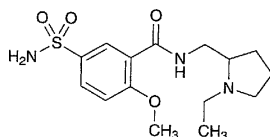


Containers and storage Containers—Well-closed containers.

Sulpiride

スルピリド



$C_{15}H_{23}N_3O_4S$: 341.43

N-(1-Ethylpyrrolidin-2-ylmethyl)-2-methoxy-5-sulfamoylbenzamide [15676-16-1]

Sulpiride, when dried, contains not less than 98.5% of $C_{15}H_{23}N_3O_4S$.

Description Sulpiride is a white, crystalline powder. It is odorless.

It is freely soluble in acetic acid (100) and in dilute acetic acid, sparingly soluble in methanol, slightly soluble in ethanol (95) and in acetone, and practically insoluble in water, in diethyl ether and in chloroform.

It is soluble in dilute hydrochloric acid and in 0.05 mol/L sulfuric acid TS.

Melting point: 175 – 182°C (with decomposition).

Identification (1) Dissolve 0.01 g of Sulpiride in 5 mL of dilute hydrochloric acid and 20 mL of water. To 5 mL of this solution add 1 mL of Dragendorff's TS: a reddish orange precipitate is produced.

(2) To 0.5 g of Sulpiride add 3 mL of sodium hydroxide solution (3 in 10), and heat: the gas evolved changes moistened red litmus paper to blue.

(3) Dissolve 0.1 g of Sulpiride in 0.05 mol/L sulfuric acid to make 100 mL. Dilute 5 mL of the solution with water to make 100 mL. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

Purity (1) Clarity of solution—Dissolve 2.0 g of Sulpiride in 7 mL of dilute acetic acid, and add water to make 20 mL: the solution is clear. Perform the test as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank: the absorbance at a wavelength of 450 nm does not exceed 0.020.

(2) Heavy metals—Proceed with 2.0 g of Sulpiride as directed under Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Sulpiride according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.050 g of Sulpiride in 10 mL of methanol, and use this solution as the sample solution. Dilute 1 mL of the sample solution, accurately measured, with methanol to make exactly 100 mL. Dilute 5 mL

of this solution, accurately measured, with methanol to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μ L each of the sample solution and the 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) (4:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): spots other than the principal spot from the sample solution have no more color than the spot from the standard solution. When the plate is exposed to iodine vapor for 30 minutes, the spots other than the principal spot from the sample solution have no more color than the spot from the standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 3 hours).

Residue on ignition Not more than 0.10% (1 g).

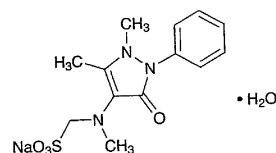
Assay Dissolve about 0.4 g of Sulpiride, previously dried and accurately weighed, in 80 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (indicator: 2 drops of crystal violet TS) until the color of the solution changes from violet through blue to bluish green. Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 34.143 mg of $C_{15}H_{23}N_3O_4S$

Containers and storage Containers—Well-closed containers.

Sulpyrine

スルピリン



$C_{13}H_{16}N_3NaO_4S \cdot H_2O$: 351.35

Monosodium [(1,5-dimethyl-3-oxo-2-phenyl-2,3-dihydro-1*H*-pyrazol-4-yl)methylamino]methanesulfonate monohydrate [5907-38-0]

Sulpyrine contains not less than 98.5% of $C_{13}H_{16}N_3NaO_4S$ (mol. wt.: 333.34), calculated on the dried basis.

Description Sulpyrine occurs as white to light yellow crystals or crystalline powder. It is odorless, and has a bitter taste.

It is very soluble in water, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

It is colored by light.

Identification (1) Add 2 drops of dilute sulfuric acid and 1 mL of chlorinated lime TS to 3 mL of a solution of Sulpyrine (1 in 15): a deep blue color develops at first, but the color immediately turns red, then gradually changes to yellow.