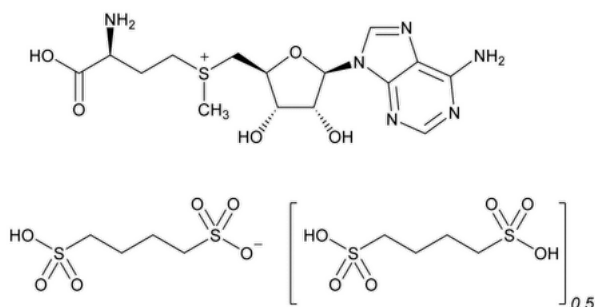


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Add the following:

▲S-Adenosyl-L-methionine 1,4-Butanedisulfonate



$C_{15}H_{23}N_6O_5S^+ \cdot C_4H_9O_6S_2^- \cdot 0.5 C_4H_{10}O_6S_2$ 725.80

S-(Adenosyl)-L-methionine 1,4-butanedisulfonate;

Adenosine, 5'-[[[(3S)-3-amino-3-carboxypropyl]methylsulfonio]-5'-deoxy-, 1,4-butanedisulfonate (salt), 1,4-butanedisulfonate (salt) (2:1:2) CAS RN®: 101020-79-5.

Adenosine, 5'-[[[(3S)-3-amino-3-carboxypropyl]methylsulfonio]-5'-deoxy-, 1,4-hydrogen butanedisulfonate (salt), 1,4-butanedisulfonic acid (2:2:1).

DEFINITION

S-Adenosyl-L-methionine 1,4-Butanedisulfonate is the salt of a mixture of diastereomers of the S-adenosyl-L-methionine ion with 1,4-butanedisulfonate. It may contain additional 1,4-butanedisulfonic acid ($C_4H_{10}O_6S_2$). It contains NLT 50.0% and NMT 56.0% of S-adenosyl-L-methionine ($C_{15}H_{23}N_6O_5S^+$), and NLT 44.0% and NMT 49.0% of 1,4-butanedisulfonic acid ($C_4H_{10}O_6S_2$), calculated on the anhydrous basis. It contains NLT 97.0% and NMT 101.0% of S-adenosyl-L-methionine 1,4-butanedisulfonate, calculated on the anhydrous basis.

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of S-adenosyl-L-methionine in the *System suitability solution*, as obtained in the test for *Content of S-Adenosyl-L-methionine*.

COMPOSITION

• **CONTENT OF S-ADENOSYL-L-METHIONINE**

[NOTE—Prepare the test solutions fresh and analyze within 1 h.]

Buffer solution: Dissolve 1.0 g of [sodium 1-octanesulfonate](#) and 12.6 g of [ammonium formate](#) in 1000 mL of [water](#) and adjust with [formic acid](#) to a pH of 2.8.

Mobile phase: [Acetonitrile](#) and *Buffer solution* (10:90)

Standard solution: 0.8 mg/mL of [USP S-Adenosyl-L-methionine 1,4-Butanedisulfonate RS](#) in *Mobile phase*

System suitability solution: 4.0 µg/mL each of [USP S-Adenosyl-L-homocysteine RS](#) and [USP S-Adenosyl-L-methionine 1,4-Butanedisulfonate RS](#) in *Mobile phase*

Sample solution: 0.8 mg/mL of S-Adenosyl-L-methionine 1,4-Butanedisulfonate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Temperatures

Autosampler: 2°–8°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: NLT 5 times the retention time of S-adenosyl-L-methionine

System suitability

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

[NOTE—The relative retention times of S-adenosyl-L-homocysteine and S-adenosyl-L-methionine are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between S-adenosyl-L-homocysteine and S-adenosyl-L-methionine, *System suitability solution*

Relative standard deviation: NMT 2.0% for S-adenosyl-L-methionine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of S-adenosyl-L-methionine ($C_{15}H_{23}N_6O_5S^+$) in the portion of S-Adenosyl-L-methionine 1,4-Butanedisulfonate taken:

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

r_U = peak area of S-adenosyl-L-methionine from the *Sample solution*

r_S = peak area of S-adenosyl-L-methionine from the *Standard solution*

C_S = concentration of [USP S-Adenosyl-L-methionine 1,4-Butanedisulfonate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of S-Adenosyl-L-methionine 1,4-Butanedisulfonate in the *Sample solution* (mg/mL)

P = assigned value for the content of S-adenosyl-L-methionine in [USP S-Adenosyl-L-methionine 1,4-Butanedisulfonate RS](#)

Acceptance criteria: 50.0%–56.0% on the anhydrous basis

• CONTENT OF 1,4-BUTANEDISULFONIC ACID

Mobile phase: 35 mM [potassium hydroxide](#) in [water](#)

Standard solution: 0.08 mg/mL of [USP 1,4-Butanedisulfonic Acid RS](#) in [water](#)

Sample solution: 0.2 mg/mL of S-Adenosyl-L-methionine 1,4-Butanedisulfonate in [water](#)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: Ion chromatography

Detector: Conductivity with self-regenerating anion suppressor current at 87 mA (or according to manufacturer's recommendations for optimal signal-to-noise ratio)

Column: 4.0-mm × 25-cm; 7.5-μm packing [L113](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 25 μL

Run time: NLT 3 times the retention time of 1,4-butanedisulfonate

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 4000

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 1,4-butanedisulfonic acid ($C_4H_{10}O_6S_2$) in the portion of S-Adenosyl-L-methionine 1,4-Butanedisulfonate taken:

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

r_U = peak area of 1,4-butanedisulfonate from the *Sample solution*

r_S = peak area of 1,4-butanedisulfonate from the *Standard solution*

C_S = concentration of [USP 1,4-Butanedisulfonic Acid RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of S-Adenosyl-L-methionine 1,4-Butanedisulfonate in the *Sample solution* (mg/mL)

Acceptance criteria: 44.0%–49.0% on the anhydrous basis

• CONTENT OF S-ADENOSYL-L-METHIONINE 1,4-BUTANEDISULFONATE

Analysis: Calculate the total content of S-adenosyl-L-methionine 1,4-Butanedisulfonate by adding the individual percentages, as obtained in the tests for *Content of S-Adenosyl-L-methionine* and *Content of 1,4-Butanedisulfonic Acid*, on the anhydrous basis.

Acceptance criteria: 97.0%–101.0% on the anhydrous basis

IMPURITIES

• RELATED COMPOUNDS

Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the *Content of S-Adenosyl-L-methionine*.