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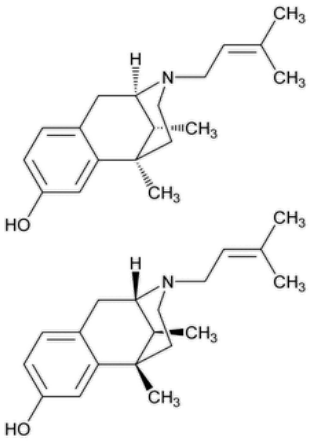
# Pentazocine



$C_{19}H_{27}NO$ 285.42

2,6-Methano-3-benzazocin-8-ol, 1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-, (2α,6α,11*R**)-;

(2*R**,6*R**,11*R**)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol CAS RN®: 359-83-1; UNII: RP4A60D26L.

## DEFINITION

Pentazocine contains NLT 98.0% and NMT 102.0% of pentazocine ($C_{19}H_{27}NO$), calculated on the dried basis.

## IDENTIFICATION

***Change to read:***

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

• **B.** The retention time of the pentazocine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

## ASSAY

• **Procedure**

**Solution A:** 15 mM sodium borate in water. Adjust with 10 N sodium hydroxide to a pH of 10.0.

**Solution B:** Methanol

**Mobile phase:** See *Table 1*.

**Table 1**

| Time (min) | Solution A (%) | Solution B (%) |
|---|---|---|
| 0 | 85 | 15 |
| 15 | 15 | 85 |
| 20 | 15 | 85 |
| 21 | 85 | 15 |

| Time (min) | Solution A (%) | Solution B (%) |
|---|---|---|
| 25 | 85 | 15 |

**Diluent:** Methanol, phosphoric acid, and water (500:1:500)

**Standard solution:** 0.025 mg/mL of USP Pentazocine RS in *Diluent*

**Sample solution:** 0.025 mg/mL of Pentazocine in *Diluent*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 225 nm

**Column:** 4.6-mm × 10-cm; 2.6-µm packing L1

**Column temperature:** 40°

**Flow rate:** 0.5 mL/min

**Injection volume:** 20 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 0.73%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of pentazocine ($C_{19}H_{27}NO$) in the portion of Pentazocine taken:

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

$r_U$ = peak response of pentazocine from the *Sample solution*

$r_S$ = peak response of pentazocine from the *Standard solution*

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

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

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

## IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

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

**Sensitivity solution:** 0.0006 mg/mL of USP Pentazocine RS in *Diluent*

**Standard solution:** 0.002 mg/mL of USP Pentazocine RS in *Diluent*

**Sample solution:** 2 mg/mL of Pentazocine in *Diluent*. Sonicate to dissolve, if necessary.

**System suitability**

**Samples:** *Sensitivity solution* and *Standard solution*

**Suitability requirements**

**Relative standard deviation:** NMT 5.0%, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

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

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

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

$r_S$ = peak response of pentazocine from the *Standard solution*

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

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

**Acceptance criteria:** See *Table 2*. The reporting threshold is 0.03%.

**Table 2**

| Name | Relative Retention Time | Acceptance Criteria, NMT (%) |
|---|---|---|
| Norpentazocine[a] | 0.6 | 0.15 |
| Pentazocine hydration product[b] | 0.9 | 0.15 |
| Pentazocine | 1.0 | — |
| Any unspecified impurity | — | 0.10 |
| Total impurities | — | 1.0 |

[a] (2*R*,6*R*,11*R*)-1,2,3,4,5,6-Hexahydro-6,11-dimethyl-2,6-methano-3-benzazocin-8-ol.

[b] (2*R*,6*R*,11*R*)-3-(3-Hydroxy-3-methylbutyl)-6,11-dimethyl-1,2,3,4,5,6-hexahydro-2,6-methanobenzo[*d*]azocin-8-ol.

## SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Pentazocine is used can be met. Where the label states that Pentazocine must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Pentazocine is used can be met.

• **Loss on Drying ⟨731⟩**

**Analysis:** Dry at a pressure of NMT 5 mm of mercury at 60° to constant weight.

**Acceptance criteria:** NMT 1.0%

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Where Pentazocine must be subjected to further processing during the preparation of injectable dosage forms to ensure acceptable levels of bacterial endotoxins, it is so labeled.

• **USP Reference Standards ⟨11⟩**

USP Pentazocine RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| PENTAZOCINE | Documentary Standards Support | SM22020 Small Molecules 2 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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