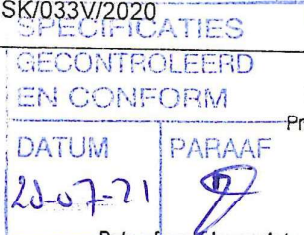




EL spol. s r.o., Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia
Accredited Testing Laboratory according to ISO/IEC 17025: 2017
Holder of the Certificate of GMP Compliance No. SK/033V/2020

Test Report No: 21/14478



Page: 1 of 2
Printout: 1 of 1

Customer: Fagron sp. z o.o.
(name and address) ul. Pasternik 26, 31354 Kraków
Division: Fagron Kraków
Contract / order: 2021 19/0033/SLP/F
Order No.: 21-06109

Customer

Date of sample receipt: 07.07.2021
Date of testing from: 07.07.2021
to: 27.07.2021
Date of Test Report issue: 27.07.2021

Description of the Sample

Laboratory No.	21-014058
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Cera cetomacrogolis emuls.
Strength / Dosage form	-
Batch No.	21F23-F01
Expiry date	-
Description of package	plastic cup
Size of package / Quantity	2 units
Manufacturer / Trader	Fagron Kraków
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Intern: Cetomacrogol Emulsifying Wax
Specification / Test procedure	External documentation with specification No.: Intern: Cetomacrogol Emulsifying Wax
Appearance of the sample	white flakes

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

Test sample: Cera cetomacrogolis emuls.

Batch: 21F23-F01 Manufacturer / Trader: Fagron Kraków

Tested sample in performed tests

is in compliance with

the specifications presented in Intern: Cetomacrogol Emulsifying Wax.

- 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.: Intern: Cetomacrogol Emulsifying Wax.

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. Silvia Strelková, Deputy Head of LFOA

Test Report will be delivered to: Fagron Kraków

Date: 27.07.2021

Approved by: Ing. Mária Gavráková, Qualified Person





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Name of the sample / Product	Cera cetomacrogolis emuls.
Strength / Dosage form	-
Batch No.	21F23-F01

Test Results

Physico-chemical testing: Intern: Cetomacrogol Emulsifying Wax

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A Sample-1	Test	-	Compliance	Compliance	Compliance	20.07.2021
Identification A Sample-2	Test	-	Compliance	Compliance	Compliance	20.07.2021
Identification B (Sulfated ash)	GA	-	≤0.1	Compliance	Compliance	19.07.2021
Acid value	VA	-	≤0.5	0.1	Compliance	20.07.2021
Refractive index at 60 °C	Refrak.	-	1.435 - 1.439	1.438	Compliance	20.07.2021
Hydroxyl value	VA	-	175 - 192	186	Compliance	21.07.2021
Solidifying point	Test	°C	45 - 53	50	Compliance	21.07.2021
Alkalinity	VA	ml 0.1M HCl	≤0.5	0.05	Compliance	20.07.2021
Saponification value	VA	-	≤2.0	<0.1	Compliance	20.07.2021
Sulfated ash	GA	%	≤0.1	0.08	Compliance	19.07.2021

Person responsible for results:

Ing. Silvia Strelková, Deputy Head of LFOA

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
Refrak.	Refractometry
Test	Test
VA	Volumetric analysis

Date: 27.07.2021
Approved by: Ing. Mária Gavľáková, Qualified Person

