine 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 Adenine RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

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

• **Related Compounds**

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

Sample solution: Dissolve 25 mg of Adenine in approximately 15 mL of boiling water. Cool, quantitatively transfer to a 25-mL volumetric flask, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 5-µm packing L85

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Analysis

Sample: *Sample solution*

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

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

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria

Individual impurity: NMT 0.1%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩:** Dry a sample at 110° for 4 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Adenine RS

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

Topic/Question	Contact	Expert Committee
ADENINE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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Pharmacopeial Forum: Volume No. PF 38(6)
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