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%

Delete the following:

• **Heavy Metals,** *Method II* ⟨231⟩: NMT 10 ppm • (official 1-Jan-2018)

• **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]	0.86	0.73	0.10
Adenine	0.73	—	—
Inosine[b]	0.42	0.73	—
Guanosine[c]	0.86	0.86	0.10
Adenosine	—	—	—
Any individual unspecified impurity	1.0	1.0	0.10
Total impurities	—	—	—

[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

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