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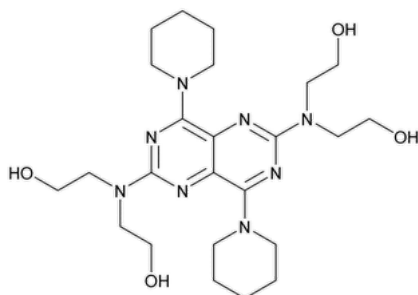
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Dipyrindamole


 $C_{24}H_{40}N_8O_4$ 504.63
Ethanol, 2,2',2'',2'''-[(4,8-di-1-piperidinylpyrimido[5,4-*d*]pyrimidine-2,6-diyl)dinitrilo]tetrakis-;2,2',2'',2'''-[(4,8-Dipiperidinopyrimido[5,4-*d*]pyrimidine-2,6-diyl)dinitrilo]tetraethanol CAS RN®: 58-32-2; UNII: 64ALC7F90C.

DEFINITION

Dipyrindamole contains NLT 98.0% and NMT 102.0% of dipyrindamole ($C_{24}H_{40}N_8O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 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

Buffer: 0.77 g/L of ammonium acetate. Adjust with glacial acetic acid to a pH of 4.0.**Mobile phase:** Methanol and *Buffer* (700:300)**Standard solution:** 0.2 mg/mL of [USP Dipyrindamole RS](#) in methanol**Sample solution:** 0.2 mg/mL of Dipyrindamole in methanol

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 288 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Flow rate:** 1.2 mL/min**Injection volume:** 10 μL**Run time:** NLT 1.7 times the retention time of dipyrindamole

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 dipyrindamole ($C_{24}H_{40}N_8O_4$) in the portion of Dipyrindamole taken:

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

 r_U = peak response of dipyrindamole from the *Sample solution* r_S = peak response of dipyrindamole from the *Standard solution* C_S = concentration of [USP Dipyrindamole RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• ORGANIC IMPURITIES

Solution A: 10 mM ammonium formate. Adjust with formic acid to a pH of 5.0.

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	80	20
2.0	80	20
17.0	5	95
19.0	5	95
21.0	80	20
25.0	80	20

Standard solution: 0.5 µg/mL each of [USP Dipyrindamole RS](#), [USP Dipyrindamole Related Compound A RS](#), [USP Dipyrindamole Related Compound B RS](#), [USP Dipyrindamole Related Compound C RS](#), [USP Dipyrindamole Related Compound D RS](#), [USP Dipyrindamole Related Compound E RS](#), and [USP Dipyrindamole Related Compound F RS](#) in methanol

Sample solution: 500 µg/mL of Dipyrindamole in methanol

Chromatographic system

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

Mode: LC

Detector: UV 295 nm

Column: 2.1-mm × 15-cm; 1.7-µm packing L1

Column temperature: 45°

Flow rate: 0.3 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 4.0 between dipyrindamole related compound D and dipyrindamole

Relative standard deviation: NMT 2.8%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each specified impurity in the portion of Dipyrindamole taken:

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

r_U = peak response of each specified impurity from the *Sample solution*

r_S = peak response of corresponding USP Reference Standard from the *Standard solution*

C_S = concentration of corresponding USP Reference Standard in the *Standard solution* (µg/mL)

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

Calculate the percentage of each unspecified impurity in the portion of Dipyrindamole taken:

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

r_U = peak response of each unspecified impurity from the *Sample solution*