

Certificate of Analysis

Product name: Chondroitini natrii sulfas
Batch number / Weight: 21C23-B08-213510 / 50 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder, hygroscopic !	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	5,5 - 7,5	6,18		
Specific optical rotation	-20 - -30	-27,5	°	
Intrinsic viscosity	0,01 - 0,15	0,04	m3 / kg	
Related substances	Conform	Conform		Data producer
Protein	<=3,0	2,6	%	Data producer
Chlorides	<=0,5	<0,5	%	
Loss on drying	<=12,0	8,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chondroitine sulphate sodium	95 - 105	100	%m/m	Data producer
Total aerobic microbial count (TAMC)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU/g	
St. aureus	Negative / gram	Conform		
Ps. aeruginosa	Negative / gram	Conform		
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Bile-tolerant gram-neg. bacteria	Negative / gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

08-10-2021

Expiration: 30-11-2024

Conclusion: APPROVED

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