



CERTIFICATE OF ANALYSIS

Name of the Material: Timolol Maleate IP		
Batch No.:	TM/151603	Control No.: TM-1506
Mfg. Date:	OCT- 2015	Exp. Date : SEP-2019
		AR No. : FP/TM/151603
TEST	RESULT	SPECIFICATION
Description	Complies	A white or almost white, crystalline powder or colorless crystals
Solubility	Complies	Soluble in Ethanol(95.0%) and in water, sparingly soluble in Chloroform, practically insoluble in ether
Identification (A) IR	Complies	Infrared absorption spectrum in KBr dispersion should be concordant with the spectrum of Timolol Maleate WRS.
Appearance of Solution	Complies	2.0% w/v solution in carbon dioxide free water is clear and not more intensely coloured than reference solution BS8
Specific Optical Rotation	-5.9	-5.7 to -6.2°
pH	3.9	10.0% w/v solution in 1M Hydrochloric acid 3.8 to 4.3 (2.0% w/v solution)
Related Substances (By HPLC)		
Individual impurity	ND	NMT 0.1%
Total impurity	ND	NMT 0.4%
Enantiomeric Purity (By HPLC)	0.20%	NMT 1.0%
Loss on drying (% w/w)	0.23%	NMT 0.5%
Sulphated ash (% w/w)	0.04%	NMT 0.1%
Assay (% w/w) as C ₁₃ H ₂₄ N ₄ O ₃ S, C ₄ H ₄ O ₄	99.78%	NLT 98.5% and NMT 101.0% on dried basis
OPINION: The sample complies with prescribed as per IP specification		
 10/10/15 Prepared by	 10/10/2015 Checked by	 10/10/15 Approved by