ISO 9001:2000 / ISO 9001:2008

BYCHEM™ **bayir chemicals**

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : GLUCOSAMINE SULFATE SODIUM CHLORIDE USP			
Batch No.	: NG/GSS/GLS/216125	Quantity	: 1000 Kg
Mfg. Date	: January - 2017	Re-test Date	: December - 2020
A.R.Number	: BC16AF0296	Date of Release	: 30/01/2017

TEST PARAMETERS	SPECIFICATIONS	RESULT	TEST METHOD/ REFERENCE
Appearance	White or almost white crystalline powder	White crystalline powder	In-house
Identification	A) Infrared Absorption. B) It meets the requirement of the tests for Chloride, Sodium and Sulfate. C)The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay.	Complies	USP
Solubility	Freely soluble in water.	Freely soluble	USP
pH of 20 mg/ml solution	3.0 to 5.0	4.0	USP
LOD at 105^0 C for 2 hrs	NMT 1.00 %	0.02 %	USP
Specific rotation of 35 mg/mL solution	$+52.0^0$ to $+54.0^0$	$+53.1^0$	USP
Sulfate	16.3 % to 17.3 %	16.9 %	USP
Potassium	No precipitation formed	Complies	USP
Heavy metals	NMT 0.001 %	< 0.001 %	USP
Arsenic	NMT 3 µg per g	< 3 µg per g	USP
Residue on ignition	23.5 % to 25.0 %	24.0 %	USP
Organic volatile impurities by GC	NMT 1000 ppm	< 30 ppm	USP
Assay by HPLC on dried basis	98.0 % - 102.0 %	99.4%	USP
Related substances by HPLC	Any individual unknown impurity – NMT 0.1 %	Not detected	In house
	Total impurities - NMT 0.5 %	Nil	In house
Total microbial count	NMT 1000 cfu/g	10 cfu/g	USP
Yeast & molds count	NMT 100 cfu/g	Absent	
E.coli	Should be absent in 1 g	Absent	
Salmonella	Should be absent in 10 g	Absent	
Pseudomonas aeruginosa	Should be absent in 1 g	Absent	
Staphylococcus aureus	Should be absent in 1 g	Absent	
Particle Size	Retention on mesh 40 – 5 to 20 %	8.50 %	In house
	Retention on mesh 60 – 15 to 30 %	25.05%	
	Passing from 120 mesh – 5 to 10 %	8.94 %	
REMARKS: THE MATERIAL COMPLIES WITH USP / INHOUSE SPECIFICATIONS			

Conclusions: *The material conforms to the USP & In-house specifications.*
Storage: *Store in tight, light-resistant containers*

Prepared By :	Checked By :	Approved By :
Date : 30/01/2017	Date : 30/01/2017	Date : 30/01/2017

Laboratory : No. 83, 84, 13th Cross, 34th Ward, Kareemsab Layout, Near Peenya 2nd Stage, Bangalore, INDIA, Pin : 560 091.
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INTERFARMA

CERTIFICATE OF ANALYSIS Nº 2520

DATE: July 30, 2018

PRODUCT : Chondroitin Sulfate Sodium - USP GRADE
SPEC CODE: CS02#02 **BATCH Nº: CS180789**
ORIGIN: Bovine **MANUF. DATE: July, 2018**
COUNTRY: Argentina **EXPIRATION DATE: July, 2023**

Organoleptic description	
Appearance	Amorphous powder
Color	White to off white
Odor	Characteristic

Identification	**Result**	**Specification**	**Test Method**
Infrared Absorption	Complies	Positive	USP 38<197K>
Sodium	Complies	Positive	USP 38<191>
Specific rotation	-27.7º	-20.0º / -30.0º	USP 38<781S>
Physical - Chemical properties	**Result**	**Specification**	**Test Method**
Clarity and color of solution	0.30	NMT 0.35	USP 38
pH	6.0	5.5 – 7.5	USP 38<791>
Loss on drying	4.9 %	NMT 5.0 %	USP 38<731>
Residue on ignition	25.4 %	(20.0 – 30.0) %	USP 38<281>
Chloride	Complies	NMT 0.50%	USP 38<221>
Sulfate	Complies	NMT 0.24 %	USP 38<221>
Ammonium	0.1 %	NMT 0.1 %	TA 002
Heavy metals	Complies	NMT 0.002%	USP 38<231 MII>
Electrophoretic purity	Complies	* (Note 1)	USP 38
Limit of protein	Complies	NMT 6.0 %	USP 38
Content of Chondroitin sulfate sodium	96.9 %	(95.0 – 105.0) %	USP 38
Bulk density	0.72 g/ml	NLT 0.60 g/ml	TA 003
Tapped density	0.94 g/ml	NLT 0.70 g/ml	TA 003
Sieve analysis	100 %	NLT 100% through US std #20	TA 502
Microbial limits	**Result**	**Specification**	**Test Method**
Total plate count	< 100 CFU/g	NMT 10^3 CFU/g	USP 38<2021>
Mold and yeast	< 100 CFU/g	NMT 10^2 CFU/g	USP 38<2021>
Enterobacteria	Complies	NMT 50 CFU/g	USP 38<2022>
Escherichia coli	Complies	Absence/g	USP 38<2022>
Clostridium spp	Complies	Absence/g	USP 38<2022>
Clostridium sulfite reducer	Complies	Absence/g	Farm. Arg. 7º Ed
Salmonella spp	Complies	Absence/g	USP 38<2022>
Staphylococcus aureus	Complies	Absence/g	USP 38<2022>
Pseudomonas aeruginosa	Complies	Absence/g	USP 38<61>

(*) Principal band of the test solution at the same position to the one obtained with standard at 100%. (**) Any secondary band of the test solution not more intense than the one obtained with standard at 2%

Storage Conditions: Store at room temperature, in a tight container and reduce the exposure to humidity conditions.

Raw material origIn: The animals from which Chondroitin sulphate sodium is derived fulfill the requirements for the health of animals suitable for human consumption.

RESULT: APPROVED

DATE: 30/July/18

Gabriela Bartel
Technical Director