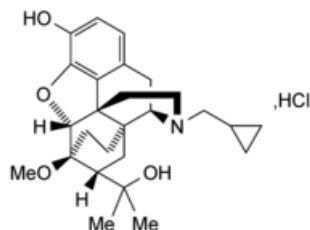




Edition: BP 2025 (Ph. Eur. 11.6 update)

Diprenorphine Hydrochloride

[General Notices](#)



$C_{26}H_{35}NO_4 \cdot HCl$ 462.1 16808-86-9

Action and use

Opioid receptor antagonist.

Preparation

Diprenorphine Injection

DEFINITION

Diprenorphine Hydrochloride is *N*-cyclopropylmethyl-7,8-dihydro-7 α -(1-hydroxy-1-methylethyl)-6-*O*-methyl-6 α ,14 α -ethanonormorphine hydrochloride. It contains not less than 98.5% and not more than 101.0% of $C_{26}H_{35}NO_4 \cdot HCl$, calculated with reference to the dried substance.

CHARACTERISTICS

A white or almost white, crystalline powder.

Sparingly soluble in [water](#); slightly soluble in [ethanol \(96%\)](#); very slightly soluble in [chloroform](#); practically insoluble in [ether](#).

IDENTIFICATION

- The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of diprenorphine hydrochloride ([RSV 18](#)).
- The [light absorption](#), [Appendix II B](#), in the range 230 to 350 nm of a 0.02% w/v solution in [0.1M hydrochloric acid](#) exhibits a maximum only at 287 nm. The [absorbance](#) at the maximum is about 0.70.
- The [light absorption](#), [Appendix II B](#), in the range 230 to 350 nm of a 0.02% w/v solution in 0.1M [sodium hydroxide](#) exhibits a maximum only at 301 nm. The [absorbance](#) at the maximum is about 1.1.
- Yields reaction A characteristic of *chlorides*, [Appendix VI](#).

TESTS

Acidity

pH of a 2.0% w/v solution, 4.5 to 6.0, [Appendix V L](#).

[Specific optical rotation](#)

In a solution prepared by dissolving 0.5 g in sufficient [methanol](#) to produce 25 mL, -97.0 to -107.0, calculated with reference to the dried substance, [Appendix V F](#).

Related substances

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using [silica gel G](#) as the coating substance and a mixture of 1 volume of [water](#), 5 volumes of [methanol](#), 30 volumes of [butan-2-one](#), 80 volumes of [acetone](#) and 100 volumes of [cyclohexane](#) as the mobile phase. Apply separately to the plate 20 µL of each of two solutions of the substance being examined in [methanol](#) containing (1) 2.0% w/v and (2) 0.020% w/v. Add at each point of application 10 µL of a mixture of 4 volumes of [methanol](#) and 1 volume of 13.5M [ammonia](#). After removal of the plate, allow it to dry in air and spray with a 1% w/v solution of [iodine](#) in [methanol](#). Any [secondary spot](#) in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%).

[Loss on drying](#)

When dried to [constant weight](#) at 105°, loses not more than 2.0% 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 0.5 g, adding 7 mL of *mercury(II) acetate solution* and using [crystal violet solution](#) as indicator. Each mL of [0.1M perchloric acid VS](#) is equivalent to 46.21 mg C₂₆H₃₅NO₄·HCl.

STORAGE

Diprenorphine Hydrochloride should be protected from light.