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Rifampin for Injection

» Rifampin for Injection contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of rifampin ($C_{43}H_{58}N_4O_{12}$).

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

USP Reference standards ⟨11⟩—

USP Rifampin RS
USP Rifampin Quinone RS

Identification—

A: It responds to *Identification* test *A* under *Rifampin Capsules*, the test solution being prepared by dissolving the contents of a container in chloroform to obtain a solution containing about 10 mg of rifampin per mL.

B: The retention time of the rifampin peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —Dissolve Rifampin for Injection in endotoxin-free water to obtain a stock solution containing 10 mg of rifampin per mL. Dilute the stock solution quantitatively, and stepwise if necessary, with endotoxin-free water to obtain a solution containing 0.12 mg of rifampin per mL: it contains not more than 0.5 USP Endotoxin Unit per mg of rifampin.

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 7.8 and 8.8, in a solution containing 60 mg of rifampin per mL.

Water Determination, *Method I* ⟨921⟩: not more than 1.0%.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Assay—

Phosphate buffer, Mobile phase, *Solvent mixture*, *Standard preparation*, *Resolution solution*, and *Chromatographic system*—Prepare as directed in the *Assay* under *Rifampin.*

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute a container of Rifampin for Injection in a volume of water, accurately measured, corresponding to the volume of diluent specified in the labeling. [Note—Use this solution within 2 hours.] Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and transfer to a suitable volumetric flask of such capacity that when diluted with acetonitrile to volume, a solution is obtained containing about 6 mg of rifampin ($C_{43}H_{58}N_4O_{12}$) per mL. [Note—Use this stock solution within 5 hours.] Dilute an accurately measured volume of this stock solution quantitatively and stepwise with *Solvent mixture* to obtain a solution having a concentration of about 0.02 mg of rifampin per mL. [Note—Prepare this final dilution immediately prior to injection into the chromatograph.]

Assay preparation 2 (where the label states the quantity of rifampin in a given volume of constituted solution)—Constitute a container of Rifampin for Injection in a volume of water, accurately measured, equivalent to the volume of diluent specified in the labeling. [Note—Use this solution within 2 hours.] Dilute an accurately measured volume of the constituted solution quantitatively and stepwise with acetonitrile to obtain a solution having a concentration of about 0.2 mg of rifampin ($C_{43}H_{58}N_4O_{12}$) per mL. [Note—Use this stock solution within 5 hours.] Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with *Solvent mixture* to volume, and mix. [Note—Prepare this final dilution immediately prior to the injection into the chromatogram.]

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Rifampin.* Calculate the quantity, in mg, of rifampin ($C_{43}H_{58}N_4O_{12}$) withdrawn from the container of constituted Rifampin for Injection, or in the volume of constituted Rifampin for Injection taken by the formula:

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

in which L is the labeled quantity, in mg, of rifampin in the container, or in the volume of constituted solution taken, D is the concentration, in mg per mL, of rifampin in *Assay preparation 1* or in *Assay preparation 2*, on the basis of the labeled quantity in the container, or in the volume of constituted solution taken, and the extent of dilution, C is the concentration, in mg per mL, calculated on the dried basis, of USP Rifampin RS in the *Standard preparation,* and r_U and r_S are the rifampin peak responses obtained from *Assay preparation 1*, or *Assay preparation 2*, and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
RIFAMPIN 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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