

Certificate of Analysis

Productname: Glucosamini sulfas 2NaCl
Number of analysis/Inspection Code: 1 / KEUR-187363B
Batchnumber: 20H25-F02-373566
Reference code / No.: 3951 / M-NA-2007001
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Chloride
Identification C	Conform	Conform		Sodium
Identification D	Conform	Conform		Sulphate
Identification E	+50,0 - +55,0	Conform		Specific optical rotation
Appearance of solution	Clear / colourless	Conform		
pH	3,0 - 5,0	4,2		10%m/V
Specific optical rotation	+50,0 - +55,0	+53,8	°	10%m/V; dried
Related substances	Conform	Conform		HPLC
Unspecified impurities	<=0,05	0,04	%	
Total impurities	<=0,2	0,0	%	
Loss on drying	<=0,5	0,0	%	105°C
Sulphated ash	23,5 - 26,0	24,7	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
D-Glucosamine sulphate. 2NaCl	98,0 - 102,0	101,5	%m/m	Dried
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		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Remark	Food quality	.		

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/27/20

Expiration: 06-2023

Conclusion: APPROVED

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