

Certificate of Analysis

Product name: **Agar pulv.**

Batch number / Weight: **23J24-B01-233817 / 250 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23J24-B01 / INS-23-8846**

Reference Code / No.: **V01408 / 1050/23**

Tests	Requirement	Result	Unit	Standard remark
Appearance	powder or crumpled strips 2-5 mm wide or sometimes flakes, colourless or pale yellow, translucent, somewhat tough becoming more brittle on dryin	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Swelling capacity	>= 10	10,0	ml	
Insoluble substances	<= 1,0	0,10	%	
Gelatine	Conform	Conform		
Loss on drying	<= 20,0	6,77	%	105 °C
Total ash	<=5,0	1,28	%	
Total aerobic microbial count (TA)	<=1000	5,0x10 ²	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU / g	
Microorganisms	Negative / gram	Conform		
Salmonella	Negative / 10 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:
Dominika Soltysik
Qualified Person

22-12-2023

Expiration: 31-10-2026

Conclusion: APPROVED

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