



PHARMACEUTICAL QUALITY INVESTIGATION BRANCH
19701 Fairchild
Irvine, CA 92612
United States

Via UPS
Return Receipt Requested

www.fda.gov

10/30/2018

Mr. Pranav Patel
CEO
Exemed Pharmaceuticals
Block No 628 A & B ECP Canal Road
Village: Luna Taluka: Padra
Vadodara, Gujarat, 391440 IN

Dear Mr. Patel:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Exemed Pharmaceuticals, FEI:3009219197, located at Block No 628 A & B Ecp Canal Road, At & Po Village Luna, Taluka Padra, Vadodara, Gujarat, 391440 IN from 08/13/2018 - 08/17/2018. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')¹. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER's Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA 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 me via telephone at (949) 608-3519 or email at Katherine.Jacobitz@FDA.HHS.GOV.

Sincerely,

Nalini D. Lebzelter -S

Digitally signed by Nalini D. Lebzelter -S
DN: cn=US, c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=2000337778, cn=Nalini D. Lebzelter
-S
Date: 2018.10.30 13:59:01 -06'00'

Nalini Lebzelter, Acting Director, Investigations Branch,
for CAPT Katherine E. Jacobitz, Director, Investigations Branch,
Division IV, Office of Pharmaceutical Quality Operations

¹ See Inspection Classification Definitions, at <https://www.fda.gov/ICECI/Inspections/ucm223231.htm>.