

Certificate of Analysis

Product name: **Levocarnitinum**

Batch number / Weight: **22B02-B10-222171 / 200 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22B02-B10 / INS-22-4502**

Reference Code / No.: **V01706 / LC211247**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder or colourless crystals, hygroscopic | Conform | | |
| Identification A | -29,0 - -32,0 | Conform | | |
| Identification B | Conform | Conform | | |
| Appearance of solution | Clear, colourless | Conform | | |
| pH | 6,5 - 8,5 | 7,87 | | |
| Specific optical rotation | -29,0 - -32,0 | -31,3 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,5 | 0,01 | % | |
| Any impurity | <=0,10 | <0,05 | % | |
| Total impurities A | <=0,5 | 0,00 | % | |
| Chlorides | <=200 | Conform | ppm | |
| Sulphates | <=300 | Conform | ppm | |
| Water (Karl Fischer) | <=1,0 | 0,34 | % | |
| Sulphated ash | <=0,1 | 0,02 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Levocarnitine | 98,0 - 102,0 | 99,74 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Methanol | <=3000 | <3000 | pmm | |
| Ethanol | <=5000 | <5000 | ppm | |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

29-08-2022

Expiration: 21-12-2024

Conclusion: APPROVED

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