

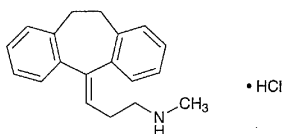
Mobile phase: A mixture of acetonitrile and water (11:9).  
Flow rate: Adjust the flow rate so that the retention time of norgestrel is about 10 minutes.

Selection of column: Proceed with 20  $\mu$ L of the standard solution under the above operating conditions. Use a column giving elution of ethinylestradiol, norgestrel and the internal standard in this order, and separating clearly each peak.

**Containers and storage** Containers—Tight containers.

## Nortriptyline Hydrochloride

塩酸ノルトリプチリン



$C_{19}H_{21}N.HCl$ : 299.84

*N*-[3-(10,11-Dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-ylidene)propyl]-*N*-methylamine monohydrochloride [894-71-3]

Nortriptyline Hydrochloride, when dried, contains not less than 98.5% of  $C_{19}H_{21}N.HCl$ .

**Description** Nortriptyline Hydrochloride occurs as a white to yellowish white, crystalline powder. It is odorless, or has a faint, characteristic odor.

It is freely soluble in acetic acid (100) and in chloroform, soluble in ethanol (95), sparingly soluble in water, and practically insoluble in diethyl ether.

The pH of a solution of Nortriptyline Hydrochloride (1 in 100) is about 5.5.

Melting point: 215 – 220°C

**Identification (1)** To 5 mL of a solution of Nortriptyline Hydrochloride (1 in 100) add 1 mL of bromine TS: the color of the test solution disappears.

**(2)** To 5 mL of a solution of Nortriptyline Hydrochloride (1 in 100) add 1 to 2 drops of a solution of quinhydrone in methanol (1 in 40): a red color gradually develops.

**(3)** Determine the absorption spectrum of a solution of Nortriptyline Hydrochloride (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

**(4)** Determine the infrared absorption spectrum of Nortriptyline Hydrochloride, previously dried, as directed in the potassium chloride disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

**(5)** A solution of Nortriptyline Hydrochloride (1 in 100) responds to the Qualitative Tests for chloride.

**Purity (1)** Clarity and color of solution—Dissolve 0.10 g of Nortriptyline Hydrochloride in 10 mL of water: the solution is clear and colorless to very light yellow.

**(2)** Heavy metals—Proceed with 1.0 g of Nortriptyline

Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

**(3)** Arsenic—Prepare the test solution with 1.0 g of Nortriptyline Hydrochloride according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

**(4)** Related substances—Dissolve 0.50 g of Nortriptyline Hydrochloride in 20 mL of chloroform, and use this solution as the sample solution. Pipet 2 mL of the sample solution, and add chloroform to make exactly 100 mL. Pipet 5 mL of this solution, add chloroform to make exactly 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 4  $\mu$ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of cyclohexane, methanol and diethylamine (8:1:1) to a distance of about 15 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

**Loss on drying** Not more than 0.5% (1 g, 105°C, 2 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.5 g of Nortriptyline Hydrochloride, previously dried, dissolve in 5 mL of acetic acid (100), add 50 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS  
= 29.984 mg of  $C_{19}H_{21}N.HCl$

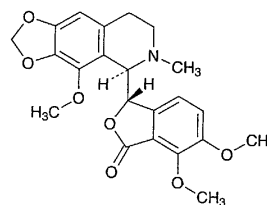
**Containers and storage** Containers—Well-closed containers.

Storage—Light-resistant.

## Noscapine

Narcotine

ノスカピン



$C_{22}H_{23}NO_7$ : 413.42

(3*S*)-6,7-Dimethoxy-3-[(5*R*)-5,6,7,8-tetrahydro-4-methoxy-6-methyl[1,3]dioxolo[4,5-*g*]isoquinolin-5-yl]isobenzofuran-1(3*H*)one [128-62-1]

Noscapine, when dried, contains not less than 98.5% of  $C_{22}H_{23}NO_7$ .