

Certificate of Analysis

Product name: **Aluminii oxidum hydricum leve**
Batch number / Weight: **21H18-B02-213413 / 500 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, amorphous powder	Conform		
Apparent volume	About 35	31,15	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		
Neutralising capacity	pH at no time >4,5	Conform		
Acid-absorbing capacity	<=35,0 ml	11,40	ml NaOH	
Chlorides	<=1	<1	%	
Sulphates	<=1	<1	%	
Arsenic	<=4	Conform	ppm	
Assay Aluminium oxide	47,0 - 60,0	52,11	%m/m	
Total aerobic microbial count (TA)	<=1000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=100	Conform	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

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

08-02-2022

Expiration: 31-08-2023

Conclusion: APPROVED

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