

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 191
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Accreditation No: LAB 191

Awarded to

Searle Pakistan Limited
C-14, Manghopir Road, S.I.T.E.
Karachi-75700, 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 **07-02-2020** 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 **06-02-2026**.

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

07-02-2023

Date

SD

Director General

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Testing Laboratory.

**Accreditation Scope of Searle Pakistan Limited. C-14, Manghopir Road,
S.I.T.E., Karachi-75700, Pakistan.**

Permanent laboratory premises

Materials/ Products 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
Aldomet Tablet 250 mg (Methyldopa 250 mg Tablets-USP)	Chemical	Assay	USP Official Monograph/ Methyldopa Tablets /HPLC– <621> Chromatography
Renitec Tablet 5 mg (Enalapril Maleate 5 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	HPLC – USP Official Monograph/ Enalapril Maleate Tablets <621> Chromatography. HPLC – USP Official Monograph/ Enalapril Maleate Tablets <621> Chromatography <711> Dissolution
Renitec Tablet 10 mg (Enalapril Maleate 10 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	HPLC – USP Official Monograph/ Enalapril Maleate Tablets <621> Chromatography. HPLC – USP Official Monograph/ Enalapril Maleate Tablets <621> Chromatography <711> Dissolution
Moduretic Tablet 5/50 mg (Amiloride Hydrochloride 5 mg and Hydrochlorothiazide 50 mg Tablets-USP)	Chemical	Assay	HPLC – USP Official Monograph/ Amiloride Hydrochloride and Hydrochlorothiazide Tablets <621> Chromatography

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Sinemet Tablet 25/250 mg (Carbidopa 25 mg and Levodopa 250 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monograph/Carbidopa and Levodopa Tablets <621> Chromatography</p> <p>HPLC – USP Official Monograph/ Carbidopa and Levodopa Tablets <621> Chromatography <711> Dissolution</p>
Andrex Capsule 40 mg (Testosterone Undecanoate 40 mg Capsules)	Chemical	Assay	HPLC – <621> Chromatography In-house method/ Testosterone Undecanoate Capsules.
Morcet Tablet 5 mg (Escitalopram 5 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Escitalopram Tablets <621> Chromatography</p> <p>HPLC – USP Official/ Monograph/Escitalopram Tablets <621> Chromatography <711> Dissolution</p>
Morcet Tablet 10 mg (Escitalopram 10 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Escitalopram Tablets <621> Chromatography</p> <p>HPLC – USP Official Monograph/Escitalopram Tablets <621> Chromatography <711> Dissolution</p>
Morcet Tablet 20 mg (Escitalopram 20 mg Tablets-USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Escitalopram Tablets <621> Chromatography</p> <p>HPLC – USP Official Monograph/ Escitalopram Tablets <621> Chromatography <711> Dissolution</p>

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<p>Ezium Capsules 20 mg (Esomeprazole 20 mg Delayed Release Capsules- USP)</p>	<p>Chemical</p>	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Esomeprazole Magnesium Delayed Release Capsules <621> Chromatography</p> <p>Buffer Stage: HPLC – USP Official Monograph/ Esomeprazole Magnesium Delayed Release Capsules <621> Chromatography <711> Dissolution</p>
<p>Ezium Capsules 40 mg (Esomeprazole 40 mg Delayed Release Capsules- USP)</p>	<p>Chemical</p>	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Esomeprazole Magnesium Delayed Release Capsules <621> Chromatography</p> <p>Buffer Stage: HPLC – USP Official Monograph/ Esomeprazole Magnesium Delayed Release Capsules <621> Chromatography <711> Dissolution</p>
<p>Zenbar Capsules 20 mg (Duloxetine 20 mg Delayed Release Capsules - USP)</p>	<p>Chemical</p>	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monograph/ Duloxetine DR Capsules<621> Chromatography</p> <p>Acid Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules <621> Chromatography/ <711> Dissolution</p> <p>Buffer Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules <621> Chromatography/ <711> Dissolution</p>
<p>Zenbar Capsules 30 mg (Duloxetine 30 mg Delayed Release Capsules - USP)</p>	<p>Chemical</p>	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monograph/ Duloxetine DR Capsules<621> Chromatography</p> <p>Acid Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules<621> Chromatography/ <711> Dissolution</p> <p>Buffer Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules<621> Chromatography/ <711> Dissolution</p>

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Zenbar Capsules 60 mg (Duloxetine 60 mg Delayed Release Capsules - USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monograph/ Duloxetine DR Capsules <621> Chromatography</p> <p>Acid Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules <621> Chromatography/ <711> Dissolution</p> <p>Buffer Stage: HPLC – USP Official Monograph/ Duloxetine DR Capsules <621> Chromatography/ <711> Dissolution</p>
Dextop Capsules 30 mg (Dexlansoprazole DDR 30 mg Capsule)	Chemical	Assay	HPLC – <621> Chromatography/ In-house method/ Dexlansoprazole DDR Capsule
Dextop Capsules 60 mg (Dexlansoprazole DDR 60 mg Capsule)	Chemical	Assay	HPLC – <621> Chromatography/ In-house method/ Dexlansoprazole DDR Capsule
Tryptanol Tablets 25 mg (Amitriptyline Hydrochloride 25 mg Tablets –USP)	Chemical	Assay	HPLC – USP Official Monograph/Amitriptyline Hydrochloride Tablets/ <621> Chromatography
Decadron Injection 4mg/mL (1mL) (Dexamethasone Sodium phosphate injection 4mg/mL – USP)	Chemical	Assay	HPLC – USP Official Monograph/ Dexamethasone Sodium Phosphate Injection/ <621> Chromatography
Decadron Injection 4mg/mL (5mL) (Dexamethasone Sodium phosphate injection 4mg/mL – USP)	Chemical	Assay	HPLC – USP Official Monograph/ Dexamethasone Sodium Phosphate Injection/ <621> Chromatography

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Selanz Capsules 30 mg (Lansoprazole Delayed-Release Capsules U.S.P)	Chemical	Assay	HPLC – USP Official Monograph/ Lansoprazole Delayed -Release Capsules <621> Chromatography
Virdi Tablets 250 mg (Azithromycin 250 mg Tablets –USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Azithromycin Tablets <621> Chromatography</p> <p>HPLC – USP Official Monographs/ Azithromycin Tablets. <621> Chromatography <711> Dissolution</p>
Virdi Tablets 500 mg (Azithromycin 500 mg Tablets –USP)	Chemical	<ul style="list-style-type: none"> • Assay • Dissolution 	<p>HPLC – USP Official Monographs/ Azithromycin Tablets <621> Chromatography</p> <p>HPLC – USP Official Monographs/ Azithromycin Tablets. <621> Chromatography <711> Dissolution</p>

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