Certificate of Analysis

Project No:		Issue Date:	08/03/2022
Client:		Laboratory:	ALS Czech Republic,s.r.o.|Pharmaceutical
Address:			Na Harfe 336/9 - Prague 9 - Vysocany
			Czech Republic 190 00
		Contact:	F&P Client Service
Contact:		Email:	czsupport.pharma@alsglobal.com
Email:		Telephone:	+420 226 226 998
Telephone:		Page:	Page 1 of 3
Order No:		Date of test:	22/02/2022 - 23/02/2022
Sampled By		Certificate No.:	TPRG010348-2 Supplementary

General Comments:

This report shall not be reproduced except in full, without prior written approval from the laboratory.
The laboratory declares that the test results relate only to the listed samples.
The information about sample representativity is not mentioned.
The sample expiry date is not mentioned.

Supplementary Certificate Issued. Sample Numbers affected: PRG1576. Additional Certificate comments: The Supplementary CoA was generated for testing purposes..

Responsible person:

Responsible for accuracy of reported results are persons listed below. The results were approved and authorized for reporting according to the procedures specified in the document CZ_SOP_D06_GMP_02 Processing of GMP Project which is in accordance with the procedures specified in FDA document CFR Title 21, Part 11.

Name/Position	Authorization Date
Barbora Hušeková, Microbiology Section Coordinator	07/03/22 13:05
Eva Hudečková, Pharmaceutical Section Supervisor	07/03/22 14:58
Kristýna Kovářová, Metals Section Supervisor	07/03/22 15:16
Štěpán Zajíček, Receiving and Admin Section Supervisor	07/03/22 14:58

GMP Control Laboratory approved by ÚSKVBL ALS Czech Republic, s.r.o.

GMP Control Laboratory approved by SÚKL ALS Czech Republic, s.r.o. evidence no. 539

Client Sample ID	Prod: VET_PRODUCT Rcvd Dt: 22/02/2022 Sched Dt: 22/02/2022 Description: TEST - VETERINARY
Laboratory Sample ID	PRG15746
Client Sampling Date/Time	

Test	Method	Result	Units	Specification	Eval	Flag
Escherichia coli	MIBI-EC01BI0-PRG	<10	bacteria/g			§2
Se	METL-SEMSDGCF1-PRG	15.5	mg/tablet			§2
Description	PHAR-FLU1-VIS#E-PRG	White to slightly yellow powder	-			§1
Subcontracted analysis	SUBC-SUB-LULEA-PRG	See attached	-			§3

This supplementary certificate replaces the previous certificate which must be invalidated
§2 Analysis was performed by ALS testing site Na Harfě 336/9, Prague 9, 190 00
§1 Analysis was performed by ALS testing site Poděbradská 540/26, Prague 9, 190 00
§3 Subcontracted Analysis

If the client does not specify the date and time of sample collection, the laboratory will specify the date on sample delivery in parentheses, instead. If the time of sample collection is specified as 0:00 it means that the client did specify the date but not the time.

The end of result part of the certificate of analysis

Brief Method Summaries

Analytical Methods	Method Descriptions
METL-SEMSDGCF1-PRG	Metals by ICP-MS - digestion
MIBI-EC01BI0-PRG	Escherichia coli - enumeration; G10
PHAR-FLU1-VIS#E-PRG	Description Flubenol 5%
SUBC-SUB-LULEA-PRG	Universal code for subcontracted service [LULEA]

Appendix 1 to Certificate of Analysis PRG10348-2

Client:
Address:

Laboratory: ALS Czech Republic,s.r.o.|Pharmaceutical
Na Harfe 336/9 - Prague 9 - Vysocany
Czech Republic 190 00

Contact:

Email:

Telephone:

Contact: F&P Client Service

Email: czsupport.pharma@alsglobal.com

Telephone: +420 226 226 998

Product Name	**Batch No.**
Product Name, Strength and Dosage Form	Batch No.

Manufacturing stages: 1.6 Quality control testing
1.6.1 Microbiological - sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical

Quality control testing was performed based on valid Technical Quality Agreement between the Client and ALS Czech Republic, s.r.o.

I hereby confirm that the manufacturing stages referred to in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements of the EU and the terms described in the Agreement for ensuring compliance with the requirements of the Marketing Authorisation(s) as provided by the Client.

Qualified person:

Name	Authorization Date
EUPRG QualityDB	08/03/22 06:34