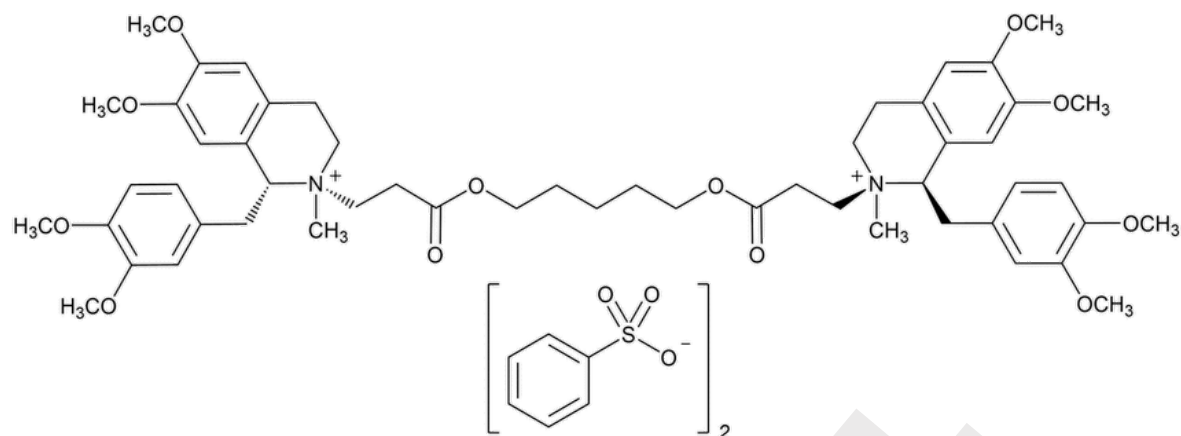


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Cisatracurium Besylate



$C_{65}H_{82}N_2O_{18}S_2$ 1243.48

Isoquinolinium, 2,2'-[1,5-pentanediy]bis[oxy(3-oxo-3,1-propanediy)]bis[1-[(3,4-dimethoxyphenyl)methyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-, dibenzenesulfonate, [1*R*-[1 α ,2 α (1'*R**,2'*R**)]]-;

(1*R*,2*R*)-2-(2-Carboxyethyl)-1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-1-veratrylisoquinolinium benzenesulfonate, pentamethylene ester CAS RN®: 96946-42-8; UNII: 80YS801MBS.

DEFINITION

Cisatracurium Besylate contains NLT 97.0% and NMT 102.0% of cisatracurium besylate ($C_{65}H_{82}N_2O_{18}S_2$), calculated on the anhydrous and solvent-free 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: 33.3 g/L of [ammonium formate](#) prepared as follows. Dissolve 32.8 g of [ammonium formate](#) in 984 mL of [water](#), and add 16 mL of [anhydrous formic acid](#).

Mobile phase: Acetonitrile, methanol, and *Buffer* (20:20:60)

Diluent: Acetonitrile, methanol, and water (20:20:60). Add 0.4 mL of anhydrous formic acid per 1 L.

System suitability solution: 0.7 mg/mL of [USP Cisatracurium Besylate System Suitability Mixture RS](#) in *Diluent*

Standard solution: 0.7 mg/mL of [USP Cisatracurium Besylate RS](#) in *Diluent*

Sample solution: 0.7 mg/mL of Cisatracurium Besylate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25.0-cm; 5- μ m packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

Run time: NLT 2.5 times the retention time of cisatracurium

System suitability**Samples:** *System suitability solution* and *Standard solution*[NOTE—See [Table 1](#) for relative retention times.]**Suitability requirements****Resolution:** NLT 2.0 between the peaks for *R-cis-R'-trans*-atracurium and cisatracurium, *System suitability solution***Tailing factor:** NMT 1.7 for cisatracurium, *System suitability solution***Relative standard deviation:** NMT 1.5%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of cisatracurium besylate ($C_{65}H_{82}N_2O_{18}S_2$) in the portion of Cisatracurium Besylate 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 Cisatracurium Besylate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Cisatracurium Besylate in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0% on the anhydrous and solvent-free basis**IMPURITIES**

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

• **ORGANIC IMPURITIES****Mobile phase, Diluent, System suitability solution, 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 Cisatracurium Besylate taken:

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

 r_U = peak response of each impurity from the *Sample solution* r_T = sum of all the peak responses from the *Sample solution***Acceptance criteria:** See [Table 1](#). Disregard any peak representing less than 0.09% of the area of the major peak.**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Benzenesulfonic acid ^a	0.10	—
<i>cis</i> -Quaternary acid ^b	0.14	0.2
(<i>R</i>)- <i>N</i> -Methylaudanosine ^c	0.16	0.2
(<i>R</i>)-Laudanosine ^d	0.20	0.6
<i>cis</i> -Quaternary methyl ester ^e	0.23	0.4
<i>cis</i> -Quaternary alcohol ^f	0.29	0.5

