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Experiment 9: Assay of Metronidazole

Metronidazole tablets (Metronidazoli compressi)

**Category.** Anti-amoebic drug; antibacterial drug.

**Additional information.** Strength in the current WHO Model list of essential medicines: 200-500 mg. **Requirements**

Comply with the monograph for "Tablets".

**Definition.** Metronidazole tablets may be film-coated and not necessarily circular in shape.

Metronidazole tablets contain not less than **95.0%** and not more than **105.0%** of the amount of C6H9N3O3 stated on the label. **Identity tests**

To a quantity of the powdered tablets equivalent to 60 mg of Metronidazole add 20 mL of water, shake, and filter. Evaporate the filtrate to a smaller volume, allow to crystallize, separate the crystals, dry at 105 °C for 1 hour, and use the dried material for tests A and B.

1. Dissolve 20 mg of the dried material in 100 mL of a mixture of solvents composed of 1 mL of sulfuric acid (~1760 g/l) TS in 350 mL of methanol R. Further dilute 1 mL of this solution to 10 mL using the same mixture of solvents. The absorption spectrum, when observed between 220 nm and 350 nm, is qualitatively similar to that of a 20 μg/mL solution of metronidazole RS in the same mixture of solvents.
2. To 25 mg of the dried material add 0.05 g of 4-dimethylaminobenzaldehyde R dissolved in 2 mL of hydrochloric acid (~70 g/l) TS; a yellowish colour is produced. Add 0.05 g of zinc R powder; the colour changes to red-orange.

**Assay.** Weigh and powder 20 tablets. Transfer a quantity of the powder, equivalent to about 0.2 g of Metronidazole, accurately weighed, to a sintered-glass filtering crucible, and extract with 6 quantities, each of 10 mL, of hot acetone R. Cool, add to the combined extracts 50 mL of acetic anhydride R and 0.1 mL of brilliant green/acetic acid TS, and titrate with perchloric acid (0.1 mol/l) VS as described under 2.6 Non-aqueous titration, Method A. Repeat the procedure without the powdered tablets being examined and make any necessary corrections. Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 17.12 mg of C6H9N3O3.