



K alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	PENTOSAN POLYSULFATE SODIUM	EXPIRATION DATE:	04/2024
FINISHED LOT NO:	PPS/119007	MFG DATE:	005/2019
CAS#	1867-66-9	SPECIFICATIONS:	USP
MANUFACTURE:	Swati Spentose Pvt. LTD UNIT - 1	COUNTRY OF ORIGIN:	INDIA

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS	RESULTS
pH of 25% w/v aqueous solution	Between 4.0 and 6.0	4.82
Moisture content (By Karl Fischer)	Not more than 10.0% w/w	2.96%
Specific optical rotation of 1% w/v	Between -52.0 ° and - 62.0 °, Calculated on dried basis	-58.23 °
Heavy Metals	Not more than 20 ppm	Less than 20 ppm
Glucuronic acid content (by UV)	Between 4.0% and 8.0%	4.68%
Free Chloride	Not more than 500 ppm	Less than 500 ppm
Related Impurities (By GPC)	• Free Glucuronic acid: Not more than 1.0%	0.2%
	• Free Sulfate: Not more than 3.0%	1.0%
Sulphated Ash	Between 34.0% w/w and 41.0% w/w	37.73%

Sulphur Content	Between 15.0% w/w and 19.0% w/w	17.45%
Sodium Content	Between 11.0% w/w and 13.3% w/w	12.22%
Relative average molecular weight (By GPC)	Between 4000 Daltons and 6000 Daltons	5033 Daltons
*Assay (By GPC)	Not less than 95.0% Calculated on dried basis. (The fiducial limits of error are not less than 80% and not more than 125%)	97.74%
Residual Solvents (By GC-HS)	Methanol: Not more than 3000 ppm	15 ppm
	Pyridine: Not more than 200 ppm	169 ppm
	N, N-Dimethylformamide: Not more than 880 ppm	Not Detected
	Methylene dichloride: Not more than 660 ppm	Not Detected
Bacterial Endotoxins	Not More than 1 EU/mg	Complies
Conclusion: as per In- House specifications		

DATE OF RELEASE: _____ **ANALYSIS #** _____

APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control