Acetylsalicylic acid tablets (Acidi acetylsalicylici compressi)

Category. Analgesic; antipyretic; nonsteroidal antiinflammatory; antimigraine drug.

Storage. Acetylsalicylic acid tablets should be kept in a tightly closed container.

Additional information. Strength in the current WHO Model list of essential medicines: 100-500 mg.

Usually no odour of acetic acid is perceptible on opening the container.

Requirements

Comply with the monograph for "Tablets".

Acetylsalicylic acid tablets contain not less than **95.0%** and not more than **105.0%** of the amount of $C_9H_8O_4$ stated on the label.

Identity tests

A. Place a quantity of the powdered tablets equivalent to 10 mg of Acetylsalicylic acid on a suitable white test plate or on a watch-glass placed on a white background, and add 1 drop of ferric chloride (25 g/l) TS; no violet colour is produced.

B. Place a quantity of the powdered tablets equivalent to 10 mg of Acetylsalicylic acid on a suitable white test plate or a watch-glass placed on a white background, and add 1 drop of potassium hydroxide/ethanol TS1. After 1 minute add 1 drop of ferric chloride (25 g/l) TS; a violet colour is produced.

Salicylic acid. To a quantity of the powdered tablets equivalent to 0.2 g of Acetylsalicylic acid add 4 mL of ethanol (~750 g/l) TS and shake. Dilute to 100 mL with cool water (not exceeding 10 °C) and filter immediately. Transfer 50 mL of the filtrate to a comparison tube, add 1 mL of freshly prepared ferric ammonium sulfate TS1, mix, and allow to stand for 1 minute. Separately and concurrently, place 3 mL of a freshly prepared solution of salicylic acid R containing 0.1 mg per mL into a second comparison tube, add 2 mL of ethanol (~750 g/l) TS, 1 mL of freshly prepared ferric ammonium sulfate TS1, and sufficient water to produce 50 mL.

Any violet colour produced in the first tube is not more intense than that produced in the second tube (0.3%).

Assay. Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 0.5 g of Acetylsalicylic acid, accurately weighed, add 30 mL of carbonate-free sodium hydroxide (0.5 mol/l) VS, and boil gently for 10 minutes. Back-titrate the excess alkali with hydrochloric acid (0.5 mol/l) VS, using phenol red/ethanol TS as indicator. Repeat the procedure without the powdered tablets being examined and make any necessary corrections.

Each mL of carbonate-free sodium hydroxide (0.5 mol/l) VS is equivalent to 45.04 mg of $C_9H_8O_4$.