

## Certificate of Analysis

**Product name:** **Chondroitini natrii sulfas**

**Batch number / Weight:** **22A11-B02-223670 / 50 G**

**Analysed according to:** **Ph.Eur.10.8**

**Number of analysis / Inspection Code** **22A11-B02 / INS-22-2914**

**Reference Code / No.:** **V01542 / 21/0003**

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	<3000	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Eurofins, CBMiA

Release:  
Dominika Soltysik  
Qualified Person

26-09-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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