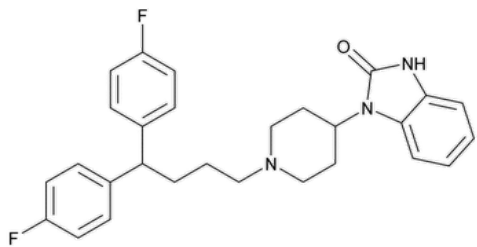


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-F6A34AA2-8415-4C1A-812E-96675EAB44D4_4_en-US
DOI: https://doi.org/10.31003/USPNF_M65060_04_01
DOI Ref: w3ys3

© 2025 USPC
Do not distribute

Pimozide



$C_{28}H_{29}F_2N_3O$ 461.55
2*H*-Benzimidazol-2-one, 1-[1-[4,4-bis(4-fluorophenyl)butyl]-4-piperidinyl]-1,3-dihydro-;
1-[1-[4,4-Bis(*p*-fluorophenyl)butyl]-4-piperidyl]-2-benzimidazolinone CAS RN®: 2062-78-4; UNII: 1HIZ4DL86F.

DEFINITION
Pimozide contains NLT 98.0% and NMT 102.0% of pimozide ($C_{28}H_{29}F_2N_3O$), calculated on the dried basis.

IDENTIFICATION
Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197K. ▲ (CN 1-May-2020)
- **B.** 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**
Solution A: 2.5 g/L of [ammonium acetate](#) and 8.5 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
10	70	30
15	70	30
20	80	20
25	80	20

System suitability solution: 0.05 mg/mL of [USP Pimozide RS](#) and 0.02 mg/mL of [USP Mebendazole RS](#) in methanol
Standard solution: 1 mg/mL of [USP Pimozide RS](#) in methanol
Sample solution: 1 mg/mL of Pimozide in methanol. [NOTE—Sonication may be needed to dissolve the sample.]
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: LC

Detector: UV 280 nm**Column:** 4.6-mm × 10-cm; 3-μm packing [L1](#)**Flow rate:** 2 mL/min**Injection volume:** 10 μL**System suitability****Samples:** *System suitability solution* and *Standard solution*[NOTE—See [Table 2](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 5.0 between pimozide and mebendazole, *System suitability solution***Tailing factor:** NMT 2.0, *Standard solution***Relative standard deviation:** NMT 0.73%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of pimozide ($C_{28}H_{29}F_2N_3O$) in the portion of Pimozide taken:

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

 r_U = peak response of pimozide from the *Sample solution* r_S = peak response of pimozide from the *Standard solution* C_S = concentration of [USP Pimozide RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Pimozide in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%• **ORGANIC IMPURITIES****Solution A, Solution B, Mobile phase, System suitability solution, and Chromatographic system:** Proceed as directed in the Assay.**Standard solution:** 0.05 mg/mL of [USP Pimozide RS](#) in methanol**Sample solution:** 10 mg/mL of Pimozide in methanol. [NOTE—Sonication may be needed to dissolve the sample.]**System suitability****Samples:** *System suitability solution* and *Standard solution*[NOTE—See [Table 2](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 5.0 between pimozide and mebendazole, *System suitability solution***Tailing factor:** NMT 2.0, *Standard solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Pimozide 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 pimozide from the *Standard solution* C_S = concentration of [USP Pimozide RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Pimozide in the *Sample solution* (mg/mL)**Acceptance criteria:** See [Table 2](#).**Table 2**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Pimozide amine ^a	0.1	0.5
Mebendazole ^b	0.88	—
Desfluoro pimozide ^c	0.9	0.5
o-Pimozide isomer ^d	0.95	0.5
Pimozide	1.0	—
Didehydropimozide ^e	1.1	0.5
Pimozide olefin ^f	1.2	0.5
Pimozide N-oxide ^g	1.3	0.5
Any individual unspecified impurity	—	0.10
Total impurities	—	1.0

^a 1-(Piperidin-4-yl)benzimidazolin-2-one.

^b Included for system suitability purposes only. Not a process impurity or degradation product.

^c 1-{1-[4-(4-Fluorophenyl)-4-phenylbutyl]piperidin-4-yl}benzimidazolin-2-one.

^d 1-{1-[4-(2-Fluorophenyl)-4-(4-fluorophenyl)butyl]piperidin-4-yl}-1*H*-benzimidazol-2-one.

^e 1-{1-[4,4-Bis(4-fluorophenyl)butyl]-1,2,3,6-tetrahydropyridin-4-yl}benzimidazolin-2-one.

^f 1-{1-[4,4-Bis(4-fluorophenyl)but-3-en-1-yl]piperidin-4-yl}benzimidazolin-2-one.

^g 1-[4,4-Bis(4-fluorophenyl)butyl]-4-(2-oxobenzimidazol-1-yl)piperidine 1-oxide.

SPECIFIC TESTS

• [Loss on Drying \(731\)](#)

Analysis: Dry at 105° to a constant weight.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP Reference Standards \(11\)](#)

[USP Mebendazole RS](#)

[USP Pimozide RS](#)

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

Topic/Question	Contact	Expert Committee
PIMOZIDE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 42(3)

Current DocID: GUID-F6A34AA2-8415-4C1A-812E-96675EAB44D4_4_en-US

DOI: https://doi.org/10.31003/USPNF_M65060_04_01

DOI ref: [w3ys3](#)

OFFICIAL