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Haloperidol Injection

DEFINITION

Haloperidol Injection is a sterile solution of Haloperidol in Water for Injection, prepared with the aid of Lactic Acid. It contains NLT 90.0% and NMT 110.0% of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$). It may contain a suitable preservative.

IDENTIFICATION

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

ASSAY

• **Procedure**

Buffer solution: 6.8 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 4.0.

Mobile phase: Methanol and *Buffer solution* (55:45)

Standard stock solution: 1 mg/mL of USP Haloperidol RS in methanol. Sonicate to aid in dissolution.

Standard solution: 0.2 mg/mL of USP Haloperidol RS in *Mobile phase* from the *Standard stock solution*

Sample solution: Nominally, 0.2 mg/mL of haloperidol in *Mobile phase* from a volume of Injection

Chromatographic system

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

Mode: LC

Detector: UV 247 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection size: 10 µL

Run time: 2.5 times the retention time of haloperidol

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of haloperidol ($C_{21}H_{23}ClFNO_2$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of haloperidol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 71.4 USP Endotoxin Units/mg of haloperidol.

• **pH ⟨791⟩:** 3.0–3.8

• **Other Requirements:** It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩
USP Haloperidol RS

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

Topic/Question	Contact	Expert Committee
HALOPERIDOL INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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