



CENTER FOR DRUG REGULATION AND RESEARCH

PERMIT TO REGISTER

This is to certify that the foreign manufacturer:

Name : **SYDLER REMEDIES PVT. LTD.**

Plant Address : **PLOT NO. M-190, M.I.D.C., WALUJ, AURANGABAD -
431136, DIST - AURANGABAD ZONE 2, INDIA**

engaged in the manufacture of the following pharmaceutical dosage form/s:


1. Non-sterile, Traditional Medicines
 - 1.1. Tablets
 - 1.2. Hard capsules
 - 1.3. Inhalers
 - 1.4. Lozenges
 - 1.5. Powder
 - 1.6. Balm
 - 1.7. Lotion
 - 1.8. Roll-on
 - 1.9. Syrup

made available in the Philippines through **AMBICA INTERNATIONAL CORPORATION**, with valid License to Operate No. CDRR-NCR-DI/E/W-61582, was found to be compliant with the requirements of **current Good Manufacturing Practice (cGMP)** consistent with Administrative Order No. 2012-008, "Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice (GMP) for Medicinal Products" and Administrative Order No. 2013-0022, "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers" after thorough evaluation and review of the updated GMP Evidence Dossier and as per recommendation of the Field Regulatory Operations Office following FDA Circular No. 2020-020, "Interim Guidelines Governing the Issuance of a Permit to Register to Drug Importers for Foreign Drug Manufacturers".

This Permit is granted to apply for product registration in scope of the approved product lines. However, this does not preclude the conduct of on-site foreign inspection upon resumption of international travel.

Issued this 30 June 2022 at Alabang, Muntinlupa City, Philippines.

**BY AUTHORITY OF THE DIRECTOR GENERAL
Per FDA Order No. 2016-005**


JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation & Research

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