

CERTIFICATE OF ANALYSIS

Product : L-ISOLEUCINE

Product number : I0711
Batch number : 016277
Date of analysis : 14-01-2021
Date of expiry : 31-01-2025

Packaging and storage : in a well closed container

| Appearance | SPECIFICATION white or almost white crystalline | RESULT complies | UNITS | REMARKS |
|------------------------|---|-----------------|-------|-------------------------------|
| Solubility | powder or flakes sparingly soluble in water, slightly soluble in alcohol, it dissolves in dilute mineral acids and in dilute | complies | | |
| | solutions of alkali hydroxides | | | |
| Appearance of solution | clear and colour ≤ GB6 | complies | | |
| Identification | conform | complies | | IR-spectrum |
| Specific rotation | +40.0 - +43.0 | +41.6 | o | dried substance |
| Related substances | conform | complies | | HPLC |
| Impurity A | ≤ 0.3 | 0,1 | % | |
| Impurity C | ≤ 0.3 | 0.1 | % | |
| Any other impurities | ≤ 0.2 | < 0.05 | % | |
| Total impurities | ≤ 1.0 | 0.2 | % | |
| Chlorides | ≤ 200 | complies | ppm | |
| Sulfate | ≤ 300 | complies | ppm | |
| Ammonium | ≤ 0.02 | < 0.02 | % | |
| Iron | ≤ 10 | complies | ppm | |
| Loss on drying | ≤ 0.5 | 0.0 | % | 105°C |
| Residue on ignition | ≤ 0.1 | 0.0 | % | |
| Assay | 98.5 – 101.0 | 99.9 | % | dried substance, titration |

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

Conclusion: approved

Released by: drs. M. van Wissen, MSc, pharmacist

Department of Quality Control Duchefa B.V.

Date: 23-06-2021

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

Duchefa Biochemie B.V.