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Colchicine Injection

» Colchicine Injection is a sterile solution of $C_{22}H_{25}NO_6$ in Water for Injection, prepared from Colchicine with the aid of Sodium Hydroxide. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{25}NO_6$.

[**Caution—**Colchicine is extremely poisonous.]

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

USP Reference standards ⟨11⟩—
USP Colchicine RS

Identification—

A: Transfer a volume of Injection, equivalent to about 2 mg of colchicine, to a separator. Add 5 mL of water, and extract with 15 mL of chloroform. Evaporate the chloroform extract, using mild heat, to dryness: 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 Colchicine RS.

B: The UV absorption spectrum of the Injection, diluted with water to a concentration of about 10 µg of colchicine per mL, exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Colchicine RS, concomitantly measured.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 166.7 USP Endotoxin Units per mg of colchicine.

pH ⟨791⟩**:** between 6.0 and 7.2, in a solution of Injection containing 1.0 mg of potassium chloride in each mL.

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

Assay—[Note—Perform all dilutions in low-actinic glassware.]

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

Assay preparation—[Note—Prepare immediately before use.] Transfer an accurately measured volume, *V* mL, of Injection, equivalent to about 1 mg of colchicine, to a 50-mL volumetric flask, dilute with a mixture of methanol and water (1:1) to volume, and mix. Pipet 30 mL of this solution into a 100-mL volumetric flask, dilute with the same mixture to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Colchicine*, and measure the responses for the colchicine peaks. Calculate the quantity, in mg, of $C_{22}H_{25}NO_6$ in each mL of the Injection taken by the formula:

$$(C/6V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of the *Standard preparation;* 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
COLCHICINE INJECTION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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