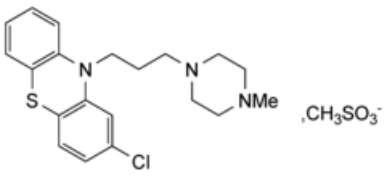
Edition: BP 2025 (Ph. Eur. 11.6 update)

# Prochlorperazine Mesilate

General Notices



$C_{20}H_{24}ClN_3S,2CH_4SO_3$ 566.2 *5132-55-8*

**Action and use**

Dopamine receptor antagonist; neuroleptic.

**Preparations**

Prochlorperazine Injection

Prochlorperazine Oral Solution

## DEFINITION

Prochlorperazine Mesilate is 2-chloro-10-[3-(4-methylpiperazin-1-yl)propyl]phenothiazine di(methanesulfonate). It contains not less than 98.0% and not more than 101.0% of $C_{20}H_{24}ClN_3S,2CH_4SO_3$, calculated with reference to the dried substance.

## PRODUCTION

Risk assessment should be used to evaluate the potential for genotoxic methanesulfonate esters to be formed in the presence of low molecular weight alcohols. If a risk of methanesulfonate ester formation is identified through risk assessment, these impurities should not exceed the threshold of toxicological concern.

## CHARACTERISTICS

A white or almost white powder.

Very soluble in *water*; sparingly soluble in *ethanol (96%)*; practically insoluble in *ether*.

## IDENTIFICATION

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of prochlorperazine mesilate *(RS 290)*.
B. Dissolve 5 mg in 2 mL of *sulfuric acid* and allow to stand for 5 minutes. A red colour is produced.

## TESTS

### Acidity

pH of a 2% w/v solution, 2.0 to 3.0, Appendix V L.

### Related substances

Complies with the test for *related substances in phenothiazines*, Appendix III A, using *mobile phase A* and dissolving the substance being examined in *methanol* containing 0.5% v/v of 13.5M *ammonia*.

### Loss on drying

When dried to constant weight at 100° at a pressure not exceeding 0.7 kPa, loses not more than 1.0% of its weight. Use 1 g.

### Sulfated ash

Not more than 0.1%, Appendix IX A.

## ASSAY

Dissolve 0.8 g in 10 mL of *water*, add 5 mL of 1M *sodium hydroxide* and extract by shaking with successive quantities of 50, 25, 25 and 25 mL of *ether*. Wash the combined ether extracts with 5 mL of *water*, shake the washings with 5 mL of *ether*, add the ether to the combined ether extracts and evaporate to dryness. Add 2 mL of *absolute ethanol* to the residue, evaporate to dryness and carry out Method I for *non-aqueous titration*, Appendix VIII A, using *1-naphtholbenzein solution* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 28.31 mg of $C_{20}H_{24}ClN_3S,2CH_4SO_3$.

## STORAGE

Prochlorperazine Mesilate should be protected from light.