The State of Maryland

Office of the Secretary of State

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Apostille

(Convention de La Haye du 5 Octobre 1961)

1. Country: United States of America
   This public document
2. has been signed by **Scott A. Poyer**
3. acting in the capacity of **Clerk of the Circuit Court**
4. bears the seal/stamp of the **Clerk of Circuit Court of Anne Arundel County**

Certified

5. at Annapolis, Maryland
6. the **1st day of May, 2019**
7. by The Secretary of State of Maryland
8. No. 483146
9. Seal

10. Signature

Secretary of State

UNCONTROLLED COPY Issued on : 18-04-2019

U.S. FOOD & DRUG ADMINISTRATION

PHARMACEUTICAL QUALITY INITIATIVES BRANCH
12420 Parklawn Drive
Rockville, MD 20857

www.fda.gov

Via UPS
Return Receipt Requested

03/28/2019

Mr. Venkatanarayan Venkataraman:

Dr. Reddy's Laboratories Ltd.
FTO - Unit 3
Survey No. 41, Bachupally Village,
Bachupally Mandal
Medchal Malkajgiri District
Telangana - 500 090, India

State of Maryland
Anne Arundel County
On this 3 day of May 20 19
before me, the undersigned,
Hanadi Alami, personally appeared
and signed the foregoing instrumen
In witness whereof I hereunto set
my hand and official Seal.
Ahmad Miski
Notary Public
My commission expires May 28, 20

214827

State of Maryland, Anne Arundel County, Sct.

I, SCOTT A. POYER, Clerk of the Circuit Court for Anne Arundel County, Maryland, a court of record, do hereby certify that **Ahmad Miski** was a commissioned/appointed and qualified Notary Public commencing on the 1st day of May, 2017.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the court May 1, 2019

Scott A. Poyer

Scott A. Poyer, Clerk
Circuit Court for Anne Arundel County, Maryland

Michael L. Chasey
BRANCH CHIEF
PHARMACEUTICAL QUALITY INITIATIVES BRANCH

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

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PHARMACEUTICAL QUALITY INITIATIVES BRANCH
12420 Parklawn Drive
Rockville, MD 20857

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Via UPS
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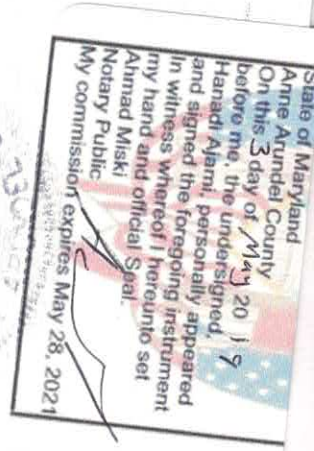
03/26/2019

Mr. Venkatanarayan Venkataraman:

Dr. Reddy's Laboratories Ltd.
FTO - Unit 3
Survey No. 41, Bachupally Village,
Bachupelly Mandal
Medchal Malkajgiri District
Telangana - 500 090, India



Dear , Mr. Venkatanarayan Venkataraman:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Dr. Reddy's Laboratories Ltd, FEI:3002949099, located at No 41 Quthbullapur Mandal, Bachupally, Telangana, 500900 India from 01/30/2019 - 02/08/2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").[1] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

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 VAI 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 Michael L. Chasey via email at Michael.Chasey@FDA.HHS.GOV.

Sincerely,

Michael L. Chasey -S

Digitally signed by Michael L. Chasey -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001298036, cn=Michael L. Chasey -S
Date: 2019.03.26 09:57:40 -04'00'

Michael L. Chasey
BRANCH CHIEF
PHARMACEUTICAL QUALITY INITIATIVES BRANCH

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