Primaquine diphosphate tablets (Primaquini diphosphatis compressi)

Category. Antimalarial drug.

Labelling. The designation on the container indicates the quantity of active ingredient in terms of the equivalent amount of primaquine.

Additional information. Strength in the current WHO Model list of essential medicines: 7.5 mg and 15 mg of primaquine base.

The tablets may be coated.

Requirements

Comply with the monograph for "Tablets".

Primaquine diphosphate tablets contain not less than **90.0%** and not more than **110.0%** of the amount of $C_{15}H_{21}N_3O$ stated on the label.

Identity tests

• Either tests A and D or tests B, C, and D may he applied.

A. To a quantity of the powdered tablets equivalent to 60 mg of Primaquine add a mixture of 10 mL of water and 2 mL of sodium hydroxide (~80 g/l) TS, and shake with two 20-mL quantities of chloroform R. Wash the chloroform extracts with water, dry with anhydrous sodium sulfate R, and evaporate to dryness. Dissolve the residue in 2 mL of chloroform R and carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from primaquine diphosphate RS similarly treated or with the *reference spectrum* of primaquine.

B. Shake a quantity of the powdered tablets equivalent to 15 mg of Primaquine with 100 mL of hydrochloric acid (0.01 mol/l) VS and filter. The absorption spectrum of this solution, when observed between 310 nm and 450 nm, exhibits two maxima at about 332 nm and 415 nm. The absorbances of a 1-cm layer at these wavelengths are between 45 and 52, and 27 and 35, respectively. Dilute 5 mL of the solution to 50 mL with hydrochloric acid (0.01 mol/l) VS. The absorption spectrum of this solution, when observed between 215 nm and 310 nm, exhibits three maxima at about 225 nm, 265 nm, and 282 nm. The absorbances of a 1-cm layer at these wavelengths are between 495 and 515, 335 and 350, and 330 and 345, respectively.

C. Shake a quantity of the powdered tablets equivalent to 25 mg of Primaquine with 10 mL of water and filter. To 2 mL of the filtrate add 3 mL of water and 1 mL of ceric ammonium sulfate/nitric acid TS; a deep violet colour is immediately produced. (Keep the remainder of the filtrate for test D.)

D. To the filtrate remaining from test C add 3 mL of nitric acid (~130 g/l) TS; it yields reaction A described under 2.1 General identification tests as characteristic of orthophosphates.

Assay. Weigh and powder 20 tablets. Transfer a quantity of the powder equivalent to about 0.15 g of Primaquine, accurately weighed, to a separatory funnel, add 20 mL of water and 5 mL of sodium hydroxide (~80 g/l) TS, and extract with four 25-mL quantities of chloroform R. Evaporate the combined chloroform extracts to a volume of about 10 mL, add 40 mL of glacial acetic acid R1, and titrate with perchloric acid (0.1 mol/l) VS, determining the end-point potentiometrically as described under 2.6 Non-aqueous titration, Method A.

Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 12.97 mg of $C_{15}H_{21}N_3O$.