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

Pethidine Tablets

General Notices

Action and use

Opioid receptor agonist; analgesic.

DEFINITION

Pethidine Tablets contain Pethidine Hydrochloride.

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

Content of pethidine hydrochloride, $C_{15}H_{21}NO_2$,HCl

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing 50 mg of Pethidine Hydrochloride with 20 mL of *chloroform*, filter, evaporate the filtrate to dryness and dry the residue at a pressure of 2 kPa. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of pethidine hydrochloride (*RS 267*).
B. Shake a quantity of the powdered tablets containing 0.2 g of Pethidine Hydrochloride with 20 mL of *water* and filter. To 5 mL of the filtrate add 10 mL of *picric acid solution R1*. The *melting point* of the crystals so obtained, after washing with *water*, is about 190°, Appendix V A.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using *kieselguhr G* as the coating substance but allowing the solvent front to ascend 12 cm above the line of application. Impregnate the dry plate by placing it in a closed tank containing a mixture of 10 volumes of *2-phenoxyethanol* and 90 volumes of *acetone* so that the plate dips about 5 mm beneath the surface of the liquid, allowing the impregnation solvent to ascend at least 15 cm, removing the plate from the tank and drying in a current of air. Use immediately, with the flow of the mobile phase in the same direction as the impregnation. Use as the mobile phase the upper layer obtained by shaking together 1 volume of *diethylamine*, 8 volumes of *2-phenoxyethanol* and 100 volumes of *petroleum spirit* (*boiling range, 50° to 70°*) and allowing it to settle.

Apply separately to the plate 5 µL of each of the following solutions. For solution (1) use the upper layer obtained by shaking a quantity of the powdered tablets containing 0.1 g of Pethidine Hydrochloride with 5 mL of *water*, filtering, shaking the filtrate with 0.5 mL of 5M *sodium hydroxide* and 2 mL of *ether* and allowing the layers to separate. For solution (2) dilute 0.5 mL of solution (1) to 50 mL with *ether*.

After removal of the plate, allow it to dry in air for 10 minutes, return the plate to the tank and repeat the development. Remove the plate, allow it to dry in air for 10 minutes and spray with a 0.2% w/v solution of *2,7-dichlorofluorescein* in *methanol*. Allow the plate to stand for 5 minutes and spray with *water* until the background is white to pale yellow. Examine in daylight. The chromatograms show red or orange spots. 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%). Examine without delay under *ultraviolet light* (*365 nm*). The chromatograms show spots with intense yellow fluorescence. 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%).

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.5 g of Pethidine Hydrochloride in 40 mL of *water*, add 2 mL of 5M *sodium hydroxide* and extract immediately with quantities of 25, 10 and 10 mL of *chloroform*. Wash each extract with the same 15 mL of *water* and filter into a dry flask. Titrate the combined extracts, which should be clear and free from droplets of *water*, with *0.05M perchloric acid VS* using 0.15 mL of *1-naphtholbenzein solution* as indicator. Each mL of *0.05M perchloric acid VS* is equivalent to 14.19 mg of $C_{15}H_{21}NO_2$,HCl.