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°: 21/03851

Customer:	Fagron sp. z o.o.	**Date of sample receipt :**	14.01.2021
(name and address)	ul. Pasternik 26, 31354 Kraków		
Division:	Fagron Kraków	**Date of testing from:**	14.01.2021
Contract / order:	2021 19/0033/SLP/F	**to:**	09.03.2021
Order No.:	21-00251	**Date of Test Report issue:**	09.03.2021

Customer
SPECIALTIES
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DATUM 11 03 21
PARAAF

Description of the Sample

Laboratory No.	**21-000566**
Type of the sample	**Pharmaceutical raw materials, drugs and auxiliary materials**
Name of the sample / Product	**Vancomycini hydrochloridum**
Strength / Dosage form	-
Batch No.	21A08-F01
Expiry date	-
Description of package	plastic cup
Size of package / Quantity	2+2 units
Manufacturer / Trader	Fagron, Krakow
Sampling / Delivery	Sample delivered by Customer
Purpose of testing	Batch release – Assessment of conformity with specification No.: Ph.Eur 10.3 07/2019:1058 corrected 10.0
Specification / Test procedure	External documentation with specification No.: Ph.Eur 10.3 07/2019:1058 corrected 10.0
Appearance of the sample	white, hygroscopic powder

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

Test sample: Vancomycini hydrochloridum **Batch:** 21A08-F01 **Manufacturer / Trader:** Fagron, Krakow

Tested sample in performed tests
is in compliance with
the specifications presented in Ph.Eur 10.3 07/2019:1058 corrected 10.0.

- 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.: Ph.Eur 10.3 07/2019:1058 corrected 10.0.

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 Cerificate 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: 09.03.2021

Approved by: Ing. Mária Gavláková, Qualified Person

Certificate of GMP compliance of the manufacturer No.: SK/033V/2020
EL spol. s r.o. SPIŠSKÁ NOVÁ VES

EL spol. s r.o., Radlinského 17A, 052 01 Spišská Nová Ves, Slovakia
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Test Report Nº: 21/03851

Description of the Sample

Laboratory No.	21-000566
Type of the sample	Pharmaceutical raw materials, drugs and auxiliary materials
Name of the sample / Product	Vancomycini hydrochloridum
Strength / Dosage form	-
Batch No.	21A08-F01

Test Results

Physico-chemical testing: Ph.Eur 10.3 07/2019:1058 corrected 10.0

Test / parameter	Test method	Unit of measurement	Limit value	Result	Statement of Compliance	Start of the Test
Identification A Sample 1 Sample 2	HPLC/UV VIS	-	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).	The principal peak in the chromatogram obtained with the test solution was similar in retention timeto the principal peak inthe chromatogram obtained with reference solution (a).	Compliance	05.03.2021
Identification B	Test	-	It gives reaction (a) of chlorides.	It gave reaction (a) of chlorides.	Compliance	28.01.2021
Appearance of solution	UV/VIS	-	The solution is clear and its A 450 nm ≤ 0.10, A 370 nm ≤ 0.65	The solution was clear and its A 450 nm = 0.03, A 370 nm = 0.26	Compliance	28.01.2021
pH	Potent.	-	2.5-4.5	3.3	Compliance	28.01.2021
Vancomycin B and related substances:						
Vancomycin B	HPLC/UV VIS	%	≥91.0	94.0	Compliance	05.03.2021
Impurity A	HPLC/UV VIS	%	≤3.0	0.24	Compliance	05.03.2021
Impurity H	HPLC/UV VIS	%	≤3.0	1.00	Compliance	05.03.2021
Impurity J	HPLC/UV VIS	%	≤1.6	0.72	Compliance	05.03.2021
sum Impurity B and E	HPLC/UV VIS	%	≤2.0	0.24	Compliance	05.03.2021
Impurity D	HPLC/UV VIS	%	≤1.5	0.18	Compliance	05.03.2021
Impurity F	HPLC/UV VIS	%	≤1.5	0.51	Compliance	05.03.2021
Impurity M	HPLC/UV VIS	%	≤1.5	0.10	Compliance	05.03.2021
Impurity G	HPLC/UV VIS	%	≤1.2	0.16	Compliance	05.03.2021
Impurity I	HPLC/UV VIS	%	≤1.2	0.37	Compliance	05.03.2021
Impurity K	HPLC/UV VIS	%	≤1.2	0.45	Compliance	05.03.2021
impurity C	HPLC/UV VIS	%	≤1.0	0.16	Compliance	05.03.2021
any other impurity eluting before vancomycin B Imp 1 RRT= 0.47 Imp 2 RRT= 0.88 Imp 3 RRT= 0.96	HPLC/UV VIS	%	≤0.8 and not more than 5 such impurities exceed 0.30 %	0.19 0.26 0.25	Compliance	05.03.2021
any other impurity eluting after vancomycin B Imp 4 RRT= 1.22 Imp 5 RRT= 1.35 Imp 6 RRT= 1.41 Imp 7 RRT= 2.02	HPLC/UV VIS	%	≤0.8 and not more than 3 such impurities exceed 0.30 %	0.18 0.36 0.13 0.33	Compliance	05.03.2021
total of impurities	HPLC/UV VIS	%	≤9.0	5.83	Compliance	05.03.2021
Sulfated ash	GA	%	≤1.0	0.12	Compliance	28.01.2021
Bacterial Endotoxins	Gel	EU/mg	≤0.25	<0.25	Compliance	05.02.2021

Person responsible for results: Ing. Eva Pjatáková Palenčárová, PhD., Head of LFOA

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Test Report Nº: 21/03851

Test Methods

Abbreviation	Method
GA	Gravimetric analysis
Gel	Gel clot method
HPLC/UV VIS	High-performance liquid chromatography with UV VIS detector
Potent.	Potentiometry
Test	Test
UV/VIS	Spectrophotometry

Date: 09.03.2021
Approved by: Ing. Mária Gavláková, Qualified Person

Certificate of GMP compliance of a manufacturer No.SK/033V/2020 EL spol. s r.o. * SPIŠSKÁ NOVÁ VES *

SPECIFICATIES GECONTROLEERD EN CONFORM
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Certificate of Analysis

STERIS

Final Report

Job No:	**P-NLD-UTC-202100074**
Report Number:	19143
Date Issued:	29-Jan-2021

Applicant:	Fagron Services B.V.
For the attention of:	Certificates of Analysis
Address:	Molenwerf 13
Postal Code:	1911DB Uitgeest
Article:	Vancomycin hydrochloride
Analysis According:	Ph. Eur. 07/2019:1058 corrected 10.0

Analysis Results Batchnumber: **21A08-F01** Date Sample(s) Received: 19-Jan-2021

		Requirement	Result
Characters			
Appearance	Appearance	White or almost white, hygroscopic powder	Complies
Tests			
Karl Fischer	Water	≤ 5.0 %	2.2 %

Released by:

Eric van Dijk
Technical Support Officer Chemistry

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 11 03 21 PARAAF

Synergy Health Utrecht B.V., a STERIS company
Reactorweg 47a, 3542 AD P.O. 8121 3503 RC Utrecht, The Netherlands
E-mail: Utrecht@steris.com
Phone: +31 (0) 302 84 30 10

Certificate of Analysis

STERIS

Final Report

Job No:	**P-NLD-EDE-202100081**
Report Number:	19791
Date Issued:	23-Feb-2021

Applicant:	Fagron Services B.V.
For the attention of:	Certificates of Analysis
Address:	Molenwerf 13
Postal Code:	1911DB Uitgeest
Article:	Vancomycin hydrochloride
Analysis According:	Inhouse Method based on Ph.Eur.

Analysis Results Batchnumber: **21A08-F01** Date Sample(s) Received: 15-Jan-2021

		Requirement	Result
Microbiology			
Assay	Vancomycin hydrochloridum Anhydrous substance	≥ 1050 IU/mg	1056 IU/mg
	Date tested		FEB/12/2021

Released by:

Dr. Ruud Santing
QP/Pharmacist

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 11 03 21 PARAAF