EL spol. s r.o., Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia
Accredited Testing Laboratory according to ISO/IEC 17025: 2017
Holder of the Certificate of GMP Compliance No. SK/033V/2020

Test Report Nº: 22/07537

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków	Date of sample receipt :	28.02.2022
Division:	Fagron Kraków	Date of testing from:	28.02.2022
Contract / order:	2022 19/0033/SLP/F	to:	16.05.2022
Order No.:	22-01647	Date of Test Report issue:	16.05.2022

Description of the Sample

Laboratory No.	**22-003662**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Levocarnitini tartras**
Strength / Dosage form	-
Batch No.	21L02-B05
Expiry date	14.10.2023
Description of package	plastic cup
Size of package / Quantity	1 unit -50 g
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Fagron INTERNAL Levocarnitini tartras
Specification / Test procedure	External documentation with specification No.: Fagron INTERNAL Levocarnitini tartras
Appearance of the sample	White, crystalline powder

Statement of Compliance / Non-compliance with the requirements / specifications

Test sample: Levocarnitini tartras **Batch:** 21L02-B05 **Manufacturer / Trader:** Fagron

Tested sample in performed tests is in compliance with the specifications presented in Fagron INTERNAL Levocarnitini tartras.

- Statement of compliance / noncompliance is presented according to customer requirements.
- Statement of compliance / noncompliance of the results with requirements is based on comparison of the test results presented in this Test Report with values presented in external document No.: Fagron INTERNAL Levocarnitini tartras.

Statements:

- **EL spol. s r.o. performs pharmaceutical quality control testing on the basis of the Manufacturer's Authorisation No. V-23/2020, issued by the State Institute for Drug Control (ŠÚKL).**
- This Certificate of Analysis shall not be reproduced except in full without approval of the Laboratory.
- Laboratory is not responsible for sampling, the results apply to the sample as received.
- Test results relate only to the sample tested and do not substitute the approval of the test item by the competent authority.
- Test equipment and instruments have been calibrated and verified in accordance with applicable metrological regulations.
- Test results can be claimed within 30 days of their sending to the customer. Claims delivered in written form only are accepted and executed.
- Return of sample remains - samples will be returned to the customer upon his written request and at his expense. In other cases, the remaining samples are discarded at the customer's expense after the expiration of the storage period (which is at least until the end of the claim period, or as agreed in the contract with a specific customer).

Test Report issued by and for Statement of Compliance is responsible: Ing. Eva Pjatáková Palenčárová, PhD., Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 16.05.2022 **Approved by:** Ing. Mária Gavlíková, Qualified Person

Certificate of GMP compliance of a manufacturer No.SK/033V/2020 EL spol. s r.o. * SPIŠSKÁ NOVÁ VES *

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Description of the Sample

Laboratory No.	22-003662
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Levocarnitini tartras
Strength / Dosage form	-
Batch No.	21L02-B05

Test Results

Physico-chemical testing: Fagron INTERNAL Levocarnitini tartras

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A. (Infrared absorption spectrophotometry)	IR	-	Compliance	Compliance	Compliance	16.05.2022
Identification B.	Test	-	It gives reaction of tartrates.	It gave reaction of tartrates.	Compliance	27.04.2022
Melting point	Melt_p	°C	about 173	174	Compliance	27.04.2022
Appearance of solution	VI	-	Solution S is clear and colourless.	Solution S was clear and colourless.	Compliance	27.04.2022
Specific optical rotation (anhydrous substance)	Polar	-	-11.0 to -9.5	-9.7	Compliance	27.04.2022
pH	Potent.	-	3.0 - 4.5	3.7	Compliance	27.04.2022
Chlorides	Test	ppm	≤200	<200	Compliance	27.04.2022
Sulfates	Test	ppm	≤200	<200	Compliance	28.04.2022
Heavy metals	Test	ppm	≤10	<10	Compliance	27.04.2022
Water	PotTitr	%	≤0.5	0.14	Compliance	02.05.2022
Sulfated ash	GA	%	≤0.1	0.07	Compliance	03.05.2022
Assay L-Carnitine	PotTitr	%	67.2 - 69.2	67.9	Compliance	29.04.2022
Assay Tartaric acid	TitrMet	%	30.8 - 32.8	32.5	Compliance	27.04.2022

Person responsible for results: Ing. Eva Pjatáková Palenčárová, PhD., Head of LFOA

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
IR	Infrared spectrometry
Melt_p	Melting point (capillary method)
Polar	Polarimetry
PotTitr	Potentiometric titration
Potent.	Potentiometry
Test	Test
TitrMet	Titrimetric method
VI	Visual inspection

Date: 16.05.2022
Approved by: Ing. Mária Gaviáková, Qualified Person

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