

Establishment Inspection Report
VISION DRUGS PRIVATE LIMITED
Choutuppal, Telangana, 508252 India

FEI: 3013648186
EI Start: 5/30/2022
EI End: 6/3/2022

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SUMMARY

This was the first FDA inspection of this facility; a preannounced, pre-approval inspection (PAI), with coverage of ANDA- 77516 Supplemental-6 "Phthaloyl Amlodipine", intermediate of API Amlodipine Besylate (Profile Code: CRU). The inspection was conducted per FACTS Assignment ID:12166873 and eNSpect Operational Id: 222277; further conducted in accordance with CPGM 7346.832: Preapproval Inspections.

The current inspection determined Vision Drugs Private Limited manufactures mostly Intermediates via chemical synthesis and two finished API's for domestic distribution. For the purposes of this inspection the firm is manufacturing only one advanced Intermediate, intended for the US market, which will undergo one last chemical reaction prior to finished dose manufacturing.

Top management officials were identified, and the current application processes reviewed for conformance to submitted data.

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The Quality System and Laboratory System were covered during this pre-approval inspection to determine the firm's conformance to submitted data such as method validation, protocol, and reports.

The firm is currently conducting manufacturing and packaging of the API intermediate in support of PAI product ANDA-77516-Supplemental-6. In addition, to assess the firm's general operations, the following is an example of what was reviewed: CAPA's, deviations, complaints, SOP's, submission batch records, equipment qualifications/calibrations, process validations and general documentation practices.

At the conclusion of the inspection, no significant deficiencies were noted. One discussion item was reviewed concerning the firm's water system and no Form FDA 483, Inspectional Observations was issued. The firm was advised that their manufacturing operations for ANDA-77516-Supplemental-6, "Phthaloyl Amlodipine", would be recommended for approval subject to final application review by the Center for Drug Evaluation and Research (CDER).

No samples were collected. There were no inspection refusals.

ADMINISTRATIVE DATA

Inspected firm: VISION DRUGS PRIVATE LIMITED
Location: 733 Mandollagudem, Survey
Choutuppal, Telangana, 508252
India
Phone: +91-9394439994
FAX:
Mailing address: 733 Mandollagudem, Survey
Choutuppal, Telangana, 508252 India
Email address: www.visiondrugs.co.in
Dates of inspection: 5/30/2022-6/3/2022
Days in the facility: 4
Participants: **Bryan L McGuckin, Investigator**

On 05/30/2022 I, Bryan L. McGuckin, CSO presented my credentials to Mr. P. Ram Mohan Rao, & Managing Director, who identified himself as the most responsible person at the site. This was a pre-announced inspection.

On 06/03/2022, I conducted an inspection closeout meeting with Mr. P. Ram Mohan Rao, Managing Director and his primary management staff. No Form FDA-483, Inspectional Observations was issued.