

	ACCREDITATION DOCUMENT	F-06/02 Issue Date: 18/08/2020 Rev. No: 09 LAB 168
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Accreditation No: LAB 168

Awarded to

**Quality Control Laboratory
BOSCH PHARMACEUTICALS (Pvt.) LTD.**

Bosch House 221, Sector 23, 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 **08-01-2019** 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 **07-01-2025**.

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

08-04-2022
Date

SD
Director General

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Testing Laboratory.

Accreditation Scope of Quality Control Laboratory, M/s **Bosch Pharmaceuticals (Pvt.) Ltd.**, Bosch House, 221-223, Sector 23, Korangi Industrial Area, 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
Fixcef (Cefixime) Suspension 100mg/5mL	Pharmaceutical	pH Water Content Assay Content Uniformity	USP44/ USP44: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Baxolyn (Ciprofloxacin HCl) Tablet 500mg	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Quinoflox (Ciprofloxacin HCl) Tablet 500mg/Tablet, 750mg/Tablet	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Calamox (Amoxicillin+ Potassium Clavulanate) Suspension 156.25mg/5ml, 312.50mg/5ml,	Pharmaceutical	pH Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Calamox (Amoxicillin+ Potassium Clavulanate) Duo Suspension 400/57mg/ml	Pharmaceutical	pH Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC (USP 44, 2021)

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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
Calamox (Amoxicillin+ Potassium Clavulanate) Tablet 375mg/Tablet, 625mg/Tablet, 100mg/Tablet	Pharmaceutical	Content Uniformity Dissolution. Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Supramox (Amoxicillin) Suspension 125mg/5ml, 250mg/5ml	Pharmaceutical	pH Assay Weight Variation	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Supramox (Amoxicillin) Capsule 250mg/Capsule, 500mg/Capsule	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Qumic (Levofloxacin) Tablet 250mg/Tablet, 500mg/Tablet, 750mg/Tablet.	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Cefrinex (Cephadrine) Suspension 125mg/5mL, 250mg/5ml,	Pharmaceutical	pH Water Content Assay Weight Variation	USP44 / USP: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Cefrinex (Cephadrine) Vial 250mg/Vial, 500mg/Vial, 1000mg/Vial	Pharmaceutical	pH Assay Weight Variation	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)

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Cefrinex (Cephadrine) Capsule 250mg/Capsule, 500mg/Capsule	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Cebosh (Cefixime) Suspension 100mg/5ml, 200mg/5m	Pharmaceutical	pH Assay Weight Variation	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Cebosh (Cefixime) Tablet 400mg/Tablet	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Cebosh (Cefixime) Capsule 400mg	Pharmaceutical	Weight Variation. Dissolution. Assay	M.S / Uniformity of Weight / Analytical Balance M.S / Liquid Chromatography / UV M.S / Liquid Chromatography / HPLC (SOP No. B1-QCT-SPF-0091)
Cefxone (Ceftriaxone) Vial 250mg/Vial, 500mg/Vial, 1000mg/Vial	Pharmaceutical	pH Weight Variation. Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Cefotax (Cefotaxime) Vial 250mg/Vial, 500mg/Vial, 100mg/Vial.	Pharmaceutical	pH Weight Variation. Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Orthofenac (Diclofenac Sodium) Injection 75mg	Pharmaceutical	pH Assay	MS / Physical Test pH / pH Meter M.S / Liquid Chromatography / UV (Bosch Spec.) (SOP No. B1-QCT-SPF-0034)

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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
Cefalor (Cefaclor) Suspension 125mg/5ml, 250mg/5ml	Pharmaceutical	pH Water Content Assay Weight variation	USP44 / USP: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Cefalor (Cefaclor) Capsule 250mg/Capsule, 500mg/Capsule	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Cefalor (Cefaclor) Drops 50mg	Pharmaceutical	pH Water Content Assay Content Uniformity	USP44 / USP: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Dromax (Cefadroxil) Suspension 125mg, 250mg	Pharmaceutical	pH Water Content Assay Weight variation	USP44 / USP: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Dromax (Cefadroxil) Drops 100mg,	Pharmaceutical	pH Water Content Assay Weight Variation	USP44 / USP: Physical Test (791) pH / pH Meter Karl Fischer USP44 / Liquid Chromatography / HPLC USP44 / Uniformity of Weight / Analytical Balance (USP 44, 2021)
Dromax (Cefadroxil) Capsule 500mg/Capsule	Pharmaceutical	Weight Variation. Dissolution. Assay	USP44 / Uniformity of Weight / Analytical Balance USP44 / Liquid Chromatography / UV USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Omezol (Omeprazole) Capsule 20mg	Pharmaceutical	Content uniformity Dissolution. Assay	USP44 / Liquid Chromatography / HPLC USP44 / Liquid Chromatography / HPLC USP44 / Liquid Chromatography / HPLC (USP 44, 2021)

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Penro (Meropenem) Vial 500mg	Pharmaceutical	pH Assay	USP44 / USP: Physical Test (791) pH / pH Meter USP44 / Liquid Chromatography / HPLC (USP 44, 2021)
Qbal (Mecobalamine) Injection 500mcg	Pharmaceutical	pH Assay	M.S / Physical Test pH / pH Meter M.S / Liquid Chromatography / UV (Bosch Spec.) (SOP No. B1-QCT-SPF-0112)
Qbal (Mecobalamine) Tablet 500mcg	Pharmaceutical	Content Uniformity Assay	JP XVI / USP: Physical Test pH / pH Meter JP XVI / Liquid Chromatography / HPLC (JP 16 th Edition)

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