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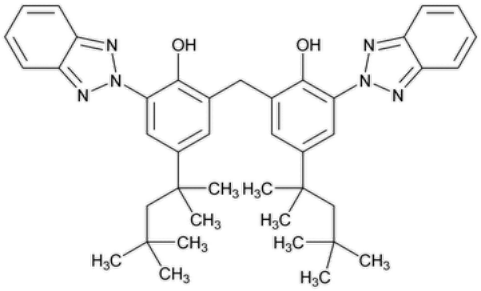
Bisoctrizole



$C_{41}H_{50}N_6O_2$ 658.87

Phenol, 2,2'-methylenebis[6-(2*H*-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)]-;

2,2'-Methylenebis[6-(2*H*-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol] CAS RN®: 103597-45-1; UNII: 8NT850T0YS.

DEFINITION

Bisoctrizole contains NLT 96.0% and NMT 102.0% of bisoctrizole ($C_{41}H_{50}N_6O_2$), calculated on the as-is basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (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**

Diluent: Tetrahydrofuran and 0.2% (w/v) aqueous solution of 1-pentane sulfonic acid sodium salt (60:40)

Solution A: 0.4 g of 1-pentane sulfonic acid sodium salt, 800 mL of methanol, 200 mL of water, and 0.5 mL of phosphoric acid

Solution B: 0.4 g of 1-pentane sulfonic acid sodium salt, 1000 mL of methanol, and 0.5 mL of phosphoric acid

Mobile phase: See *Table 1*. Return to original conditions and re-equilibrate the system.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
1	70	30
11	3	97
40	3	97

System suitability solution: 0.8 mg/mL of bisoctrizole from USP Bisoctrizole Resolution Mixture RS prepared as follows. Transfer USP Bisoctrizole Resolution Mixture RS to a suitable volumetric flask, dissolve in tetrahydrofuran, and dilute with *Diluent* to volume.

Standard solution: 0.8 mg/mL of USP Bisoctrizole RS prepared as follows. Transfer USP Bisoctrizole RS to a suitable volumetric flask, dissolve in tetrahydrofuran equivalent to 60% of the final volume, and dilute with *Diluent* to volume.

Sample solution: Transfer 80 mg of Bisoctrizole to a 100-mL volumetric flask. Dissolve in 60 mL of tetrahydrofuran, and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 346 nm

Column: 3.0-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—See *Table 2* for the relative retention times for bisoctrizole and the bisoctrizole isomer.]

Suitability requirements

Resolution: NLT 1.5 between bisoctrizole and the bisoctrizole isomer, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bisoctrizole ($C_{41}H_{50}N_6O_2$) in the portion of Bisoctrizole 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 Bisoctrizole RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 96.0%–102.0% on the as-is basis

IMPURITIES

• **LIMIT OF BISOCTRIZOLE RELATED COMPOUND A AND BISOCTRIZOLE ISOMER**

Diluent, Solution A, Solution B, Mobile phase, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard stock solution A: 0.65 mg/mL of USP Bisoctrizole RS in tetrahydrofuran

Standard stock solution B: 0.40 mg/mL of USP Bisoctrizole Related Compound A RS in tetrahydrofuran

Standard solution: Transfer 5 mL of *Standard stock solution A* and 1.0 mL of *Standard stock solution B* to a 100-mL volumetric flask. Add 60 mL of tetrahydrofuran, and dilute with *Diluent* to volume.

System suitability

Sample: *System suitability solution*

[NOTE—See *Table 2* for the relative retention times for bisoctrizole related compound A and the bisoctrizole isomer.]

Suitability requirements

Resolution: NLT 1.5 between bisoctrizole and the bisoctrizole isomer

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bisoctrizole related compound A in the portion of Bisoctrizole taken:

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

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

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

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

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

Calculate the percentage of bisoctrizole isomer in the portion of Bisoctrizole taken:

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

r_U = peak response of bisoctrizole isomer from the *Sample solution*

r_S = peak response of bisoctrizole from the *Standard solution*

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

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

Acceptance criteria: See *Table 2*.

• **ORGANIC IMPURITIES**

Diluent, Solution A, Solution B, Mobile phase, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual unspecified impurity in the portion of Bisoctrizole taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each individual impurity

r_T = sum of the responses of all the peaks

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Bisoctrizole related compound A[a]	0.42	0.5
Bisoctrizole	1.0	—
Bisoctrizole isomer[b]	1.1	4.0
Any individual unspecified impurity	—	0.10
Total impurities	—	4.0

[a] 2-(2*H*-Benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol.

[b] Phenol, 2,2'-methylenebis[6-(2*H*-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)]

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Bisoctrizole RS

USP Bisoctrizole Related Compound A RS

2-(2*H*-Benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol.

$C_{20}H_{25}N_3$ 323.43

USP Bisoctrizole Resolution Mixture RS

A mixture of approximately 1.5% of bisoctrizole isomer [phenol, 2,2'-methylenebis[6-(2*H*-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)]] in a matrix of bisoctrizole.

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

Topic/Question	Contact	Expert Committee
BISOCTRIZOLE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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