

Fagron Services BV
Molenwerf 13

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

CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum
BATCH NUMBER : 17C21-B09
ANALYTICAL NUMBER :
RECEPTION DATE : 24-Mar-2017 9:36:59 AM and 17-May-2017 9:23:13 AM (additional sample)
ENTRY NUMBER : ACE-2017-00043806
START OF ANALYSIS : 29/03/17 and 31/05/17 (additional sample)

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	White or almost white, crystalline powder or white or colourless, acicular crystals	White crystalline powder
IDENTIFICATIONS		
A. Melting point	158 °C to 161 °C	159°C
B. IR Spectrum	IR spectrum complies with reference spectrum	Complies (x5)
TESTS		
Appearance of solution	Clear and colourless	Clear and colourless
Related substances by HPLC		
Impurity A	≤ 0.1 %	< 0.03 % ¹
Impurity B	≤ 0.05 %	< 0.03 % ¹
Impurity C	≤ 0.02 %	< 0.02 % ²
Any other impurity	≤ 0.05 %	< 0.05 % ²
Total	≤ 0.2 %	< 0.2 %
Chlorides	≤ 100 ppm	< 100 ppm
Sulfates	≤ 200 ppm	< 200 ppm
Loss on drying	0.5 %	0.1%
Sulfated ash	≤ 0.1 %	0.0%
Particle size by sieve		
< 180 µm	≥ 97 %	98% ³
< 150 µm	≥ 90 %	97% ³
Particle size by laser diffraction		
< 180 µm	For information	99.2 % ⁴ // 97.6 % ³
D50	For information	50.5 µm ⁴ // 49.3 µm ³
ASSAYS		
Salicylic acid content	99.0 to 100.5 % (dried substance)	99.5 %

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366) with exception EX027322 and EX028615, and EX029782

CONCLUSION : COMPLIES FOR ALL THE OTHER TESTS

¹ 0.03% = Disregard limit

² Not detected

³ Performed on additional sample received on May 2017 and using air jet for size particule by sieve

⁴ Performed on initial sample received on March 2017

Analyst
EPN,JBU, DO, LB,EFI/APT, EJN, JGI

Pharmacist

4-8-17

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum (180)
BATCH NUMBER : 1 17C21-B09
ANALYTICAL NUMBER
RECEPTION DATE : 17-May-2017 9:23:13 AM
ENTRY NUMBER : **ACE-2017-00068404**
START OF ANALYSIS : 31/05/17

TESTS	SPECIFICATIONS	RESULTS
TESTS		
Particle size by sieve		
< 180 µm	≥ 97 %	98 % ¹
< 150 µm	≥ 90 %	97 % ¹
Particle size by laser diffraction		
< 180 µm	For information	97 %
D50	For information	49 µm

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366)

CONCLUSION : COMPLIES FOR PERFORMED TESTS

¹ Sieve particule size was done using air jet

Analyst
JGI

Pharmacist

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum (180)
BATCH NUMBER : 2 17C21-B09
ANALYTICAL NUMBER :
RECEPTION DATE : 17-May-2017 9:23:13 AM
ENTRY NUMBER : **ACE-2017-00068405**
START OF ANALYSIS : 31/05/17

TESTS	SPECIFICATIONS	RESULTS
TESTS		
Particle size by sieve		
< 180 µm	≥ 97 %	98 % ¹
< 150 µm	≥ 90 %	97 % ¹
Particle size by laser diffraction		
< 180 µm	For information	98 %
D50	For information	48 µm

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366)

CONCLUSION : COMPLIES FOR PERFORMED TESTS

¹ Sieve particule size was done using air jet

Analyst
JGI

Pharmacist

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum (180)
BATCH NUMBER : 3 17C21-B09
ANALYTICAL NUMBER
RECEPTION DATE : 17-May-2017 9:23:13 AM
ENTRY NUMBER : **ACE-2017-00068406**
START OF ANALYSIS : 31/05/17

TESTS	SPECIFICATIONS	RESULTS
TESTS		
Particle size by sieve		
< 180 µm	≥ 97 %	98 % ¹
< 150 µm	≥ 90 %	97 % ¹
Particle size by laser diffraction		
< 180 µm	For information	98 %
D50	For information	47 µm

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366)

CONCLUSION : COMPLIES FOR PERFORMED TESTS

¹ Sieve particule size was done using air jet

Analyst
JGI

Pharmacist

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum (180)
BATCH NUMBER : 4 17C21-B09
ANALYTICAL NUMBER
RECEPTION DATE : 17-May-2017 9:23:13 AM
ENTRY NUMBER : **ACE-2017-00068407**
START OF ANALYSIS : 31/05/17

TESTS	SPECIFICATIONS	RESULTS
TESTS		
Particle size by sieve		
< 180 µm	≥ 97 %	98 % ¹
< 150 µm	≥ 90 %	97 % ¹
Particle size by laser diffraction		
< 180 µm	For information	98 %
D50	For information	49 µm

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366)

CONCLUSION : COMPLIES FOR PERFORMED TESTS

¹ Sieve particule size was done using air jet

Analyst
ELR JGI

Pharmacist

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Acidum salicylicum (180)
BATCH NUMBER : 5 17C21-B09
ANALYTICAL NUMBER
RECEPTION DATE : 17-May-2017 9:23:13 AM
ENTRY NUMBER : **ACE-2017-00068408**
START OF ANALYSIS : 31/05/17

TESTS	SPECIFICATIONS	RESULTS
<u>TESTS</u>		
Particle size by sieve		
< 180 µm	≥ 97 %	98 % ¹
< 150 µm	≥ 90 %	97 % ¹
Particle size by laser diffraction		
< 180 µm	For information	97 %
D50	For information	50 µm

NOTE: Analysis performed according to European Pharmacopeia 9th edition (01/2017:0366)

CONCLUSION : COMPLIES FOR PERFORMED TESTS

¹ Sieve particule size was done using air jet

Analyst
JGI

Pharmacist