

$$\begin{aligned} & \text{Amount (mg) of } C_{19}H_{17}NOS \\ &= \text{amount (mg) of Tolnaftate Reference Standard} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.

Tolnaftate Solution

トルナフトート液

Tolnaftate Solution contains not less than 90% and not more than 110% of the labeled amount of tolinaftate ($C_{19}H_{17}NOS$: 307.41).

Method of preparation Prepare as directed under Liquids and Solutions, with Tolnaftate.

Identification (1) Spot 1 drop of Tolnaftate Solution on filter paper. Spray hydrogen hexachloroplatinate (IV)-potassium iodide TS on the paper: a light yellow color develops in the spot.

(2) To a volume of Tolnaftate Solution, equivalent to 0.02 g of Tolnaftate according to the labeled amount, add chloroform to make 10 mL, and use this solution as the sample solution. Separately, dissolve 0.02 g of Tolnaftate Reference Standard in 10 mL of chloroform, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with toluene to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spot from the sample solution and that from the standard solution show the same R_f value.

Assay Pipet a volume of Tolnaftate Solution, equivalent to about 0.02 g of tolinaftate ($C_{19}H_{17}NOS$), add exactly 4 mL of the internal standard solution, then add chloroform to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.4 g of Tolnaftate Reference Standard, previously dried in vacuum at a pressure not exceeding 0.67 kPa at 65°C for 3 hours, and dissolve in chloroform to make exactly 100 mL. Pipet 5 mL of this solution, add exactly 4 mL of the internal standard solution, then add chloroform to make 50 mL, and use this solution as the standard solution. Perform the test with 10 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S , of the peak area of tolinaftate to that of the internal standard, respectively.

$$\begin{aligned} & \text{Amount (mg) of tolinaftate } (C_{19}H_{17}NOS) \\ &= \text{amount (mg) of Tolnaftate Reference Standard} \\ & \quad \times \frac{Q_T}{Q_S} \times \frac{1}{20} \end{aligned}$$

Internal standard solution—A solution of diphenyl phthalate in chloroform (3 in 200).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and 15 to 30 cm in length, packed with octadecylsilylated silica gel for liquid chromatography (5 to 10 μ m in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: A mixture of methanol and water (7:3).

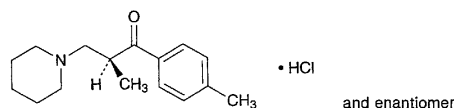
Flow rate: Adjust the flow rate so that the retention time of tolinaftate is about 14 minutes.

Selection of column: Proceed with 10 μ L of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of the internal standard and tolinaftate in this order with the resolution between these peaks being not less than 5.

Containers and storage Containers—Tight containers.

Tolperisone Hydrochloride

塩酸トルペリゾン



$C_{16}H_{23}NO \cdot HCl$: 281.82
(*RS*)-2-Methyl-1-(4-methylphenyl)-3-piperidin-1-ylpropan-1-one monohydrochloride [3644-61-9]

Tolperisone Hydrochloride, when dried, contains not less than 98.5% of $C_{16}H_{23}NO \cdot HCl$.

Description Tolperisone Hydrochloride occurs as a white, crystalline powder. It has a slight, characteristic odor.

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

It is hygroscopic.

The pH of a solution of Tolperisone Hydrochloride (1 in 20) is between 4.5 and 5.5.

Melting point: 167 – 174°C

Identification (1) Dissolve 0.2 g of Tolperisone Hydrochloride in 2 mL of ethanol (95), add 2 mL of 1,3-dinitrobenzene TS and 2 mL of sodium hydroxide TS, and heat: a red color develops.

(2) To 5 mL of a solution of Tolperisone Hydrochloride (1 in 20) add 2 to 3 drops of iodine TS: a red-brown precipitate is produced.

(3) Dissolve 0.5 g of Tolperisone Hydrochloride in 5 mL of water, add 2 mL of ammonia TS, and filter. Acidify 5 mL of the filtrate with dilute nitric acid: the solution responds to the Qualitative tests for chloride.

Absorbance $E_{1\text{cm}}^{1\%}$ (257 nm): 555 – 585 (after drying, 5 mg, ethanol (95), 500 mL).

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Tolperisone Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Sulfate—Perform the test using 4.0 g of Tolperisone