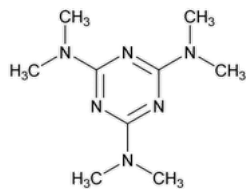


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Altretamine



$C_9H_{18}N_6$ 210.28
1,3,5-Triazine-2,4,6-triamine, *N,N,N',N'',N''',N''''*-hexamethyl-;
Hexamethylmelamine CAS RN[®]: 645-05-6.

DEFINITION

Altretamine contains NLT 98.0% and NMT 102.0% of altretamine ($C_9H_{18}N_6$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#) 197A or 197K ▲ (CN 1-MAY-2020) : Meets the requirements
- **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**

Solution A: 1.7 g/L of [dibasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 7.0 ± 0.1.

Solution B: Acetonitrile

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
3	100	0
25	50	50
28	50	50
29	100	0
35	100	0

Standard stock solution: 1.0 mg/mL of [USP Altretamine RS](#) prepared as follows. Dissolve a suitable amount of [USP Altretamine RS](#) in about 40% of the flask volume of acetonitrile. Sonicate as needed to dissolve. Add [water](#) almost to volume and allow the solution to reach room temperature. Dilute with [water](#) to volume and mix.

Standard solution: 0.1 mg/mL of [USP Altretamine RS](#) in [water](#) from *Standard stock solution*

Sample stock solution: 1.0 mg/mL of Altretamine prepared as follows. Dissolve a suitable amount of Altretamine in about 40% of the flask volume of acetonitrile. Sonicate as needed to dissolve. Add [water](#) almost to volume and allow the solution to reach room temperature. Dilute with [water](#) to volume and mix.

Sample solution: 0.1 mg/mL of Altretamine in [water](#) from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 242 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L96](#)**Flow rate:** 1.5 mL/min**Injection volume:** 20 μL. [NOTE—An in-line filter may be needed to reduce system pressure.]**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of altretamine ($C_9H_{18}N_6$) in the portion of Altretamine 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 Altretamine RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Altretamine in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis**IMPURITIES**• **RESIDUE ON IGNITION (281):** NMT 0.1%• **ORGANIC IMPURITIES****Solution A, Solution B, Mobile phase, Standard solution, and Sample solution:** Prepare as directed in the Assay.**Sensitivity solution:** 0.06 μg/mL of [USP Altretamine RS](#) in [water](#) from *Standard solution***Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 215 and 242 nm (see [Table 2](#))**Column:** 4.6-mm × 25-cm; 5-μm packing [L96](#)**Flow rate:** 1.5 mL/min**Injection volume:** 20 μL**System suitability****Samples:** *Standard solution* and *Sensitivity solution***Suitability requirements****Tailing factor:** NMT 1.5, *Standard solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Signal-to-noise ratio:** NLT 10 for the altretamine peak, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of altretamine from the *Standard solution* C_S = concentration of [USP Altretamine RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Altretamine in the *Sample solution* (mg/mL) F = relative response factor (see [Table 2](#))**Acceptance criteria:** See [Table 2](#). The reporting threshold is NMT 0.06%.**Table 2**