



Test Report N^o: 22/06515

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Description of the Sample

Laboratory No.	22-003147
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Hesperidinum Ph.Eur. (2 sample)
Strength / Dosage form	-
Batch No.	21J13-B09

Test Results

Physico-chemical testing: Specification Fagron INTERNAL Hesperidinum

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Solubility	Test	-	Practically insoluble in water and ethanol (96 %), soluble in sodium hydroxide	Practically insoluble in water and ethanol (96 %), soluble in sodium hydroxide	✓ Compliance	28.04.2022
Identification A. (Thin layer chromatography) Sample 1 Sample 2	TLC chrom	-	Compliance	Compliance ✓	Compliance	29.04.2022
Identification B. (Infrared absorption spectrophotometry) Sample 1 Sample 2	IR	-	Compliance	Compliance ✓	Compliance	25.04.2022
Insoluble substances	GA	%	≤4.0	1.78 ✓	Compliance	21.04.2022
Heavy metals	Test	ppm	≤20	<20 ✓	Compliance	27.04.2022
Loss on drying	GA	%	≤5.0	4.02 ✓	Compliance	21.04.2022
Sulfated ash	GA	%	≤0.3	0.27 ✓	Compliance	28.04.2022
Assay Hesperidinum (dried substance)	HPLC	%	90.0 - 110.0	94.5 ✓	Compliance	26.04.2022

Person responsible for results:

Ing. Eva Pjataková Palenčárová, PhD., Head of LFOA

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
HPLC	High-performance liquid chromatography
IR	Infrared spectrometry
TLC chrom	Thin layer chromatography
Test	Test

Date: 01.05.2022

Approved by: Ing. Mária Gavláková, Qualified Person



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Customer

Customer: Fagron sp. z o.o.
(name and address) ul. Pasternik 26, 31354 Kraków
Division: Fagron Kraków
Contract / order: 2022 19/0033/SLP/F
Order No.: 22-01418

Date of sample receipt: 18.02.2022
Date of testing from: 18.02.2022
to: 01.05.2022
Date of Test Report Issue: 01.05.2022

Description of the Sample

Laboratory No.	22-003147
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Hesperidinum Ph.Eur. (2 sample)
Strength / Dosage form	-
Batch No.	21J13-B09 ✓
Expiry date	-
Description of package	plastic cup
Size of package / Quantity	2 unit ✓
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Specification Fagron INTERNAL Hesperidinum ✓
Specification / Test procedure	External documentation with specification No.: Specification Fagron INTERNAL Hesperidinum
Appearance of the sample	brown powder ✓

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

Test sample: Hesperidinum Ph.Eur. (2 sample) Batch: 21J13-B09 Manufacturer / Trader: Fagron

Tested sample in performed tests
is in compliance with
the specifications presented in Specification Fagron INTERNAL Hesperidinum.

- 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.: Specification Fagron INTERNAL Hesperidinum.

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 Pjatková Palenčárová, PhD., Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 01.05.2022

Approved by: Ing. Mária Gaviáková, Qualified Person