



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No:

PPB/INS/MAA/RPT/149/21

25th February 2022

RE: MARKET AUTHORIZATION AUDIT CLOSURE

In reference to the audit that was performed on **11th & 12th November, 2021** by a team of GMP inspectors from the Pharmacy and Poisons Board at **Nandani Medical Laboratories Pvt Ltd** situated at 221/05, Bicholi Hapsi, Kanadia Road, Indore (Madhya Pradesh) India, the site is considered **to be compliant** with PPB requirements and Current WHO Good Manufacturing Practice standards for Human dosage forms, categories and activities listed below;

Dosage form	Category	Manufacturing activities
Parenteral Preparations	Cephalosporin: Injections SVP General Products: Injections SVP & LVP	All Manufacturing activities

This allows the Directorate of Product Evaluation and Registration to continue the evaluation of the submitted dossiers and accept new product dossiers submitted within the validity period of the site's compliance status.

Please note that acceptance of compliance with WHO GMP does not necessarily mean that any product under registration has been granted marketing authorization. You will be notified of the outcome of the assessment pending your marketing authorization/retention application in due course.

This compliance status shall be deemed to be valid until the **12th day of November 2024** unless it is invalidated under any of the following conditions;

1. The activities and/or categories certified herewith are changed.
2. The site is no longer considered to be in compliance with WHO cGMP.
3. The manufacturing site is changed.

The responsibility for the quality of the individual batches of the Pharmaceutical Products manufactured in this site and marketed in Kenya lie with the manufacturer. PPB reserves the right to inspect the manufacturing site at any time it deems necessary.

Please do not hesitate to send an email to **gmp@pharmacyboardkenya.org** should you require any further information regarding the closing of this inspection and report.

A handwritten signature in blue ink, consisting of a series of loops and a long horizontal stroke extending to the right.

Dr. Ahmed Mohamed

DIRECTOR HEALTH PRODUCTS & TECHNOLOGIES