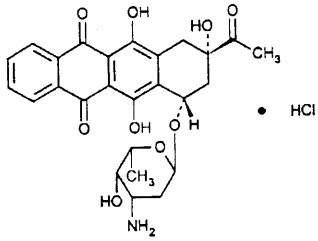
Idarubicin Hydrochloride



$C_{26}H_{27}NO_9$ HCl 533.95
5,12-Naphthacenedione, 9-acetyl-7-[(3-amino-2,3,6-trideoxy-α- L- *lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,9,11-trihydroxyhydrochloride, (7 *S-cis*)-.
(1*S*,3 *S*)-3-Acetyl-1,2,3,4,6,11-hexahydro-3,5,12-trihydroxy-6,11-dioxo-1-naphthacenyl 3-amino-2,3,6-trideoxy-α- L- *lyxo*-hexopyranoside, hydrochloride [*57852-57-0*].

» Idarubicin Hydrochloride contains not less than 960 µg and not more than 1030 µg of $C_{26}H_{27}NO_9$ HCl per mg, calculated on the anhydrous basis.
Caution— *Great care should be taken to prevent inhaling particles of Idarubicin Hydrochloride and exposing the skin to it.*

Packaging and storage— Preserve in tight containers.

USP Reference standards <11> — *USP Idarubicin Hydrochloride RS* .

Identification—

A: *Infrared Absorption* ⟨ 197K ⟩ .

B: The chromatogram of the *Assay preparation* obtained in the *Assay* exhibits a major peak for idarubicin, the retention time of which corresponds to that in the chromatogram of the *Standard preparation* obtained in the *Assay*.

Crystallinity ⟨ 695 ⟩ : meets the requirements.

pH ⟨ 791 ⟩ : between 5.0 and 6.5, in a solution containing 5 mg per mL.

Water, *Method I* ⟨ 921 ⟩ : not more than 5.0%.

Chromatographic purity— Using the chromatogram of the *Assay preparation* obtained in the *Assay*, and disregarding the solvent peak, calculate the percentage of each impurity taken by the formula:

$$100r_i / r_S,$$

in which r_i is the response of each impurity peak, and r_S is the sum of the responses of all the peaks: not more than 1.0% of any individual impurity is found, and the sum of all impurities is not more than 3.0%.

Assay—

Mobile phase— Prepare a mixture of water, acetonitrile, methanol, and phosphoric acid (540:290:170:2). Dissolve 1 g of sodium lauryl sulfate in 1000 mL of this solution, adjust with 2 N sodium hydroxide to a pH