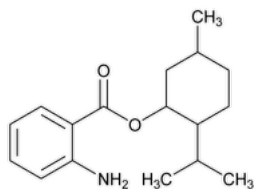


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Meradimate



C₁₇H₂₅NO₂ 275.39
Cyclohexanol, 5-methyl-2-(1-methylethyl)-, 2-aminobenzoate;
Anthranilic acid, p-menth-3-yl ester CAS RN®: 134-09-8; UNII: J9QGD600UZ.

DEFINITION
Meradimate contains NLT 95.0% and NMT 105.0% of meradimate (C₁₇H₂₅NO₂).

IDENTIFICATION

Change to read:

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

Change to read:

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

- Sample solution:** 5 µg/mL in alcohol
Acceptance criteria: Meets the requirements
- **C.** 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**
Standard solution: 20.0 mg/mL of [USP Meradimate RS](#) in *tert*-butyl methyl ether
Sample solution: 20 mg/mL of Meradimate in *tert*-butyl methyl ether

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

- Mode:** GC
Detector: Flame ionization
Column: 0.32-mm × 25-m; coated with a 0.1-µm film of G1
Temperatures
Injector: 240°
Detector: 260°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	8	240	10

- Carrier gas:** Helium
Flow rate: 6 mL/min
Injection type: Split ratio, 30:1
[NOTE—The split ratio can be modified to optimize performance.]
Injection volume: 1 µL
System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of meradimate ($C_{17}H_{25}NO_2$) in the portion of Meradimate 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 Meradimate RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Meradimate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity

r_T = sum of all the peak responses

Acceptance criteria

Any individual impurity: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **ACIDITY**

Sample: 5.0 mL of Meradimate

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Transfer 50 mL of alcohol to a suitable container, add 1 mL of phenolphthalein TS, and add sufficient volume of *Titrant* to obtain a persistent pink color. Transfer 50 mL of this solution to a suitable container, add the *Sample*, and titrate with *Titrant*.

Acceptance criteria: NMT 0.2 mL of *Titrant* per mL of Meradimate is necessary.

• **OPTICAL ROTATION, Specific Rotation (781S):** -4° to $+4^\circ$

Sample solution: 10 mg/mL in alcohol

• **REFRACTIVE INDEX (831):** 1.540–1.544 at 20°

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **USP REFERENCE STANDARDS (11).**

[USP Meradimate RS](#)

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

Topic/Question	Contact	Expert Committee
MERADIMATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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