

17.06.2022

Statement for Cholinii dihydrogenocitras

I hereby declare that lots 21K09-B16 and 20H11-F03 indicate production lot 3020378.

Ewelina Gadziowska
Qualified Person

Certificate of Analysis

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Analytical Report: AAK93059

Eurofins Sample Number: EB20AA3867-1

Version: 2

 Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

 Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033486

Eurofins Sample Number EB20AA3867-1	
Original Received Date:	20-Aug-2020
Description:	Cholinii dihydrogenocitras
Lot Number:	20H11-F03
Containers Submitted:	1 Tank(s)
General Method Reference: 14ACE468 and 20ACE525	

Analysis	Specification	Result	Unit
Characters Appearance	White, crystalline powder	White, crystalline powder	----
Method: 14ACE468 Analysis Date: 01-Sep-2020 to 01-Sep-2020			
Identification A : Melting Point	101 to 105	104	°C
Method: 14ACE468 Analysis Date: 01-Sep-2020 to 02-Sep-2020			
Identification C	Brown lamellar crystals form	Meets Requirements	----
Method: 14ACE468 Analysis Date: 15-Sep-2020 to 15-Sep-2020			
Identification D	Give the reaction of citrates	Meets Requirements	----
Method: 14ACE468 Analysis Date: 02-Sep-2020 to 02-Sep-2020			
Appearance of solution	The solution is clear and colourless.	Meets Requirements	----
Method: 14ACE468 Analysis Date: 01-Sep-2020 to 01-Sep-2020			
Acidity	≤ 20.5	20.0	mL
Method: 14ACE468 Analysis Date: 02-Sep-2020 to 02-Sep-2020			
Triméthylamine	The paper do not color in blue	Meets Requirements	----
Method: 14ACE468 Analysis Date: 02-Sep-2020 to 02-Sep-2020			



Analysis	Specification	Result	Unit
Chloride	≤250	< 250	ppm
Refer to Laboratory OOS Investigation EXC-EB20AB4949 Method: 14ACE468 Analysis Date: 30-Sep-2020 to 30-Sep-2020			
Ammonium salts	The solution remains colored red	Meets Requirements	----
Method: 14ACE468 Analysis Date: 02-Sep-2020 to 02-Sep-2020			
Heavy metals : Method A	≤ 20	<20	ppm
Method: 14ACE468 Analysis Date: 02-Sep-2020 to 02-Sep-2020			
Loss on Drying	≤ 1.0	0.5	%
Method: 14ACE468 Analysis Date: 03-Sep-2020 to 04-Sep-2020			
Sulfated ash	≤ 0.1	0.1	%
Method: 14ACE468 Analysis Date: 31-Aug-2020 to 31-Aug-2020			
Assay	98.0 to 101.0	99.8	% on dried substance
Method: 14ACE468 Analysis Date: 03-Sep-2020 to 03-Sep-2020			
pH	3.5-4.5	3.7	----
Method: Current Ph Eur (2.2.3) Analysis Date: 02-Sep-2020 to 02-Sep-2020			

Sample Compliance Assessment

Test level investigations were conducted for the following:

EB20AA3867-1

Meets specification(s) for the following test(s) but an investigation was conducted:

- Chloride - Laboratory OOS EXC-EB20AB4949

The Sample meets requirement(s) for all remaining test(s) where specifications were applied.

Contracted Company: Eurofins Pharma Quality Control Les Ulis Testing

9 Avenue de Laponie, Les Ulis, Courtaboeuf Cedex, 91978 France
EPQC_ServiceClient@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.





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BioPharma
Product Testing


Certificate of Analysis

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SPECIFICATIES GECONTROLEERD EN CONFORM	
DATUM 10 12 20	PARAAF 

Reviewed and electronically signed for Qualified Person Approval by
Alexandra HIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 12-Nov-2020 12:11:31 UTC+01:00