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Digoxin Injection

» Digoxin Injection is a sterile solution of Digoxin in Water for Injection and Alcohol or other suitable solvents. It contains not less than 90.0 percent and not more than 105.0 percent of the labeled amount of $C_{41}H_{64}O_{14}$.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass. Avoid exposure to excessive heat.

USP Reference standards ⟨11⟩—

USP Digoxin RS

Identification—

A: Injection meets the requirements for *Identification* test *A* under *Digoxin Oral Solution.*

B: *Chloramine T–trichloroacetic acid reagent, Spotting solvent,* and *Standard solution*—Proceed as directed for *Identification* test *B* under *Digoxin Oral Solution*.

Test solution—Pipet a volume of Injection, equivalent to 0.5 mg of digoxin, into a separator, and add 5 mL of water. Extract with three 10-mL portions of chloroform, combining the extracts in a conical flask. Evaporate the combined chloroform extracts on a steam bath with the aid of a current of air to dryness. (If traces of water or propylene glycol remain, dry the flask in vacuum at 100° for 30 minutes.) Dissolve the residue in 2 mL of *Spotting solvent*.

Procedure—Apply 10 µL of the *Test solution* and 10 µL of the *Standard solution* on a line parallel to and about 2.5 cm from the bottom edge of a reversed-phase thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture to which is permanently bonded octadecylsilane (C18). Allow the spots to dry, and place the plates in a developing chamber containing a mixture of methanol and water (7:3). Develop the chromatogram until the solvent front has moved about 15 cm above the line of application. Remove the plate, and allow the solvent to evaporate. Spray the plate with *Chloramine T–trichloroacetic acid reagent*, freshly mixed, and heat in an oven at 110° for 10 minutes. Examine the plate under long-wavelength UV light: the R_F value of the principal spot in the chromatogram of the *Test solution* corresponds to that of the *Standard solution*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 200.0 USP Endotoxin Units per mg of digoxin.

Alcohol Determination ⟨611⟩**:** between 9.0% and 11.0% of C_2H_5OH.

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

Assay—

Mobile phase—Proceed as directed in the *Assay* under *Digoxin*.

Standard preparation—Dissolve an accurately weighed quantity of USP Digoxin RS in diluted alcohol, and dilute quantitatively with diluted alcohol to obtain a solution having a known concentration of about 250 µg per mL. Use a sonic bath to aid dissolution. If necessary, dilute quantitatively to match, approximately, the concentration of the Injection.

Chromatographic system and *System suitability preparation*—Proceed as directed in the *Assay* under *Digoxin*.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and Injection into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of $C_{41}H_{64}O_{14}$ in each mL of the Injection taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Digoxin RS in the *Standard preparation;* and r_U and r_S are the responses for the digoxin peaks obtained from the Injection and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
DIGOXIN INJECTION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

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