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Nicotine Polacrilex Gum

» Nicotine Polacrilex Gum contains an amount of Nicotine Polacrilex $[(C_4H_6O_2)_x(C_{10}H_{10})_y](C_{10}H_{14}N_2)$ equivalent to not less than 90 percent and not more than 120 percent of the labeled amount of nicotine ($C_{10}H_{14}N_2$).

USP Reference standards ⟨11⟩—
USP Nicotine Bitartrate Dihydrate RS
USP Polacrilex Resin RS

Identification—

A: *Developing solvent*—Prepare a mixture of chloroform, acetone, and diethylamine (40:5:5).
Test solution—Cut several pieces of Gum into small pieces with scissors, and weigh. Transfer a portion of the Gum, equivalent to about 4 mg of nicotine, to a centrifuge tube. Add 5 mL of chloroform, sonicate for about 30 minutes to dissolve the nicotine, and centrifuge for about 10 minutes. Cool to about 15°, and add two 3-mL portions of 0.5 N hydrochloric acid with gentle mixing, and release excess pressure if necessary. Mix the contents of the tube by shaking, and centrifuge the mixture for about 10 minutes. Transfer 5 mL of the upper aqueous layer to a separatory funnel, and adjust with 0.5 N sodium hydroxide solution to a pH greater than 10.0. Add 3 mL of chloroform, and shake gently. Use the chloroform layer as the *Test solution.*
Standard solution—Transfer 10 mg of USP Nicotine Bitartrate Dihydrate RS to a separatory funnel, add 10 mL of water, and mix to dissolve. Adjust with 0.5 N sodium hydroxide to a pH greater than 10.0. Add 3 mL of chloroform, with gentle shaking, and use the chloroform layer as the *Standard solution.*
Procedure—Separately apply 10 µL each of the *Test solution* and the *Standard solution* about 1.5 cm from the lower edge of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩). Air-dry, place the plate in a chromatographic tank that has been saturated with *Developing solvent*, and develop the chromatogram until the solvent front has moved about 7 cm. Remove the plate from the chamber, and allow to air-dry. Examine the plate under short-wavelength UV light: the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution* (*presence of nicotine*).

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) —Use USP Polacrilex Resin RS and a test specimen prepared as follows. Cut a piece of Gum into small pieces with scissors. Place the pieces in a 50-mL centrifuge tube, add about 20 mL of *n*-hexane, and place in an ultrasonic bath for about 30 minutes. Centrifuge at about 2500 rpm for about 5 minutes. Decant the hexane phase, and add 10 mL of 2 N hydrochloric acid. Shake the tube carefully, and open the stopper slightly to relieve any excess pressure. Add 10 mL of alcohol, and shake the tube carefully with the stopper slightly open. Centrifuge again as described above, and decant the liquid, taking care to avoid contamination of the precipitate with the gum material. Add 1 mL to 3 mL of water, mix gently to resuspend the precipitate, and filter. Wash the residue on the filter with water and then with alcohol. Dry the filter and residue at about 105° for 1 hour (*presence of polacrilex*).

Uniformity of dosage units ⟨905⟩: meets the requirements.

Assay—

Acetate buffer—Prepare a mixture containing 13.6 g of sodium acetate and 57.2 mL of glacial acetic acid in 1000 mL of water.
Solvent—Prepare a mixture of water, acetonitrile, 0.25 M sodium 1-decanesulfonate, and *Acetate buffer* (785:150:40:25).
Mobile phase—Prepare a mixture containing water, acetonitrile, *Acetate buffer*, and 0.25 M sodium 1-decanesulfonate (685:200:75:40).
Standard preparation—Dissolve an accurately weighed quantity of USP Nicotine Bitartrate Dihydrate RS in *Solvent* to obtain a *Standard stock solution* having a known concentration of about 1.25 mg per mL. Dilute a volume of this solution quantitatively with *Solvent* to obtain a *Standard preparation* having a known concentration of about 125 µg per mL (40 µg of nicotine per mL).
Assay preparation—Place one piece of Gum, accurately weighed, in a stoppered flask, add about 50 mL of *n*-hexane, and transfer 50.0 mL of *Solvent.* Add a stirring bar, insert the stopper in the flask, and stir vigorously for about 30 minutes or until the test specimen has been dispersed. Remove from the stirring mechanism, and allow to stand for about 30 minutes or until the phases have separated. Remove an aliquot of the lower layer, taking care not to remove a large quantity of the insoluble excipients, and filter, discarding the first few mL of the filtrate. Use the clear filtrate as the *Assay preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm stainless steel column containing packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, record the chromatograms, and measure the peak responses as directed for *Procedure:* the column efficiency is not less than 2500 theoretical plates, the tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—[NOTE—Perform the following procedure on 10 individual pieces of Gum, and use the average of the calculated values as the assay value. Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the quantity, in mg, of nicotine ($C_{10}H_{14}N_2$) in the Gum taken by the formula:

$$50C(162.23/462.41)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Nicotine Bitartrate Dihydrate RS on the anhydrous basis in the *Standard preparation*, 162.23 and 462.41 are the molecular weights of nicotine and anhydrous nicotine bitartrate, respectively, and r_U and r_S are peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NICOTINE POLACRILEX GUM	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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