



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.	TML 160303	Batch Size	18.0 Kg.
Mfg. Date	03/2016	Exp. Date	02/2021
Sampled Qty.	60 g+10g	Sampled by & on	AHW/20.03.2016
Pack Size	1 X 5 Kg	Q.C.Ref.No.	16-BPC-0219

SR.NO	TEST APPLIED	RESULTS	LIMITS
1.	Characteristics	Almost white crystalline powder	A white or almost white, crystalline powder or colourless crystals. Melts at about 199°C with decomposition
2.	Solubility	Complies	Soluble in water and in ethanol (96%)
3.	Melting Point	Melts at 199.6°C	Its melts at about 199°C with decomposition
4.	Identification	Complies	
	A. Specific optical rotation	-5.97°	-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 ₈ .
6.	pH	4.1	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.37%	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	ND	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%	NLT 98.5 % & NMT 101.0 %
*12	Particle Size by Malvern mastersizer method	90 % < 259.833 Microns	D ₉₀ less than 300 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 R1-CEP 2003-070-Rev 02.

DATE OF RELEASE 29.03.2016	 Mr.N.V.Nalawade	 Mr.P.K.Palav	 Mr.V.A.Sawant
	ANALYST	CHECKED BY	APPROVED BY QA

L:RS-Q-076:FCOA/A

Regd. Office : B-8, MIDC Industrial Area, Waluj - 431 136, Dist - Aurangabad, State : Maharashtra INDIA.