Clotiazepam Tablets

クロチアゼパム錠

Clotiazepam Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of clotiazepam ($C_{16}H_{15}ClN_2OS$: 318.82).

Method of preparation Prepare as directed under Tablets, with Clotiazepam.

Identification Determine the absorption spectrum of the sample solution obtained in the Assay as directed under Ultraviolet-visible Spectrophotometry <*2.24*>: it exhibits maximum between 260 nm and 264 nm.

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

To 1 tablet of Clotiazepam Tablets add 35 mL of 0.1 mol/L hydrochloric acid TS, stir until the tablet is completely disintegrated, stir for a further 10 minutes, and add 0.1 mol/L hydrochloric acid TS to make exactly 50 mL. Centrifuge this solution, pipet V mL of the supernatant liquid, add 0.1 mol/L hydrochloric acid TS to make exactly V' mL so that each mL contains about 10 μg of clotiazepam ($C_{16}H_{15}ClN_2OS$), and use this solution as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of clotiazepam ($C_{16}H_{15}ClN_2OS$)
$= M_S \times A_T / A_S \times V' / V \times 1 / 50$

M_S: Amount (mg) of clotiazepam 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 1st fluid for dissolution test as the dissolution medium, the dissolution rate in 45 minutes of Clotiazepam Tablets is not less than 80%.

Start the test with 1 tablet of Clotiazepam 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 of the filtrate, pipet V mL of the subsequent filtrate, add the dissolution medium to make exactly V' mL so that each mL contains about 5.6 μg of clotiazepam ($C_{16}H_{15}ClN_2OS$), and use this solution as the sample solution. Separately, weigh accurately about 28 mg of clotiazepam for assay, previously dried at 80℃ for 3 hours, and dissolve in ethanol (95) to make exactly 25 mL. Pipet 5 mL of this solution, and add the dissolution medium to make exactly 100 mL. Pipet 5 mL of this solution, add the dissolution medium to make exactly 50 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 262 nm as directed under Ultraviolet-visible Spectrophotometry <*2.24*>, using the dissolution medium as the blank.

Dissolution rate (%) with respect to the labeled amount of clotiazepam ($C_{16}H_{15}ClN_2OS$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 18$

M_S: Amount (mg) of clotiazepam for assay taken

C: Labeled amount (mg) of clotiazepam ($C_{16}H_{15}ClN_2OS$) in 1 tablet

Assay To 20 Clotiazepam Tablets add 350 mL of 0.1 mol/L hydrochloric acid TS, stir until the tablets are completely disintegrated, stir for a further 10 minutes, and add 0.1 mol/L hydrochloric acid TS to make exactly 500 mL. Centrifuge this solution, pipet V mL of the supernatant liquid, add 0.1 mol/L hydrochloric acid TS to make exactly V' mL so that each mL contains about 10 μg of clotiazepam ($C_{16}H_{15}ClN_2OS$), and use this solution as the sample solution. Separately, weigh accurately about 25 mg of clotiazepam for assay, previously dried at 80℃ for 3 hours, and dissolve in 0.1 mol/L hydrochloric acid TS to make exactly 50 mL. Pipet 2 mL of this solution, add 0.1 mol/L hydrochloric acid TS 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 261 nm as directed under Ultraviolet-visible Spectrophotometry <*2.24*>.

Amount (mg) of clotiazepam ($C_{16}H_{15}ClN_2OS$) in 1 tablet
$= M_S \times A_T / A_S \times V' / V \times 1 / 100$

M_S: Amount (mg) of clotiazepam for assay taken

Containers and storage Containers－Tight containers.
Storage－Light-resistant.

Add the following to 9.41 Reagents, Test Solutions:

Clotiazepam for assay $C_{16}H_{15}ClN_2OS$ [Same as the monograph Clotiazepam. When dried, it contains not less than 99.0% of clotiazepam ($C_{16}H_{15}ClN_2OS$).]