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# Ifosfamide for Injection

» Ifosfamide for Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_7H_{15}Cl_2N_2O_2P$.

*Caution—Great care should be taken in handling Ifosfamide, as it is a potent cytotoxic agent and suspected carcinogen.*

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

**USP Reference standards ⟨11⟩**—
USP Ifosfamide 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**—

**A:** (See *Thin-layer Chromatographic Identification Tests ⟨201⟩*.)

*Developing solvent*—Prepare a mixture of isopropyl alcohol and toluene (1:1).

*Standard solution*—Dissolve 20.0 mg of USP Ifosfamide RS in 1.0 mL of alcohol.

*Test solution*—Dissolve 20 mg of Ifosfamide for Injection in 1.0 mL of alcohol.

*Procedure*—Apply separately 10 µL each of the *Standard solution* and the *Test solution* to a thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture, allow the spots to dry, and develop the plate in a paper-lined chromatographic chamber equilibrated with *Developing solvent* for about 15 minutes prior to use. Allow the chromatogram to develop until the solvent front has moved about 15 cm. Remove the plate, mark the solvent front, and air-dry for 5 minutes. Place the plates into a chromatographic chamber containing iodine crystals, and view the spots that develop. [Note—For better detection, overspray the iodine stain with a mixture of alcohol and water (1:1).] The $R_F$ value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution*.

**B:** The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation,* both relative to the internal standard, as obtained in the *Assay*.

**Bacterial Endotoxins Test ⟨85⟩**—It contains not more than 0.125 USP Endotoxin Unit per mg.

**pH ⟨791⟩**: between 4.0 and 7.0 in a solution prepared as directed for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*, determined 30 minutes after its preparation.

**Water Determination, *Method I* ⟨921⟩**: not more than 0.3%.

**Other requirements**—It meets the requirements for *Sterility Tests ⟨71⟩*, *Uniformity of Dosage Units ⟨905⟩*, and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

**Assay**—

*Mobile phase, Internal standard solution, Standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay* under *Ifosfamide*.

*Assay preparation*—Select an accurately counted number of containers of Ifosfamide for Injection, the combined contents of which are equivalent to about 6 g of Ifosfamide. Dissolve the contents of each container in water and combine all of the solutions in a 1000-mL volumetric flask. Rinse each container with water, and add the rinsings to the volumetric flask. Dilute with water to volume, and mix. Transfer 10.0 mL of the resulting solution to a 100-mL volumetric flask, add 4.0 mL of *Internal standard solution*, dilute with water to volume, and mix.

*Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Ifosfamide*. Calculate the quantity, in g, of $C_7H_{15}Cl_2N_2O_2P$ in each container of Ifosfamide for Injection taken by the formula:

$$10(C/N)(R_U/R_S)$$

in which $C$ is the concentration, in mg per mL, of USP Ifosfamide RS in the *Standard preparation; N* is the number of containers selected for the *Assay preparation,* and $R_U$ and $R_S$ are the ratios of the responses of the ifosfamide peak to the ethylparaben 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 |
|---|---|---|
| IFOSFAMIDE FOR INJECTION | Documentary Standards Support | SM32020 Small Molecules 3 |

**Chromatographic Database Information:** Chromatographic Database

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