LABO QUERCUS

pharmaceutical contract analysis
GMP certification 1843 H - V - IMP

CERTIFICATE OF ANALYSIS

Our Ref. :	F18/2032-01	Date of application :	05/10/2018
Our Sample Id. :	28202	Date of reception :	08/10/2018
		Date start of analysis :	08/10/2018
		Date of end of analysis:	24/10/2018

		Applicant
Product :	Acidum salicylicum (90)	FAGRON Services BV
Lot number :	18I17-B03 (Mengstaal)	Molenwerf 13
Customer product number :	501513/189090	1911 DB Uitgeest
Customer reference :		NETHERLANDS
		+31 251 36 14 52

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	158 °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 %
Sulfated ash (Ph.Eur.2.4.14)	NMT 0,1 %	0.03 %
Related substances (HPLC)		
Impurity A (HPLC)	NMT 0,1 %	0.03 %
Impurity B (HPLC)	NMT 0,05 %	<0.03 %
Impurity C (HPLC)	NMT 0,02 %	Not detected
Total impurity (HPLC)	NMT 0,2 %	0.03 %
Unspecified impurities (HPLC)	NMT 0,05 %	<0.03 %
Assays		
Assay Salicylic acid (titration)	99.0% to 100.5% (dried substance)	99.3 %

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CERTIFICATE OF ANALYSIS

Our Ref. :	F18/2032-01	Date of application :	05/10/2018
Our Sample Id. :	28202	Date of reception :	08/10/2018
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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
Date of Issue:	25/10/2018	
	This is an electronic signature	

25-10-2018

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		Applicant
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Customer product number :	501513/189090	Molenwerf 13
Customer reference :		1911 DB Uitgeest
		NETHERLANDS
		+31 251 36 14 52

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

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
F18/2033-01 - 28203 - Lot number : 18I17-B03 (M006)		
Identifications		
Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE

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

F18/2033-02 - 28204 - Lot number : 18I17-B03 (M007)		
Identifications		
Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE

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

F18/2033-03 - 28205 - Lot number : 18I17-B03 (M008)		
Identifications		
Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE

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

F18/2033-04 - 28206 - Lot number : 18I17-B03 (M009)		
Identifications		
Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE

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

25.10.2018

LABO QUERCUS

pharmaceutical contract analysis
GMP certification 1843 H - V - IMP

CERTIFICATE OF ANALYSIS

Date of application :	05/10/2018
Date of reception :	08/10/2018
Date start of analysis :	08/10/2018
Date of end of analysis:	24/10/2018

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

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
F18/2033-05 - 28207 - Lot number : 18I17-B03 (M010)		
Identifications		
Identification B (IR Ph.Eur.2.2.24)	Similar spectra for sample and reference.	POSITIVE

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
Date of Issue:	25/10/2018	
	This is an electronic signature	

25-10-2018

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Fagron Services BV
Molenwerf 13

1911 DB Uitgeest(NETHERLANDS)
A l'attention de : Quality Assurance

CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum
BATCH NUMBER : 18I17-B03
ANALYTICAL NUMBER
RECEPTION DATE : 05-Oct-18 4:44:34 PM
ENTRY NUMBER : **ACE-2018-00082740**
START OF ANALYSIS : 22/10/2018

TESTS	SPECIFICATIONS	RESULTS
TESTS		
Particle size by sieve < 90 µm	≥ 97 %	98 %
Particle size D50 by laser diffraction	For information	13.29 µm

NOTE: Analysis performed according to European Pharmacopoeia 9th edition (01/2017:0366) and synoptic 1-P-LB-WI-9050616

CONCLUSION : COMPLIES FOR PERFORMED TESTS

26-10-2018

Analyst
ER

Approbator

Certificat validé le 26/10/2018 2:00:02 PM informatiquement par :
Alexandra HAIRON Chargée de validation