

Certificate of Manufacture / Conformance

Product name: Charcoal, activated
Batch number: 19G02-B10-194369
Base unit: 50g
Expiration date: 02.03.2022
Quality: Ph. Eur.
Manufacturing date: 25.10.2019
Inspection report no.: INS-19-03014

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%	0,3	%	
Alkali-soluble coloured substances	acc. to Ph. Eur.	conform		
Ethanol (96%) soluble substances	max. 0,5 %	0,08	%	
Fluorescent substances	acc. to Ph. Eur.	conform		
Sulfides	acc. to Ph. Eur.	conform		
Copper	max. 25 ppm	<2	ppm	El. spol
Lead	max. 10 ppm	<2	ppm	El. spol
Zinc	max. 25 ppm	<2	ppm	El. spol
Loss on drying	max. 15%	3,3	%	
Sulfated ash	max. 5,0%	3,15	%	
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: 10.12.2019
Conclusion: Approved