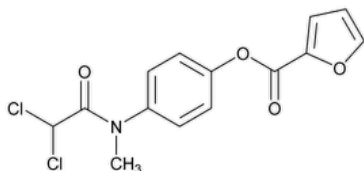


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Diloxanide Furoate



$C_{14}H_{11}Cl_2NO_4$ 328.15

4-(N-Methyl-2,2-dichloroacetamido)phenyl 2-furoate;

2,2-Dichloroacetamido-4-N-methylphenyl 2-furoate CAS RN®: 3736-81-0; UNII: YP4N72IW34.

DEFINITION

Diloxanide Furoate contains NLT 98.0% and NMT 102.0% of diloxanide furoate ($C_{14}H_{11}Cl_2NO_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

Change to read:

- B. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-MAY-2020)

Analytical wavelength: 258 nm

Sample solution: 14 µg/mL in alcohol

Acceptance criteria: Meets the requirements

- C.

Sample: 20 mg

Analysis: Burn the *Sample* by using the method in [Oxygen Flask Combustion \(471\)](#), using 10 mL of 1 N sodium hydroxide as the absorbing liquid. When the process is complete, acidify the liquid with nitric acid, and add a solution of silver nitrate (5 in 100).

Acceptance criteria: A white precipitate forms.

ASSAY

- **PROCEDURE**

Sample solution: 300 mg of Diloxanide Furoate in 50.0 mL of dried pyridine

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N tetrabutylammonium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Titrate the *Sample solution* with *Titrant*. Perform a blank determination. Each mL of 0.1 N tetrabutylammonium hydroxide is equivalent to 32.82 mg of diloxanide furoate ($C_{14}H_{11}Cl_2NO_4$).

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

IMPURITIES

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

- **ORGANIC IMPURITIES**

Standard solution: Dilute 0.5 mL of *Sample solution* with chloroform to 200 mL.

Sample solution: 100 mg/mL of Diloxanide Furoate in chloroform

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Dichloromethane and methanol (96:4)

Analysis: Examine the plate under short-wavelength UV light.
Acceptance criteria: Any secondary spot obtained from the *Sample solution* is not more intense than the spot obtained from the *Standard solution*.

SPECIFIC TESTS

- MELTING RANGE OR TEMPERATURE (741):** 114°–116°
- ACIDITY**
Sample solution: Shake 3 g of Diloxanide Furoate in 50 mL of water. Filter, wash the residue with three 20-mL portions of water, and combine the filtrate and washings.
Analysis: Titrate the *Sample solution* with 0.1 N sodium hydroxide VS using phenolphthalein TS as the indicator.
Acceptance criteria: NMT 1.3 mL of 0.1 N sodium hydroxide is required for neutralization
- LOSS ON DRYING (731).**
Analysis: Dry at 105° to constant weight.
Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers at controlled room temperature.
- USP REFERENCE STANDARDS (11).**
[USP Diloxanide Furoate RS](#)

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

Topic/Question	Contact	Expert Committee
DILOXANIDE FUROATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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