

Certificate of Analysis

Product name: **Chondroitini natrii sulfas**

Batch number / Weight: **22A11-B02-220496 / 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	6,60		
Specific optical rotation	-20 - -30	-26,3	°	
Intrinsic viscosity	0,01 - 0,15	0,04	m3 / kg	
Related substances	Conform	Conform		DP
Protein	<=3,0	0,00025	%	Data producer
Chlorides	<=0,5	<0,5	%	
Loss on drying	<=12,0	8,70	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chondroitine sulphate sod	95 - 105	99,05	%m/m	Data producer
Total aerobic microbial count (TA)	<=1000	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<1	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
Acetone	<5000 ppm	<5000	ppm	
Methanol		<3000	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Soltysik
Qualified Person

11-05-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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