



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

OFFICE OF THE DIRECTOR DRUG EVALUATION AND RESEARCH (DER)

DIRECTORATE

Plot 1, Isolo Industrial Scheme, Oshodi-Apapa Expressway, Isolo, Lagos

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Ref. No: DER/PO/SSZ/02489/VOL.I/08

Date: 17th April, 2025

The Managing Director,
Carlos Pharmaceuticals Limited,
Ayade Industrial Park,
Km 15 Goodluck Jonathan Bypass,
Calabar, Cross River State

Dear Sir,

**NOTIFICATION OF OUTCOME OF GOOD MANUFACTURING PRACTICE (GMP)
INSPECTION**

Kindly recall that your factory was inspected by a team of NAFDAC inspectors on the 26th & 27th March, 2025. The scope of the inspection covered a follow-up to the last Pre-Production inspection and a Pre-Registration Inspection.

Following the high level of management and staff commitment to GMP compliance as observed, the outcome of the inspection indicated that your facility met the minimum GMP requirements. Therefore, a letter of Authority to manufacture on the following lines:

Non- Beta lactam product lines;

1. Oral Solid Dosage Forms (OSD) – Tablets, Capsules and Dry Powder
2. Oral Liquid Dosage Forms (OLD) -Syrups
3. Topical Preparations- Creams and Ointment is now being processed.

In addition, your application for registration of products may now be considered. You are requested to liaise with the Pharma Operations Division of Drug Evaluation and Research (DER) Directorate for sampling of the under-listed products for laboratory analysis.

S/No.	NAME OF PRODUCT	PACK SIZE	INGREDIENTS
1	Carlos® Artemeter Lumefantrine Tablets 80/480mg	1X6	Artemether and Lumefantrine
2	Carlos® Artemeter Lumefantrine Tablets 20/120mg	1X24	Artemether and Lumefantrine

3	Carlos® Tenoxicam Capsules 20mg	10X10	Tenoxicam
4	Carlos® Piroxicam Capsules 20mg	10X10	Piroxicam
5	Carlos® Ibuprofen Suspension 100mg/5ml	100ml	Ibuprofen
6	Carlos® Cetirizine Syrup 5mg/5ml	100ml	Cetirizine
7	Itis® Methyl salicylate Ointment 30g/jar	30g	Methyl Salicylate

You are however expected to submit your CAPA Plan of actions taken to close the few deficiencies using the table below and provide objective evidences of completion of corrective action in an electronic editable format to amuda.k@nafdac.gov.ng and copy der.pharmaquarters@nafdac.gov.ng.

S/N	Audit findings (observations)	Root cause analysis	Correction	Corrective Action(s)	Indicators for Completion	Timeline	Responsibility	CAPA Status
Critical								
Major								
Others								

For the Corrective Action Plan Signature of Responsible Person and Managing Director of Manufacturing company;

***Responsible Person:**

Name:

Signature: _____ Date: _____

Managing Director

Name:

Signature: _____ Date: _____

*The "Responsible Person" is the person responsible at the manufacturer for the implementation of the corrective action plan.

Kindly acknowledge receipt and revert with your CAPA plan on the deficiencies within 14 calendar days of receiving this letter.

Thank you.



Amuda Kayode
Director (DER)
For: Director-General (NAFDAC).