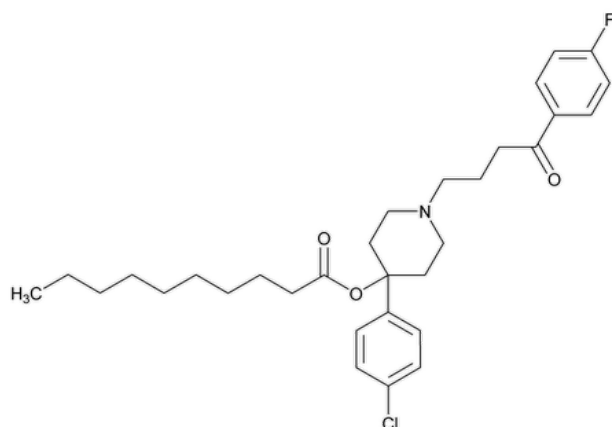


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-C1F95443-3F2A-48EE-8D3A-AD4983BC4A8C_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M36470_05_01
 DOI Ref: k1vnd

© 2025 USPC
 Do not distribute

Haloperidol Decanoate

Change to read:



$C_{31}H_{41}ClFNO_3$ ▲530.12▲ (USP 1-May-2021)

Decanoic acid, 4-(4-chlorophenyl)-1-[4-(4-fluorophenyl)-4-oxobutyl]-4-piperidinyl ester;

▲4-(4-Chlorophenyl)-1-[4-(4-fluorophenyl)-4-oxobutyl]piperidin-4-yl decanoate▲ (USP 1-May-2021) CAS RN®: 74050-97-8; UNII: AC20PJ4101.

Change to read:

DEFINITION

Haloperidol Decanoate contains NLT 97.0% and NMT 103.0% of ▲haloperidol decanoate▲ (USP 1-May-2021) ($C_{31}H_{41}ClFNO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** ▲197A or▲ (USP 1-May-2021) 197M

Change to read:

- **B.** The retention time of the major peak ▲▲ (USP 1-May-2021) of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Delete the following:

- ▲• **C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)**

Sample solution: Mix 0.1 g of the sample with 0.5 g of [anhydrous sodium carbonate](#) in a porcelain crucible. Heat over open flame for 10 min.

Allow to cool. Dissolve the residue in 5 mL of dilute [nitric acid](#), and filter. Dilute 1 mL of the filtrate with 1 mL of [water](#).

Acceptance criteria: Meets the requirements of test A▲ (USP 1-May-2021)

ASSAY

Change to read:

• PROCEDURE

Solution A: 27 g/L of [tetrabutylammonium hydrogen sulfate](#) in [water](#)

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
30	40	60
35	40	60
40	80	20
45	80	20

Standard solution: 0.2 mg/mL of [USP Haloperidol Decanoate RS](#) in [methanol](#)

Sample solution: 0.2 mg/mL of Haloperidol Decanoate in [methanol](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4-mm × 10-cm; 3-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection ▲volume:▲ (USP 1-May-2021) 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT ▲0.73%▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of haloperidol decanoate ($C_{31}H_{41}ClFNO_3$) in the portion of ▲Haloperidol Decanoate▲ (USP 1-May-2021) 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 Decanoate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Haloperidol Decanoate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, and ▲Chromatographic system:▲ (USP 1-May-2021) Proceed as directed in the Assay.

System suitability solution: 0.05 mg/mL each of [USP Haloperidol Decanoate RS](#) and [USP Bromperidol Decanoate RS](#) in [methanol](#)

Standard stock solution: 0.2 mg/mL of [USP Haloperidol Decanoate RS](#) in [methanol](#)

Standard solution: 0.05 mg/mL of [USP Haloperidol Decanoate RS](#) in [methanol](#), from *Standard stock solution*

▲Sensitivity solution: 0.005 mg/mL of [USP Haloperidol Decanoate RS](#) in [methanol](#), from *Standard stock solution*▲ (USP 1-May-2021)

Sample solution: 10 mg/mL of Haloperidol Decanoate in [methanol](#)

▲ (USP 1-May-2021)

System suitability