



## Certificate of Analysis

Project No:	Issue Date:	17/03/2022
Client: Address:	Laboratory:	ALS Czech Republic,s.r.o. Pharmaceutical Na Harfe 336/9 - Prague 9 - Vysocany Czech Republic 190 00
Contact:	Contact:	F&P Client Service
Email:	Email:	czsupport.pharma@alsglobal.com
Telephone:	Telephone:	+420 226 226 998
Order No:	Date of test:	10/03/2022 - 17/03/2022
Sampled By	Certificate No.:	TPRG010673-1 Final

### 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.

### 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	17/03/22 11:31
Eva Hudečková, Pharmaceutical Section Supervisor	17/03/22 10:47



Issue Date: 17/03/2022  
 Page: Page 2 of 2  
 Project:  
 Client:



Client Sample ID

Prod: PUW-U1  
 Rcvd Dt: 10/03/2022  
 Sched Dt: 09/03/2022  
 Description: PUW-U1-220309/4, 04:30; Project: PUW-U1-čištěná voda  
 Extra Comments: dle ČL/PhEur  
 Date / Time Sampled: 09/03/2022 04:30

Laboratory Sample ID  
 Client Sampling Date/Time

PRG16177

Test	Method	Result	Units	Specification	Eval	Flag
Bac. Endo.	MIBI-BETOX03BH0-PRG	<0.025	EU/ml	≤0.25 IU/mL	Pass	§2
Viable microorganisms	MIBI-TVC01BE0-PRG	0	CFU/mL	≤100 CFU/mL	Pass	§2
Heavy Metals	PHAR-HMETLEA#1-PRG	≤0.1	ppm	≤0.1 ppm	Pass	§1
Nitrates	PHAR-NO3VISL2E#1-PRG	≤0.2	ppm	≤0.2 ppm	Pass	§1
Appearance	PHAR-SENZL5E#C-PRG	Clear colourless liquid.	-	Clear colourless liquid	Pass	§1

§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

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
MIBI-BETOX03BH0-PRG	Bacterial endotoxins - Turbidimetric m.; G13
MIBI-TVC01BE0-PRG	Total Viable Count - Aqua Dialysi and Aqua Purificata; G12
PHAR-HMETLEA#1-PRG	Heavy metals - Aqua Dialysi, Purificata, pro Injezione
PHAR-NO3VISL2E#1-PRG	Nitrates (NO3) - Aqua Purificata, pro Injezione
PHAR-SENZL5E#C-PRG	Sensory quality - Aqua Purificata