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: 22/00038

Customer

Customer: (name and address)	Fagron sp. z o.o. ul. Pasternik 26, 31354 Kraków
Division:	Fagron Kraków
Contract / order:	2021 19/0033/SLP/F
Order No.:	21-10012

Date of sample receipt :	26.10.2021
Date of testing from:	26.10.2021
to:	07.01.2022
Date of Test Report Issue:	07.01.2022

Description of the Sample

Laboratory No.	**21-023994**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Calcii orotas dihydricus**
Strength / Dosage form	-
Batch No.	21I30-B02
Expiry date	30.09.2024
Description of package	plastic cup
Size of package / Quantity	2 units
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Internal- Client Requirment
Specification / Test procedure	External documentation with specification No.: Internal- Client Requirment
Appearance of the sample	White crystalline powder

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

Test sample: Calcii orotas dihydricus **Batch:** 21I30-B02 **Manufacturer / Trader:** Fagron

Tested sample in performed tests is in compliance with the specifications presented in Internal- Client Requirment.

- 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.: Internal- Client Requirment.

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 Cerificate 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: 07.01.2022 **Approved by:** Ing. Mária Gaviáková, Qualified Person