Perphenazine Maleate Tablets

マレイン酸ペルフェナジン錠

Perphenazine Maleate Tablets contain not less than 93% and not more than 107% of the labeled amount of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$: 636.11).

Method of preparation Prepare as directed under Tablets, with Perphenazine Maleate.

Identification (1) Shake a quantity of powdered Perphenazine Maleate Tablets, equivalent to 0.04 g of Perphenazine Maleate according to the labeled amount, with 3 mL of dilute hydrochloric acid and 30 mL of water, centrifuge, filter the supernatant solution, add 3 mL of ammonia solution (28) to the filtrate, and extract with three 10-mL portions of chloroform. [Reserve the aqueous layer, and use for test (4).] Wash the combined chloroform extracts with two 5-mL portions of water, and separate the chloroform layer. Evaporate 6 mL of the chloroform solution on a water bath to dryness. Proceed with the residue as directed in the Identification (1) under Perphenazine Maleate.

(2) Evaporate 20 mL of the chloroform solution obtained in (1) on a water bath to dryness, dissolve the residue in 20 mL of methanol, and filter, if necessary. Warm the filtrate, add 5 mL of a warm solution of 2,4,6-trinitrophenol in methanol (1 in 25), allow to stand for 4 hours, and proceed as directed in the Identification (2) under Perphenazine Maleate.

(3) To 2 mL of the filtrate obtained in the Assay add water to make 50 mL. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 253 nm and 257 nm and between 303 nm and 313 nm.

(4) Filter, if necessary, the aqueous layer reserved in (1), evaporate the filtrate to make about 5 mL, add 2 mL of dilute sulfuric acid, and extract with two 10-mL portions of diethyl ether. Combine the diethyl ether extracts, evaporate on a water bath to dryness, dissolve the residue in 5 mL of sulfuric acid TS, and add 1 to 2 drops of potassium permanganate TS: the red color of potassium permanganate TS fades immediately.

Content uniformity Disintegrate 1 tablet of Perphenazine Maleate Tablets by shaking with 15 mL of 0.1 mol/L hydrochloric acid TS, shake vigorously with 50 mL of methanol, add water to make exactly 100 mL, and centrifuge. Pipet x mL of the supernatant liquid, add water to make exactly V mL of a solution containing about 6 μg of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$) in each ml, and use this solution as the sample solution. Separately, weigh accurately 0.03 g of perphenazine maleate for assay, previously dried at 105°C for 3 hours, dissolve in 15 mL of 0.1 mol/L hydrochloric acid TS and 50 mL of methanol, and add water to make exactly 100 mL. Pipet 5 mL of this solution, add 3 mL of 0.1 mol/L hydrochloric acid TS, 10 mL of methanol and water to make exactly 250 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 255 nm as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank.

Amount (mg) of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$)
= amount (mg) of perphenazine maleate for assay $\times \frac{A_T}{A_S} \times \frac{V}{50} \times \frac{1}{x}$

Assay Weigh accurately and powder not less than 20 Perphenazine Maleate Tablets. Weigh accurately a portion of the powder, equivalent to about 0.04 g of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$), shake well with 15 mL of 1 mol/L hydrochloric acid TS and 50 mL of methanol, add water to make exactly 100 mL, and filter. Discard the first 20 mL of the filtrate, measure exactly 5 mL of the subsequent filtrate, add water to make exactly 250 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.04 g of perphenazine maleate for assay, previously dried at 105°C for 3 hours, dissolve in a mixture of 15 mL of 1 mol/L hydrochloric acid TS and 50 mL of methanol, and add water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 250 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 255 nm as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank.

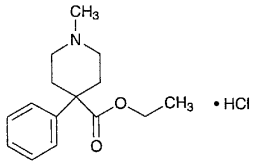
Amount (mg) of perphenazine maleate ($C_{21}H_{26}ClN_3OS.2C_4H_4O_4$)
= amount (mg) of perphenazine maleate for assay $\times \frac{A_T}{A_S}$

Containers and storage Containers—Tight containers. Storage—Light-resistant.

Pethidine Hydrochloride

Operidine

塩酸ペチジン



$C_{15}H_{21}NO_2.HCl$: 283.79
Ethyl 1-methyl-4-phenylpiperidine-4-carboxylate monohydrochloride [*50-13-5*]

Pethidine Hydrochloride, when dried, contains not less than 98.0% of $C_{15}H_{21}NO_2.HCl$.

Description Pethidine Hydrochloride occurs as a white, crystalline powder.

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

The pH of a solution dissolved 1.0 g of Pethidine Hydrochloride in 20 mL of water is between 3.8 and 5.8.

Identification (1) Determine the absorption spectrum of a solution of Pethidine Hydrochloride (1 in 2000) as direct-