

Adenosine 5'-Triphosphate Disodium Enteric-coated Tablets

Dissolution <6.10>

[pH 1.2] Perform the test with 1 tablet of Adenosine 5'-Triphosphate Disodium Enteric-coated Tablets at 75 revolutions per minute according to the Paddle method, using 900 mL of 1st fluid for dissolution test 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 1st fluid for dissolution test to make exactly V' mL so that each mL contains about 22 μg of adenosine triphosphate disodium ($\text{C}_{10}\text{H}_{14}\text{N}_5\text{Na}_2\text{O}_{13}\text{P}_3 \cdot 3\text{H}_2\text{O}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately 22 mg of Adenosine Triphosphate Disodium RS (previously determine the water <2.48> with 0.1 g by back titration in volumetric titration. Use a mixture of ethylene glycol for water determination and methanol for water determination (3:2) instead of methanol for water determination), and dissolve in 1st fluid for dissolution test to make exactly 20 mL. Pipet 2 mL of this solution, add 1st fluid for dissolution test to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, and determine the absorbances, A_T and A_S , at 259 nm.

The requirements are met if Adenosine 5'-Triphosphate Disodium Enteric-coated Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of adenosine triphosphate disodium ($\text{C}_{10}\text{H}_{14}\text{N}_5\text{Na}_2\text{O}_{13}\text{P}_3 \cdot 3\text{H}_2\text{O}$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 90 \times 1.098$$

M_S : Amount (mg) of Adenosine Triphosphate Disodium RS, calculated on the anhydrous basis

C : Labeled amount (mg) of adenosine triphosphate disodium ($\text{C}_{10}\text{H}_{14}\text{N}_5\text{Na}_2\text{O}_{13}\text{P}_3 \cdot 3\text{H}_2\text{O}$) in 1 tablet

[pH 6.8] Perform the test with 1 tablet of Adenosine 5'-Triphosphate Disodium Enteric-coated Tablets at 75 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test 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 2nd fluid for dissolution test to make exactly V' mL so that each mL contains about 22 μg of adenosine triphosphate disodium ($\text{C}_{10}\text{H}_{14}\text{N}_5\text{Na}_2\text{O}_{13}\text{P}_3 \cdot 3\text{H}_2\text{O}$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Adenosine

Triphosphate Disodium RS (previously determine the water <2.48> with 0.1 g by back titration in volumetric titration. Use a mixture of ethylene glycol for water determination and methanol for water determination (3:2) instead of methanol for water determination), and dissolve in 2nd fluid for dissolution test to make exactly 20 mL. Pipet 2 mL of this solution, add 2nd fluid for dissolution test to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, and determine the absorbances, A_T and A_S , at 259 nm.

The requirements are met if Adenosine 5'-Triphosphate Disodium Enteric-coated Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of adenosine triphosphate disodium ($C_{10}H_{14}N_5Na_2O_{13}P_3 \cdot 3H_2O$)

$$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 90 \times 1.098$$

M_S : Amount (mg) of Adenosine Triphosphate Disodium RS, calculated on the anhydrous basis

C : Labeled amount (mg) of adenosine triphosphate disodium ($C_{10}H_{14}N_5Na_2O_{13}P_3 \cdot 3H_2O$) in 1 tablet

Dissolution Requirements			
Labeled amount	pH	Specified minute	Dissolution rate
20 mg	1.2	120 minutes	Not more than 5%
	6.8	45 minutes	Not less than 85%
21.96 mg	1.2	120 minutes	Not more than 5%
	6.8	45 minutes	Not less than 85%
60 mg	1.2	120 minutes	Not more than 5%
	6.8	60 minutes	Not less than 85%

Adenosine Triphosphate Disodium RS Adenosine Triphosphate Disodium. It contains not less than 99.0% of adenosine triphosphate disodium ($C_{10}H_{14}N_5Na_2O_{13}P_3$), calculated on the anhydrous basis.