

Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-A2A25AC3-2590-4AEC-BEF8-2A6D7705E2B8_1_en-US
DOI: https://doi.org/10.31003/USPNF_M19740_01_01
DOI Ref: sfz2r

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Do not distribute

Colchicine Tablets

» Colchicine Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{25}NO_6$.

Packaging and storage—Preserve in well-closed, light-resistant containers.

USP REFERENCE STANDARDS (11)—

[USP Colchicine RS](#)

Identification—Weigh a portion of ground Tablets, equivalent to about 20 mg of colchicine, triturate with 20 mL of water, allow the solids to settle, and filter the supernatant into a separator. Extract with 30 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](#).

Dissolution, Procedure for a Pooled Sample (711)—[NOTE—Conduct this procedure without delay, under subdued light, and using low-actinic glassware.]

Medium: water; 500 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{22}H_{25}NO_6$ dissolved, employing the procedure set forth in the Assay under [Colchicine](#), making any necessary modifications.

Tolerances—Not less than 75% (*Q*) of the labeled amount of $C_{22}H_{25}NO_6$ is dissolved in 30 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

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.] Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 0.6 mg of colchicine, to a 100-mL volumetric flask, add about 50 mL of a mixture of methanol and water (1:1), and shake by mechanical means for 15 minutes, rinsing down the walls of the flask at about 8 minutes. Dilute with the same mixture to volume, and pass through a 0.45- μ m membrane filter.

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 the portion of Tablets taken by the formula:

$$0.1C(r_u/r_s)$$

in which *C* is the concentration, in μ g 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 TABLETS	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. PF 30(1)

01/11/25/ 10:15 AM

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