

## CERTIFICATE OF ANALYSIS

Product

COLCHICINE

Product number

C1305

Batch number

017497

Quality

USP

Date of production

xx-05-2022

Date of analysis

24-05-2022

Date of expiry

30-04-2027

Packaging and storage

in a well-closed container, protected from light

SPECIFICATION

RESULT

UNITS REMARKS

Appearance

pale yellow to pale greenish-

complies

yellow amorphous or crystalline

powder

Solubility

soluble in water, freely soluble

complies

in alcohol and chloroform, slightly soluble in ether

complies

IR-spectrum

Identification Specific optical rotation conform -240 - -250

-243.90

Water

 $\leq 2.00$ 

1.14

Karl Fischer

Limit of colchiceine

conform

complies

Limit of ethylacetate Sum of all impurities  $\leq 8.00$  $\leq 5.00$ 

4.62 2.35

%

Chloroform Methylene chloride ≤ 100

Not detected

ppm

residual solvent residual solvent

Methanol

 $\leq 600$ 

< 541

ppm ppm

%

Assay

< 3000  $\geq$  94.00-101.00

142 97.34 residual solvent 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: 17-01-2023

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