



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

Orphenadrine Hydrochloride Tablets

[General Notices](#)

Action and use

Anticholinergic.

DEFINITION

Orphenadrine Hydrochloride Tablets contain Orphenadrine Hydrochloride.

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

Content of orphenadrine hydrochloride, $C_{18}H_{23}NO \cdot HCl$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Extract a quantity of the powdered tablets containing 0.15 g of Orphenadrine Hydrochloride with [chloroform](#), filter and evaporate the filtrate to dryness. The residue complies with the following tests.

- A. Dissolve 5 mg in 2 mL of [sulfuric acid](#). An orange-red colour is produced.
- B. Dissolve 50 mg in 10 mL of [ethanol](#) (50%), add 10 mL of [picric acid solution R1](#) and allow to stand. The [melting point](#) of the precipitate, after recrystallisation from [ethanol](#) (96%), is about 89° or about 107°, [Appendix V A](#).
- C. Yields reaction A characteristic of *chlorides*, [Appendix VI](#).

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 70 mg of Orphenadrine Hydrochloride as completely as possible in a mixture of 5 mL of [water](#) and 5 mL of [2M hydrochloric acid](#). Without delay extract with four 15 mL quantities of [chloroform](#), filter the combined extracts and evaporate to about 20 mL. Carry out Method I for [non-aqueous titration](#), [Appendix VIII A](#), using [0.02M perchloric acid VS](#), adding 2 mL of *mercury(II) acetate solution* and determining the end point [potentiometrically](#). Each mL of [0.02M perchloric acid VS](#) is equivalent to 6.118 mg of $C_{18}H_{23}NO \cdot HCl$.