

Certificate of Manufacture / Conformance

Product name: Charcoal, activated

Batch number: 20D30-B08-201495

Base unit: 50g

Expiration date: 07.03.2023

Quality: Ph. Eur.

Manufacturing date: 03.07.2020

Inspection report no.: INS-20-02165

Parameter	Limit value	Result	Unit	Laboratory
Appearance	black, light powder free from grittiness	conform		
Identification	acc. to Ph. Eur.	conform		
Acidity or alkalinity	acc. to Ph. Eur.	conform		
Acid-soluble substances	max. 3%	0,72	%	
Alkali-soluble coloured substances	acc. to Ph. Eur.	conform		
Ethanol (96%) soluble substances	max. 0,5 %	0,05	%	
Fluorescent substances	acc. to Ph. Eur.	conform		
Sulfides	acc. to Ph. Eur.	conform		
Copper	max. 25 ppm	10	ppm	El. spol
Lead	max. 10 ppm	<2	ppm	El. spol
Zinc	max. 25 ppm	<2	ppm	El. spol
Loss on drying	max. 15%	5,20	%	
Sulfated ash	max. 5,0%	3,22	%	
Adsorption power	acc. to Ph. Eur.	conform		
Microbial contamination	-TAMC: max. 10 ³ CFU/g -TYMC: max. 10 ² CFU/g	<10 <10	CFU/g	CBMIA
Residual solvents	CPMP/ICH/82 206/06	conform		data producer
Elemental impurities	CHMP/ICH/353369/2013	conform		data producer
TSE/BSE-statement	no contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory Fagron Poland, CBMIA and El spol.

Release:

Dominika Sołtysik

Qualified Person



Fagron sp. z o.o.

Dominika Sołtysik

osoba wykwalifikowana
qualified person

Date of releasing: 16.07.2020

Conclusion: Approved