Diluent: Methanol and water (65:35)

Mobile phase: Methanol and Buffer (65:35)

Standard stock solution: 0.5 mg/mL of USP Altretamine RS in a mixture of methanol and water (70:30), prepared by first dissolving the Standard in methanol and then diluting with water to final volume.

Standard solution: 0.05 mg/mL of USP Altretamine RS

in Diluent, from Standard stock solution

Sample stock solution: Transfer 25 mg of Altretamine to a 50-mL volumetric flask. Dissolve in 35 mL of methanol, and dilute with water to volume.

Sample solution: 0.05 mg/mL of Altretamine in Diluent,

from Sample stock solution Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC

Detector: UV 227 nm

Column: 4.6-mm × 30-cm; packing L1

Flow rate: 2 mL/min Injection volume: 10 µL 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 (C₉H₁₈N₆) in the portion of Altretamine taken:

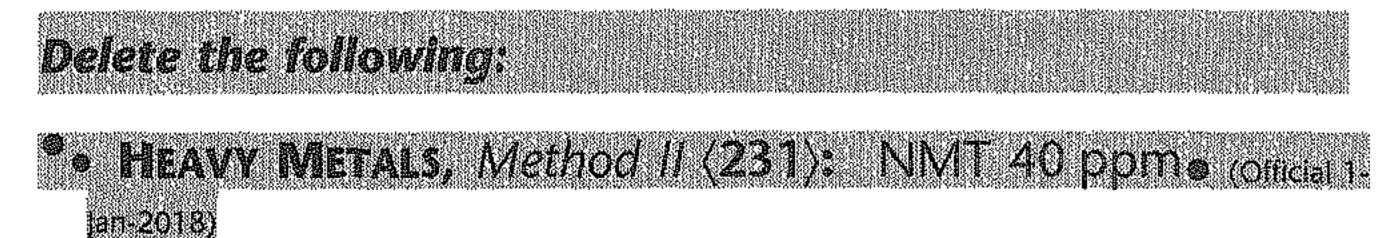
Result =
$$(r_U/r_S) \times (C_S/C_U) \times 100$$

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 the *Sample solution* (mg/mL) Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• RESIDUE ON IGNITION (281): NMT 0.1%



SPECIFIC TESTS

• WATER DETERMINATION, Method I (921): NMT 1%

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in tight containers, and store at controlled room temperature.

• USP REFERENCE STANDARDS (11)
USP Altretamine RS

Altretamine Capsules

DEFINITION

Altretamine Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of altretamine (C₉H₁₈N₆).

IDENTIFICATION

• A. Infrared Absorption (197K)

Sample: Remove as completely as possible the contents of 5 Capsules, and dissolve, with shaking, in 10 mL of chloroform. Filter, and evaporate the chloroform solution to dryness.

Acceptance criteria: Meet 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

Buffer: 0.79 g/L of ammonium carbonate in water. Adjust with a solution of formic acid (1 in 10) or ammonium hydroxide (1 in 10) to a pH of 8.0 ± 0.05 .

Diluent: Methanol and water (65:35)

Mobile phase: Methanol and Buffer (65:35)
Standard stock solution: 0.5 mg/mL of USP Altretamine RS in a mixture of methanol and water (70:30), prepared by first dissolving the Standard in methanol and then diluting with water to final volume. Standard solution: 0.05 mg/mL of USP Altretamine RS

in Diluent, from Standard stock solution

Sample stock solution: Remove as completely as possi-

ble the contents of NLT 20 Capsules, and weigh. Mix the combined contents, and transfer as completely as possible to a 500-mL volumetric flask. Add 325 mL of methanol, and sonicate. Dilute with water to volume. Sample solution: Transfer a volume of the Sample stock

solution, equivalent to 10 mg of altretamine, to a 200-mL volumetric flask, and dilute with *Diluent* to volume.

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC

Detector: UV 227 nm

Column: 4.6-mm × 30-cm; packing L1

Flow rate: 2 mL/min Injection volume: 10 µL 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 (C₉H₁₈N₆) in the portion of Capsules taken:

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)

= nominal concentration of the Sample solution

(mg/mL)
Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Dissolution (711)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 30 min Detector: UV 242 nm

Standard solution: USP Altretamine RS in Medium **Analysis:** Determine the amount of C₉H₁₈N₆ dissolved from UV absorbances on filtered portions of the solution under test, suitably diluted if necessary with Medium, compared with the Standard solution.

Tolerances: NLT 80% (Q) of the labeled amount of $C_9H_{18}N_6$ is dissolved.

 Uniformity of Dosage Units (905): Meet the requirements

ADDITIONAL REQUIREMENTS

 PACKAGING AND STORAGE: Preserve in tight, light-resistant containers, and store at controlled room temperature.

