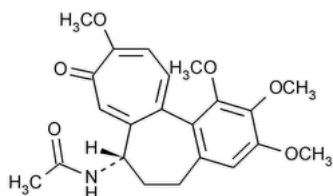


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Apr-2023
 Document Type: USP Monographs
 DocId: GUID-87856ACA-1B8F-48B8-8A61-FCDD01844B68F_7_en-US
 DOI: https://doi.org/10.31003/USPNF_M19720_07_01
 DOI Ref: tsp50

© 2025 USPC
 Do not distribute

Colchicine

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-colchicine-20230331.



C₂₂H₂₅NO₆ 399.44

Acetamide, N-(5,6,7,9-tetrahydro-1,2,3,10-tetramethoxy-9-oxobenzo[a]heptalen-7-yl)-, (S)-;

Colchicine CAS RN®: 64-86-8; UNII: SML2Y3J35T.

Change to read:

DEFINITION

Colchicine is an alkaloid contained in various species of *Colchicum* and in other genera. It contains NLT 94.0% and NMT ▲102.0%▲ (RB 1-Apr-2023) of colchicine (C₂₂H₂₅NO₆), calculated on the anhydrous, solvent-free basis.

[CAUTION—Colchicine is extremely poisonous.]

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K

[NOTE—Disregard any peak occurring at 1735 cm⁻¹.]

ASSAY

Change to read:

• PROCEDURE

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

Mobile phase: Dilute 45 mL of 0.5 M [monobasic potassium phosphate](#) with water to 450 mL. Add 530 mL of methanol, cool to room temperature, and add [methanol](#) to bring the volume to 1000 mL. Adjust with 0.5 M [phosphoric acid](#) to a pH of 5.5 ± 0.05, and pass through a 0.45-µm membrane filter.

Standard solution: 6 µg/mL of [USP Colchicine RS](#) in a mixture of [methanol](#) and [water](#) (1:1). This solution is stable for 4 months when stored tightly stoppered and in the dark.

Sample solution: 6 µg/mL of Colchicine in a mixture of [methanol](#) and [water](#) (1:1)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing [L7](#)

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 4500 theoretical plates

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the responses for all peaks recorded during 1.5 times the retention time for colchicine.

Calculate the percentage of colchicine (C₂₂H₂₅NO₆) in the portion of Colchicine taken:

Result = $(r_U / r_S) \times (C_S / C_U) \times 100$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Colchicine RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Colchicine in the *Sample solution* (µg/mL)

Acceptance criteria: 94.0%–▲102.0%▲ (RB 1-Apr-2023) on the anhydrous, solvent-free basis

IMPURITIES

• **LIMIT OF COLCHICEINE**

Analysis: To 5 mL of a 10-mg/mL solution of colchicine, add 2 drops of [ferric chloride TS](#).

Acceptance criteria: No definite green color is produced.

• **LIMIT OF ETHYL ACETATE**

Internal standard solution: Dilute 0.5 mL of *n*-propyl alcohol with [water](#) to 100 mL.

Standard solution: Transfer 1.0 mL of ethyl acetate, 0.5 mL of diacetone alcohol, and 0.5 mL of *n*-propyl alcohol to a 1000-mL volumetric flask and dilute with [water](#) to volume. Mix well. This solution contains 0.9 mg/mL of ethyl acetate.

Sample solution: Add 250 mg of Colchicine, accurately weighed, to a 10-mL volumetric flask, and dissolve in about 8.0 mL of [water](#). Add 1.0 mL of *Internal standard solution*, dilute with [water](#) to volume, and mix well.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m; coated with a 1-µm film of phase G16

Temperatures

Injection port: 180°

Detector: 220°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	20
40	20	200	10

Carrier gas: Helium

Flow rate: 5.72 mL/min

Injection volume: 2 µL

Injection type: Split ratio, 15:1

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 15.0% for the peak response ratios of ethyl acetate to the *n*-propyl alcohol peak, and of diacetone alcohol to the *n*-propyl alcohol peak, in replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethyl acetate in the portion of Colchicine taken:

Result = $(R_U / R_S) \times (C_S / C_U) \times 100$

R_U = peak response ratio of ethyl acetate to *n*-propyl alcohol from the *Sample solution*

R_S = peak response ratio of ethyl acetate to *n*-propyl alcohol from the *Standard solution*

C_S = concentration of ethyl acetate in the *Standard solution* (mg/mL)

C_U = concentration of Colchicine in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 8.0%

• **CHROMATOGRAPHIC PURITY**

Procedure: Proceed as directed in the Assay.

Acceptance criteria: NMT 5.0% other than that due to colchicine, eluting within 1.5 times the retention time for colchicine

- **RESIDUAL SOLVENTS (467):** Meets the requirements, except that the limit of chloroform is 100 ppm

SPECIFIC TESTS

- **OPTICAL ROTATION (781S), Procedures, Specific Rotation**

Sample solution: 10 mg/mL, in alcohol

Acceptance criteria: -240° to -250°, calculated on the anhydrous, solvent-free basis

- **WATER DETERMINATION (921), Method I :** NMT 2.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

- **USP REFERENCE STANDARDS (11).**

[USP Colchicine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
COLCHICINE	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 43(2)

Current DocID: GUID-87856ACA-1B8F-48B8-8A61-FCD01844B68F_7_en-US

DOI: https://doi.org/10.31003/USPNF_M19720_07_01

DOI ref: [tsp50](#)