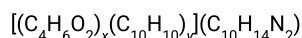
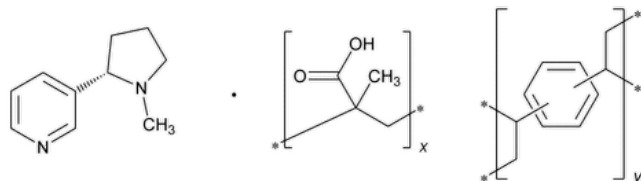


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Nicotine Polacrilex



2-Propenoic acid, 2-methyl-, polymer with diethenylbenzene, complex with (S)-3-(1-methyl-2-pyrrolidinyl)pyridine;

Methacrylic acid polymer with divinylbenzene, complex with nicotine CAS RN®: 96055-45-7.

DEFINITION

Nicotine Polacrilex is a weak carboxylic cation-exchange resin prepared from methacrylic acid and divinylbenzene, in complex with nicotine. It may contain glycerin. Glycerin-free Nicotine Polacrilex contains NLT 95.0% and NMT 115.0% of the labeled amount of nicotine ($C_{10}H_{14}N_2$), calculated on the dried basis. Glycerin-containing Nicotine Polacrilex contains NLT 95.0% and NMT 115.0% of the labeled amount of nicotine ($C_{10}H_{14}N_2$), calculated on the anhydrous basis.

[NOTE—Nicotine Polacrilex is also known as Nicotine Resinate.]

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy \(for Nicotine\)](#): 197K or 197A▲ (CN 1-May-2020)

Sample: Transfer an amount of Nicotine Polacrilex equivalent to 100 mg of nicotine to a 100-mL glass-stoppered tube. Add 20 mL of 1 M ammonium hydroxide, 5 mL of [10 M sodium hydroxide](#), and 20 mL of [n-hexane](#). Shake for 5 min, and allow the phases to separate. Transfer the upper hexane phase to an evaporating dish, and evaporate on a steam bath.

Standard: Use [USP Nicotine Bitartrate Dihydrate RS](#), and prepare as directed for the *Sample*.

Acceptance criteria: Meets the requirements

Change to read:

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy \(for Polacrilex\)](#): 197K or 197A▲ (CN 1-May-2020)

Standard: Transfer a portion of [USP Polacrilex Resin RS](#), equivalent to the amount of Nicotine Polacrilex used to prepare the *Sample solution* in the Assay, to a glass-stoppered tube. Add 10 mL of 1 M ammonium hydroxide, shake for 10 min, and then centrifuge. Decant the ammonia solution from the residue, and wash the residue by shaking it with three 10-mL volumes of water, decanting the water phase after each shaking. Wash with 10 mL of [0.1 N hydrochloric acid](#), decant the liquid, and dry the residue at 105°.

Sample: Use the residue obtained from the *Sample solution* in the Assay. Decant the ammonia solution remaining from the residue, and wash the residue by shaking it with three 10-mL volumes of [water](#), decanting the water phase after each shaking. Wash with 10 mL of [0.1 N hydrochloric acid](#), decant the liquid, and dry the residue at 105°.

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

Solution A: Add 25 mL of 1 M acetic acid to 900 mL of [water](#), and then add 6 mL of [ammonium hydroxide](#). Adjust with either 2 M acetic acid or 2 M ammonium hydroxide to a pH of 10.0, and dilute with [water](#) to 1000 mL.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#). [NOTE—Re-equilibration time may be adjusted, if necessary.]

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
3	100	0
3.01	95	5
28	74	26
32	60	40
33	100	0
35	100	0

System suitability solution: 1.5 mg/mL of [USP Nicotine Bitartrate Dihydrate RS](#) and 6 µg/mL of [USP Nicotine Related Compound G RS](#) in [water](#)

Standard solution: 1.8 mg/mL of [USP Nicotine Bitartrate Dihydrate RS](#) in [water](#)

Sample solution: Nominally 0.6 mg/mL of nicotine prepared as follows. Transfer an amount of Nicotine Polacrilex equivalent to 30 mg of nicotine to a glass-stoppered tube. Add 10.0 mL of 1 M ammonium hydroxide, shake vigorously for 10 min, and then centrifuge. Transfer 5.0 mL of the clear solution to a 25-mL volumetric flask, add 5 mL of 1 M acetic acid, and dilute with [water](#) to volume. Retain the residue from centrifugation for use in *Identification B*.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2.5 between nicotine and nicotine related compound G, *System suitability solution*

Tailing factor: NMT 2.0 for nicotine, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nicotine ($C_{10}H_{14}N_2$) in the portion of Nicotine Polacrilex taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of nicotine from the *Sample solution*

r_S = peak response of nicotine from the *Standard solution*

C_S = concentration of [USP Nicotine Bitartrate Dihydrate RS](#) on the anhydrous basis in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of nicotine, 162.23

M_{r2} = molecular weight of anhydrous nicotine bitartrate, 462.41