Natco Pharma Limited
Regd. Off. : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad - 500034.
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

August 12, 2019

Corporate Relationship Department
M/s. BSE Ltd
Dalal Street, Fort
Mumbai- 400 001

Scrip Code: **524816**

Manager – Listing
M/s. National Stock Exchange of India Ltd
"Exchange Plaza", Bandra – Kurla Complex
Bandra (E) **Mumbai -400 051**

Scrip Code: **NATCOPHARM**

Dear Sir

Please find enclosed the Press Release for your information.

Thanking you

Yours faithfully
For NATCO Pharma Limited

M Adinarayana
Company Secretary &
Vice President (Legal & Corp Affairs)

Natco Pharma Limited
Regd. Off. : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad - 500034.
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

Ref: PR/10 /2019-2020 ***Press Release***

USFDA COMPLETES INSPECTION OF NATCO's MEKAGUDA ACTIVE PHARMACEUTICAL INGREDIENT FACILITY

Hyderabad, India, August 12th, 2019

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) is pleased to announce completion of a regulatory inspection from the United States Food and Drug Administration (USFDA) for its Active Pharmaceutical Ingredient (API) facility in Mekaguda Village, near Hyderabad, India, which was conducted during the period 5th August, 2019 to 9th August, 2019.

At the end of the inspection, the facility received six observations mostly procedural in nature. The company believes that none of observations are related to data integrity and that all the observations can be addressed within a short period of time.

Key points of the observations in Form 483 outlined below:

- Supplier & service provider agreements to be made more robust. Some procedural improvements in gowning section recommended.
- Employees engaged in the manufacturing and packaging areas require more effective training.
- Procedural improvements needed in process revalidation protocols and approval of alternate supplier sources.
- Visual stains were observed in some early stage reactors that need further diagnosis and improvement. 'Status tags' for certain drying process equipment were not to be found.
- Incident report not raised for software systemic error found in Karl-Fisher instrument in the QC lab.
- Procedural and handling gaps found in settling plate management in the microbiology lab.

The company will provide due justifications and corrective action plan within the next 15 working days to address the above USFDA observations.

Forwarded for favour of publication

For NATCO Pharma Limited

M Adinarayana

M Adinarayana
Company Secretary &
Vice President (Legal & Corp Affairs)