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

Neostigmine Tablets

General Notices

Action and use

Cholinesterase inhibitor.

DEFINITION

Neostigmine Tablets contain Neostigmine Bromide.

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

Content of neostigmine bromide, $C_{12}H_{19}BrN_2O_2$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Triturate a quantity of the powdered tablets containing 60 mg of Neostigmine Bromide with two 5 mL quantities of hot *chloroform* and filter. Evaporate the filtrate to dryness on a water bath, extract the residue with 5 mL of hot *water*, cool and filter. To 0.1 mL of the filtrate add 0.5 mL of 5M *sodium hydroxide* and evaporate to dryness on a water bath. Heat quickly in an oil bath to about 250° and maintain at this temperature for about 30 seconds. Cool, dissolve the residue in 1 mL of *water*, cool in ice and add 1 mL of *diazobenzenesulfonic acid solution*. A cherry-red colour is produced.
B. The aqueous filtrate obtained in text A yields the reactions characteristic *of bromides*, Appendix VI.

ASSAY

Weigh and powder 20 tablets. Transfer a quantity of the powder containing 0.15 g of Neostigmine Bromide to a semi-micro ammonia-distillation apparatus, add 20 mL of a 50% w/v solution of *sodium hydroxide* and 0.5 mL of a 2% solution of *octan-2-ol* in *liquid paraffin*. Pass a current of steam through the mixture, collect the distillate in 50 mL of *0.01M sulfuric acid VS* until the total volume is about 200 mL and titrate the excess of acid with *0.02M sodium hydroxide VS* using *methyl red solution* as indicator. Repeat the operation without the powdered tablets. The difference between the titrations represents the amount of acid required to neutralise the dimethylamine produced. Each mL of *0.01M sulfuric acid VS* is equivalent to 6.064 mg of $C_{12}H_{19}BrN_2O_2$.

STORAGE

Neostigmine Tablets should be protected from light.