Table 1 *(Continued)*

Time (min)	Buffer Solution (%)	Acetonitrile (%)	Water (%)
5	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%

Delete the following:

- **HEAVY METALS,** *Method II* ⟨231⟩**:** NMT 10 µg/g • (official 1-Jan-2018)
- **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%

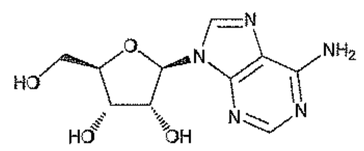
SPECIFIC TESTS

- **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

Adenosine



$C_{10}H_{13}N_5O_4$ 267.24
6-Amino-9-β-D-ribofuranosyl-9*H*-purine;
9-β-D-Ribofuranosyladenine [58-61-7].

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. INFRARED ABSORPTION ⟨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

- **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 tetrabutyl ammonium 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*