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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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