



FOR OFFICIAL USE ONLY

Ref: M-7950

25 February 2020

Mr Vikrant Sonawane
Director, Veko Care Private Limited
Plot No.: E-48 & 49, MIDC Ranjangaon,
District – Pune,
Maharashtra 412220, India

Dear Vikrant,

CONFIRMATION: OVERSEAS SITE GMP COMPLIANCE

The APVMA has now completed its review the audit of the facility listed below, and is satisfied that this manufacturer meets the requirements for the manufacture of the products nominated in the Pre-Audit Notification form (FM_MQL45), which was signed by the audit owner Vikrant Sonowane on 24 July 2019.

The following site was last inspected for GMP compliance by an APVMA-authorized auditor on **23 – 25 September 2019**. Provided no further contrary evidence is received, the APVMA will recognise the GMP compliance of this site, for the steps and/or products specified, for a period of 27 months from the date of the last inspection.

Therefore, provided no further contrary evidence is received, the following site will be recognised until **23 December 2021** for the following steps and product types:

Manufacturing site name:

Veko Care Private Limited

Manufacturing site address:

Plot No.: E-48 & 49, MIDC Ranjangaon,
District – Pune, Maharashtra 412220,
India

Steps of Manufacture:

Quality assurance (QA) of raw materials, Formulation including Blending, dry milling, wet milling, granulation, filling, analysis and testing (physical, chemical, Antibiotic assay), storage (in process/quarantine), release for supply (final quality release of finished product), packaging (including strip, blister or sachet), labelling, secondary packaging, secondary labelling, tableting, tablet coating, pellet extrusion (bolus) and spray drying.

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