

CERTIFICATE OF ANALYSIS

Product

COLCHICINE

Product number

C1305

Batch number

019528

Date of production

xx-06-2025

Date of analysis

08-07-2025

Date of expiry

31-05-2030

Packaging and storage

in a well-closed container, protected from light

SPECIFICATION

RESULT

UNITS REMARKS

Appearance

yellowish white, amorphous or

complies

crystalline powder

Solubility

very soluble in water, rapidly

complies

complies

complies

recrystalizing from concentrated solutions as the sesquihydrate, freely

soluble in ethanol (96%), practically insoluble in cyclohexane

Identification:
- A (IR-spectrum)

conform conform

- B (TLC) Appearance of solution conform complies clear and colour \leq ref.sol. GY₃ complies

Specific optical rotation Water -235 - -250 -247.5 ≤ 2.0 1.03

Limit of colchiceine Limit of ethylacetate ≤ 2.0 1.03 % complies ≤ 6.0 4.46 %

Residual solvents:
- Chloroform

≤ 100 ≤ 600 not detected ppm

- Methylene chloride

not detected ppm not detected ppm

- Methanol Assay \leq 3000 97.0 - 102.0

not detected ppm 99.88 %

anhydrous substance

anhydrous substance

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

Conclusion: approved

Released by:

Q. de Hoog, MSc, pharmacist

Department of Quality Control Duchefa Biochemie B.V.

Date: 17-09-2025

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

Duchefa Biochemie B.V.