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Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-6ECC9B03-C47B-45E0-821A-5E8A9B739653_2_en-US
DOI: https://doi.org/10.31003/USPNF_M4920_02_01
DOI Ref: eye0c

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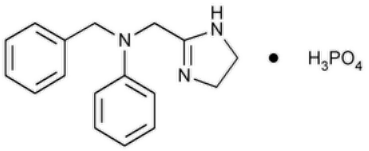
Antazoline Phosphate



$C_{17}H_{19}N_3 \cdot H_3PO_4$ 363.35

1*H*-Imidazole-2-methanamine, 4,5-dihydro-*N*-phenyl-*N*-(phenylmethyl)-, phosphate (1:1);

2-[(*N*-Benzylanilino)methyl]-2-imidazoline phosphate (1:1) CAS RN®: 154-68-7; UNII: VPR5FPH326.

DEFINITION

Antazoline Phosphate contains NLT 98.0% and NMT 102.0% of antazoline phosphate ($C_{17}H_{19}N_3 \cdot H_3PO_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

• **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: Dilute 1.0 mL of formic acid with water to 1000 mL.

Mobile phase: Acetonitrile and *Solution A* (17:83)

Diluent: Acetonitrile and water (17:83)

Standard solution: 0.2 mg/mL of USP Antazoline Phosphate RS in *Diluent*

System suitability solution: 1 µg/mL of USP Antazoline Related Compound A RS in the *Standard solution*

Sample solution: 0.2 mg/mL of Antazoline Phosphate in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 240 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing L11

Temperatures

Column: 35°

Autosampler: 4°

Flow rate: 0.5 mL/min

Injection volume: 5 µL

System suitability

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

[Note—The relative retention times of antazoline and antazoline related compound A are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between antazoline and antazoline related compound A, *System suitability solution*

Tailing factor: NMT 1.5 for antazoline, *Standard solution*

Relative standard deviation: NMT 0.73% for antazoline, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of antazoline phosphate ($C_{17}H_{19}N_3 \cdot H_3PO_4$) in the portion of Antazoline Phosphate taken:

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

r_U = peak response from the *Sample solution*

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r_S = peak response from the *Standard solution*

C_S = concentration of USP Antazoline Phosphate RS in the *Standard solution* (mg/mL)

C_U = concentration of Antazoline Phosphate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Solution A: Dilute 1.0 mL of formic acid with water to 1000 mL.

Mobile phase: Acetonitrile and *Solution A* (17:83)

Diluent: Acetonitrile and water (17:83)

Standard solution A: 5 µg/mL of USP Antazoline Related Compound A RS and 1.0 mg/mL of USP Antazoline Phosphate RS in *Diluent*

Standard solution B: 1 µg/mL of USP Antazoline Phosphate RS in *Diluent*

Sample solution: 1.0 mg/mL of Antazoline Phosphate in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 240 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing L11

Temperatures

Column: 35°

Autosampler: 4°

Flow rate: 0.5 mL/min

Injection volume: 5 µL

Run time: NLT 4 times the retention time of antazoline

System suitability

Samples: *Standard solution A* and *Standard solution B*

[Note—The relative retention times of antazoline and antazoline related compound A are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between antazoline and antazoline related compound A peaks, *Standard solution A*

Relative standard deviation: NMT 5.0% for antazoline, *Standard solution B*

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Calculate the percentage of antazoline related compound A in the portion of Antazoline Phosphate taken:

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

r_U = peak response of antazoline related compound A from the *Sample solution*

r_S = peak response of antazoline related compound A from *Standard solution A*

C_S = concentration of USP Antazoline Related Compound A RS in *Standard solution A* (mg/mL)

C_U = concentration of Antazoline Phosphate in the *Sample solution* (mg/mL)

Calculate the percentage of any individual unspecified impurity in the portion of Antazoline Phosphate taken:

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

r_U = peak response of any impurity from the *Sample solution*

r_S = peak response of antazoline phosphate from *Standard solution B*

C_S = concentration of USP Antazoline Phosphate RS in *Standard solution B* (mg/mL)

C_U = concentration of Antazoline Phosphate in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*. Disregard any impurity peaks less than 0.05%.

Table 1

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Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Antazoline phosphate	1.0	—
Antazoline related compound A[a]	1.1	0.5
Any individual unspecified impurity	—	0.5
Total impurities	—	1.0

[a] *N*-(2-Aminoethyl)-2-[benzyl(phenyl)amino]acetamide.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample: 20 mg/mL

Acceptance criteria: 4.0–5.0

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Antazoline Phosphate RS

USP Antazoline Related Compound A RS

N-(2-Aminoethyl)-2-[benzyl(phenyl)amino]acetamide.

$C_{17}H_{21}N_3O$ 283.38

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ANTAZOLINE PHOSPHATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-6ECC9B03-C47B-45E0-821A-5E8A9B739653_2_en-US

DOI: https://doi.org/10.31003/USPNF_M4920_02_01

DOI ref: eye0c

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