

Certificate of Analysis

Product name: **Acidum acetylsalicylicum**

Batch number / Weight: **22J18-B02-224370 / 250 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22J18-B02 / INS-22-8960**

Reference Code / No.: **V00581 / 22287**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Identification B	156 - 161	160,2	°C	
Melting point	About 143	139,7	°C	
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,03	%	
Impurity B	<=0,15	<0,03	%	
Impurity C	<=0,15	<0,03	%	
Impurity D	<=0,15	<0,03	%	
Impurity E	<=0,15	<0,03	%	
Impurity F	<=0,15	<0,03	%	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,25	0,00	%	
Loss on drying	<=0,5	0,11	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Acetylsalicylic acid	99,5 - 101,0 (dried substance)	99,68	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetic acid	<=0,5% (LOD)	Conform		

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Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

29-11-2022

Expiration: 28-02-2025

Conclusion: APPROVED

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl