

Certificate of analysis

CoA number: **COA-099521** Date: **18 May 2018**
Quality order number: **QC-00043395**
Product name: **Aqupharm 1 solutie perfuzabila, 5000 ml, 2 T HU**
Item number: **10489** Batch number: **18051093**
Manufacturing date: **May 2018** Expiration date: **Apr 2021**

Test	Unit	Specification	Result
Appearance		Clear	Clear
Colour		Colourless	Colourless
Visible particles		Free from visible particles	Free from visible particles
Identification - Sodium		Complies	Complies
Identification - Chloride		Complies	Complies
Extractable volume	ml	$\geq 5,000$	5,020
Assay - sodium chloride	mg/ml	8.55 - 9.45	9.00
pH	pH	4.50 - 7.00	6.06
Particulate matter: sub-visible particles $\geq 10 \mu\text{m}$	PART/ml	≤ 25	1
Particulate matter: sub-visible particles $\geq 25 \mu\text{m}$	PART/ml	≤ 3	0
Bacterial endotoxins	EU/ml	≤ 0.25	< 0.25
Sterility		Sterile	Sterile

Resolution: This batch is in compliance with current ed. E.P. and B.P.



QUALITY CONTROL MANAGER

Cristina Diaconescu

18.05.2018

Analyses are validated through electronic signature.