

**Colchicine tablets (Colchicini compressi)****Category.** Drug used for the treatment of gout.**Requirements**Comply with the monograph for [Tablets](#).Colchicine tablets contain not less than 90.0% and not more than 110.0% of the amount of  $C_{22}H_{25}NO_6$  stated on the label.**Identity tests**

-Either test A alone or tests B and C may be applied.

A. Triturate a quantity of the powdered tablets equivalent to about 20 mg of Colchicine with 20 mL of water. Allow the solids to settle and filter the supernatant liquid into a separatory funnel. Shake with 30 mL of chloroform R. Evaporate the chloroform layer to dryness using mild heat. 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 colchicine RS or with the *reference spectrum* of colchicine.

B. The absorption spectrum of the solution obtained in the "Assay", when observed between 230 nm and 380 nm, exhibits two maxima at about 243 nm and 350 nm. The ratio of the absorbance at 243 nm to that at 350 nm is between 1.80 and 2.00.

C. Suspend a quantity of the powdered tablets in 1.5 mL of ethanol (~750g/l) TS and filter. Place a few drops of the filtrate on a porcelain dish and evaporate to dryness on a water-bath. Mix the residue with 3 drops of sulfuric acid (~1760g/l) TS; a lemon yellow colour is produced. Add 1 drop of nitric acid (~690g/l) TS; the colour changes to greenish blue, turning rapidly to reddish and finally becoming yellowish. Following this add about 0.5 mL of sodium hydroxide (~200g/l) TS; the colour turns to red.

**Related substances**

Carry out the test as described under [1.14.1 Thin-layer chromatography](#), using a suitable aluminium oxide R as the coating substance, containing a substance that fluoresces at about 254 nm, and a mixture of 125 volumes of chloroform R, 100 volumes of acetone R and 2 volumes of ammonia (~260g/l) TS as the mobile phase. Apply separately to the plate 2 µL of each of the following 2 µL solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 5 mg of Colchicine with 5 mL of chloroform R, filter and evaporate the filtrate to dryness in a current of air. Dissolve the residue as completely as possible in about 0.1 mL of ethanol (~750g/l) TS. Allow to settle and use the supernatant liquid. For solution (B) dilute 1 volume of solution A to 20 volumes with ethanol (~750g/l) TS. 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 B.

**Assay**

The operations described below must be carried out in subdued light.

Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 0.5 mg of Colchicine add 10 mL of dehydrated ethanol R and shake for 30 minutes. Centrifuge, separate and wash the residue with dehydrated ethanol R. Combine the extract and washings and dilute to 50 mL with the same solvent. Measure the absorbance of a 1 cm layer at the maximum at about 350 nm against a solvent cell containing dehydrated ethanol R.

Calculate the percentage content of  $C_{22}H_{25}NO_6$  using the absorptivity value of 42.5 ( $A_{1cm}^{1\%} = 425$ ).

**Uniformity of content**

The operations described below must be carried out in subdued light.

Place 1 tablet in a centrifuge tube and add 10 mL of dehydrated ethanol R. Crush the tablet to a fine powder, shake for 30 minutes, centrifuge and wash the residue with dehydrated ethanol R. Combine the extract and washings and dilute to produce a solution of 0.01 mg/mL of dehydrated ethanol R. Measure the absorbance of a 1 cm layer at the maximum at about 350 nm against a solvent cell containing dehydrated ethanol R.

Calculate the tablet content of  $C_{22}H_{25}NO_6$  in mg using the absorptivity value of 42.5 ( $A_{1cm}^{1\%} = 425$ ). The tablets comply with the test for [5.1 Uniformity of content for single-dose preparations](#).