National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : QUALITY CONTROL LABORATORY - NAVIN SAXENA RESEARCH AND TECHNOLOGY PRIVATE LIMITED, PLOT NO. 667,669,670, NEW AREA, KASEZ, GANDHIDHAM, KUTCH, GUJARAT, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-10768 **Page No** 1 of 2

Validity 01/07/2022 to 30/06/2024 **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	Esomeprazole Magnesium Trihydrate	Identification by UV - Vis Spectroscopy	IP (Page no. 183-185)
2	CHEMICAL- DRUGS & PHARMACEUTICALS	Esomeprazole Magnesium Trihydrate	Identification by UV - Vis Spectroscopy	Ph Eur 9.0 – 2402-2404
3	CHEMICAL- DRUGS & PHARMACEUTICALS	Esomeprazole Magnesium Trihydrate	Identification by UV - Vis Spectroscopy	USP43-NF38 – 1714
4	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Assay by HPLC	IP (Page no. 2989-2990)
5	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Assay by HPLC	Ph Eur 9.0 (Page no.3410-3412)
6	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Assay by HPLC	USP 44(5) In-Process Revision: Pregabalin Capsules'
7	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Assay by HPLC	USP43-NF38 (Page no. – 3674)
8	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Dissolution	USP 44(5) In-Process Revision: Pregabalin Capsules'
9	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Enantiomeric Purity by HPLC	IP (Page no. 2989-2990)
10	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Enantiomeric Purity by HPLC	Ph Eur 9.0 (Page no.3410-3412)
11	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Enantiomeric Purity by HPLC	USP43-NF38 (Page no. - 3674)
12	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Identification by Infrared Spectroscopy	IP (Page no. 2989-2990)
13	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Identification by Infrared Spectroscopy	Ph Eur 9.0 (Page no.3410-3412)
14	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Identification by Infrared Spectroscopy	USP43-NF38 (Page no. – 3674)
15	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Loss on Drying	IP (Page no. 2989-2990)
16	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Loss on Drying	Ph Eur 9.0 (Page no.3410-3412)
17	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Loss on Drying	USP43-NF38 (Page no. – 3674)
18	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Polymorphism by XRPD	GTP/FP/001-00

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19	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Related Substances by HPLC	IP (Page no. 2989-2990)
20	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Related Substances by HPLC	Ph Eur 9.0 (Page no.3410-3412)
21	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Related Substances by HPLC	USP 44(5) In-Process Revision: Pregabalin Capsules'
22	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Related Substances by HPLC	USP43-NF38 (Page no. – 3674)
23	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Water Content (by Karl Fischer)	Ph Eur 9.0 (Page no.3410-3412)
24	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Water Content (by Karl Fischer)	IP (Page no. 2989-2990)
25	CHEMICAL- DRUGS & PHARMACEUTICALS	Pregabalin	Water Content (by Karl Fischer)	USP43-NF38 (Page no. – 3674)