



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°: 21/03691

Page: 2 of 3

Printout: 1 of 1

Description of the Sample

Laboratory No.:	21-000790
Type of the sample:	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / product:	Oxatriptanum
Strength / Dosage form:	-
Batch No.:	20L23-F01

Test Results

Physico-chemical testing: Method of Analysis Oxatriptanum

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A : infrared absorption	IR	-	vyhovuje	Compliance	Compliance	25.01.2021
Identification B : Related substances	HPLC_UVVIS	-	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	08.02.2021
Specific rotation (anhydrous material)	Polar	°	-38 to -30	-32	Compliance	02.02.2021
pH	Potent.	-	4.0-7.0	5.2	Compliance	02.02.2021
As	ICP-MS	ppm	≤1.5	<0.01	Compliance	25.01.2021
Heavy metals	Test	ppm	≤15	<15	Compliance	11.02.2021
Water	PotTit	%	≤2.0	0.8	Compliance	29.01.2021
Sulfated ashes	GA	%	≤0.1	0.08	Compliance	01.02.2021
Related substances :						
L-tryptophan	HPLC_UVVIS	%	-	0.10	Compliance	08.02.2021
Any other Impurity RRT=1.07 RRT=1.14 RRT=1.20 RRT=1.34 RRT=1.88 RRT=2.25 RRT=2.36 RRT=2.42	HPLC_UVVIS	%	-	0.06 0.03 0.01 0.02 0.04 0.06 0.02 0.03	Compliance	08.02.2021
Total Impurities	HPLC_UVVIS	%	≤0.5	0.37	Compliance	08.02.2021
Assay of Oxatriptanum (anhydrous substance)	PotTit	%	98.0 - 101.0	100.6	Compliance	12.02.2021

Person responsible for results:

Ing. Silvia Strelová, Deputy Head of LFOA

Test equipment and instruments used for testing have been calibrated and verified according to valid metrological regulations.





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Page: 3 of 3
Printout: 1 of 1

Abbreviations

Abbreviation	Method
GA	Gravimetric analysis
HPLC_UVVIS	High-performance liquid chromatography with UV-visible detector
ICP-MS	Inductively coupled plasma mass spectrometry
IR	Infrared spectrometry
Polar	Polarimetry
PotTitr	Potentiometric titration
Potent.	Potentiometry
Test	Test

Abbreviation	
RRT	relative retention time

Date: 05.03.2021
Approved by: Ing. Mária Gavláková, Qualified Person

