Diazepam Tablets

Dissolution a *<6.10>*   Perform the test with 1 tablet of Diazepam Tablets at 100 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. 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 water to make exactly V' mL so that each mL contains about 2.2 µg of diazepam ($C_{16}H_{13}ClN_2O$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Diazepam RS, previously dried at 105ºC for 2 hours, and dissolve in ethanol (95) to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly 200 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 230 nm as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, using water as the blank.

   The requirements are met if Diazepam Tablets conform to the dissolution requirements.

   Dissolution rate (%) with respect to the labeled amount of diazepam ($C_{16}H_{13}ClN_2O$)
   $$= M_S \times A_T/A_S \times V'/V \times 1/C \times 9$$

   M_S: Amount (mg) of Diazepam RS
   C: Labeled amount (mg) of diazepam ($C_{16}H_{13}ClN_2O$) in 1 tablet

<div align="center">Dissolution Requirements a</div>

Labeled amount	Specified minute	Dissolution rate
2 mg	90 minutes	Not less than 75%
5 mg	90 minutes	Not less than 75%
10 mg	120 minutes	Not less than 70%

Dissolution b *<6.10>*   Perform the test with 1 tablet of Diazepam Tablets at 75 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. 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 water to make exactly V' mL so that each mL contains about 2.2 µg of diazepam ($C_{16}H_{13}ClN_2O$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Diazepam RS, previously dried at 105ºC for 2 hours, and dissolve in ethanol (95) to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly

200 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 230 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using water as the blank.

The requirements are met if Diazepam Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of diazepam ($C_{16}H_{13}ClN_2O$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 9$

M_S: Amount (mg) of Diazepam RS
C: Labeled amount (mg) of diazepam ($C_{16}H_{13}ClN_2O$) in 1 tablet

<div align="center">Dissolution Requirements b</div>

Labeled amount	Specified minute	Dissolution rate
2 mg	60 minutes	Not less than 75%
5 mg	60 minutes	Not less than 75%