

FDC Limited

CIN: L24235MH1940PLC003176

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Certificate of Analysis

Product	TIMOLOL MALEATE EP		
Batch No.	021F074	Batch Size	5 Kg.
Mfg. Date	06.2021	Exp. Date	05.2026
Sampled Qty.	NA	Sampled by & on	NA
Pack Size	1 X 5 Kg	Inspection lot no.	40000151159
COA Version	Copy 01		

SR.NO	TEST APPLIED	RESULTS	LIMITS
1.	Characteristics	Almost white crystalline powder	White or almost white, crystalline powder or colourless crystals.
2.	Solubility	Complies	Soluble in water and in ethanol (96%)
3.	Melting Point	Melts at 198.6°C	Its melts at about 199°C with decomposition
4.	Identification	Complies	
	A. Specific optical rotation	-5.89°	-5.7° to -6.2°
	B. IR	IR spectrum of sample is concordant with that of standard	IR spectrum of sample should be concordant with that of standard
	C. By TLC	NA	The principal spot in the chromatogram obtained with test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution
	D. Colour test	NA	The colour becomes violet-blue.
5.	Appearance of Solution	Complies	Solution S is clear and not more intensely coloured than reference solution B _s .
6.	pH	4.03	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.08%	Impurity A : NMT 1.0 %
8.	Related substances by HPLC	Complies	
	Impurity B	BDL	NMT 0.2 %.
	Impurity C	ND	NMT 0.2 %
	Impurity D	ND	NMT 0.2 %
	Impurity E	ND	NMT 0.2 %.
	Impurity F	ND	NMT 0.15 %.
	Unspecified impurities	0.05%	NMT 0.10 % of each
	Total impurities	0.05%	NMT 0.25 %
9.	Loss on drying	0.2%	NMT 0.5 %
10.	Sulphated Ash	0.05%	NMT 0.1 %
11.	Assay by potentiometric titration	99.9 %	98.5 % - 101.0 % (on dried basis)
*12.	Residual Solvents	Complies	
	Acetone	643 ppm	NMT 5000 ppm
	Tert-Butanol	ND	NMT 500 ppm
	Dichloromethane	1 ppm	NMT 500 ppm
	Chloroform	ND	NMT 50 ppm
	Benzene	ND	NMT 2 ppm
	Toluene	BDL	NMT 500 ppm
*13	Particle Size (By Microscopic Method)	90 % < 50 Microns	90% < 50 Microns

* Implies Additional In-House Test / BDL Implies Below detection limit./ NA Implies Not Applicable/**Customer requested test
Result: The sample complies with the standards of quality prescribed in EP10 /FPS:4000000819/R2

DATE OF RELEASE 13.07.2021	Mr. A.T. Phadatare PREPARED BY	Mr. P.A. Palav CHECKED BY Manager QC	Mr. V.A. Sawant APPROVED BY QA Sr. Manager QA
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