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Glycine Irrigation

» Glycine Irrigation is a sterile solution of Glycine in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of glycine ($C_2H_5NO_2$).

Packaging and storage—Preserve in single-dose containers, preferably of Type I or Type II glass.

USP Reference standards ⟨11⟩—

USP Glycine RS

Identification—Evaporate a portion of Irrigation to dryness, and obtain the IR absorption spectrum of a mineral oil dispersion of the residue: it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Glycine RS.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.5 Endotoxin Unit per mL.

pH ⟨791⟩: between 4.5 and 6.5, determined potentiometrically on a portion to which 0.3 mL of saturated potassium chloride has been added for each 100 mL.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, except that the container in which the solution is packaged may be designed to empty rapidly and may exceed 1000 mL in capacity.

Assay—Dilute an accurately measured volume of Irrigation, equivalent to about 150 mg of glycine, with water to 25 mL, and add 10 mL of formaldehyde TS, previously adjusted to a pH of 9.0, and 5 drops of mixed indicator solution (prepared by dissolving 75 mg of phenolphthalein and 25 mg of thymol blue in a mixture of equal volumes of alcohol and water to make 100 mL). Titrate with 0.1 N sodium hydroxide VS until the yellow color disappears and a faint violet color appears. Each mL of 0.1 N sodium hydroxide is equivalent to 7.507 mg of glycine ($C_2H_5NO_2$).

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

Topic/Question	Contact	Expert Committee
GLYCINE IRRIGATION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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