Sulfinpyrazone Tablets

スルフィンピラゾン錠

Sulfinpyrazone Tablets contain not less than 93% and not more than 107% of the labeled amount of sulfinpyrazone ($C_{23}H_{20}N_2O_3S$: 404.48).

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

Identification (1) Weigh a portion of powdered Sulfinpyrazone Tablets, equivalent to 2 mg of Sulfinpyrazone according to the labeled amount, add 1 mL of acetic acid (100), and shake. To this solution add 1 mL of palladium (II) chloride TS and 2 mL of chloroform, and shake: a yellow color develops in the chloroform layer.

(2) Determine the absorption spectrum of the sample solution obtained in the Assay as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 257 nm and 261 nm.

Dissolution test Perform the test with 1 tablet of Sulfinpyrazone Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of the 2nd fluid under the Disintegration Test as the test solution. Take 20 mL or more of the dissolved solution 45 minutes after starting the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, pipet 2 mL of the subsequent, add the 2nd fluid to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Sulfinpyrazone Reference Standard, previously dried at 105°C for 2 hours, dissolve in the 2nd fluid to make exactly 100 mL. Pipet 10 mL of this solution, add the 2nd fluid 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 the standard solution at 259 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Sulfinpyrazone Tablets in 45 minutes is not less than 80%.

Dissolution rate (%) with respect to the labeled amount of sulfinpyrazone ($C_{23}H_{20}N_2O_3S$)

$$= W_S \times \frac{A_T}{A_S} \times 9$$

W_S: Amount (mg) of Sulfinpyrazone Reference Standard.

Assay Weigh accurately, and powder not less than 20 Sulfinpyrazone Tablets. Weigh accurately a portion of the powder, equivalent to about 0.05 g of sulfinpyrazone ($C_{23}H_{20}N_2O_3S$), add 25 mL of methanol, and shake for 15 minutes. To this solution add 50 mL of sodium hydroxide TS, shake, cool, and add water to make exactly 200 mL. After centrifuging, pipet 4 mL of the supernatant liquid, add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of Sulfinpyrazone Reference Standard, previously dried at 105°C for 2 hours, dissolve in 25 mL of methanol, add 50 mL of sodium hydroxide TS, and cool. To this solution add water to make exactly 200 mL, pipet 4 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 these solutions at 260 nm as directed under the Ultraviolet-visible Spectrophotometry.

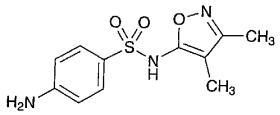
Amount (mg) of sulfinpyrazone ($C_{23}H_{20}N_2O_3S$)
= amount (mg) of Sulfinpyrazone Reference Standard
$\times \frac{A_T}{A_S}$

Containers and storage Containers—Well-closed containers.

Sulfisoxazole

Sulfafurazole

スルフイソキサゾール



$C_{11}H_{13}N_3O_3S$: 267.30
4-Amino-*N*-(3,4-dimethylisoxazol-5-yl)benzenesulfonamide [*127-69-5*]

Sulfisoxazole, when dried, contains not less than 99.0% of $C_{11}H_{13}N_3O_3S$.

Description Sulfisoxazole occurs as white crystals or crystalline powder. It is odorless, and has a slightly bitter taste.

It is freely soluble in pyridine and in *n*-butylamine, soluble in methanol, sparingly soluble in ethanol (95), slightly soluble in acetic acid (100), and very slightly soluble in water and in diethyl ether.

It dissolves in dilute hydrochloric acid, in sodium hydroxide TS and in ammonia TS.

It is gradually colored by light.

Identification (1) Dissolve 0.01 g of Sulfisoxazole in 1 mL of dilute hydrochloric acid and 4 mL of water: the solution responds to the Qualitative Tests for primary aromatic amines.

(2) Dissolve 0.02 g of Sulfisoxazole in 5 mL of water and 1 mL of *n*-butylamine, add 2 to 3 drops of copper (II) sulfate TS, and shake well. Add 5 mL of chloroform, shake, and allow to stand: a blue-green color develops in the chloroform layer.

(3) Dissolve 0.01 g of Sulfisoxazole in 1 mL of pyridine, add 2 drops of copper (II) sulfate TS, and shake. Add 3 mL of water and 5 mL of chloroform, shake, and allow to stand: a light yellow-brown color develops in the chloroform layer.

(4) To 0.5 g of Sulfisoxazole add 2 mL of acetic acid (100), dissolve by heating under a reflux condenser, add 1 mL of acetic anhydride, and boil for 10 minutes. Add 10 mL of water, cool, and alkalize with about 7 mL of a solution of sodium hydroxide (3 in 10). Filter, if necessary, immediately acidify by adding acetic acid (100) dropwise, collect the produced precipitate, recrystallize from methanol, and dry at 105°C for 1 hour: the crystals melt between 208°C and 210°C.