Praziquantel tablets (Praziquanteli compressi)

Category. Anthelminthic drug.

Additional information. Strength in the current WHO Model list of essential medicines: 150mg, 600mg.

Requirements

Comply with the monograph for "Tablets".

Praziquantel tablets contain not less than **90.0%** and not more than **110.0%** of the amount of $C_{19}H_{24}N_2O_2$ stated on the label.

Identity tests

• Either test A alone or tests B, C, and D may be applied.

To a quantity of the powdered tablets equivalent to about 0.1g of Praziquantel add 10ml of chloroform R, shake, and filter. Evaporate the filtrate to dryness and dry the residue at 50°C under reduced pressure (not exceeding 0.6kPa or about 5mm of mercury). Use the residue for tests A and D.

A. Carry out the examination with the residue as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from praziquantel RS or with the *reference spectrum* of praziquantel.

B. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

C. The absorption spectrum of the solution obtained in the "Assay", when observed between 230nm and 350nm, exhibits two maxima at about 264 nm and 272nm.

D. Melting temperature of the residue, about 138°C.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R5 as the coating substance and a mixture of 85 volumes of toluene R and 15 volumes of methanol R as the mobile phase. Apply separately to the plate, in a current of nitrogen R, 10 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.25g of Praziquantel with 5ml of chloroform R, filter, and use the filtrate. For solution (B) use 0.05g of praziquantel RS per mL of chloroform R. Then apply 2 µl of each of the following 2 solutions in chloroform R containing (C) 0.5mg of praziquantel RS per mL, and (D) 1.0mg of praziquantel RS per mL. Allow the mobile phase to ascend 7cm. After removing the plate from the chromatographic chamber, allow it to dry in a current of warm air, place in a chamber with iodine vapours, and allow to stand for 20 minutes. Examine the chromatogram immediately in daylight.

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution C, except one spot above the main spot which is not more intense than that obtained with solution D.

Assay. Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 25mg of Praziquantel add 50ml of ethanol (~750g/l) TS, shake, and dilute to volume with the same solvent. Filter and discard the first 5ml of the filtrate. Measure the absorbance of a 1-cm layer at the maximum at about 264nm against a solvent cell containing ethanol (~750g/l) TS. Calculate the percentage content of $C_{19}H_{24}N_2O_2$ by comparison with a solution containing 0.50mg of praziquantel RS per mL of ethanol (~750g/l) TS.