

CERTIFICATE OF ANALYSIS

Our Ref. : F18/2032-01

Our Sample Id. : 28202

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

Applicant

Product : Acidum salicylicum (90)

FAGRON Services BV

Lot number : 18117-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 %

25-10-2018 R

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

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

[Faint, illegible handwritten text and a signature]
25-10-2018

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

Applicant

Product : Acidum salicylicum (90) FAGRON Services BV
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 : 18117-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 : 18117-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 : 18117-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 : 18117-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

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 : 18117-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

Signature of Patsy Peeters
25-10-2018

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

[Handwritten signature and date 26-10-2018]

Analyst
ER

Approbator

Page 1 of 1