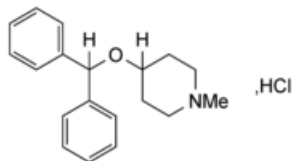




Edition: BP 2025 (Ph. Eur. 11.6 update)

Diphenylpyraline Hydrochloride

[General Notices](#)



$C_{19}H_{23}NO \cdot HCl$ 317.9 132-18-3

Action and use

[Histamine](#) H_1 receptor antagonist; antihistamine.

DEFINITION

Diphenylpyraline Hydrochloride is 4-benzhydryloxy-1-methylpiperidine hydrochloride. It contains not less than 98.0% and not more than 101.0% of $C_{19}H_{23}NO \cdot HCl$, calculated with reference to the dried substance.

CHARACTERISTICS

A white or almost white powder; odourless or almost odourless.

Freely soluble in [water](#) and in [ethanol \(96%\)](#); practically insoluble in [ether](#).

IDENTIFICATION

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of diphenylpyraline hydrochloride ([RS 106](#)).
- B. Yields the reactions characteristic of *chlorides*, [Appendix VI](#).

TESTS

Related substances

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

- (1) Dissolve 45 mg of [bibenzyl](#) (internal standard) in sufficient [dichloromethane](#) to produce 100 mL.
- (2) Dissolve 0.20 g of the substance being examined in 20 mL of [water](#), make the solution alkaline with 5M [ammonia](#) and extract with three 25-mL quantities of [dichloromethane](#). Shake the combined extracts with 10 g of [anhydrous sodium sulfate](#), filter, evaporate the filtrate to dryness at about 30° and dissolve the residue in 2 mL of [dichloromethane](#).

(3) Prepare solution (3) in the same manner as solution (2) but dissolve the residue in 2 mL of solution (1).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a glass column (1.5 m×4 mm) packed with [silanised diatomaceous support](#) (80 to 100 mesh) coated with 3% w/w of phenyl methyl silicone fluid (50% phenyl) (OV-17 is suitable).
- (b) Use [nitrogen](#) as the carrier gas.
- (c) Use an oven temperature of 165°. Allow the chromatography to proceed for 3 times the retention time of bibenzyl.
- (d) Increase the oven temperature to 240° to elute the diphenylpyraline from the column.

LIMITS

In the chromatogram obtained with solution (3):

the sum of the areas of any [secondary peaks](#) is not greater than the area of the peak due to the internal standard.

[Loss on drying](#)

When dried to constant weight at 105°, loses not more than 1.0% of its weight. Use 1 g.

[Sulfated ash](#)

Not more than 0.1%, [Appendix IX A](#).

ASSAY

Carry out Method I for [non-aqueous titration](#), [Appendix VIII A](#), using 0.2 g, adding 5 mL of *mercury(II) acetate solution* and determining the end-point [potentiometrically](#). Each mL of [0.1M perchloric acid VS](#) is equivalent to 31.79 mg of $C_{19}H_{23}NO, HCl$.