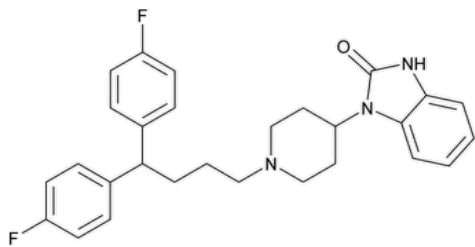


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Pimozide



$C_{28}H_{29}F_2N_3O$ 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