

Name Manufacturer	MEDITES PHARMA, spol. s r.o.
Department	Quality Control
Certificate	Certificate of Analysis

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

1. Product identification



Product name:	CITRASOL 4%
REF:	601031
Lot Number	A0043120
Manufacturing Date	2020 09 26
Expiry Date	2022 08
Packaging type	18 x 250 ml in a cardboard box
Packaging material	non – PVC bag; connectors: Tulip red cap, injection connector secondary packaging
Unit volume	250 ml

2. Finished product Analysis Compliance


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

<i>Parameter</i>	<i>Specification</i>	<i>Result</i>	<i>Reference</i>
<i>Physical and Chemical parameters</i>			
Identification of Active Compound	Identity test for presence of Sodium (Na ⁺) and Citrates has to be satisfactory (passed).	Comply	PRG453
Clarity	The product must be clear.	Comply	PRG453
Actual acidity – pH	6.7 – 7.4	Comply	PRG453
Aluminium	< 30 µg/L	Comply	PRG453
Available volume	The volume of the solution in the bag must not be lower than the volume printed on the PP bag.	Comply	PRG453
Assay of sodium	9.08 - 9.54 g/L	Comply	PRG453
Assay of citrates	24.3 - 26.8 g/L	Comply	PRG453
Contamination by particles under the visibility level	Particles of size ≥ 10 µm max. 25/ml. Particles of size ≥ 25 µm max. 3/ml.	Comply	P/408/20
<i>Microbiological parameters</i>			
Limit test for bacterial endotoxins	< 0.25 IU/ml	Comply	2193/20
Sterility	The product has to be sterile.	Comply	20/0585

3. QC Final Approval

Designated Authority	Name	Job title	Signature	Date
Prepared By	Petra Šrámková	QA / QC Specialist		18.2.2021
Reviewed By	Radmila Doleželová	QA / QC Manager		18.2.2021

4. Final Release Approval

Designated Authority	Name	Job title	Signature	Date
Reviewed By	Radmila Doleželová	QA / QC Manager		18.2.2021

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



Certificate of Analysis

Project No:	PRG453	Issue Date:	09/10/2020
Client:	MEDITES PHARMA, spol. s r.o., Rožnov pod Radhoštěm	Laboratory:	ALS Czech Republic, s.r.o. Pharmaceutical
Address:	1. máje 2625 Rožnov pod Radhoštěm 756 61 Czech Republic		Na Harfe 336/9 - Prague 9 - Vysocany Czech Republic 190 00
Contact:	Radmila Dolezelova	Contact:	F&P Client Service
Email:	radmila_dolezelova@meditespharma.cz	Email:	czsupport.pharma@alsglobal.com
Telephone:	571115905	Telephone:	+420 226 226 998
Order No:		Page:	Page 1 of 2
Sampled By		Date of test:	05/10/2020 - 08/10/2020
		Certificate No.:	TPRG000438-1 Final

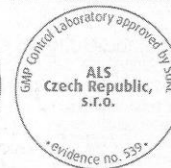
General Comments:

This report shall not be reproduced except in full, without prior written approval from the laboratory.
The laboratory declares that the test results relate only to the listed samples.
The information about sample representativity is not mentioned.
The sample expiry date is not mentioned.

Responsible person:

Responsible for accuracy of reported results are persons listed below. The results were approved and authorized for reporting according to the procedures specified in the document CZ_SOP_D06_GMP_02 Processing of GMP Project which is in accordance with the procedures specified in FDA document CFR Title 21, Part 11.

Name/Position	Authorization Date
Eva Hudečková, Pharma Section Supervisor	09/10/20 07:43
Miroslava Juričová, Metals Section Coordinator	08/10/20 17:23



Issue Date: 09/10/2020
 Page: Page 2 of 2
 Project: PRG453
 Client: MEDITES PHARMA, spol. s r.o., Rožnov pod Radhoštěm



Client Sample ID		Prod: CITRASOL 4% Citrasol 4% 250 ml Rcvd Dt: 01/10/2020 Sched Dt: 01/10/2020 Sample Date: 01/10/2020 Description: Citrasol 4% (250 ml); č.š. A0043120				
Laboratory Sample ID		PRG681				
Client Sampling Date/Time		01/10/2020 00:00				
Test	Method	Result	Units	Specification	Eval	Flag
Al	METL-ALMSFXVJ0-PRG	<10	µg/L	<30 µg/L	Pass	§2
Na	METL-NAMSFVC2-PRG	9.34	g/L	9.08 - 9.54 g/L	Pass	§2
Na - ID	METL-IDENoes-NA-PRG	Pass	-	Pass	Pass	§2
Citrates	PHAR-CITRA2#M1-PRG	25.5	g/L	24.3 - 26.8 g/L	Pass	§1
Actual acidity (pH)	PHAR-PHP2-ELE#M1-PRG	7.0	-	6.7 - 7.4	Pass	§1
Citrates	PHAR-CITR2-ID#MC-PRG	Pass	-	Complies to test	Pass	§1
Clarity	PHAR-SENZL1#MC-PRG	The sample is clear.	-	The sample is clear.	Pass	§1
Available volume	PHAR-AVOLUM1#MC-PRG	250	mL	min. 250 ml	Pass	§1

§2 Analysis was performed by ALS testing site Na Harfě 336/9, Prague 9, 190 00
 §1 Analysis was performed by ALS testing site Poděbradská 540/26, Prague 9, 190 00

If the client does not specify the date and time of sample collection, the laboratory will specify the date on sample delivery in parentheses, instead. If the time of sample collection is specified as 0:00 it means that the client did specify the date but not the time.

The end of result part of the certificate of analysis

Brief Method Summaries

Analytical Methods	Method Descriptions
METL-ALMSFXVJ0-PRG	Metals by ICP-MS - fixation
METL-IDENoes-NA-PRG	Metals by ICP-OES-A - fixation
METL-NAMSFVC2-PRG	Metals by ICP-MS - fixation
PHAR-AVOLUM1#MC-PRG	Volume; G184
PHAR-CITR2-ID#MC-PRG	Identification; G174
PHAR-CITRA2#M1-PRG	Assay of citric acid / citrate; Medites
PHAR-PHP2-ELE#M1-PRG	pH; G183 - Medites
PHAR-SENZL1#MC-PRG	Clarity/Coloration; G182

LAL TEST
Limit test for bacterial endotoxins (BET)
in CITRASOL 4%...

The test was carried out using work equipments and procedure in accordance with SOP:10.05.06.02 LAL test.

Controlled product: CITRASOL 4% 250 ml Lot No.: ... A0043120

Endotoxin limit: 0,25 EU/ml Analysis No.: ... 2.193/20

LAL Reagent: Pyrotell (ACC) Declared sensitivity λ 0,03 EU/ml ..

Lysate: --- Lot No.: ... 518-11-902

- dissolved in reconstitution buffer

Endotoxin: --- Lot No.: ... 170

Validation of the kit (confirmation of sensitivity) carried out on : 14.5.2020

Preparation of the product:

Dilution:

Quantity of undiluted product in ml: 1,0 Initial pH: 6,96

Quantity of buffer (Tris ...) in ml: 7,0

Quantity of water for BET in ml: ---

Test result CITRASOL 4%:

Determination	Sample	Positive control	Negative control
		1. 50 μ l 0,125 IU endotoxin/ml + 50 μ l buffer TRIS 1 2. 50 μ l 0,125 IU endotoxin/ml + 50 μ l sample 1:3 buffer TRIS 1	100 μ l buffer TRIS 1
1.	-	+	-
2.	-	+	-

Test result CITRASOL CPD50 / ACD-A:

Determination	Sample	Positive control	Negative control
		1. 50 μ l 0,125 IU endotoxin/ml + 50 μ l water for BET 2. 50 μ l 0,125 IU endotoxin/ml + 50 μ l sample 1:3 buffer TRIS 2	100 μ l water for BET
1.		---	---
2.		---	---

Test result CITRASOL 0,5%:

Determination	Sample	Positive control	Negative control
		1. 50 μ l 0,5 IU endotoxin/ml + 50 μ l water for BET 2. 50 μ l 0,5 IU endotoxin/ml + 50 μ l sample	100 μ l water for BET
1.		---	---
2.		---	---

Evaluation:

The sample complies test for BET according to Ph.Eur. 9: yes no

QC: *Trankl* Date of execution: 1.10.2020

QP: *Mel* Date of control: 1.10.2020

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

Particle Sizing Systems, Inc.
Santa Barbara, Calif., USA

10.06.02.10/16.9.2019

Particle Analysis Report

CITRASOL 4% 250ml A0043120 P/408/20
File Name = A0043120.1CB Time Date = 9:43:53 10/ 1/2020
Sensor Model: LE400-0.5 EXT S/N: 9811901 Cal. File: 9811901S.sns
Date of Calibration: 06-11-19
Control File: C:\PSS\SWS788\sws788.rcp

Elapsed Time of Data Collection = 40 Sec.
Background File = NONE

Number of Pulls = 4 Volume of Pull = 5.0 ml

Large Volume Injectables

Cumulative Number of Particles Per Pull Volume

PULL	CH1 10.0	CH2 25.0 (um)
------	-------------	------------------

1 *	12	0
2	22	0
3	15	0
4	11	0

MEAN #	16	0
#/ml	3	0
LIMIT	25	3
TEST	Passed	Passed

* First pull was not included.

Operator's Name: sramkova

Operator's Signature Sramkova Date 1.10.2020

Supervisor's Approval [Signature] Date 1.10.2020

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



IMUNA PHARM a.s.,
Jarková 269/17
082 22 Šarišské Michaľany

Protokol o skúške / Protocol of analysis

Prípravok: Name of the product:	CITRASOL 4 %	Balenie / Packaging	250 ml
---	---------------------	-------------------------------	---------------

Číslo šarže / Batch No.:	A0043120	Č. protokolu OKK / QCD protocol No.:	20/0585
Zadávateľ / Customer:	MEDITES PHARMA	Č. protokolu zadávateľa / Customer protocol No.:	Zmluva o dielo z 27.3.2017 /
Skúšku vykonal / Analysed by:	ITEST plus s.r.o.		The works contract from 27.3.2017

Skúška / Test	Akceptačné kritériá / Acceptance criteria	Výsledok / Result
Sterilita / Sterility (2.6.1.)	sterilný / sterile	sterilný / sterile
Záver: Výsledky skúšok	VYHOVUJÚ	NR-C 115 10.08.13 časť 1
Conclusion: Results of tests	COMPLY	with specification NR-C 115 10.08.13 supplement 1

Protokol o skúške vypracoval pracovník OKK / Certificat of Analysis issued by worker of QC:

Mgr. Klaudia Vargová

Dátum / Date: 16.10.2020

Meno a podpis / Name and signature

Dátum / Date: 16.10.2020

Mgr. Daniel Žatko, PhD.

Meno a podpis vedúceho OKK / Ing. Viera Michalová, PhD.

Name and signature of the Head of QC Department