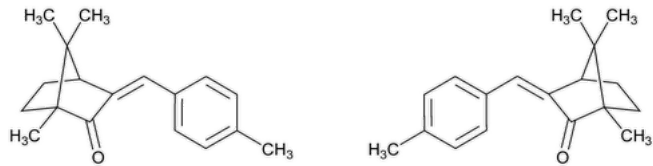


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Enzacamene

Change to read:



$C_{18}H_{22}O$ 254.37
Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-[(4-methylphenyl)methylene]-;
(±)-3-(p-Methylbenzylidene)camphor;
▲4-Methylbenzylidene camphor;
1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one▲(USP 1-Dec-2022) CAS RN®: 36861-47-9; UNII: 8I3XWY40L9.

DEFINITION
Enzacamene contains NLT 98.0% and NMT 102.0% of enzacamene ($C_{18}H_{22}O$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** ▲197A or▲(USP 1-Dec-2022) 197K
- **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:** 197U
Sample solution: 10 µg/mL in [methanol](#)
Acceptance criteria: Meets the requirements

ASSAY

Change to read:

- **PROCEDURE**
Standard solution: 250 µg/mL each of camphor and ▲[USP Enzacamene RS](#)▲(USP 1-Dec-2022) in ▲[methylene chloride](#)▲(USP 1-Dec-2022)
Sample solution: 250 µg/mL of Enzacamene in ▲[methylene chloride](#)▲(USP 1-Dec-2022)
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 30-m fused-silica capillary; coated with a 0.25-µm layer of phase G1
Temperatures
Injection port: 295°
Detector: 305°
Column: See [Table 1](#). The column temperature is maintained at 300° until the end of the procedure.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	5
100	10	230	10
230	10	300	

Carrier gas: Helium

Flow rate: 1.2 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.0 for enzacamene

Relative standard deviation: NMT 2.0% for enzacamene

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of enzacamene (C₁₈H₂₂O) in the portion of Enzacamene taken:

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

r_U = peak response ▲ of enzacamene ▲ (USP 1-Dec-2022) from the *Sample solution*

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

C_S = concentration of ▲ [USP Enzacamene RS](#) ▲ (USP 1-Dec-2022) in the *Standard solution* (mg/mL)

C_U = concentration of ▲▲E▲ (ERR 1-Dec-2022) nzacamene in ▲ (USP 1-Dec-2022) the *Sample solution* (mg/mL)

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

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES**

Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Camphor ^a	0.2	0.02
Enzacamene	1.0	—
Any ▲▲ (USP 1-Dec-2022) unspecified impurity	—	0.1
Total impurities	—	0.5

^a ▲ (1*R*,4*R*)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one.▲ (USP 1-Dec-2022)

SPECIFIC TESTS

• [Loss on Drying \(731\)](#)

Analysis: Dry under vacuum at 50° to constant weight.

Acceptance criteria: NMT 0.2%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.