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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 CAS RN®: 64024-15-3; UNII: A36BX04PPX.

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

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U▲](#) (CN 1-MAY-2020)

Sample solution: 80 µg/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](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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