



FDA U.S. FOOD & DRUG
ADMINISTRATION

Office of Process and Facilities
Division of Inspectional
Assessment
10903 New Hampshire Avenue
White Oak Building 51 - Room
4238
Silver Spring, Maryland 20993

06/01/2018

QbD Research & Development Lab Private Limited
P - 26 T S S I A House
2nd Floor; Rd No 16/T
Thane, Maharashtra , IN, 400604

Reference: Inspection Date(s):01/22/2018 - 01/24/2018

Location: QbD Research and Development Lab Private Limited
P - 26 T S S I A House
2nd Floor; Rd No 16/T
Thane, 400604 , IN

Dear Mr. Nilesh C. Dhamorikar

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted 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.

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 there is any question about the released information, feel free to contact me at 240-402-6671.

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

Sincerely,

Vidya B. Pai -S

Digitally signed by Vidya B. Pai-S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Vidya B. Pai -S,
0.9.2342.19200300.100.1.1=2001508768
Date: 2018.06.01 08:38:30 -04'00'

FEI: 3006121542

Enclosure: Establishment Inspection Report (EIR)

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