

Certificate of analysis

CoA number: **COA-100272** Date: **24 May 2018**
 Quality order number: **QC-00043801**
 Product name: **Aqupharm 11 solutie perfuzabila, 5000 ml, 2 T HU**
 Item number: **10490** Batch number: **18051154**
 Manufacturing date: **May 2018** Expiration date: **Apr 2021**

Test	Unit	Specification	Result
Appearance		Clear solution, no visible particles	Clear solution, no visible particles
Colour		Colourless	Colourless
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	1
Identification - Lactate		Complies	Complies
Identification - Calcium		Complies	Complies
Identification - Potassium		Complies	Complies
Identification - Sodium		Complies	Complies
Extractable volume	ml	$\geq 5,000$	5,100
pH	pH	5.00 - 7.00	6.29
Assay-Sodium Lactate, calculated like $\text{C}_3\text{H}_6\text{O}_3$	mg/ml	2.30 - 2.80	2.55
Assay - Calcium Chloride dihydrate	mg/ml	0.25 - 0.29	0.27
Assay - Potassium	mg/ml	0.19 - 0.22	0.20
Assay - Total Chloride	mg/ml	3.70 - 4.20	3.90
Assay - Sodium	mg/ml	2.70 - 3.20	3.00
Bacterial endotoxins	EU/ml	≤ 0.25	< 0.25
Sterility		Sterile	Sterile

Analyses are validated through electronic signature.

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



QUALITY CONTROL MANAGER

Cristina Diaconescu

Cristina Diaconescu 24.05.2018

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