

CIN NO. : U24110GJ1992PTC018370

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MECK PHARMACEUTICALS & CHEMICALS PVT. LTD.



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CERTIFICATE OF ANALYSIS

PRODUCT		GLUCOSAMINE SULFATE POTASSIUM CHLORIDE USP		
BATCH NO	GP/01/17/014	BATCH QTY	1000KG	
MFG DT.	AUG-2017	AR NO	FP17187	
EXP. DT	JUL-2022	RELEASE DATE	11/08/17	
Sr. No	TESTS	SPECIFICATION	TEST METHOD RF	RESULT
01	Appearance	White to off white, crystalline powder	Visual	White crystalline powder
02	Identification	A. Infrared absorption spectrum is comparable to the reference standard B. It should meet the requirement of the test for chloride C. The major peak in chromatogram should be confirm to the standard sample	USP<197K> USP<191> USP/NF	Complies Complies Complies
03	Specific optical rotation (2.5% solution in water)	Between +47°C to +53°C	USP/NF<781S>	+50.20°
04	Residue on ignition	Between 26.5% to 31.0%	USP/NF<281>	28.54%
05	pH (2.0% solution in water)	Between 3.0 to 5.0	USP/NF<791>	4.68
06	Loss On Drying (At 105°C for 2 Hrs)	Not more than 1.0 %	USP/NF<731>	0.21%
07	Sodium content	To comply	USP/NF	Complies
08	Sulfate content	Between 15.5% to 16.5%	USP/NF<221>	16.16%
09	Particle size	100% pass through a 80 mesh sieve	USP/NF<786>	Complies
10	Assay by HPLC	Not less than 98.0% and Not more than 102.0% on dried basis	USP/NF	99.83%
11	Heavy metal	Not more than 10ppm	USP/NF<231>	Complies
12	HEAVY METALS			
	Arsenic	Not more than 3.0ppm	USP/NF<730>	Complies
	Lead	Not more than 3.0 ppm	USP/NF<730>	Complies
	Cadmium	Not more than 3.0 ppm	USP/NF<730>	Complies
	Mercury	Not more than 0.1 ppm	USP/NF<730>	Complies
13	MICROBIAL TEST			
	Total aerobic count	Not more than 500 cfu/gm	USP/NF<2021>	25 cfu/gm
	Total yeast & mold count	Not more than 100 cfu/gm	USP/NF<2021>	10 cfu/gm
	Escherichia coil	Absent /gm	USP/NF<2022>	Absent
	Pseudomonas aeruginosa	Absent /gm	USP/NF<2022>	Absent
	Salmonella spp.	Absent /gm	USP/NF<2022>	Absent
	Staphylococcus aureus	Absent /gm	USP/NF<2022>	Absent
REMARKS: PRODUCT IS RELEASED AS PER ABOVE SPECIFICATION				
ANALYSED BY Date: <i>meck</i> 11/08/17		APPROVED BY Date: <i>meck</i> 11/08/17		