

PRODUCT IN FOCUS

EXSYN[®]
ESSENTIAL CHEMISTRY

Colchicine

INTRODUCTION

Colchicine belongs to a class of drugs called Uricosuric agents.

It is an alkaloid used in the symptomatic relief of pain in attacks of gouty arthritis, pseudogout, sarcoidal arthritis, calcific tendinitis and to treat the inflammatory symptoms of Familial Mediterranean Fever.

It appears as odourless or nearly odourless pale yellow needles or powder that darkens on exposure to light.

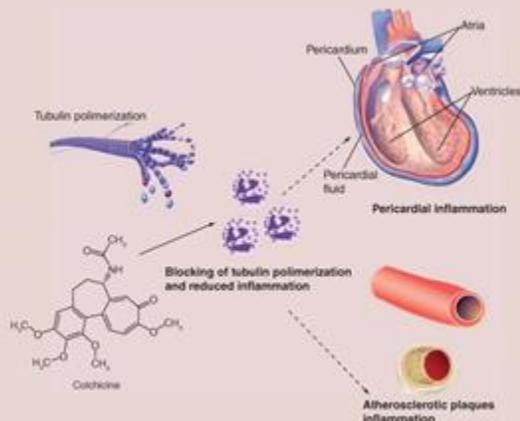
Manufacture

It is derived from the bulb-like corms of the *Colchicum autumnale* plant, also known as autumn crocus.

Synonyms	N-[(7S)-1,2,3,10-Tetramethoxy-9-oxo-5,6,7,9-tetrahydrobenzo[a]heptalen-7-yl]-acetamide
CAS no.	64-86-8
EINECS no.	200-598-5
Molecular formula	C ₂₂ H ₂₅ NO ₆
Molecular weight	399.44
Structure	

Applications

- Gout and Pseudogout:** Colchicine has been known as a treatment for gout for several millenia. It is also recommended for the treatment of acute flares, as well as flare prophylaxis, in patients with pseudogout or calcium pyrophosphate crystal arthritis.
- Familial Mediterranean Fever:** Colchicine has been the treatment of choice for Familial Mediterranean Fever (FMF) a hereditary autoinflammatory condition since the 1970's.
- Uses in Dermatology:** Colchicine has been reported to be an efficacious and well-tolerated treatment for numerous dermatologic diseases. Behçet's disease, epidermolysis bullosa acquisita, leukocytocastic vasculitis, Sweet's syndrome and recurrent aphthous stomatitis are some of the few dermatologic diseases in which treatment with colchicine has been studied.
- New Potential Indications:** The potential uses of colchicine have broadened significantly over the last few years as new studies have emerged demonstrating novel applications within oncology, immunology, cardiology, and dermatology.

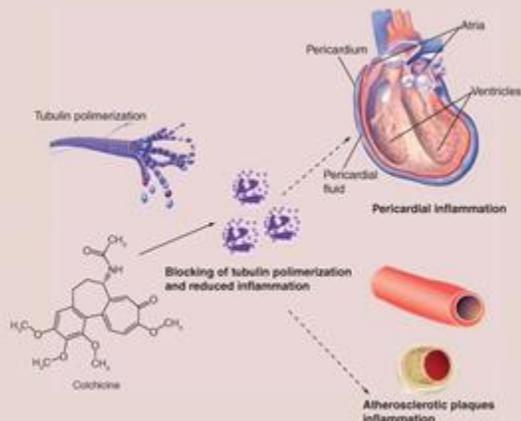


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SPECIFICATIONS – EP/BP

Test	Unit	Specification
Appearance	-	Yellowish-White, amorphous or crystalline powder
Solubility	-	Very soluble in water, rapidly re-crystallizing from concentrated solutions as the sesquihydrate, freely soluble in Ethanol (96%), practically insoluble in Cyclohexane
Identification		
A. By U.V.	-	The ratio of absorbance measured at 243 nm to that measured 350 nm is 1.7 to 1.9
B. By IR	-	The IR absorption spectrum of the preparation of the test specimen and working standard, exhibits maxima only at the same wave lengths
C. By Chemical	-	The organic layer is greenish-yellow
D. By Chemical	-	A brownish-red colour develops
Appearance of solution	-	Solution S is clear (2.2.1) and not more intensely coloured than reference solution GY ₃ (2.2.2, Method II) Either the solution does not change colour or it become green. Not more than 0.1 ml of 0.01 M Sodium hydroxide is required to change the colour of the indicator to blue
Acidity or Alkalinity	-	
Specific optical rotation	-	-250° to -235°, calculated on the anhydrous substance
Related substances (by HPLC)		
• Impurity 'A'	%	Max 3.0
• Impurity 'G'	%	Max 0.25
• Impurity 'E'	%	Max 0.20
• Unspecified impurities	%	Max 0.10
• Total impurities	%	Max 4.0
Impurity F	%	Max 0.2
Ethyl acetate (by GC)	%	Max 6.0
Water content (by KF)	%	Max 2.0% determined on 0.500 gm



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SPECIFICATIONS – EP/BP ...continued

Test	Unit	Specification
Sulphated ash	-	Max 0.1% determined on 0.500 gm
Residual solvents (by HSGC)		
• Methanol	ppm	NMT 3000
• Acetone	ppm	NMT 5000
• Methylene Dichloride	ppm	NMT 600
• Chloroform	ppm	NMT 500
Assay (Potentiometer)	%	97.0 to 102.0

STORAGE

Store in a dry and well-ventilated area.

PACKING

1 kg aluminum foil in steel container.

REGISTRATION / CERTIFICATION

ISO, WHO-GMP, Written Confirmation (WC), DMF as per EP/BP/USP & Certificate of Suitability (CEP) to European monograph.

No matter the quantity you need, our exceptional quality and service will make ExSyn your supplier of choice! If you need any additional information or SDS, please contact us.