

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 176
---	-----------------------------------	---

Accreditation No: LAB 176

Awarded to

**SAMI Pharmaceuticals (Pvt) Limited Quality Control Lab,
F-95, Off Hub River Road, S.I.T.E, 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 **08-07-2019** 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 **07-07-2025**

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

03-08-2022
Date

SD
Director General

 <p>Pakistan National Accreditation Council</p>	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 176
--	-----------------------------------	---

Testing Laboratory.

Accreditation Scope of SAMI Pharmaceuticals (Pvt) Limited Quality Control
Lab.

F-95, Off Hub River Road, S.I.T.E, Karachi, 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
Sedil Syrup (Cetirizine Dihydrochloride)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38 / pH /pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Neo-Sedil Syrup (Levo-Cetirizine Dihydrochloride)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38 /pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Lacasil Syrup (Lactitol)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38 / pH /pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Bisleri Syrup (Iron Poly Maltose)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH /pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Dicloran Injection 3ml (Diclofenac Sodium)	Pharmaceutical Physical Testing	pH	2022 USP 41 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2012 / Pycnometer
Novidat inj. 200mg/100ml (Ciprofloxacin)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220

03-08-2022
Date

Sd
Director

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 176
---	-----------------------------------	---

Novidat inj. 400mg/100ml (Ciprofloxacin)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220
Grasil inj. 500mg/2ml (Amikacin Sulphate)	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Grasil inj. 250mg/2ml (Amikacin Sulphate	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Grasil inj. 100mg/2ml (Amikacin Sulphate	Pharmaceutical Physical Testing	pH	2022 USP 41 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Grasil inj. 50mg/2ml (Amikacin Sulphate	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Grasil inj. 25mg/2ml (Amikacin Sulphate	Pharmaceutical Physical Testing	pH	2022 USP 43 NF 38/ pH / pH meter S220
		Specific Gravity	BP 2022 / Pycnometer
Novidat 250mg Ciprofloxacin HCL)Tablet	Pharmaceutical Chemical Testing	Dissolution	USP 43/NF38/ DISSOLUTION UNIT/SPECTROPHOTOM ETER
		Assay	USP 43/NF38/HPLC
Novidat 500mg Tablet (Ciprofloxacin HCL)	Pharmaceutical Chemical Testing	Dissolution	USP 43/NF38/ DISSOLUTION UNIT/SPECTROPHOTOM ETER
		Assay	USP 43/NF38/HPLC
Mofest 400mg Tablet (Moxifloxacin HCL)	Pharmaceutical Chemical Testing	Dissolution	USP 43/NF38/ DISSOLUTION UNIT/SPECTROPHOTOM ETER

03-08-2022
Date

Sd
Director



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 176

		Assay	USP 43/NF38/HPLC
Tonoflex-P-Tablet 325mg/37.5mg (Paracetamol/ Tramadol Hydrochloride)	Pharmaceutical Chemical Testing	Dissolution	USP 43/NF38/ DISSOLUTION UNIT/ HPLC
		Assay	USP 43/NF38/HPLC
Tonoflex-P Forte Tablet 650mg/75mg (Paracetamol/ Tramadol Hydrochloride)	Pharmaceutical Chemical Testing	Dissolution	USP 43/NF38/ DISSOLUTION UNIT/ HPLC
		Assay	USP 43/NF38/HPLC
TONOFLEX SR 100mg TABLETS (Tramadol HCL)	Pharmaceutical Microbiological Testing	Microbial Enumeration Test	<ul style="list-style-type: none"> • USP 44, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use
TONOFLEX SR 100mg TABLETS (Tramadol HCL)	Pharmaceutical Microbiological Testing	Test for Specified Micro-organisms	<ul style="list-style-type: none"> • USP 44, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use

03-08-2022
Date

Sd

Director

<p>BISLERI CHEWABLE TABLET (Iron (III) Hydroxide Polymaltose Complex, Folic Acid)</p>	<p>Pharmaceutical Microbiological Testing</p>	<p>Microbial Enumeration Test</p>	<ul style="list-style-type: none"> • USP 44, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use
<p>BISLERI CHEWABLE TABLET (Iron (III) Hydroxide Polymaltose Complex, Folic Acid)</p>	<p>Pharmaceutical Microbiological Testing</p>	<p>Test for Specified Micro-organisms</p>	<ul style="list-style-type: none"> • USP 44, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use
<p>ROLAC 100mg CAPSULE (Itraconazole)</p>	<p>Pharmaceutical Microbiological Testing</p>	<p>Microbial Enumeration Test</p>	<ul style="list-style-type: none"> • USP 44, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Test • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 176

ROLAC 100mg CAPSULE (Itraconazole)	Pharmaceutical Microbiological Testing	Test for Specified Micro-organisms	<ul style="list-style-type: none"> • USP 44, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms • USP 44, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations And Substances for Pharmaceutical Use
TONOFLEX 100mg INJECTION (Tramadol HCL)	Pharmaceutical Microbiological Testing	Sterility Test	<ul style="list-style-type: none"> • USP 44, <71> Sterility Tests
BISLERI - S 100mg INJECTION (Iron Sucrose Complex)	Pharmaceutical Microbiological Testing	Sterility Test	<ul style="list-style-type: none"> • USP 44, <71> Sterility Tests
Benzoic acid	Pharmaceutical Chemical Testing	Acid base titration	<ul style="list-style-type: none"> • BP (ph. Eur. Monograph)
Citric acid	Pharmaceutical Chemical Testing	Acid base titration	<ul style="list-style-type: none"> • BP (ph. Eur. Monograph)
Sodium Hydroxide	Pharmaceutical Chemical Testing	Acid base titration	<ul style="list-style-type: none"> • BP (ph. Eur. Monograph)
Enier 8mg Tablet	Pharmaceutical Chemical Testing	Disintegration	<ul style="list-style-type: none"> • British Pharmacopeia 2021, Appendix XII,1.Disintegration/Equipment Disintegration unit
Enier 16mg Tablet	Pharmaceutical Chemical Testing	Disintegration	<ul style="list-style-type: none"> • British Pharmacopeia 2021, Appendix XII,1.Disintegration/Equipment Disintegration unit

03-08-2022
Date

Sd

Director



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 18/08/2020
Rev. No: 09
LAB 176

Enier 24mg Tablet	Pharmaceutical Chemical Testing	Disintegration	<ul style="list-style-type: none"> British Pharmacopeia 2021, Appendix XII,1.Disintegration/Equipment Disintegration unit
ROLAC 100mg CAPSULE (Itraconazole)	Pharmaceutical Chemical Testing	Assay	<ul style="list-style-type: none"> British Pharmacopeia 2021,Liquid chromatography , Appendix IIID/Equipment used HPLC
ROLAC 100mg CAPSULE (Itraconazole)	Pharmaceutical Chemical Testing	Dissolution	<ul style="list-style-type: none"> British Pharmacopeia 2021,Dissolution test , Appendix XIIB/Equipment used HPLC and dissolution apparatus
Delanzo DR 60mg Capsule (Dexlansoprazole)	Pharmaceutical Testing	Assay test	<ul style="list-style-type: none"> USP 44,Chromatography <621>/Equipment used HPLC
Delanzo DR 60mg Capsule (Dexlansoprazole)	Pharmaceutical Chemical Testing	Dissolution test	<ul style="list-style-type: none"> USP 44, Dissolution Test <711>/Equipment used Dissolution unit and spectrophotometer
Delanzo DR 30mg Capsule (Dexlansoprazole)	Pharmaceutical Chemical Testing	Assay test	<ul style="list-style-type: none"> USP 44,Chromatography <621>/Equipment used HPLC
Delanzo DR 30mg Capsule (Dexlansaoprazole)	Pharmaceutical Chemical Testing	Dissolution test	<ul style="list-style-type: none"> USP 44, Dissolution Test <711>/Equipment used Dissolution unit and spectrophotometer
Novidat 125mg/5ml Suspension (Ciprofloxacin HCl)	Pharmaceutical Chemical Testing	Assay	<ul style="list-style-type: none"> USP 44,Chromatography <621>/Equipment used HPLC
Novidat 250mg/5ml Suspension (Ciprofloxacin HCl)	Pharmaceutical Chemical Testing	Assay	<ul style="list-style-type: none"> USP 44,Chromatography <621>/Equipment used HPLC

03-08-2022
Date

Sd
Director

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 176
---	-----------------------------------	---

Provas N Tablets (Paracetamol +Orphenadrine citrate)	Pharmaceutical Chemical Testing	Assay	<ul style="list-style-type: none"> • USP 44,Chromatography <621>/Equipment used HPLC
Provas N Tablets (Paracetamol +Orphenadrine citrate)	Pharmaceutical Chemical Testing	Dissolution	<ul style="list-style-type: none"> • USP 44, Dissolution Test <711>/Equipment used Dissolution unit and HPLC
Provas N forte Tablets (Paracetamol +Orphenadrine citrate)	Pharmaceutical Chemical Testing	Assay	<ul style="list-style-type: none"> • USP 44,Chromatography <621>/Equipment used HPLC
Provas N forte Tablets (Paracetamol +Orphenadrine citrate)	Pharmaceutical Chemical Testing	Dissolution	<ul style="list-style-type: none"> • USP 44, Dissolution Test <711>/Equipment used Dissolution unit and HPLC
TONOFLEX SR 100mg TABLETS (Tramadol HCL)	Pharmaceutical Chemical Testing	Weight variation	<ul style="list-style-type: none"> • British Pharmacopeia 2021, Consistency of Formulated preparation/Equipment used weighing balance

03-08-2022
Date

Sd

Director