

Laboratory **Gangwal Laboratory Analytical Services, (A Division of Gangwal Chemicals Private Limited), Plot No. T-7, Tarapur MIDC, Boisar, Maharashtra**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-7795**

Page 1 of 2

Validity **30.08.2018 to 29.08.2020**

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
-----	----------------------------	-------------------------	---	--

CHEMICAL TESTING

I.	DRUGS & PHARMACEUTICALS			
1.	Active Pharmaceutical Ingredients			
a.	Timolol Maleate	Identification by FT-IR	IP 2018, Page No.: 3376	Qualitative (4500 cm ⁻¹ to 400 cm ⁻¹)
		Assay by HPLC	USP 41- NF- 36 Page No.: 4096	50% to 150% of Standard
		Related Substances by HPLC	IP 2018, Page No.: 3376	0.03 % (LOQ) to 150 % of 0.1 % Standard
		Residual Solvents by GC	In-house STP (SOP) No: GLS/STP/RM001 Ver. No.: 00 Effective Date: 05-Sep-18	2.2 % (LOQ) to 150 % of 5000 ppm Acetone 0.3 % (LOQ) to 150 % of 3000 ppm Methanol 14.1 % (LOQ) to 150 % of 600 ppm MDC 2.1 % (LOQ) to 150 % of 5000 ppm Tert-Butyl Alcohol 2.0 % (LOQ) to 150 % of 890 ppm Toluene
		pH	IP 2018, Page No.: 3376 USP - 41- NF- 36 Page No.: 4096	1.0 to 12.0
		LOD	IP 2018, Page No.: 3376 USP - 41- NF- 36 Page No.: 4096	0.0 to 0.5 %
		Specific Optical Rotation	IP 2018, Page No.: 3376	- 5.7° to - 6.2°
		Elemental determination (Mercury)	In-house STP (SOP) No: GLS/STP/RM001 Ver. No.: 00 Effective Date: 05-Sep-18	1.5 ppm (LOQ) to 3 ppm

Laboratory **Gangwal Laboratory Analytical Services, (A Division of Gangwal Chemicals Private Limited), Plot No. T-7, Tarapur MIDC, Boisar, Maharashtra**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-7795**

Page 2 of 2

Validity **30.08.2018 to 29.08.2020**

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
b.	Isoxsuprine Hydrochloride	Identification by UV-Visible spectrophotometer	IP 2018, Page No.: 2338 USP - 41- NF- 36 Page No.: 2285	200 nm to 400 nm
c.	Complexol- HP (HPBCD) / Hydroxy propyl betadex	Related substances (Impurity A)	BP 2018, Page No.: 1263	0.03 % (LOQ) to 150 % of 0.1 % Standard
		Limit of Betadex, Propylene Glycol, & Other Related Substances	USP - 41- NF- 36 Page No.: 5385	0.03 % (LOQ) to 150 % of 0.1 % Standard
d.	L-Carnitine L-Tartrate	Assay by HPLC	In-house STP (SOP) No: GLS/STP/RM002 Ver. No.: 00 Effective Date: 05-Sep-18	67.2 % to 69.2 % of L-Carnitine 30.8 % to 32.8 % of L-Tartrate
2.	Excipients			
a.	Lactose Monohydrate	Water Content by Potentiometric titration with Karl Fischer Reagent	IP 2018, Page No.: 2371 USP - 41- NF- 36 Page No.: 5414	4.5 % to 5.5 %