Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-BE435BBE-CE83-4F77-B71A-90D28236E1B6_3_en-US
DOI: https://doi.org/10.31003/USPNF_M62290_03_01
DOI Ref: c5h0s

Pentazocine Injection

DEFINITION

Pentazocine Injection is a sterile solution of Pentazocine in Water for Injection, prepared with the aid of Lactic Acid. It contains NLT 95.0% and NMT 105.0% of the labeled amount of pentazocine ($C_{19}H_{27}NO$).

IDENTIFICATION

- **A.** The retention time of the pentazocine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum 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
25	85	15

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

Standard solution: 0.024 mg/mL of USP Pentazocine RS in *Diluent*

Sample solution: Nominally 0.024 mg/mL of pentazocine from Injection in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm. For *Identification B*, use a diode array detector in the range of 200–400 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 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pentazocine ($C_{19}H_{27}NO$) in the portion of Injection 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 = nominal concentration of pentazocine in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

- **Organic Impurities**

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

Sensitivity solution: 0.5 µg/mL of USP Pentazocine RS in *Diluent*

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

Sample solution: Nominally 1 mg/mL of pentazocine from Injection in *Diluent*

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 Injection 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 = nominal concentration of pentazocine in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Norpentazocine[a]	0.6	0.2
Pentazocine hydration product[b]	0.9	0.2
Pentazocine	1.0	—
Any unspecified impurity	—	0.2
Total impurities	—	0.5

[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⟩:** NMT 5.8 USP Endotoxin Units/mg of pentazocine
- **pH ⟨791⟩:** 4.0–5.0
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Store at 20°–25°.
- **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 INJECTION	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:
Pharmacopeial Forum: Volume No. PF 42(5)

Current DocID: GUID-BE435BBE-CE83-4F77-B71A-90D28236E1B6_3_en-US
Previous DocID: GUID-BE435BBE-CE83-4F77-B71A-90D28236E1B6_1_en-US
DOI: https://doi.org/10.31003/USPNF_M62290_03_01
DOI ref: c5h0s