Name Manufacturer:	**MEDITES PHARMA, spol. s r.o.**
Department:	Quality Control
Certificate of Analysis No.:	**23/0001**

We MEDITES PHARMA, spol. s r.o. hereby declare that:

1. Product identification

Product name:	**CITRASOL 4%**
REF:	601031
Lot Number:	A0080922
Manufacturing Date:	29.12.2022
Expiry Date:	2024 11
Packaging type:	30 x 250 ml in a cardboard box
Packaging material:	injection port, infusion port, secondary foil
Unit volume:	250 ml
Contract manufacturing:	IMUNA PHARM, a.s. Jarková 269/17, 082 22 Šarišské Michaľany, Slovakia

2. Finished product Analysis Compliance

Each production batch was sampled, tested and released to MEDITES PHARMA in accordance with specification NR - C115 CITRASOL, part 1.

Parameter	*Specification*	*Result*	*Reference*
Physical and Chemical parameters			
Identification of Active Compound	Identity test for presence of Sodium (Na^+) and Citrates has to be satisfactory (passed).	Pass	PRG15594
Clarity	The product must be clear.	The sample is clear.	PRG15594
Actual acidity – pH	6.7 – 7.4	6.9	PRG15594
Aluminium	< 30 µg/L	20	PRG15594
Available volume	The volume of the solution in the bag must not be lower than the volume printed on the PP bag.	250	PRG15594
Assay of sodium	9.08 - 9.54 g/L	9.33	PRG15594
Assay of citrates	24.3 - 26.8 g/L	25.5	PRG15594
Contamination by particles under the visibility level	Particles of size ≥ 10 µm max. 25/ml	1	23-0004
	Particles of size≥ 25 µm max. 3/ml	0	
Microbiological parameters			
Limit test for bacterial endotoxins	< 0.25 IU/ml	< 0.06	23-0004
Sterility	Sterile	Sterile	23-0003

Conclusion: Results of test comply with specification NR-C 115, part 1.
The original results of analyses by external laboratories are attached to the analytical certificate.

Protocol of analysis issued worker of QC:
Date: 13.2.2023

Radmila Doleželová
Name and signature

Date: 13.2.2023

MEDITES PHARMA
spol. s r.o.
756 61 Rožnov pod Radhoštěm

Libuše Franová
Name and signature of the Head of QC Department