

MECK PHARMACEUTICALS & CHEMICALS PVT. LTD.



FORMAT NO: QAS/F/051
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CERTIFICATE OF ANALYSIS

PRODUCT:		N-ACETYLGLUCOSAMINE USP	
BATCH NO	NAG/01/18/002	BATCH QTY	100KG
MFG DT.	AUG-2018	AR NO	FP18157
EXP. DT	JUL-2023	RELEASE DATE	28/08/18
Sr. No.	TESTS	SPECIFICATION	RESULT
01	Appearance	White to off white crystalline powder	White crystalline Powder
02	Identification	Should confirm to, A. Infrared B. Test for Optical rotation.(+39.0° to +43.0°) C. The major peak in Chromatogram should confirm to the standard sample.	Complies +40° Complies
03	Residue On Ignition	Not more than 0.1%	0.08%
04	Chloride and Sulfate	Not More Than 0.1%	Complies
05	Melting range	196°C-205°C	198°C
06	PH (1.00% solution in water)	Between 6.0 and 8.0	6.60
07	Loss on drying (at 105 °C for 2.0 Hrs)	Not more than 0.5%	0.24%
08	Assay by HPLC	Between 98% to 102%	99.75%
09	Related substance by HPLC Glucosamine	Not more than 1.0%	0.21%
	Individual impurity	Not more than 0.5%	0.02%
	Total impurities	Not more than 2.0%	0.20%
10	ELEMENTAL IMPURITIES		
	Arsenic	Not more than 1 ppm	Complies
	Lead	Not more than 10 ppm	Complies
11	MICROBIAL		
	Total Aerobic Bacterial Count	NMT 1000 cfu/gm	25cfu/gm
	Total yeast & mold Count	NMT 1000 cfu/gm	10 cfu/gm
	Escherichia coli	Absent/gm	Absent
	Salmonella Spp.	Absent/gm	Absent
REPORT: THE PRODUCT IS RELEASED AS PE USP SPECIFICATION.			
Analysed By		Approved By	
Date: 28/08/18		Date: 28/08/18	



South Asia