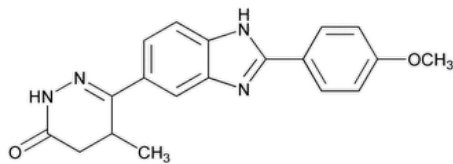


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Pimobendan



$C_{19}H_{18}N_4O_2$ 334.37
3(2*H*)-Pyridazinone, 4,5-dihydro-6-[2-(4-methoxyphenyl)-1*H*-benzimidazol-5-yl]-5-methyl-, (±)-;
(±)-4,5-Dihydro-6-[2-(*p*-methoxyphenyl)-5-benzimidazolyl]-5-methyl-3(2*H*)-pyridazinone;
6-[2-(4-Methoxyphenyl)-1*H*-benzimidazol-5-yl]-5-methyl-4,5-dihydropyridazin-3(2*H*)-one CAS RN®: 74150-27-9.

DEFINITION
Pimobendan contains NLT 98.0% and NMT 102.0% of pimobendan ($C_{19}H_{18}N_4O_2$), calculated on the anhydrous basis.

IDENTIFICATION
Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A, 197K, or 197M. ▲ (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: 3.0 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with suitably diluted [phosphoric acid](#) to a pH of 2.5.
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	85	15
6	80	20
20	20	80
20.1	85	15
30	85	15

Standard solution: 0.1 mg/mL of [USP Pimobendan RS](#) in [methanol](#)
Sample solution: 0.1 mg/mL of Pimobendan in [methanol](#)
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC
Detector: UV 290 nm
Column: 4.6-mm × 12.5-cm; 5-μm packing [L1](#) or 4.0-mm × 12.5-cm; 5-μm packing [L1](#)

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pimobendan ($C_{19}H_{18}N_4O_2$) in the portion of Pimobendan 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 Pimobendan RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

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

• ORGANIC IMPURITIES

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

System suitability solution: 5 µg/mL each of [USP Pimobendan Related Compound A RS](#) and [USP Pimobendan Related Compound B RS](#) in methanol

Standard solution: 50 µg/mL of [USP Pimobendan RS](#) in [methanol](#)

Sample solution: 5.0 mg/mL of Pimobendan in [methanol](#)

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between pimobendan related compound A and pimobendan related compound B, *System suitability solution*

Tailing factor: 0.8–1.5, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Pimobendan 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 pimobendan from the *Standard solution*

C_S = concentration of [USP Pimobendan RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pimobendan in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 2](#). Disregard any peak below 0.05%.

Table 2