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Idarubicin Hydrochloride for Injection

» Idarubicin Hydrochloride for Injection is a sterile mixture of Idarubicin Hydrochloride and Lactose. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{26}H_{27}NO_9 \cdot HCl$.

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

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

USP Reference standards ⟨11⟩—
USP Idarubicin 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 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*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 8.9 USP Endotoxin Units per mg of idarubicin hydrochloride, a solution of Idarubicin Hydrochloride for Injection containing 0.07 mg of idarubicin hydrochloride per mL being used in the *Test Procedure*.

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 5.0 and 7.0, in a solution constituted as directed in the labeling, water being used as the diluent.

Water Determination, *Method I* ⟨921⟩: not more than 4.0%, the *Test Preparation* being prepared as directed for a hygroscopic specimen.

Other requirements—It meets the requirements for *Uniformity of Dosage Units ⟨905⟩* and for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

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

Assay preparation—Dilute the contents of 1 container of Idarubicin Hydrochloride for Injection quantitatively with *Diluent* to obtain a solution containing about 0.5 mg of idarubicin hydrochloride per mL.

Procedure—Proceed as directed for *Procedure* under *Idarubicin Hydrochloride*. Calculate the quantity, in mg, of $C_{26}H_{27}NO_9 \cdot HCl$ in the container of Idarubicin Hydrochloride for Injection taken by the formula:

$$(C/1000)(L/D)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of idarubicin hydrochloride ($C_{26}H_{27}NO_9 \cdot HCl$) in the *Standard preparation; L* is the labeled quantity, in mg, of idarubicin hydrochloride in the container; D is the concentration, in mg per mL, of idarubicin hydrochloride in the *Assay preparation* on the basis of the labeled quantity in the container and the extent of dilution; and r_U and r_S are the responses of the idarubicin peak 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
IDARUBICIN HYDROCHLORIDE FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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