

CERTIFICATE OF ANALYSIS

Product COLCHICINE

Product number C1305 Batch number 016551 Quality USP Date of production xx-11-2020 Date of analysis 19-11-2020 Date of expiry 30-11-2025

Packaging and storage in a well-closed container, protected from light

Appearance	SPECIFICATION pale yellow to pale greenish- yellow amorphous or crystalline powder	RESULT complies	UNITS	REMARKS
Solubility	soluble in water, freely soluble in alcohol and chloroform, slightly soluble in ether	complies		
Identification	conform	complies		IR-spectrum
Specific optical rotation	-240250	-243.54	0	
Water	≤ 2.0	0.38	%	Karl Fischer
Limit of colchiceine	conform	complies		
Limit of ethylacetate	≤ 8.0	5.31	%	
Sum of all impurities	≤ 5.0	2.57	%	
Chloroform	≤ 100	not detected	ppm	residual solvent
Methylene chloride	≤ 600	150	ppm	residual solvent
Methanol	≤ 3000	128	ppm	residual solvent
Assay	94.0 - 101.0	98.32	%	anhydrous substance

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist

Department of Quality Control Duchefa B.V.

Date: 29-10-2021

The buyer is responsible to test each batch to ensure the product is suitable for its specific purpose.