

Certificate of Analysis

Product name: **Aluminii oxidum hydricum leve**

Batch number / Weight: **22H22-B01-222313 / 500 G**

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

Number of analysis / Inspection Code **22H22-B01 / INS-22-7255**

Reference Code / No.: **V01479 / 22-248-30**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, amorphous powder	Conform		
Apparent volume	About 35	33,05	ml / 5 g	
Identification A	White jelly	Conform		
Appearance of solution	<ref. susp. II <GY6	Conform		
Alcaline impurities	Conform	Conform		
Neutralising capacity	pH after 10 min. >1,8	Conform		
Neutralising capacity	pH after 10 min. >2,3	Conform		
Neutralising capacity	pH after 20 min. >3,0	Conform		
Acid-absorbing capacity	<=35,0 ml	7,75	ml NaOH	
Chlorides	<=1	<1	%	
Sulphates	<=1	<1	%	
Arsenic	<=4	Conform	ppm	
Assay Aluminium oxide	47,0 - 60,0	56,70	%m/m	
Total aerobic microbial count (TA)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU/g	
Bile-tolerant gram-neg. bacteria	Negative / gram	Conform		
E. coli	Negative / gram	Conform		
Metallic residues	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

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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:

Ewelina Gadzinowska

Qualified Person

30-10-2022

Expiration: 31-07-2024

Conclusion: APPROVED

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