# National Accreditation Board for Testing and Calibration Laboratories

## SCOPE OF ACCREDITATION

**Laboratory Name :** GANGWAL LABORATORY ANALYTICAL SERVICES, (A DIVISION OF GANGWAL HEALTHCARE PRIVATE LIMITED), PLOT NO. T-7, TARAPUR MIDC, BOISAR, MAHARASHTRA, INDIA

**Accreditation Standard** ISO/IEC 17025:2017

**Certificate Number** TC- 7795 **Page No** 1 of 2

**Validity** 09/12/2021 to 30/03/2023 **Last Amended on** -

| S.No | Discipline / Group | Materials or Products tested | Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed | Test Method Specification against which tests are performed and / or the techniques / equipment used |
|---|---|---|---|---|
| Permanent Facility | | | | |
| 1 | CHEMICAL- DRUGS & PHARMACEUTICALS | Complexol-HP (HPBCD) / Hydroxy Propyl Betadex | RS by HPLC Any other impurity | USP-42-NF-37 Page no. 5764 |
| 2 | CHEMICAL- DRUGS & PHARMACEUTICALS | Complexol-HP (HPBCD) / Hydroxy Propyl Betadex | RS by HPLC Limit of Betadex | USP-42-NF-37 Page no. 5764 |
| 3 | CHEMICAL- DRUGS & PHARMACEUTICALS | Complexol-HP (HPBCD) / Hydroxy Propyl Betadex | RS by HPLC Limit of Propeylene Glycol | USP-42-NF-37 Page no. 5764 |
| 4 | CHEMICAL- DRUGS & PHARMACEUTICALS | Complexol-HP (HPBCD) / Hydroxy Propyl Betadex | RS by HPLC Total Impurities | USP-42-NF-37 Page no. 5764 |
| 5 | CHEMICAL- DRUGS & PHARMACEUTICALS | Isoxsuprine Hydrochloride | Identification by UV-Visible Spectrophotometer | IP Page no. 2338 |
| 6 | CHEMICAL- DRUGS & PHARMACEUTICALS | L-Carnitine | Assay by HPLC | In-house STP (SOP) No. : GLS/STP/RM002 Ver. No.:00 Effective Date: 05 Sep-18 |
| 7 | CHEMICAL- DRUGS & PHARMACEUTICALS | L-Tartrate | Assay by HPLC | In-house STP (SOP) no: GLS/STP/RM002 Ver. No.:00 Effective Date: 05 Sep-18: 2018 |
| 8 | CHEMICAL- DRUGS & PHARMACEUTICALS | Lactose Monohydrate | Water Content by Potentiometric titration with Karl-Fischer Reagent | IP Page no. 2371 |
| 9 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Assay by HPLC | USP-42-NF-37 Page no. 4351 |
| 10 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Elemental determination (Mercury) | In-House STP (SOP) No.: GLS/STP/RM001 Ver. No.: 00 Effective Date: 05-Sep-18 |
| 11 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Identification by FT-IR | IP Page no. 3376 |
| 12 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | LOD | IP 2018 Page no. 3376, USP 42-NF-37 Page no. 4351 |
| 13 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | pH | IP 2018 Page no.3376, USP-42-NF-37 Page no.4351 |
| 14 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Impurity C | IP Page no. 3376 |
| 15 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Impurity B | IP Page no. 3376 |
| 16 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Impurity D | IP Page no. 3376 |

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| 17 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Impurity E | IP Page no. 3376 |
| 18 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Impurity F | IP Page no. 3376 |
| 19 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Substances by HPLC Single Maximum Impurity | IP Page no. 3376 |
| 20 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Related Subsutances by HPLC Total Impurities | IP Page no. 3376 |
| 21 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Residual Solvents by GC (Acetone) | In-House STP (SOP) No. GLS/STP/RM001 Ver.No. : 00 Effective Date: 05-Sep-18 |
| 22 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Residual Solvents by GC (MDC) | In-House STP (SOP) No. GLS/STP/RM001 Ver.No. : 00 Effective Date: 05-Sep-18 |
| 23 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Residual Solvents by GC (Methanol) | In-House STP (SOP) No. GLS/STP/RM001 Ver.No. : 00 Effective Date: 05-Sep-18 |
| 24 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Residual Solvents by GC (Tert - Butyl Alcohol) | In-House STP (SOP) No. GLS/STP/RM001 Ver.No. : 00 Effective Date: 05-Sep-18 |
| 25 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Residual Solvents by GC (Toluene) | In-House STP (SOP) No. GLS/STP/RM001 Ver.No. : 00 Effective Date: 05-Sep-18 |
| 26 | CHEMICAL- DRUGS & PHARMACEUTICALS | Timolol Maleate | Specific Optical Rotation | IP Page no. 3376 |