

Certificate of Analysis

Productname: Agar pulv.
Number of analysis/Inspection Code: 1 / KEUR-187455B
Batchnumber: 20F23-F04-373264
Reference code / No.: 3440 / 840/20
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colorless or weak yellow powder	Conform		
Identification A	Conform	Conform		
Identification B	Brownish violet / pale yellow	Conform		
Identification C	White	Conform		
Identification D	Conform	Conform		
Swelling capacity	≥ 10	11,2	ml	
Insoluble substances	$\leq 1,0$	0,6	%	
Gelatine	Conform	Conform		
Loss on drying	$\leq 20,0$	7,7	%	105°C
Total ash	$\leq 5,0$	1,0	%	
Total aerobic microbial count (TAMC)	$\leq 10^3$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	Conform	CFU / g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/02/20

Expiration: 06-2023

Conclusion: APPROVED

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