

CERTIFICATE OF ANALYSIS

Our Ref. : F21/1103-01

Our Sample Id. : 52416

FAGRON Services BV
Molenwerf 13
1911 DB Uitgeest
NETHERLANDS

Product :	Trichosol	Date of application :	26/05/2021
Lot number :	0067421	Date of reception :	28/05/2021
Customer product number :	520919/N520919	Date start of analysis :	11/06/2021
Customer reference :	N/A	Date of end of analysis :	11/06/2021

Test Method : WNF (ANA-FAG-102/1)

Spec Reference : Customer

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	Clear to turbid liquid	Complies
Colour	Light yellow to yellow.	Complies
Other tests		
Density (Ph.Eur.2.2.5)	0,990 - 1,030 g/mL	1.016 g/mL
pH (Ph.Eur.2.2.3)	1,50 - 2,50	2.07

CONCLUSION : The sample complies with the specifications of the performed analysis.

Issued By:	Ingrid Van den Broeck	Patsy Peeters
	Office Manager/HR	Industrial Pharmacist, QP
Date of Issue:	11/06/2021	
	This is an electronic signature	



Kraków, 26.04.2021r.

Certificate of analysis no. 21/06989

Description of the sample:

Name of the sample:	TrichoSol hydrophilic base
Batch number:	0067421
Expiration date:	-
Required specifications:	PM0363 Ver.00

Test results:

Parameter	Limit value	Result	Statement of compliance	Testing laboratory
Appearance	Light yellow liquid	Light yellow liquid	complies	EISpol
Color	Light yellow to yellow	Light yellow	complies	
Odor	Characteristic	Characteristic	complies	
Aspect	Clear to turbid liquid	Slightly turbid liquid	complies	
Density (20°C)	0,990 – 1,030	1,016	complies	
pH (20°C)	1,50 - 2,50	1,97	complies	

Date of analysis: 7-23.04.2021

Statement of compliance:

The sample meets the requirements for performed tests.

Approved by:

Fagron sp. z o.o.
Barbara Berkowicz
specjalista ds. kontroli jakości
26.04.2021

Fagron sp. z o.o.
Justyna Kujbor
specjalista ds. kontroli
26.04.2021



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: 21/06989

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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.: 21-02793

Customer

Date of sample receipt : 07.04.2021
Date of testing from: 07.04.2021
to: 23.04.2021
Date of Test Report Issue: 23.04.2021

Description of the Sample

Laboratory No.	21-006348
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	TrichoSol hydrophilic base-1L
Strength / Dosage form	-
Batch No.	0067421
Expiry date	10.02.2023
Description of package	plastic bottle
Size of package / Quantity	1 unit
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: COA Products code: PM0363 Ver.00
Specification / Test procedure	External documentation with specification No.: COA Products code: PM0363 Ver.00
Appearance of the sample	light yellow liquid

Test Results

Physico-chemical testing: COA Products code: PM0363 Ver.00

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Color	Test	-	Light yellow to yellow	Light yellow	Compliance	15.04.2021
Odor	Test	-	Characteristic	Characteristic	Compliance	15.04.2021
Aspect	Test	-	Clear to turbid liquid	Slightly turbid liquid	Compliance	15.04.2021
Density (20°C)	GA	-	0.990 - 1.030	1.016	Compliance	15.04.2021
pH (20°C)	Potent.	-	1.50 - 2.50	1.97	Compliance	15.04.2021

Person responsible for results:

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

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
Potent.	Potentiometry
Test	Test



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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 Pjataková Palenčárová, PhD., Head of LFOA

Test Report will be delivered to:

Fagron Kraków

Date: 23.04.2021

Approved by: Ing. Mária Gavláková, Qualified Person

