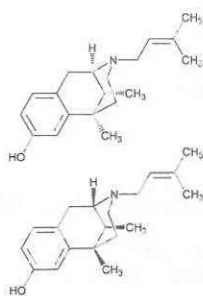


Pentazocine



$C_{19}H_{27}NO$ 285.42
 2,6-Methano-3-benzazocin-8-ol, 1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-, (2 α ,6 α ,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 [359-83-1].

DEFINITION

Pentazocine contains NLT 98.0% and NMT 101.5% of pentazocine ($C_{19}H_{27}NO$), calculated on the dried basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION** (197K)
- **B. ULTRAVIOLET ABSORPTION** (197U)
 Sample solution: 80 μ g/mL in 0.01 N hydrochloric acid
 Analytical wavelength: 278 nm
 Acceptance criteria: Absorptivities do not differ by more than 3.0%, calculated on the dried basis.

ASSAY

- **PROCEDURE**
 Sample solution: Dissolve about 500 mg of Pentazocine in 50 mL of glacial acetic acid.
 Analysis: Add 1 drop of crystal violet TS to the *Sample solution*, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 28.54 mg of pentazocine ($C_{19}H_{27}NO$).
 Acceptance criteria: 98.0%–101.5% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION** (281): NMT 0.2%
- **ORDINARY IMPURITIES** (466)
 Standard solution: Methanol
 Test solution: Methanol
 Eluant: Chloroform, methanol, and isopropylamine (94:3:3)
 Visualization: Heat the plate in an oven at 105° for 15 min. Cool, follow with visualization technique 17, and view under short-wavelength UV light.
 Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE** (741): 147°–158°, with slight darkening
- **LOSS ON DRYING** (731)
 Analysis: Dry at a pressure not exceeding 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.
- **USP REFERENCE STANDARDS** (11)
 USP Pentazocine RS

Pentazocine Hydrochloride

$C_{19}H_{27}NO \cdot HCl$ 321.88
 2,6-Methano-3-benzazocin-8-ol, 1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-, hydrochloride, (2 α ,6 α ,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 hydrochloride [64024-15-3].

DEFINITION

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

IDENTIFICATION

- **A. ULTRAVIOLET ABSORPTION** (197U)
 Sample solution: 80 μ g/mL of pentazocine
 Medium: 0.01 N hydrochloric acid
 Analytical wavelength: 278 nm
 Acceptance criteria: Absorptivities do not differ by more than 3.0%, calculated on the dried basis. [NOTE—The molecular weight of pentazocine ($C_{19}H_{27}NO$) is 285.43.]
- **B. IDENTIFICATION—ORGANIC NITROGENOUS BASES** (181)
 Standard solution: Dissolve 50 mg of USP Pentazocine RS in 25 mL of 0.01 N hydrochloric acid in a separator, and use this in place of the *Standard solution* specified.
 Acceptance criteria: Meets the requirements
- **C. IDENTIFICATION TESTS—GENERAL, Chloride** (191): A solution (1 in 100) meets the requirements.

ASSAY

- **PROCEDURE**
 Sample solution: Dissolve 650 mg of Pentazocine Hydrochloride in 50 mL of glacial acetic acid.
 Analysis: To the *Sample solution* add 10 mL of mercuric acetate TS and 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 32.19 mg of pentazocine hydrochloride ($C_{19}H_{27}NO \cdot HCl$).
 Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION** (281): NMT 0.2%
- **ORDINARY IMPURITIES** (466)
 Standard solution: Methanol, USP Pentazocine RS being used
 Test solution: Methanol
 Eluant: Chloroform, methanol, and isopropylamine (94:3:3)
 Visualization: Heat the plate in an oven at 105° for 15 min. Cool, follow with visualization technique 17, and view under short-wavelength UV light.
 Acceptance criteria: The total of any ordinary impurities observed does not exceed 1.0%.

SPECIFIC TESTS

- **LOSS ON DRYING** (731)
 Analysis: Dry at a pressure not exceeding 5 mm of mercury at 100° to constant weight.
 Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS** (11)
 USP Pentazocine RS