



**Chewable Mebendazole tablets**  
**Draft revision for *The International Pharmacopoeia***  
**(October 2007)**

***DRAFT REVISION FOR DISCUSSION***

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**CHEWABLE MEBENDAZOLE TABLETS**  
**Draft revision for *The International Pharmacopoeia***  
**(October 2007)**

**Mebendazoli compressi .....**

**Chewable Mebendazole tablets**

**Category.** Anthelmintic drug.

**Labelling.** The designation on the container should state that the tablets should be chewed thoroughly before being swallowed.

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

**Requirements**

Comply with the monograph for "[Tablets](#)".

**Definition.** Chewable mebendazole tablets contain Mebendazole in a suitable basis that may contain suitable flavouring agents. Chewable mebendazole tablets contain not less than 90.0% and not more than 110.0% of the amount of  $C_{16}H_{13}N_3O_3$  stated on the label.

**Identity tests**

- A. See the test described below under "Related substances". The principal spot obtained with solution B corresponds in position, appearance, and intensity with that obtained with solution D.
- B. Shake a quantity of the powdered tablets equivalent to 0.04 g of Mebendazole with 2 ml of sodium hydroxide (~80 g/l) TS and heat the yellowish coloured suspension until dissolved; the solution is yellow. Add a few drops of copper (II) sulfate (160 g/l) TS; a greenish precipitate is produced. Add a few drops of ammonia (~100 g/l) TS; the colour of the precipitate turns to greenish blue.

- C. To a quantity of the powdered tablets equivalent to 0.04 g of Mebendazole add 2 ml of sulfuric acid (~1760 g/l) TS; a yellow solution is produced. Carefully dilute with 3 ml of water; the yellow colour disappears. Filter and add 1 ml of silver nitrate (40 g/l) TS; a white precipitate is formed which does not dissolve in an excess of ammonia (~100 g/l) TS.

**Disintegration.** The requirements for disintegration do not apply to Chewable mebendazole tablets.

**Related substances.** Carry out the test as described under [1.14.1 Thin-layer chromatography](#), using silica gel R4 as the coating substance and a mixture of 90 volumes of chloroform R, 5 volumes of methanol R, and 5 volumes of anhydrous formic acid R as the mobile phase. Apply separately to the plate 10 µl of each of the following four solutions. For solution (A) shake a quantity of the powdered tablets equivalent to 50 mg of Mebendazole with a mixture of 1 ml of anhydrous formic acid R and 9 ml of chloroform R, filter, and use the clear filtrate. For solution (B) dilute 5 ml of solution A to 10 ml using the same mixture of solvents, and for solution (C) dilute 0.5 ml of solution A to 10 ml using the same mixture of solvents. For solution (D) dissolve 12.5 mg of mebendazole RS in 5 ml of the same mixture of solvents. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254 nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution C.

**Assay.** Weigh and powder 20 tablets. Transfer a quantity of the powder equivalent to about 0.1 g of Mebendazole, accurately weighed, to a 100-ml volumetric flask with 50 ml of anhydrous formic acid R. Heat in a water-bath at 50 °C for 15 minutes. Cool, add water to volume, mix, and filter through a sintered-glass filter. Transfer 10 ml of the filtrate to a 250-ml separator, add 50 ml of water and 50 ml of chloroform R. Shake for about 2 minutes, allow the phases to separate, and transfer the chloroform layer to a second 250-ml separator. Wash the aqueous layer with two portions, each of 10 ml, of chloroform R, adding the washings to the second separator, and discard the aqueous layer. Wash the combined chloroform extracts with a mixture of 4 ml of hydrochloric acid (0.1

mol/l) VS and 50 ml of a previously diluted solution of 5 ml of anhydrous formic acid R with 45 ml of water. Transfer the chloroform layer to a 100-ml volumetric flask. Extract the aqueous washings with two portions, each of 10 ml, of chloroform R, add these chloroform extracts to the chloroform solution in the volumetric flask, dilute with 2-propanol R to volume, and mix. Further dilute 5 ml of this solution to 100 ml with 2-propanol R, and mix. For the *reference solution* transfer 20 mg of mebendazole RS, accurately weighed, to a 100-ml volumetric flask and add 90 ml of chloroform R, 7 ml of 2-propanol R, and 2 ml of a mixture of 0.2 ml of anhydrous formic acid R and 1.8 ml of water. Shake until the solid has dissolved, add 2-propanol R to volume, and mix. Transfer 5 ml of this solution to a 200-ml volumetric flask, dilute with 2-propanol R to volume, and mix. For the reagent blank mix 45 ml of chloroform R with 1 ml of a mixture of 0.1 ml of anhydrous formic acid R and 0.9 ml of water using a 100-ml volumetric flask, dilute to volume with 2-propanol R, and mix. Transfer 5 ml of this solution to a second 100-ml volumetric flask, dilute to volume with 2-propanol R, and mix.

Without delay measure the absorbance (1.6) of the *sample* and the *reference solutions* in a 1-cm layer at the maximum at about 247 nm against a solvent cell containing the reagent blank. Calculate the amount in mg of  $C_{16}H_{13}N_3O_3$  in the sample being examined using the following formula:  $20C(A_u/A_s)$ , in which  $C$  is the concentration, in mg per ml, of mebendazole RS in the *reference solution*, and  $A_u$  and  $A_s$  are the absorbances for the *sample* and *reference solutions*, respectively.

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