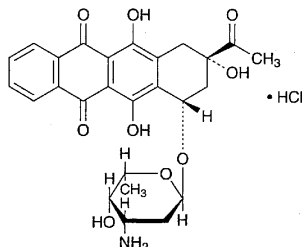


## Idarubicin Hydrochloride

塩酸イダルビシン



$C_{26}H_{27}NO_9 \cdot HCl$ : 533.95  
 (2*S*,4*S*)-2-Acetyl-4-(3-amino-2,3,6-trideoxy- $\alpha$ -*L*-lyxo-hexopyranosyloxy)-1,2,3,4-tetrahydro-2,5,12-trihydroxynaphthacene-6,11-dione monohydrochloride  
 [57852-57-0]

Idarubicin Hydrochloride contains not less than 960  $\mu$ g (potency) per mg, calculated on the anhydrous basis. The potency of Idarubicin Hydrochloride is expressed as mass (potency) of idarubicin hydrochloride ( $C_{26}H_{27}NO_9 \cdot HCl$ ).

**Description** Idarubicin Hydrochloride occurs as a yellow-red powder.

It is sparingly soluble in methanol, and slightly soluble in water and in ethanol (95).

**Identification (1)** Determine the absorption spectra of solutions of Idarubicin Hydrochloride and Idarubicin Hydrochloride Reference Standard in methanol (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare these spectra: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectra of Idarubicin Hydrochloride and Idarubicin Hydrochloride Reference Standard as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare these spectra: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Dissolve 2 mg of Idarubicin Hydrochloride in 3 mL of water, and add 1 mL of dilute nitric acid and 3 drops of silver nitrate TS: a white turbidity is produced.

**Absorbance**  $E_{1\text{ cm}}^{1\%}$  (482 nm): 204 – 210 (0.02 g calculated on the anhydrous basis, methanol, 1000 mL).

**Optical rotation**  $[\alpha]_D^{20}$ : +191 – +197° (0.02 g calculated on the anhydrous basis, methanol, 20 mL, 100 mm).

**pH** The pH of a solution of Idarubicin Hydrochloride (1 in 200) is between 5.0 and 6.5.

**Purity (1)** Clarity and color of solution—Being specified separately.

- (2) Heavy metals—Being specified separately.
- (3) Related substances—Being specified separately.
- (4) Residual solvent—Being specified separately.

**Water** Not more than 5.0% (0.5 g, volumetric titration, direct titration).

**Residue on ignition** Being specified separately.

**Bacterial endotoxins** Less than 8.9 EU/mg (potency).

**Assay** Weigh accurately an amount of Idarubicin Hydrochloride and Idarubicin Hydrochloride Reference Standard, equivalent to about 0.01 g (potency), dissolve each in the mobile phase containing no sodium lauryl sulfate to make exactly 50 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with exactly 20  $\mu$ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine peak areas,  $A_T$  and  $A_S$ , of idarubicin of these solutions.

Amount [ $\mu$ g (potency)] of  $C_{26}H_{27}NO_9 \cdot HCl$   
 = amount [mg (potency)] of Idarubicin Hydrochloride  
 Reference Standard  $\times \frac{A_T}{A_S} \times 1000$

**Operating conditions—**

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

**Column:** A stainless steel column 3.9 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (4  $\mu$ m in particle diameter).

**Column temperature:** A constant temperature of about 35°C.

**Mobile phase:** Dissolve 10.2 g of potassium dihydrogenphosphate in a suitable amount of water, add 1 mL of phosphoric acid and water to make 750 mL, and add 250 mL of tetrahydrofuran. To 500 mL of this solution add 0.72 g of sodium lauryl sulfate and 0.5 mL of *N,N*-dimethyl-*n*-octylamine, and adjust to pH 4 with 2 mol/L sodium hydroxide TS.

**Flow rate:** Adjust the flow rate so that the retention time of idarubicin is about 15 minutes.

**System suitability—**

**System performance:** When the procedure is run with 20  $\mu$ L of the standard solution under the above operating conditions, the number of theoretical steps of the peak of idarubicin is not less than 3000 steps.

**System repeatability:** When the test is repeated 6 times with 20  $\mu$ L of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of idarubicin is not more than 2.0%.

**Containers and storage** Containers—Tight containers.

## Idoxuridine

イドクスウリジン

