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Niacinamide Injection

» Niacinamide Injection is a sterile solution of Niacinamide in Water for Injection. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_6N_2O$.

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

USP Reference standards ⟨11⟩—

USP Niacinamide RS

Identification—Dilute a quantity of the Injection, equivalent to about 200 mg of niacinamide, with water to about 10 mL. Add 1 mL of 2.5 N sodium hydroxide, evaporate on a steam bath to dryness, add 5 mL of water, and similarly evaporate to about 1 mL: during the initial evaporation, the odor of ammonia is perceptible. Neutralize to litmus paper with 3 N hydrochloric acid, add 1 mL of the acid in excess, and place the solution in a refrigerator for 2 hours. Then filter, wash the precipitated niacin with small portions of ice-cold water until free from chloride, and dry at 105° for 1 hour: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Niacinamide RS.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 3.5 USP Endotoxin Units per mg of niacinamide.

pH ⟨791⟩: between 5.0 and 7.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—Proceed with Injection as directed for under *Niacin or Niacinamide Assay ⟨441⟩, Chemical Method*, using *Standard Niacinamide Preparation* as the *Standard Preparation* in the *Assay Procedure*, and the following as the *Assay Preparation.* Dilute an accurately measured volume of Injection, equivalent to about 50 mg of niacinamide, with water to 500 mL in a volumetric flask, and mix. Pipet 10 mL of the solution into a 100-mL volumetric flask, dilute with water to volume, and mix. Calculate the quantity, in mg, of $C_6H_6N_2O$ in each mL of the Injection taken by the formula:

$$(50/V)(A_U/A_S)$$

in which V is the volume, in mL, of Injection taken.

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

Topic/Question	Contact	Expert Committee
NIACINAMIDE INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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