



Edition: BP 2025 (Ph. Eur. 11.6 update)

Sulpiride Tablets

[General Notices](#)

Action and use

Dopamine receptor antagonist; neuroleptic.

DEFINITION

Sulpiride Tablets contain Sulpiride.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of sulpiride, $C_{15}H_{23}N_3O_4S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

To a quantity of the powdered tablets containing 0.2 g of Sulpiride add 20 mL of [methanol](#), shake for 5 minutes, filter and evaporate the filtrate to dryness. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of sulpiride ([RS 391](#)).

Related substances

- A. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.
- (1) Add 20 mL of [methanol](#) to a quantity of the powdered tablets containing 0.2 g of Sulpiride, shake for 5 minutes, filter, evaporate the filtrate to dryness and dissolve the residue in 10 mL of [methanol](#).
 - (2) 0.02% w/v of [sulpiride impurity A EPCRS](#) in [methanol](#).
 - (3) Dilute 1 volume of solution (2) to 10 volumes with [methanol](#).

CHROMATOGRAPHIC CONDITIONS

- Use a [silica gel HF₂₅₄](#) precoated plate (Analtech Uniplates are suitable).
- Use the mobile phase as described below.
- Apply 10 µL of each solution.
- Develop the plate to 10 cm.
- After removal of the plate, dry in air, spray with [ninhydrin solution](#) and heat at 100° to 105° for 15 minutes.

MOBILE PHASE

2 volumes of 13.5M [ammonia](#), 10 volumes of [1,4-dioxan](#), 14 volumes of [methanol](#) and 90 volumes of [dichloromethane](#).

LIMITS

Any spot in the chromatogram obtained with solution (1) corresponding to the principal spot in the chromatogram obtained with solution (2) is not more intense than the spot in the chromatogram obtained with solution (3) (0.1%).

B. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Add 20 mL of [methanol](#) to a quantity of the powdered tablets containing 0.2 g of Sulpiride, shake for 5 minutes, filter, evaporate the filtrate to dryness and dissolve the residue in sufficient of the mobile phase to produce 200 mL.
- (2) Dilute 3 volumes of solution (1) to 100 volumes with the mobile phase and dilute 1 volume of this solution to 10 volumes with the mobile phase.
- (3) 0.01% w/v of [sulpiride BPCRS](#) and 0.01% w/v of [sulpiride impurity B EPCRS](#) in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [octylsilyl silica gel for chromatography](#) (5 µm) (Zorbax RX C8 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.5 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 240 nm.
- (f) Inject 20 µL of each solution.
- (g) For solution (1) and solution (2) allow the chromatography to proceed for 2.5 times the retention time of sulpiride.

MOBILE PHASE

10 volumes of [acetonitrile](#), 10 volumes of [methanol](#) and 80 volumes of a solution containing 0.68 % w/v of [potassium dihydrogen orthophosphate](#) and 0.1% w/v of [sodium octanesulfonate](#), adjusted to pH 3.3 using [orthophosphoric acid](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution factor](#) between the two principal peaks is at least 2.5.

LIMITS

In the chromatogram obtained with solution (1):

the sum of the areas of any [secondary peaks](#) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.3%).

ASSAY

Weigh and powder 20 tablets. Mix a quantity of the powder containing 0.1 g of Sulpiride with about 50 mL of 0.1M [sodium hydroxide](#) for 5 minutes with the aid of ultrasound, add sufficient 0.1M [sodium hydroxide](#) to produce 100 mL and filter, discarding the first 10 mL of filtrate. Dilute 5 mL of the filtrate to 100 mL with 0.1M [sodium hydroxide](#) and measure the [absorbance](#) of the solution at the maximum at 291 nm, [Appendix II B](#), using 0.1M [sodium hydroxide](#) in the reference cell. Calculate the content of C₁₅H₂₃N₃O₄S in the tablets from the [absorbance](#) of a 0.005% w/v solution of [sulpiride BPCRS](#) in 0.1M [sodium hydroxide](#) using the declared content of C₁₅H₂₃N₃O₄S in [sulpiride BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Sulpiride.