

ACCREDITATION DOCUMENT

F-06/02

Issue Date: 18/08/2020

Rev. No: 09 LAB 331

Accreditation No: LAB 331

Awarded to

Quality Control Laboratory HOECHST PAKISTAN LIMITED Plot # 23, Sector 22, Korangi Industrial Area Karachi, Pakistan

The scope of accreditation is in accordance with the standard specifications outlined in the following page(s) of this document. The accredited scope shall be visible and legible in areas such as customer service, sample-receiving section etc. and shall not mislead its users.

The accreditation was first time granted on **05-05-2025** by Pakistan National Accreditation Council.

The laboratory complies with the requirements of ISO/IEC 17025:2017.

The accreditation requires regular surveillance, and is valid until **04-05-2028**.

The decision of accreditation made by Pakistan National Accreditation Council implies that the organization has been found to fulfill the requirements for accreditation within the scope.

The organization however, itself is responsible for the results of performed measurements/tests.

PAKISTAN NATIONAL ACCREDITATION COUNCIL

05-05-2025	SD_
Date	Director General



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Testing Laboratory.

Accreditation Scope of Quality Control Laboratory, Hoechst Pakistan Limited, Plot #23, Sector 22, Korangi Industrial Area Karachi, Pakistan.

Permanent laboratory premises



Materials/Product s tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured /technique	Reference to standardized method (e.g. ISO 14577-1:2003)/ Internal method reference
	Chemical Testing	Assay(HPLC)	USP2024 Chromatography <621> HPLC.
	Chemical Testing	Identification (HPLC)	USP2024 Chromatography <621> HPLC.
	Chemical Testing	Dissolution (UV)	USP 2024 (711) Dissolution. (857) Ultraviolet-visible spectrophotometer
	Pharmaceutical Microbiological Testing	Microbial Enumeration Test	USP 2024, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test
Flagyl (Metronidazole) Tablet 400mg			USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Pharmaceutical Microbiological Testing	Test for Specified Micro- organisms	 USP 2024, <62>Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use
Flagyl (Metronidazole) Infusion 500mg/100ml	Chemical Testing	Assay(UV)	BP 2024 Ultraviolet-visible spectrophotometer
Flagyl (Metronidazole as	Chemical Testing	Assay (HPLC)	BP2024 Appendix III D. Chromatography, HPLC
benzoate) Suspension 200mg/5ml	Chemical Testing	Identification (HPLC)	BP2024 Appendix III D. Chromatography, HPLC

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	Pharmaceutical Microbiological Testing Pharmaceutical	Microbial Enumeration Test	USP 2024, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test USP 2024, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use USP 2024, <62> Microbiological Examination
	Microbiological Testing	Specified Micro- organisms	of Nonsterile Products: Tests for Specified Microorganisms • USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Chemical Testing	Assay(HPLC)	USP 2024 Chromatography <621> HPLC
Phenergan (Promethazine HCl) Elixir 5mg/5ml	Pharmaceutical Microbiological Testing	Microbial Enumeration Test	 USP 2024, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Pharmaceutical Microbiological Testing	Test for Specified Micro- organisms	 USP 2024, <62>Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Chemical Testing	Assay(HPLC)	USP 2024 Chromatography <621> HPLC
Tavanic 250mg & 500mg Tablet (Levofloxacin)	Chemical Testing	Dissolution(UV)	USP 2024 (711) Dissolution. (857) Ultraviolet-visible spectrophotometer
	Pharmaceutical Microbiological Testing	Microbial Enumeration Test	 USP 2024, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Pharmaceutical Microbiological	Test for Specified	USP 2024, <62>Microbiological Examination of Nonsterile Products: Tests for Specified

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	Testing	Micro- organisms	Microorganisms • USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Chemical Testing	Assay(HPLC)	USP 2024 Chromatography <621> HPLC
	Chemical Testing	Dissolution (UV)	USP 2024 (711) Dissolution. (857) Ultraviolet-visible spectrophotometer
Tarivid 200mg Tablet (Ofloxacin)	Pharmaceutical Microbiological Testing	Microbial Enumeration Test	 USP 2024, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test USP 2024, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
	Pharmaceutical Microbiological Testing	Test for Specified Micro- organisms	 USP 2024, <62>Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms USP 2024, <1111>Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use

<u>05-05-2025</u>	