

## Certificate of Analysis

**Product name:** Cellulose microcrystalline

**Batch number:** 20K23-B10-204117

**Base unit:** 1 kg

**Expiration date:** 31.08.2024

**Quality:** Ph. Eur.

**Manufacturing date:** 18.12.2020

**Inspection report no.:** INS-20-04984


Parameter	Limit value	Result	Unit	Laboratory
Appearance	white or almost white, fine or granular powder	conform		Fagron Poland
Identification A	acc. to Ph. Eur	conform		El Spol
Identification B	acc. to Ph. Eur	conform		El Spol
Identification C	acc. to Ph. Eur	conform		El Spol
pH	+33,0 to (+39,0)	7,0		El Spol
Conductivity	max. 75 $\mu\text{S}/\text{cm}^{-1}$	49	$\mu\text{S}/\text{cm}^{-1}$	El Spol
Ether-soluble substances	max. 0,05 %	0,003	%	El Spol
Water-soluble substances	max. 0,25 %	0,15	%	El Spol
Loss on drying	max. 7,0 %	3,5	%	El Spol
Sulfated ash	max. 0,1 %	0,06	%	El Spol
Microbial contamination	Absence of <i>Pseudomonas aeruginosa</i> / 1g	conform		CBMiA
	Absence of <i>Staphylococcus aureus</i> / 1g	conform		CBMiA
	Absence of <i>Escherichia coli</i> / 1g	conform		CBMiA
	Absence of <i>Salmonella</i> / 10g	conform		CBMiA
	TAMC: max. $10^3$ CFU/g	<10	CFU/g	CBMiA
	TYMC: max. $10^2$ CFU/g	<10	CFU/g	CBMiA
Elemental impurities	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
TSE/BSE-statement	no contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory: Fagron Poland.

Release:

Ewelina Gadzinowska

Qualified Person


 Fagron sp. z o.o.  
 Ewelina Gadzinowska  
 osoba wykwalifikowana  
 qualified person

Date of releasing: 18.12.2020

Conclusion: Approved

fagron.pl

Fagron sp. z o.o.

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