

Certificate of Analysis

Productname: Aqua purificata Bag In Box

Inspection No: I06997/0821/536

Batchnumber: 21C24-T07-087209

Expiration date: 31.08.2024

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

Sample Unit: 1 x 5 l

Batch Size: 1 536 x 5 l

Identification of producer: V01454

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear and colourless liquid.	Conform			
TESTS					
Conductivity	$\leq 5,1$	1,0	$\mu\text{S.cm}^{-1}$		
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	$\leq 0,001$	0,0007	%		
Microbiology	Conform	Conform			
TAMC	≤ 102	< 102	CFU/g		
Metallic residues	CHMP/ICH/353369/2013	Conform			

Performed by: SVÚ Olomouc

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA



Date: 07.09.2021

Conclusion: APPROVED

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