

mol/L perchloric acid VS until the color of the solution changes from purple through blue to blue-green (indicator: 2 to 3 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 21.122 mg of C₁₀H₁₃NO₄

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Methyldopa Tablets

メチルドパ錠

Methyldopa Tablets contain not less than 90% and not more than 110% of the labeled amount of methyldopa (C₁₀H₁₃NO₄; 211.21).

Method of preparation Prepare as directed under Tablets, with Methyldopa.

Identification (1) To a quantity of powdered Methyldopa Tablets, equivalent to 0.1 g of Methyldopa according to the labeled amount, add 10 mL of water, and heat in a water bath for 5 minutes with occasional shaking. After cooling, centrifuge for 5 minutes at 2000 rotations per minute, apply 1 drop of the supernatant solution to a filter paper, and dry with warm air. Place 1 drop of ninhydrin TS over the spot, and heat for 5 minutes at 100°C: a purple color develops.

(2) To 0.5 mL of the supernatant liquid obtained in the Identification (1) add 2 mL of 0.05 mol/L sulfuric acid TS, 2 mL of iron (II) tartrate TS and 4 drops of ammonia TS, and shake well: a deep purple color develops.

(3) To 0.7 mL of the supernatant liquid obtained in the Identification (1) add 0.1 mol/L hydrochloric acid TS to make 20 mL. To 10 mL of this solution add 0.1 mol/L hydrochloric acid TS to make 100 mL, and determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 277 nm and 283 nm.

Dissolution test Perform the test with 1 tablet of Methyldopa Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of water as the test solution. Take 30 mL or more of the dissolved solution 60 minutes after start of the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, pipet the subsequent *V* mL, add water to make exactly *V'* mL so that each mL contains about 25 μg of methyldopa (C₁₀H₁₃NO₄) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 0.056 g of methyldopa for assay (its loss on drying is determined, separately, at 125°C for 2 hours), and dissolve in water to make exactly 200 mL. Pipet 10 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, *A_T* and *A_S*, of the sample solution and the standard solution at 280 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Methyldopa Tablets in 60 minutes is not less than 75%.

Dissolution rate (%) with respect to the labeled amount of methyldopa (C₁₀H₁₃NO₄)

$$= W_S \times \frac{A'}{A_S} \times \frac{V'}{V} \times \frac{1}{C} \times 45$$

W_S: Amount (mg) of methyldopa for assay, calculated on the dried basis.

C: Labeled amount (mg) of methyldopa (C₁₀H₁₃NO₄) in 1 tablet.

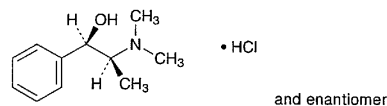
Assay Weigh accurately and powder not less than 20 Methyldopa Tablets. Weigh accurately a portion of the powder, equivalent to about 0.1 g of methyldopa (C₁₀H₁₃NO₄), add 50 mL of 0.05 mol/L sulfuric acid TS, shake thoroughly for 15 minutes, add 0.05 mol/L sulfuric acid TS to make exactly 100 mL, and filter through a dry filter paper. Discard the first 20 mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 0.11 g of Methyldopa Reference Standard (previously dry at 125°C for 2 hours, and determine the loss on drying), dissolve in 0.05 mol/L sulfuric acid TS to make exactly 100 mL, and use this solution as the standard solution. Pipet 5 mL each of the sample solution and the standard solution, add exactly 5 mL of iron (II) tartrate TS, and add ammonia-ammonium acetate buffer solution, pH 8.5, to make exactly 100 mL. Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution prepared with 5 mL of 0.05 mol/L sulfuric acid TS in the same manner, as the blank. Determine the absorbances, *A_T* and *A_S*, of the subsequent solutions of the sample solution and the standard solution at 520 nm, respectively.

$$\begin{aligned} &\text{Amount (mg) of methyldopa (C}_{10}\text{H}_{13}\text{NO}_4) \\ &= \text{amount (mg) of Methyldopa Reference Standard,} \\ &\quad \text{calculated on the dried basis} \\ &\quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Well-closed containers.

dl-Methylephedrine Hydrochloride

dl-塩酸メチルエフェドリン



C₁₁H₁₇NO·HCl: 215.72
(1*RS*,2*SR*)-2-Dimethylamino-1-phenylpropan-1-ol
monohydrochloride [18760-80-0]

dl-Methylephedrine Hydrochloride, when dried, contains not less than 99.0% of C₁₁H₁₇NO·HCl.

Description *dl*-Methylephedrine Hydrochloride occurs as colorless crystals or a white, crystalline powder. It is odorless, and has a bitter taste.

It is freely soluble in water, soluble in ethanol (95), slightly soluble in acetic acid (100), and practically insoluble in acetic anhydride and in diethyl ether.