



HUMAN AND ANIMAL DRUG
INVESTIGATIONS BRANCH 1

10/24/2024

Shiva Analyticals (India) Pvt. Ltd.
Bangaluru, Karnataka, 562114, India

Reference: Inspection Date(s): 11/29/2023 - 12/01/2023

Location: Shiva Analyticals (India) Pvt. Ltd.
Bangaluru, Karnataka, 562114, India

Dear Facility Contact, Rajnish Singh:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that was conducted by or on behalf of the U.S. Food and Drug Administration (FDA) at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. Visit the FDA website at (www.fda.gov) and search for 'FOIA Request' to submit a FOIA request.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Adam Cooke via telephone at 919-420-1955 x1118 or email at Adam.Cooke@FDA.HHS.GOV.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Adam R.
Cooke -S

Digitally signed
by Adam R.
Cooke -S
Date: 2024.10.24
13:05:49 -04'00'

FEI:3006192929

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration
www.fda.gov

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