



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 N<sup>o</sup>: 22/05678

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### Description of the Sample

Laboratory No.	22-003182
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Oxtripitanum
Strength / Dosage form	-
Batch No.	22A17-B03

### Test Results

#### Physico-chemical testing: INTERNAL Oxtripitanum

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A (infrared absorption)	IR	-	Compliance	Compliance ✓	Compliance	30.03.2022
Identification B (related substances)	HPLC	-	The main peak in the chromatogram obtained with the test solution is equivalent to the main peak in the chromatogram obtained with the standard solution.	The main peak in the chromatogram obtained with the test solution was equivalent to the main peak in the chromatogram obtained with the standard solution. ✓	Compliance	17.03.2022
Specific rotation (anhydrous material)	Polar	°	-38 to -30	-32 ✓	Compliance	05.04.2022
pH	Potent.	-	4.0-7.0	5.7 ✓	Compliance	05.04.2022
Arsenic	ICP-MS	ppm	≤1.5	<0.1 ✓	Compliance	24.03.2022
Heavy metals	Test	ppm	≤15	<15 ✓	Compliance	07.04.2022
Water	PotTitr	%	≤2.0	0.31 ✓	Compliance	22.03.2022
Sulfated ashes	GA	%	≤0.1	0.05 ✓	Compliance	05.04.2022
Related substances :						
L-tryptophan	HPLC	%	-	0.11	-	17.03.2022
any other impurity RRT= 1.06	HPLC	%	-	0.06	-	17.03.2022
any other impurity RRT= 1.13	HPLC	%	-	0.03	-	17.03.2022
any other impurity RRT= 1.77	HPLC	%	-	0.04	-	17.03.2022
any other impurity RRT= 2.10	HPLC	%	-	0.01	-	17.03.2022
any other impurity RRT= 2.23	HPLC	%	-	0.02	-	17.03.2022
total impurities	HPLC	%	≤0.5	0.29 ✓	Compliance	17.03.2022
Assay of Oxtripitanum (anhydrous substance)	PotTitr	%	98.0 - 101.0	99.7 ✓	Compliance	05.04.2022
Residual solvents:						
methanol	GC/FID	ppm	≤1000	76 ✓	Compliance	04.04.2022
terz-butylmethylether	GC/FID	ppm	≤100	<2 ✓	Compliance	04.04.2022

Person responsible for results:

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



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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.: 22-01439

Date of sample receipt: 21.02.2022  
Date of testing from: 21.02.2022  
to: 14.04.2022  
Date of Test Report Issue: 14.04.2022

### Description of the Sample

Laboratory No.	22-003182
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Oxtripitanum ✓
Strength / Dosage form	-
Batch No.	22A17-B03 ✓
Expiry date	10.07.2024 ✓
Description of package	plastic cup
Size of package / Quantity	1 unit -12 g ✓
Manufacturer / Trader	Fagron
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: INTERNAL Oxtripitanum ✓
Specification / Test procedure	External documentation with specification No.: INTERNAL Oxtripitanum
Appearance of the sample	creme to brown powder, hygroscopic ✓

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

Test sample: Oxtripitanum Batch: 22A17-B03 Manufacturer / Trader: Fagron

Tested sample in performed tests  
is in compliance with  
the specifications presented in INTERNAL Oxtripitanum.

- 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 Oxtripitanum.

### Statements:

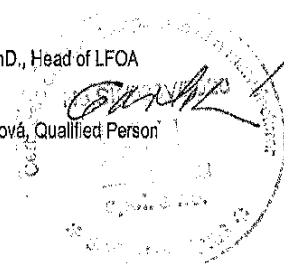
- EL spol. s r.o. performs pharmaceutical quality control testing on the basis of the Manufacturer's Authorisation No. V-23/2020, issued by the State Institute for Drug Control (ŠÚKL).
- This Certificate of Analysis shall not be reproduced except in full without approval of the Laboratory.
- Laboratory 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: 14.04.2022

Approved by: Ing. Mária Gavláková, Qualified Person





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**Test Methods**

Abbreviation	Method
GA	Gravimetric analysis
GC/FID	Gas chromatography with flame ionization detector
HPLC	High-performance liquid chromatography
ICP-MS	Inductively coupled plasma mass spectrometry
IR	Infrared spectrometry
Polar	Polarimetry
PotTitr	Potentiometric titration
Potenti	Potentiometry
Test	Test

Date: 14.04.2022  
Approved by: Ing. Mária Gavláková, Qualified Person

