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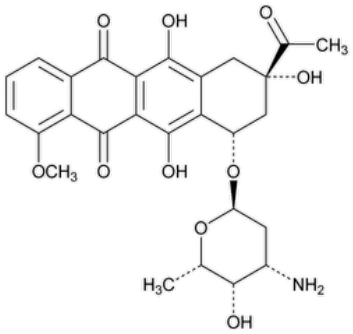
Daunorubicin Hydrochloride



• HCl

$C_{27}H_{29}NO_{10} \cdot HCl$ 563.98

5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8*S*-*cis*)-, hydrochloride.

(1*S*,3*S*)-3-Acetyl-1,2,3,4,6,11-hexahydro-3,5,12-trihydroxy-10-methoxy-6,11-dioxo-1-naphthacenyl 3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranoside hydrochloride CAS RN®: 23541-50-6; UNII: UD984I04LZ.

» Daunorubicin Hydrochloride has a potency equivalent to not less than 842 µg and not more than 1030 µg of $C_{27}H_{29}NO_{10}$ per mg.

[**Caution—**Great care should be taken to prevent inhaling particles of Daunorubicin Hydrochloride and exposing the skin to it.]

Packaging and storage—Preserve in tight containers, protected from light and excessive heat.

USP Reference Standards ⟨11⟩—
USP Daunorubicin Hydrochloride RS

Identification—

A: The IR absorption spectrum of a potassium bromide dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Daunorubicin Hydrochloride RS.

B: The retention time of the main peak obtained with the *Assay preparation* corresponds to that obtained with the *Standard preparation* as directed in the *Assay*.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 4.5 and 6.5, in a solution containing 5 mg per mL.

Water Determination, *Method I* ⟨921⟩: not more than 3.0%.

Assay—

Mobile phase—Mix 62 volumes of water and 38 volumes of acetonitrile, and adjust with phosphoric acid to a pH of 2.2 ± 0.2. The acetonitrile concentration may be varied to meet system suitability requirements and to provide a suitable elution time for daunorubicin. Filter the solution through a membrane filter (1 µm or finer porosity), and degas.

Standard preparation—Dissolve an accurately weighed quantity of USP Daunorubicin Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 250 µg of daunorubicin per mL.

Resolution solution—Prepare a solution of doxorubicin hydrochloride in the *Standard preparation* containing about 250 µg per mL.

Assay preparation—Transfer about 25 mg of Daunorubicin Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The chromatograph is equipped with a 254-nm detector and a 4.6-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.7 for doxorubicin and 1.0 for daunorubicin; and the resolution, *R,* between the doxorubicin peak and the daunorubicin peak is not less than 3. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the potency, in µg of $C_{27}H_{29}NO_{10}$ per mg, taken by the formula:

$$100(C/W)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of daunorubicin in the *Standard preparation; W* is the weight, in mg, of Daunorubicin Hydrochloride taken; and r_U and r_S are the daunorubicin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DAUNORUBICIN HYDROCHLORIDE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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