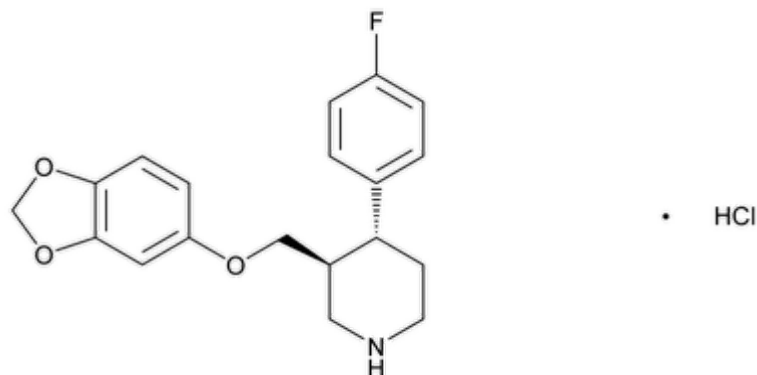


## Paroxetine Hydrochloride

### Change to read:



Click image to enlarge

$C_{19}H_{20}FNO_3 \cdot HCl$  365.83

$\blacktriangle C_{19}H_{20}FNO_3 \cdot HCl \cdot \frac{1}{2}H_2O \blacktriangle$  (IRA 1-May-2021) 374.83

Piperidine, 3-[(1,3-benzodioxol-5-yloxy)methyl]-4-(4-fluorophenyl)-, hydrochloride, (3*S*-*trans*)-; (-)-(3*S*,4*R*)-4-(*p*-Fluorophenyl)-3-[(3,4-methylenedioxy)phenoxy]methyl]piperidine hydrochloride;

$\blacktriangle$ (3*S*,4*R*)-3-[(Benzodioxol-5-yloxy)methyl]-4-(4-fluorophenyl)piperidine hydrochloride.  $\blacktriangle$  (IRA 1-May-2021)

Anhydrous [78246-49-8]; UNII: 3I3T11UD2S.

Hemihydrate [110429-35-1]; UNII: X2ELS050D8.

### DEFINITION

Paroxetine Hydrochloride is anhydrous or contains one-half molecule of water of hydration. It contains NLT 98.5% and NMT 102.0% of paroxetine hydrochloride ( $C_{19}H_{20}FNO_3 \cdot HCl$ ), calculated on the anhydrous and solvent-free basis.

### IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197M, 197K, or 197A

**Standard:** Dissolve [USP Paroxetine Hydrochloride RS](#) in a mixture of [water](#) and [isopropyl alcohol](#) (1 in 10). Heat to 70° to dissolve, recrystallize, and dry the residue under vacuum at 50° for 3 h.

**Sample:** Dissolve Paroxetine Hydrochloride in a mixture of [water](#) and [isopropyl alcohol](#) (1 in 10). Heat to 70° to dissolve, recrystallize, and dry the residue under vacuum at 50° for 3 h.

**Acceptance criteria:** Meets the requirements

- **B. IDENTIFICATION TESTS—GENERAL** (191), *Chemical Identification Tests, Chloride*

**Sample solution:** 10 mg/mL of Paroxetine Hydrochloride in [methanol](#) and [water](#) (50:50)

**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

#### Change to read:

- **PROCEDURE**

**Buffer:** 0.05 M [ammonium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 4.5.



















