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

June 6, 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)

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Ref: PR/ 6 /2019-2020 **Press Release**

USFDA COMPLETES INSPECTION OF NATCO's KOTHUR FORMULATION FACILITY

Hyderabad, India, June 6th, 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 Formulation facility in Kothur Village, near Hyderabad, India, which was conducted during the period 30th May, 2019 to 5th June, 2019.

At the end of the inspection, the facility received nine observations, with no repeat observations and mostly procedural in nature. The company believes that none of observations are related to data integrity and that all of the observations can be addressed within a short period of time.

Key points of the observations in Form 483 outlined below:

- Field Alert Report (FAR) was not submitted within three (3) days of receipt of information of failure of distributed batches to meet specifications. Although the out of specifications (OOS) result was invalidated, but FAR was not submitted within three (3) days of detection of OOS.

  Out of trend results of a distributed batch were not extrapolated to obtain expected impurity value at the end of shelf life.

- Annual product reviews of one of the products were not approved in time.
- Visual inspection of products carried out as a part of investigation was not properly documented.
- SOP on manual interpretation of impurity peaks was made effective in November 2018, but the interpretation of impurity peaks performed prior to November 2018 were not reviewed for appropriateness and accuracy.

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- Retest results performed by original analyst were considered for reporting rather than average of all retest results from the original and 2nd analyst.
- Documentation of chemical surface swabbing performed per cleaning validation on one of the products provides no description of each of individual sub swabbing samples performed for each sample location.
- Master Production and control records for one of the product does not include the operational parameters of peristaltic pumps used.
- Mechanical stirrer used in the manufacturing of one of the product does not have documented range or speed verification using a calibrated tachometer.
- Standard weights used to perform daily calibration of balances, or ferrous and non-ferrous metal test pieces used during qualification of metal detector are not traceable to a unique identification code in calibration logs.

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

Forwarded for favour of publication

For NATCO Pharma Limited

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