

CERTIFICATE OF ANALYSIS

Our Ref. : F20/1197-01

Our Sample Id. : 42533

FAGRON Services BV
Molenwerf 13
1911 DB Uitgeest
NETHERLANDS

Product : Acidum salicylicum (90)
Lot number : 20E07-F01 (Mengstaal)
Customer product number : 501513/189090
Customer reference :

Date of application : 13/05/2020
Date of reception : 14/05/2020
Date start of analysis : 05/06/2020
Date of end of analysis : 27/07/2020

Test Method : Ph.Eur.01/2017:0366

Spec Reference : Ph.Eur.01/2017:0366

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	White or almost white, crystalline powder or white or colourless, acicular crystals.	Complies
Appearance of solution	The solution is clear (2.2.1) and colourless (2.2.2, Method II)	Complies
Identifications		
Identification A (MP Ph.Eur.2.2.14)	158 - 161 °C	160 °C
Other tests		
Chlorides (Ph.Eur.2.4.4)	NMT 100 ppm	Complies
Sulfates	NMT 200 ppm	Complies
Loss on drying (Ph.Eur. 2.2.32)	NMT 0,5 %	0.0 %
Sulfated ash (Ph.Eur.2.4.14)	NMT 0,1 %	0.04 %
Related substances (HPLC)		
Impurity A (HPLC)	NMT 0,1 %	0.04 %
Impurity B (HPLC)	NMT 0,05 %	<0,03%
Impurity C (HPLC)	NMT 0,02 %	not detected
Total impurity (HPLC)	NMT 0,2 %	0.04 %
Unspecified impurities (HPLC)	NMT 0,05 %	not detected
Assays		
Assay Salicylic acid (titration)	99.0% to 100.5% (dried substance)	99.8 %

CONCLUSION : The sample complies with the specifications of the performed analysis.

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Our Sample Id. : 42533

Issued By: Ingrid Van den Broeck

Office Manager/HR

Patsy Peeters

Industrial Pharmacist, QP

Date of Issue: 27/07/2020

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SPECIFICATIES GECONTROLEERD EN CONFORM	
DATUM 070020	PARAAAF RW

CERTIFICATE OF ANALYSIS**FAGRON SERVICES NEDE****Molenwerf 13
1911 DB Uitgeest
NETHERLANDS**

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Test Method : Ph.Eur.01/2017:0366
Spec Reference : Ph.Eur.01/2017:0366

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
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F20/1198-01 - 42534 - Lot number : 20E07-F01 (M001)**Identifications**

Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE
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CONCLUSION : The sample complies with the specifications of the performed analysis.

F20/1198-02 - 42535 - Lot number : 20E07-F01 (M002)**Identifications**

Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE
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CONCLUSION : The sample complies with the specifications of the performed analysis.

F20/1198-03 - 42536 - Lot number : 20E07-F01 (M003)**Identifications**

Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE
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CONCLUSION : The sample complies with the specifications of the performed analysis.

F20/1198-04 - 42537 - Lot number : 20E07-F01 (M004)**Identifications**

Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE
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CERTIFICATE OF ANALYSIS

Test Method : Ph.Eur.01/2017:0366

Spec Reference : Ph.Eur.01/2017:0366

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
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CONCLUSION : The sample complies with the specifications of the performed analysis.

F20/1198-05 - 42538 - Lot number : 20E07-F01 (M005)**Identifications**

Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE
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CONCLUSION : The sample complies with the specifications of the performed analysis.

Issued By: Ingrid Van den Broeck

Patsy Peeters

Office Manager/HR

Industrial Pharmacist, QP

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

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033457

Eurofins Sample Number EB20AA2257-1	
Original Received Date:	14-May-2020
Description:	Acidum salicylicum (90)
Lot Number:	20E07-F01
Containers Submitted:	5 Tank(s)
General Method Reference: 1-P-LB-WI -9050616	

Analysis	Specification	Result	Unit
Particle-size distribution estimation by analytical sieving			
Particles < 90µm	≥ 97	97	%
Method: Current EP			
Analysis Date: 26-May-2020 to 23-Jun-2020			

Particle size analysis by laser light diffraction			
D10	----	7.24	µm
D50	----	20.11	µm
D90	----	43.15	µm
Method: Current Ph Eur (2.9.31)			
Analysis Date: 03-Aug-2020 to 04-Aug-2020			

Sample Compliance Assessment	
EB20AA2257-1 meets the requirement(s) for all listed 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.

