

## ACCREDITATION DOCUMENT

F-06/02

**Issue Date: 10/08/15** 

Rev. No: 07 LAB 090

**Accreditation No: LAB 090** 

#### Awarded to

# Quality Control Laboratory KAIZEN PHARMACEUTICAL (PVT.) LIMITED, Address: E 127-129, North Western Industrial Zone, Bin Qasim 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 **16-07-2015** by Pakistan National Accreditation Council.

The laboratory complies with the requirements of ISO/IEC 17025:2005.

The accreditation requires regular surveillance, and is valid until **01-08-2021**.

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

02-08-2018	
Date	Director General



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### **Testing Laboratory.**

Accreditation Scope of KAIZEN PHARMACEUTICAL (PVT.) LIMITED, Karachi, Pakistan.

Permanent laboratory premises



Materials/Prod ucts tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured	Reference to standardized method (e.g. ISO 14577- 1:2003)/ Internal method reference
Servaz 250mg and 500mg Tablet (Azithromycin)	Pharmaceutical Testing  Pharmaceutical Testing  Pharmaceutical Testing	Assay  Dissolution  Identification	USP 39 NF 34 (2016) Volume 3 /Liquid chromatography/ HPLC  USP 39 NF34 (2016) Volume 3 /Test (711) Dissolution / Apparatus II(Paddle)  USP 39 NF 34 (2016) Volume 3
Claract 250mg and 500mg Tablet	Pharmaceutical Testing	Assay	/Liquid chromatography/ HPLC  USP 39 NF 34 (2016) Volume 3 /Liquid chromatography/ HPLC
(clarithromycin)	Pharmaceutical Testing	Dissolution	USP 39 NF34 (2016) Volume 3 /Test (711) Dissolution / Apparatus II(Paddle)
	Pharmaceutical Testing	Identification	USP 39 NF 34 (2016) Volume 3 /Liquid chromatography/ HPLC

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Materials/Pr oducts tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured	Reference to standardized method (e.g. ISO 14577- 1:2003)/ Internal method reference
Dolotec 550mg Tablet	Pharmaceutical Testing	Assay	USP 39 NF 34 (2016) Volume 5 /Liquid chromatography/ HPLC
(Naproxen Sodium)	Pharmaceutical Testing	Dissolution	USP 39 NF34 (2016) Volume 5 /Test (711) Dissolution / Apparatus II(Paddle)
	Pharmaceutical Testing	Identification	USP 39 NF 34 (2016) Volume 5 /Liquid chromatography/ HPLC
Mylinco 500mg Capsule	Pharmaceutical Testing	Assay (Azithromycin)	USP 39 NF 34 (2016) Volume 5 /Liquid chromatography/ HPLC
(Lincomycin)	Pharmaceutical Testing	Dissolution (Azithromycin)	USP 39 NF34 (2016) Volume 5 /Test (711) Dissolution / Apparatus II(Paddle)
	Pharmaceutical Testing	Identification (Azithromycin)	USP 39 NF 34 (2016) Volume 5 /Liquid chromatography/ HPLC

Director