

CERTIFICATE OF ANALYSIS

PRODUCT	Croscarmellose Sodium U.S.P.	TEST DATE	24-Feb-2023
PARAMETER	STANDARD SPECIFICATIONS	RESULTS OBTAINED	CONCLUSION
Description	White, free flowing powder	Complies	QUALIFIED
Identification	A	Complies	QUALIFIED
	B	Complies	QUALIFIED
	C	Complies	QUALIFIED
Solubility	Complies	Complies	QUALIFIED
pH	5.0-7.0	6.0	QUALIFIED
O.V.I.(Methanol)	NMT 3000 ppm	1320 ppm	QUALIFIED
Loss on drying	NMT 10.0%	5.60%	QUALIFIED
Sodium Chloride and Sodium Glycolate	NMT 0.5%	Complies	QUALIFIED
Heavy Metals (dry basis)	NMT 10ppm	Complies	QUALIFIED
Degree of substitution	0.6-0.85	0.82	QUALIFIED
Content of water soluble substance	1.0-10.0%	9.60%	QUALIFIED
Settling Volume	10ml-30ml	22ml	QUALIFIED
Total microbial count	NMT 1000 CFU/gm	NMT 100CFU/gm	QUALIFIED
Yeast & Molds	NMT 100 CFU/gm	NMT 10 CFU/gm	QUALIFIED
E. Coli	1 gm is free from E coli	Absent	QUALIFIED
Residue on ignition	14.0%-28.0%	22.88%	QUALIFIED
BATCH NO.	-	QUANTITY	-
CUSTOMER'S NAME	-	FINAL CONCLUSION	QUALIFIED

Month/Yr of Manufacturing : Feb - 2023
Month/Yr of Expiry : Jan - 2028
Drug License No. : G/1014