

CERTIFICATE OF ANALYSIS

Product

COLCHICINE

Product number

C1305

Batch number

017133

Ouality

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 greenishyellow amorphous or crystalline complies

powder

Solubility

Identification

soluble in water, freely soluble

complies

in alcohol and chloroform,

slightly soluble in ether conform

complies

IR-spectrum

Specific optical rotation

-240 - -250

-243.90

Water

 ≤ 2.00

1.14

Karl Fischer

Limit of colchiceine

conform ≤ 8.00

complies 4.62

%

%

Limit of ethylacetate Sum of all impurities

 ≤ 5.00

2.35

%

Chloroform Methylene chloride ≤ 100

Not detected

ppm

residual solvent

Methanol

< 600

< 541

ppm

residual solvent

Assay

< 3000 $\geq 94.00 - 101.00$ 142 97.34 ppm %

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: 30-06-2022

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

Duchefa Biochemie B.V.