Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-3E24EF19-DAB0-4499-A2EA-8BDE9A09B612_3_en-US
DOI: https://doi.org/10.31003/USPNF_M56520_03_01
DOI Ref: g8f50

Niacin Injection

» Niacin Injection is a sterile solution of Niacin and niacin sodium in Water for Injection, made with the aid of Sodium Carbonate or Sodium Hydroxide. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_5NO_2$.

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

USP Reference standards ⟨11⟩—

USP Niacin RS

Identification—To a volume of Injection, equivalent to about 100 mg of niacin, add 0.3 mL of 3 N hydrochloric acid, evaporate, if necessary, on a steam bath to about 2 mL, and allow to stand for 1 hour in a cool place. Filter by suction, wash with small volumes of ice-cold water until the last washing does not give a reaction for chloride, and dry at 105° for 1 hour: the niacin so obtained responds to *Identification* tests *A* and *B* under *Niacin*.

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

pH ⟨791⟩: between 4.0 and 6.0.

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

Assay—Proceed with Injection as directed for *Niacin or Niacinamide Assay ⟨441⟩, Chemical Method*, using *Standard Niacin Preparation* as the *Standard Preparation* in the *Assay Procedure*, and the following as the *Assay Preparation*. Transfer an accurately measured volume of Injection, equivalent to about 50 mg of niacin, to a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a 200-mL volumetric flask, dilute with water to volume, and mix. Calculate the quantity, in mg, of $C_6H_5NO_2$ 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
NIACIN 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-3E24EF19-DAB0-4499-A2EA-8BDE9A09B612_3_en-US
Previous DocID: GUID-3E24EF19-DAB0-4499-A2EA-8BDE9A09B612_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56520_03_01
DOI ref: g8f50