

Certificate of Analysis

Productname: Agar pulv.

Number of analysis/Inspection Code: 1 / KEUR-184706B

Batchnumber: 20F23-F04-372057

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	<= 1,0	0,6	%	
Gelatine	Conform	Conform		
Loss on drying	<= 20,0	7,7	%	105°C
Total ash	<=5,0	1,0	%	
Total aerobic microbial count (TAMC)	<=10 ³	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=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 + microbieel.

Release:

Paul Hofman

Pharmacist - Qualified Person

08/03/20

Expiration: 06-2023

Conclusion: APPROVED

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