



# FDC Limited

CIN : L24239MH1940PLC003176

Factory : Plot No. 19 & 20/2 MIDC Area, Village Dhatav, Roha, Dist. Raigad, State : Maharashtra, INDIA  
Phone - (02194) 263580, 263692, 263653, Fax - 263264, Email - roha@fdcindia.com

## Certificate of Analysis

Product	TIMOLOL MALEATE EP		
Batch No.	027K056	Batch Size	5 Kg.
Mfg. Date	11.2017	Exp. Date	10.2022
Sampled Qty.	NA	Sampled by & on	NA
Pack Size	1 X 5 Kg	Inspection lot no.	40000038807

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 198.86°C	Its melts at about 199°C with decomposition
4.	Identification	Complies	
	A. Specific optical rotation	-5.8°	-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 <sub>s</sub> .
6.	pH	4.15	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.26%	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	BDL	NMT 0.10 % of each
	Total impurities	NIL	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	Particle Size by Malvern mastersizer method	90 % < 156.761 Microns	D <sub>90</sub> less than 300 Microns

*In the last steps of the synthesis acetone is used as solvent. Its residual content is limited by the test for loss on drying described in the monograph with a limit of not more than 0.5 %*

\* Implies Additional In-House Test / BDL Implies Below detection limit./ NA Implies Not Applicable

Result: The sample complies with the standards of quality prescribed in EP/FPS:4000000819-3/R1

DATE OF RELEASE 07.12.2017	 Mr. M.N. Mahabale ANALYST	 Mr. P.K. Palav CHECKED BY Dy. Manager QC	 Mr. V.A. Sawant APPROVED BY QA Sr. Manager QA
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SOP:RS-Q-314:F1/A