eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAM72724
Eurofins Batch Number JJ21AA0196
Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: IOQ6PH19016859

General Method Reference: EP Carbomers: 1299

Eurofins Sample Number JJ21AA0196-1	
Original Received Date:	21-Jan-2021
Description:	Carbomerum 974P; 501941
Lot Number:	21A18-F01
Containers Submitted:	1 Container
Client Sample ID:	M001

Eurofins Sample Number JJ21AA0196-2	
Original Received Date:	21-Jan-2021
Description:	Carbomerum 974P; 501941
Lot Number:	21A18-F01
Containers Submitted:	1 Container
Client Sample ID:	M002

Eurofins Sample Number JJ21AA0196-3	
Original Received Date:	21-Jan-2021
Description:	Carbomerum 974P; 501941
Containers Submitted:	1 Container
Client Sample ID:	Pooled sample M001 en M002 van batch 21A18-F01

Analysis/Sample	Specification	Result	Unit
Ph Eur Characters Appearance			
JJ21AA0196-1	White or almost white, fluffy, hygroscopic powder	Meets Requirements-White, fluffy, hygroscopic powder	----
JJ21AA0196-2	White or almost white, fluffy, hygroscopic powder	Meets Requirements-White, fluffy, hygroscopic powder	----
Method: Current Ph Eur Analysis Date 03-Feb-2021 to 03-Feb-2021 for JJ21AA0196-1 through JJ21AA0196-2			
Ph Eur Identification B			
JJ21AA0196-1	A highly viscous gel is formed.	Meets Requirements	----
JJ21AA0196-2	A highly viscous gel is formed.	Meets Requirements	----
Method: Current Ph Eur Analysis Date 03-Feb-2021 to 03-Feb-2021 for JJ21AA0196-1 through JJ21AA0196-2			

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 22 02 21 PARAAF

Analysis/Sample	Specification	Result	Unit
Ph Eur Identification C			
JJ21AA0196-1	A white precipitate is immediately produced.	Meets Requirements	----
JJ21AA0196-2	A white precipitate is immediately produced.	Meets Requirements	----
Method: Current Ph Eur Analysis Date 03-Feb-2021 to 03-Feb-2021 for JJ21AA0196-1 through JJ21AA0196-2			
Ph Eur Identification D			
JJ21AA0196-1			
Initial result	An orange colour is produced.	Meets Requirements	----
Final result	A yellow colour is produced.	Meets Requirements	----
JJ21AA0196-2			
Initial result	An orange colour is produced.	Meets Requirements	----
Final result	A yellow colour is produced.	Meets Requirements	----
Method: Current Ph Eur Analysis Date 19-Feb-2021 to 19-Feb-2021 for JJ21AA0196-1 through JJ21AA0196-2			
Ph Eur Free acrylic acid 1p/1i			
JJ21AA0196-3	Not more than 0.25	<0.01	%
Method: Current Ph Eur (2.2.29)(2.2.25)(2.2.46) Analysis Date 09-Feb-2021 to 09-Feb-2021 for JJ21AA0196-3			
Ph Eur Benzene 3p/1i			
JJ21AA0196-3	Not greater than 2	Not detected	ppm
Method: Current Ph Eur (2.4.24, System A)(2.2.28) Analysis Date 15-Feb-2021 to 17-Feb-2021 for JJ21AA0196-3			
Ph Eur Loss on drying			
JJ21AA0196-3	Maximum 3.0	1.1	%
Method: Current Ph Eur (2.2.32) Analysis Date 05-Feb-2021 to 05-Feb-2021 for JJ21AA0196-3			
Ph Eur Sulfated ash			
JJ21AA0196-3	Maximum 4.0	1.6	%
Method: Current Ph Eur (2.4.14) Analysis Date 11-Feb-2021 to 12-Feb-2021 for JJ21AA0196-3			

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Version: 1

Analysis/Sample	Specification	Result	Unit
Ph Eur Assay			
JJ21AA0196-3			
Carboxylic acid (dried substance)	56.0 to 68.0	58.5	%
Method: Current Ph Eur (2.2.20) Analysis Date 05-Feb-2021 to 05-Feb-2021 for JJ21AA0196-3			
Ph Eur Apparent viscosity rotational			
JJ21AA0196-3	29400 - 39400	34475	mPa.s
For JJ21AA0196-3: Client specification Method: Current Ph Eur (2.2.10)(2.2.20) Analysis Date 27-Jan-2021 to 27-Jan-2021 for JJ21AA0196-3			

Sample Compliance Assessment

Samples JJ21AA0196-1 through JJ21AA0196-3 meet the requirement(s) for all listed test(s) where specifications were applied.

Contracted Company: PROXY Laboratories Chemistry and Biochemistry

Archimedesweg 25, 2333 CM, Leiden, The Netherlands
PROXYcustomer@eurofins.com

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

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DATUM 22 02 21 | PARAAF

Reviewed and electronically signed for Quality Assurance Approval by
Monique de Graaf, Analytical Review Officer
for Eurofins PROXY Laboratories B.V., on 19-Feb-2021 16:03:17 UTC+01:00