

Certificate of Analysis

Productname: Aqua purificata Bag In Box

Inspection No: I02633/0321/536

Sample Unit: 1 x 5 l

Batchnumber: 20L22-T01-085061

Batch Size: 1 536 x 5 l

Expiration date: 31.03.2024

Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0

Identification of producer: V01454

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear and colourless liquid.	Conform			
TESTS					
Conductivity	$\leq 5,1$	1,1	$\mu\text{S.cm}^{-1}$		
Nitrates	$\leq 0,2$	$< 0,2$	$\mu\text{g/g}$		
Acidity or alkalinity	Conform	Conform			
Oxidisable substances	Conform	Conform			
Chlorides	Conform	Conform			
Sulphates	Conform	Conform			
Ammonium	$\leq 0,2$	$< 0,2$	$\mu\text{g/g}$		
Calcium and magnesium	Conform	Conform			
Residue on evaporation	$\leq 0,001$	0,0008	%		
Microbiology	Conform	Conform			
TAMC	≤ 102	< 102	CFU/g		
Metallic residues	CHMP/ICH/353369/2013	Conform			

Performed by: SVU

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA


Date: 07.04.2021

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

Name
Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

Address
Holická 1098/31m, Olomouc
Post Code 779 00

Phone No. +420585222590
Fax No. +420 585 226 521