



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.	027F001	Batch Size	5 Kg
Mfg. Date	06.2017	Exp. Date	05.2022
Sampled Qty.	116 g	Sampled by & on	ADP / 12.06.2017
Pack Size	1 x 5 Kg	Inspection lot no.	40000025030

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 197.11°C	Its melts at about 199°C with decomposition
4.	Identification	Complies	
	A. Specific optical rotation	-5.9°	-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	3.97	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.14%	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	0.2%	NMT 0.5 %
10.	Sulphated Ash	0.05%	NMT 0.1 %
11.	Assay by potentiometric titration	100.1%	98.5 % - 101.0 % (on dried basis)
*12.	Particle Size by Malvern mastersizer method	90 % < 166.399 Microns	D ₉₀ less than 300 Microns

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

Result: The sample complies with the standards of quality prescribed in EP 9.0/FPS:4000000819/R1

DATE OF RELEASE 22.06.2017	 Mr. S.R. Rane ANALYST	 Mr. P.K. Palav CHECKED BY Dy. Manager QC	 Mr. V.A. Sawant APPROVED BY QA Sr. Manager QA
-------------------------------	------------------------------	--	---