Nortriptyline Hydrochloride Tablets

ノルトリプチリン塩酸塩錠

Nortriptyline Hydrochloride Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of nortriptyline ($C_{19}H_{21}N$: 263.38).

Method of preparation Prepare as directed under Tablets, with Nortriptyline Hydrochloride.

Identification (1) Determine the absorption spectrum of the sample solution obtained in the Assay as directed under Ultraviolet-visible Spectrophotometry *<2.24>* using diluted 0.1 mol/L hydrochloric acid TS (1 in 50) as the blank: it exhibits a maximum between 237 nm and 241 nm.

(2) To a quantity of powdered Nortriptyline Hydrochloride Tablets, equivalent to 10 mg of nortriptyline ($C_{19}H_{21}N$), add 10 mL of ethanol (99.5), shake thoroughly, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 11 mg of nortriptyline hydrochloride in 10 mL of ethanol (99.5), and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography *<2.03>*. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (4:1:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): principal spot obtained from the sample solution and the spot from the standard solution show the same color tone and *R*f value.

Uniformity of dosage units *<6.02>* Perform the test according to the following method: it meets the requirement of the Content uniformity test.

To 1 tablet of Nortriptyline Hydrochloride Tablets add a suitable volume of 0.1 mol/L hydrochloric acid TS, disperse the fine particles by sonicating, add a suitable volume of 0.1 mol/L hydrochloric acid TS, sonicate, extract for 15 minutes while occasional shaking. Shake for 15 minutes, and add 0.1 mol/L hydrochloric acid TS to make exactly V mL so that each mL contains about 0.5 mg of nortriptyline ($C_{19}H_{21}N$). Centrifuge this solution, pipet 2 mL of the supernatant liquid, add water to make exactly 100 mL, and use this solution as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of nortriptyline ($C_{19}H_{21}N$)
$= M_S \times A_T / A_S \times V / 50 \times 0.878$

M_S: Amount (mg) of nortriptyline hydrochloride for assay taken

Dissolution *<6.10>* When the test is performed at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium, the dissolution rates in 30 minutes of a 10-mg tablet and a 25-mg tablet are not less than 70% and not less than 80%, respectively.

Start the test with 1 tablet of Nortriptyline Hydrochloride Tablets, withdraw not less than 20 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL or more of the filtrate, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 11 μg of nortriptyline ($C_{19}H_{21}N$), and use this solution as the sample solution. Separately, weigh accurately about 25 mg of nortriptyline hydrochloride for assay, previously dried at 105℃ for 2 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and standard solution at 239 nm as directed under Ultraviolet-visible Spectrophotometry *<2.24>*.

Dissolution rate (%) with respect to the labeled amount of nortriptyline ($C_{19}H_{21}N$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 45 \times 0.878$

M_S: Amount (mg) of nortriptyline hydrochloride for assay taken

C: Labeled amount (mg) of nortriptyline ($C_{19}H_{21}N$) in 1 tablet

Assay Weigh accurately the mass of not less than 20 tablets of Nortriptyline Hydrochloride Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 50 mg of nortriptyline ($C_{19}H_{21}N$), add 50 mL of 0.1 mol/L hydrochloric acid TS, sonicate, and extract for 15 minutes while occasional shaking. Shake for 15 minutes, and add 0.1 mol/L hydrochloric acid TS to make exactly 100 mL. Centrifuge this solution, pipet 2 mL of the supernatant liquid, add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 28 mg of nortriptyline hydrochloride for assay, previously dried at 105℃ for 2 hours, and dissolve in 0.1 mol/L hydrochloric acid TS to make exactly 50 mL. Pipet 2 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and standard solution at 239 nm as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, using diluted 0.1 mol/L hydrochloric acid TS (1 in 50) as the blank.

Amount (mg) of nortriptyline ($C_{19}H_{21}N$)
$= M_S \times A_T / A_S \times 2 \times 0.878$

M_S: Amount (mg) of nortriptyline hydrochloride for assay taken

Containers and storage Containers—Tight containers.

Add the following to 9.41 Reagents, Test Solutions:

Nortriptyline hydrochloride $C_{19}H_{21}N.HCl$ [Same as the namesake monograph]

Nortriptyline hydrochloride for assay $C_{19}H_{21}N.HCl$ [Same as the monograph Nortriptyline Hydrochloride. When dried, it contains not less than 99.0% of nortriptyline hydrochloride ($C_{19}H_{21}N.HCl$).]