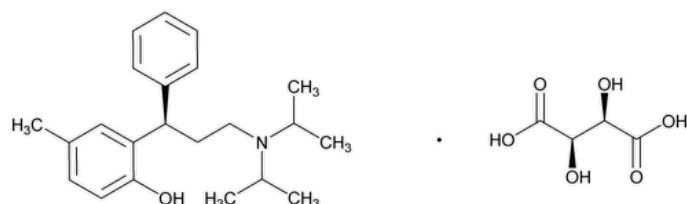


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Tolterodine Tartrate



$C_{22}H_{31}NO \cdot C_4H_6O_6$ 475.57

(R)-2-[3-[Bis(1-methylethyl)amino]-1-phenylpropyl]-4-methylphenol (2R,3R)-2,3-dihydroxybutanedioate (1:1) (salt);

(+)-(R)-2-[α-[2-(Diisopropylamino)ethyl]benzyl]-p-cresol L-tartrate (1:1) (salt);

(R)-2-[3-(Diisopropylamino)-1-phenylpropyl]-4-methylphenol tartrate CAS RN®: 124937-52-6; UNII: 5T619TQR3R.

DEFINITION

Tolterodine Tartrate contains NLT 97.0% and NMT 103.0% of tolterodine tartrate ($C_{22}H_{31}NO \cdot C_4H_6O_6$), calculated on the as-is 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

Mobile phase: [Acetonitrile](#), [water](#), and [phosphoric acid](#) (330:670:1)

Standard solution: 0.35 mg/mL of [USP Tolterodine Tartrate RS](#) in *Mobile phase*

Sample solution: 0.35 mg/mL of Tolterodine Tartrate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1.0 mL/min

Injection volume: 5 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0% from six replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tolterodine tartrate ($C_{22}H_{31}NO \cdot C_4H_6O_6$) in the portion of Tolterodine Tartrate 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 Tolterodine Tartrate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Tolterodine Tartrate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the as-is basis

IMPURITIES

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

• ORGANIC IMPURITIES

Solution A: [Acetonitrile](#), [water](#), and [perchloric acid](#) (100:900:1.5)

Solution B: [Acetonitrile](#), [water](#), and [perchloric acid](#) (500:500:1.5)

Solution C: [Acetonitrile](#)

Mobile phase: See [Table 1](#). Return to original conditions, and re-equilibrate the system.

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	75	25	0
5	75	25	0
22	0	100	0
47	0	0	100
57	0	0	100

Diluent: [Acetonitrile](#) and [water](#) (50:50)

System suitability solution: 10 mg/mL of [USP Tolterodine System Suitability Mixture RS](#) in *Diluent*. See [Table 2](#) for relative retention times of the main components of the mixture.

Table 2

Component of USP Tolterodine System Suitability Mixture RS	Relative Retention Time
<i>p</i> -Cresol	0.75
<i>trans</i> -Cinnamic acid	0.81
Monoisopropyl tolterodine	0.88
Tolterodine	1.0
Diol impurity	1.18
Tolterodine dimer ^a	1.44
6-Methyl-4-phenylchroman-2-ol ^a	1.48
Diol acetate impurity	1.54
6-Methyl-4-phenylchroman-2-one	1.59

^a Undefined stereochemistry.

Standard solution: 0.01 mg/mL of [USP Tolterodine Tartrate RS](#) in *Diluent*