

# FDC Limited

CIN.: L24239MH1940PLC003176



Factory : Plot No. 19 & 20/2 MIDC Area, Village Dhatav, Roha, Dist. Raigad, State : Maharashtra. INDIA  
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## Certificate of Analysis

Product	TIMOLOL MALEATE EP		
Batch No.	029D052	Batch Size	5 Kg.
Mfg. Date	04.2019	Exp. Date	03.2024
Sampled Qty.	NA	Sampled by & on	NA
Pack Size	1 X 5 Kg	Inspection lot no.	40000082515

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 198.7°C	Its melts at about 199°C with decomposition
4.	Identification	Complies	
	A. Specific optical rotation	-5.99°	-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>8</sub> .
6.	pH	4.03	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.10%	Impurity A : NMT 1.0 %
8.	Related substances by HPLC	Complies	
	Impurity B	BDL	NMT 0.2 %.
	Impurity C	BDL	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	0.1%	NMT 0.5 %
10.	Sulphated Ash	0.05%	NMT 0.1 %
11.	Assay by potentiometric titration	99.7 %	98.5 % - 101.0 % (on dried basis)
*12.	Residual Solvents	Complies	
	Acetone	698 ppm	NMT 5000 ppm
	Tert-Butanol	BDL	NMT 500 ppm
	Dichloromethane	BDL	NMT 500 ppm
	Chloroform	BDL	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/

Result: The sample complies with the standards of quality prescribed in EP 9.1 /FPS:4000000819/R1

DATE OF RELEASE 21.05.2019	 Mr. A.M. Shigvan 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