



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

Pentazocine Tablets

[General Notices](#)

Action and use

Opioid receptor agonist; analgesic.

DEFINITION

Pentazocine Tablets contain Pentazocine Hydrochloride.

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

Content of pentazocine hydrochloride, $C_{19}H_{27}NO \cdot HCl$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 0.1 g of Pentazocine Hydrochloride with 10 mL of [water](#), filter (Whatman GF/C is suitable), add 1 mL of 1M [sodium hydroxide](#) and shake the resulting solution with 20 mL of [chloroform](#). Wash the chloroform extract with 5 mL of [water](#), dry over [anhydrous sodium sulfate](#) and filter. Evaporate the chloroform using a rotary evaporator and dry the oily residue at 60° at a pressure of 2 kPa for 1 hour. The [infrared absorption spectrum](#) of the powdered residue, [Appendix II A](#), is concordant with the *reference spectrum* of pentazocine (form B) ([RS 261](#)). If the spectra are not concordant, dissolve the residue in [chloroform](#), evaporate to dryness and prepare a new spectrum of the residue.

Related substances

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 94 volumes of [chloroform](#), 3 volumes of [methanol](#) and 3 volumes of [isopropylamine](#) as the mobile phase. Apply separately to the plate 10 μ L of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 0.2 g of Pentazocine Hydrochloride with 10 mL of 0.1M [methanolic ammonia](#) for 10 minutes, centrifuge and use the supernatant liquid. For solution (2) dilute 1 volume of solution (1) to 100 volumes with the same solvent. For solution (3) dilute 1 volume of solution (1) to 200 volumes with the same solvent. For solution (4) dilute 1 volume of solution (1) to 400 volumes with the same solvent. After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). Heat the plate at 105° for 15 minutes, allow to cool, expose to iodine vapour and re-examine under [ultraviolet light \(254 nm\)](#). By each method of visualisation any [secondary spot](#) in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2), not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) and not more than four such spots are more intense than the spot in the chromatogram obtained with solution (4). Disregard any spot remaining on the line of application.

ASSAY

<https://nhathuocngocanh.com/bp/>

Weigh and powder 20 tablets. Shake a quantity of the powder containing 25 mg of Pentazocine Hydrochloride with 100 mL of [water](#) for 15 minutes, add 2.5 mL of 1M [hydrochloric acid](#) and sufficient [water](#) to produce 250 mL and filter. Measure the [absorbance](#) of the filtrate at the maximum at 278 nm, [Appendix II B](#). Calculate the content of $C_{19}H_{27}NO \cdot HCl$ taking 61.2 as the value of $A(1\%, 1\text{ cm})$ at the maximum at 278 nm.