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Daunorubicin Hydrochloride for Injection

» Daunorubicin Hydrochloride for Injection is a sterile mixture of Daunorubicin Hydrochloride and Mannitol. It contains the equivalent of not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{27}H_{29}NO_{10}$.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*; protect from light.

USP Reference standards ⟨11⟩—
USP Daunorubicin Hydrochloride RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Identification—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*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 4.3 USP Endotoxin Units per mg of daunorubicin.

pH ⟨791⟩: between 4.5 and 6.5, in the solution constituted as directed in the labeling.

Water Determination, *Method I* ⟨921⟩: not more than 3.0%, the *Test Preparation* being prepared as directed for a hygroscopic specimen.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Daunorubicin Hydrochloride*.

Assay preparation—Transfer the contents of 1 vial of Daunorubicin Hydrochloride for Injection with the aid of *Mobile phase* to an appropriate volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution containing about 0.25 mg of daunorubicin per mL.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Daunorubicin Hydrochloride*. Calculate the quantity, in mg, of $C_{27}H_{29}NO_{10}$ in the vial of Daunorubicin Hydrochloride for Injection taken by the formula:

$$(CV/1000)(r_U/r_S)$$

in which V is the volume, in mL, of the *Assay preparation*, and the other terms are as defined therein.

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

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

Chromatographic Database Information: Chromatographic Database

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