CIN NO.: U24110GJ1992PTC018370

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## MECK PHARMACEUTICALS & CHEMICALS PVT. LTD.



FORMAT NO:QAS/F/051

## **CERTIFICATE OF ANALYSIS**

PRODUC				DROCHLORIDE USP							
BATCH NO MFG DT. EXP. DT		GH/01/18/002 AUG-2018 JUL-2023		BATCH QTY AR NO RELEASE DATE	1000 KG FP18140 28/08/18						
						Sr. No.		TESTS		SPECIFICATION	RESULT
						01	Appearance		White	to off white crystalline powder	White crystalline Powder
02	Identification		A. Infr B. It sh of tl C. The	confirm to, ared meet the requirement could meet the requirement ne test for chloride. major peak in omatogram should confirm ne standard sample.	Complies Complies Complies						
03	Specific optical Rotation (2.5% Solution in water)			en +70.0° and +73.0°	+72°						
04	Residue On Ignition		Not mo	ore than 0.1%	0.08 %						
05	pH (2.0% solution in water)		Between 3.0 and 5.0		4.40						
06	Loss on drying (at 105 °C for 2.0 Hrs)		Not mo	ore than 1.0%	0.21 %						
07	Sulfate Content		Not more than 0.24 %		Complies						
08	Particle size		100% r	pass through 80 mesh	Complies						
09	Assay by HPLC			en 98.0% and 102%	99.50 %						
10	Heavy Metal			X							
	Arsenic		Not mo	ore than 3 ppm	Complies						
	Lead		Not mo	ore than 3 ppm	Complies						
	Cadmium			ore than 3 ppm	Complies						
	Mercury			ore than 0.1 ppm	Complies						
11	MICROBIAL TEST										
	Total Bacterial Count		NMT 5	00 cfu/gm	20 cfu/gm						
	Total yeast & mold Count			00 cfu/gm	<10cfu/gm						
	Escherichia coli		Absent		Absent						
	Salmonella Spp.		Absent/gm		Absent						
	Staphylococcus aureus		Absent		Absent						
	Pseudomonas aeruginosa		Absent		Absent						

REPORT: THE PRODUCT IS COMPLIES AS PER USP SPECIFICATION.

Analysed By

Approved By Date:





WORKS: 3/A, KAILASH IND. ESTATE, VILLAGE: IYAVA, TAL: SANAND, DIST.: AHMEDABAD.

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