

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.	027A007	Batch Size	6 Kg.
Mfg. Date	01.2017	Exp. Date	12.2021
Sampled Qty.	116g.	Sampled by & on	NND / 12.01.2017
Pack Size	1 X 6 Kg	Inspection lot no.	40000012723

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 199.8°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 _s .
6.	pH	4.1	3.8 - 4.3
7.	Enantiomeric purity by HPLC	0.18%	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	100.3%	98.5 % - 101.0 % (on dried basis)
*12	Particle Size by Malvern mastersizer method	90 % < 69.110 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 EP/FPS:4000000819/R1

DATE OF COMPILATION 28.01.2017	 31.01.17 Mr. M.N. Mahabale	 31.01.17 Mr. P.K. Palav	 31.01.17 Mr. V.A. Sawant
	ANALYST	CHECKED BY Dy. Manager QC	APPROVED BY QA Sr. Manager QA

Regd. Office : B-8, MIDC Industrial Area, Waluj - 431 136, Dist - Aurangabad, State - Maharashtra, INDIA
SOP-RS-Q-314:F1/A