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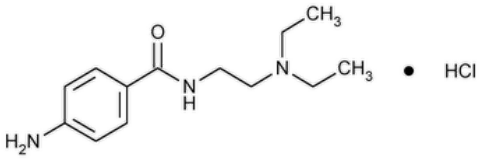
Procainamide Hydrochloride



$C_{13}H_{21}N_3O \cdot HCl$ 271.79

Benzamide, 4-amino-*N*-[2-(diethylamino)ethyl]-, monohydrochloride.

p-Amino-*N*-[2-(diethylamino)ethyl]benzamide monohydrochloride CAS RN®: 614-39-1; UNII: SI4064O0LX.

» Procainamide Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{13}H_{21}N_3O \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Aminobenzoic Acid RS
USP Procainamide Hydrochloride RS

Identification—

A: *Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197K*.

B: *Standard solution*—Use the *Standard solution* containing 0.2 mg of USP Procainamide Hydrochloride RS per mL, prepared as directed under *Ordinary impurities*.

Test solution—Dilute the *Test solution,* prepared as directed under *Ordinary impurities,* with methanol to obtain a solution containing about 0.2 mg of procainamide hydrochloride per mL.

Adsorbent, Eluant, and *Visualization*—Prepare as directed in *Ordinary impurities.*

Procedure—Proceed as directed for *Procedure* under *Ordinary impurities ⟨466⟩*: the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution.*

Melting range ⟨741⟩: between 165° and 169°.

Loss on drying ⟨731⟩—Dry it at 105° for 4 hours: it loses not more than 0.3% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Ordinary impurities ⟨466⟩—

Test solution: methanol.

Standard solution: methanol.

Adsorbent: chromatographic silica gel.

Eluant: a mixture of chloroform, methanol, and ammonium hydroxide (70:30:0.7).

Visualization: 1, followed by spraying with a 1 in 2000 solution of fluorescamine in acetone and viewing with UV light at 366 nm.

Limit of free *p*-aminobenzoic acid—

Mobile phase and *Resolution solution*—Proceed as directed in the *Assay.*

Standard solution—Quantitatively dissolve an accurately weighed quantity of USP Aminobenzoic Acid RS in *Mobile phase* to obtain a solution having a known concentration of about 0.25 µg per mL.

Test solution—Transfer 25.0 mL of the stock solution used to prepare the *Assay preparation* to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. This solution contains about 0.25 mg of procainamide hydrochloride per mL.

Chromatographic system—Proceed as directed for *Chromatographic system* in the *Assay.* In addition, the tailing factor for the *p*-aminobenzoic acid peak in the chromatogram obtained from the *Resolution solution* is not more than 2.0; and the relative standard deviation for replicate injections of the *Standard solution* is not more than 3.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the *p*-aminobenzoic acid peaks. Calculate the percentage of *p*-aminobenzoic acid in the

portion of Procainamide Hydrochloride taken by the formula:

$$20(C/W)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Aminobenzoic Acid RS in the *Standard solution; W* is the weight, in mg, of Procainamide Hydrochloride taken to prepare the stock solution for the *Assay preparation;* and r_U and r_S are the *p*-aminobenzoic acid peak responses obtained from the *Test solution* and the *Standard solution,* respectively. The limit is 0.1%.

Assay—

Mobile phase—Prepare a suitable mixture of water, methanol, and triethylamine (140:60:1); adjust with phosphoric acid to a pH of 7.5 ± 0.1; filter; and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Procainamide Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 0.5 mg per mL. Quantitatively dilute an accurately measured volume of this stock solution with *Mobile phase* to obtain a *Standard preparation* having a known concentration of about 0.05 mg per mL.

Change to read:

Resolution solution—Dissolve a quantity of ▲*p*-aminobenzoic acid▲ (ERR 1-Jun-2024) in *Mobile phase* to obtain a solution containing about 0.1 mg per mL. Pipet 10 mL of this solution and 10 mL of the stock solution used to prepare the *Standard preparation* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Transfer about 50 mg of Procainamide Hydrochloride, accurately weighed, to a 100-mL volumetric flask; dissolve in and dilute with *Mobile phase* to volume and mix. Transfer 10.0 mL of this stock solution to a second 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 280-nm detector and a 3.9-mm × 30-cm column that contains 10-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between the *p*-aminobenzoic acid and procainamide peaks is not less than 5.0. The relative retention times are about 0.5 for *p*-aminobenzoic acid and 1.0 for procainamide hydrochloride. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{13}H_{21}N_3O \cdot HCl$ in the portion of Procainamide Hydrochloride taken by the formula:

$$1000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Procainamide Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the 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
PROCAINAMIDE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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