Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-DBFE2C97-BCAE-4778-8E0B-9D76ED094B2F_3_en-US
DOI: https://doi.org/10.31003/USPNF_M25960_03_01
DOI Ref: t8emw

Digitoxin Injection

» Digitoxin Injection is a sterile solution of Digitoxin in 5 to 50 percent (v/v) of alcohol, and may contain Glycerin or other suitable solubilizing agents. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{41}H_{64}O_{13}$.

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

USP Reference standards ⟨11⟩—
USP Digitoxin RS

Identification—

A: To a portion of Injection, equivalent to about 1 mg of digitoxin, add 10 mL of water, and extract with 10 mL of chloroform. Evaporate the chloroform extract on a steam bath with the aid of a current of air to dryness. Dissolve the residue in 2 mL of a solution prepared by mixing 0.3 mL of ferric chloride TS and 50 mL of glacial acetic acid, and underlay with 2 mL of sulfuric acid: at the zone of contact of the two liquids a brown color, which gradually changes to light green, then to blue, is produced, and finally the entire acetic acid layer acquires a blue color.

B: To a portion of Injection, equivalent to about 0.2 mg of digitoxin, add 10 mL of water, and extract with 10 mL of chloroform. Evaporate the chloroform extract on a steam bath with the aid of a current of air to dryness. Add 2 mL of a freshly prepared 1 in 100 solution of *m*-dinitrobenzene in alcohol, and allow to stand for 10 minutes with frequent shaking. Add 2 mL of a 1 in 200 solution of tetramethylammonium hydroxide in alcohol, and mix: a red-violet color develops slowly and then fades.

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

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 111.0 USP Endotoxin Units per mg of digitoxin.

Alcohol Determination ⟨611⟩: between 90.0% and 110.0% of the labeled percentage of C_2H_5OH.

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

Assay—

Mobile phase, Standard preparation, System suitability preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Digitoxin*.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 1 mg of digitoxin, to a 25-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Digitoxin*. Calculate the quantity, in µg, of $C_{41}H_{64}O_{13}$ in each mL of the Injection taken by the formula:

$$25(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Digitoxin RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, and r_U and r_S are the peak responses 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
DIGITOXIN INJECTION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable
Current DocID: GUID-DBFE2C97-BCAE-4778-8E0B-9D76ED094B2F_3_en-US
Previous DocID: GUID-DBFE2C97-BCAE-4778-8E0B-9D76ED094B2F_1_en-US
DOI: https://doi.org/10.31003/USPNF_M25960_03_01
DOI ref: t8emw