

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	A0011421
Manufacturing Date	2021 02 15
Expiry Date	2023 01
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>
Physical and Chemical parameters			
Identification of Active Compound	Identity test for presence of Sodium (Na ⁺) and Citrates has to be satisfactory (passed).	Comply	PRG3763
Clarity	The product must be clear.	Comply	PRG3763
Actual acidity – pH	6.7 – 7.4	Comply	PRG3763
Aluminium	< 30 µg/L	Comply	PRG3763
Available volume	The volume of the solution in the bag must not be lower than the volume printed on the PP bag.	Comply	PRG3763
Assay of sodium	9.08 - 9.54 g/L	Comply	PRG3763
Assay of citrates	24.3 - 26.8 g/L	Comply	PRG3763
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/110/21
Microbiological parameters			
Limit test for bacterial endotoxins	< 0.25 IU/ml	Comply	482/21
Sterility	The product has to be sterile.	Comply	T101416

Issue Date: 01/03/2021
 Page: Page 2 of 2
 Project: PRG3763
 Client: MEDITES PHARMA, spol. s r.o., Rožnov pod Radhoštěm



Client Sample ID		Prod: CITRASOL 4% Citrasol 4% 250 ml Rcvd Dt: 18/02/2021 Sched Dt: 18/02/2021 Sample Date: 18/02/2021 Description: Citrasol 4% (250 ml), č.s. A0011421 Date / Time Sampled: 18/02/2021				
Laboratory Sample ID		PRG5908				
Client Sampling Date/Time		18/02/2021 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	9.30	g/L	9.08 - 9.54 g/L	Pass	\$2
Na - ID	METL-IDENOEES-NA-PRG	Pass	-	Pass	Pass	\$2
Citrates	PHAR-CITRA2#M1-PRG	25.7	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	Complies to test	-	Complies to test	Pass	\$1
Clarity	PHAR-SENZL1#MC-PRG	The sample is clear.	-	The sample is clear.	Pass	\$1
Available volume	PHAR-AVOLUM1#M0-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-IDENOEES-NA-PRG	Metals by ICP-OES-A - fixation
METL-NAMSFVC2-PRG	Metals by ICP-MS - fixation
PHAR-AVOLUM1#M0-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



ITEST plus s.r.o. biological tests, laboratory diagnostics

Kontrolní laboratoř ITEST plus
Kladská 1032,
500 03 Hradec Králové 3
místo provedení zkoušky
Kontrolní laboratoř BV
Bílé Vchynice 10
533 16 Vápno u Přelouče
tel/fax: 466 937 106, mail: itestbv@itest-plus.cz

MEDITES PHARMA , spol. s.r.o.

1. máje 2625

75661 Rožnov pod Radhoštěm

ATEST č. T101416 o zkoušce na sterilitu

Testovaný vzorek:

č. testu	název přípravku (vzorku) *	číslo šarže *	obal	ml *
T101416	CITRASOL 4%	A0011421	PP vak	250

*vzorky číslo: 10ks TZHALV210:č.š.:F0KB77639C TR:č.š.:090221B

Datum přijetí vzorku: **24.02.2021**

Test provedl: Perduřáková K.

Datum zahájení zkoušení: **24.02.2021**

Datum posledního hodnocení: **10.03.2021**

Metoda: Ph.Eur.10, SOP-K.1.01, membránová filtrace-steritest

Výsledky:

Thioglykolanová půda, 30°C až 35°C	STERILNÍ
TSB /půda z hydrolyzátů soji a kaseinu/ 20°C až 25°C	STERILNÍ

ZÁVĚR

Vzorek přípravku **VYHOVUJE** zkoušce na sterilitu
provedené podle Ph.Eur.10

Datum vystavení: **10.03.2021**



Hodnotil a uvolnil:


RNDr. Jiří Pospíšil, CSc.
vedoucí kontrolní laboratoře

Bez písemného souhlasu laboratoře se nesmí atest reprodukovat jinak než celý. Data dodaná zákazníkem jsou označena*.

Za správnost údajů dodaných zákazníkem, které mají vliv na výsledek zkoušky, laboratoř nenese odpovědnost.

Nejistotu měření nelze na tuto zkoušku aplikovat. Výsledky se týkají pouze vzorků, které byly předmětem zkoušení.

Vzorky byly zpracovány tak, jak byly přijaty.

----- Konec výsledkové části atestu -----

IZ: SOP-K.1.01/3/5

Výtisk číslo: 1

strana 1/1

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.: A0011421

Endotoxin limit: 0,25 EU/ml Analysis No.: 482/21

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

Lysate: --- Lot No.: 519-08-932

- 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: 6,93

Quantity of buffer (Tris 1) 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. 10: yes no

QC: *[Signature]*

Date of execution: 22.2.2021

QP: *[Signature]*

Date of control: 22.2.2021

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

MEDITES PHARMA
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Roznov pod Radostom

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

10.06.02.10/16.9.2019

Particle Analysis Report

CITRASOL 4% A0011421 P/110/21
File Name = A0011421.1CB Time Date = 7:51: 7 2/23/2021
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)
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1 *	16	1
2	11	1
3	9	1
4	6	2

MEAN #	8	1
#/ml	1	0
LIMIT	25	3
TEST	Passed	Passed

* First pull was not included.

Operator's Name: sramkova

Operator's Signature *Sramkova* Date 23.2.2021

Supervisor's Approval *[Signature]* Date 23.2.2021

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10.08.02.101.20.80.01

10.08.02.101.20.80.01

10.08.02.101.20.80.01

VEDITES PHARMA
s.r.l.
100 01 Rožnov pod Radhoštěm