



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

25th January, 2017

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

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

Scrip Code: 524816

Scrip Code: NATCOPHARM

Dear Sir,

Sub: Press Release

Please find enclose herewith the Press Release for your information.

Thanking you.

Yours faithfully

For NATCO Pharma Limited

A handwritten signature in blue ink, appearing to read "M Adinarayana".

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



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Ref:PR/16/2016-17

Press Release

NATCO updates on USFDA inspection at its Kothur Formulation Facility

Hyderabad, India, January 25th, 2017

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) updated that an inspection was conducted by the United States Food & Drug Administration (USFDA) at its Pharmaceutical Formulations facility in Kothur, near Hyderabad, between January 16-24, 2017.

At the end of the inspection, the facility received six observations, all of which are correctable and procedural, and which the company believes are minor in nature. The observations are related to complaint and incident investigations, stability backlog and procedural SOP's. A copy of the observations is attached.

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

Forwarded for favor of publication

For NATCO Pharma Limited

A handwritten signature in blue ink, appearing to read "Rajesh Chebiyam", written over a horizontal line.

Vice President – Corporate Communications

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION											
DISTRICT ADDRESS AND PHONE NUMBER 1401 Rockville Pike, Ste 200N (HFM-650) Rockville, MD 20852-1448 (301)827-6220 Fax: (301)827-1944		DATE(S) OF INSPECTION 1/16/2017-1/24/2017* FD NUMBER 3004540906									
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Bhimavarapu Rami (B.R.) Reddy, Director - Formulations											
FIRM NAME NATCO Pharma Limited		STREET ADDRESS Kothur Village, Mahaboob Nagar District									
CITY, STATE, ZIP CODE, COUNTRY Mahaboob Nagar, Telangana, 509 228 India		TYPE ESTABLISHMENT INSPECTED Manufacturer									
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.											
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: QUALITY SYSTEM											
OBSERVATION 1 The responsibilities and procedures applicable to the quality control unit are not fully followed.											
Specifically, 1. The responsibilities and procedures applicable to the quality control unit are not fully followed. A. Complaint investigations are inadequate. For example, 1) Complaint N/IV/MC/15/016, received 20Jul15 due to lack of effectiveness of [REDACTED] [REDACTED] concluded the product met specifications; however, the QC laboratory failed to perform an assay on the returned sample and did not evaluate the retention sample. 2) Complaint N/IV/MC/15/009, received 09Apr15 due to lack of effectiveness of [REDACTED] immediate release tablets concluded the complaint was unsubstantiated because the lot number was unavailable. SOP IVQA/001-06, "Handling of Complaints", requires at least two (2) attempts to obtain the product sample; however the investigation report does not document the dates, times, or persons contacted to request the product lot number or sample. B. Incident investigations are not conducted in a timely manner. For example, the following incident investigations regarding stability samples not tested within their required timeframe were not closed within the 15 working days required by SOP GQA/01-02, "Reporting, Investigation, and Disposition of Incidents": <table border="1" style="width: 100%; margin-top: 10px;"> <thead> <tr> <th style="text-align: center;">Investigation #</th> <th style="text-align: center;">Date Open</th> <th style="text-align: center;">Date Closed</th> <th style="text-align: center;"># days open</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="height: 40px;"> </td> </tr> </tbody> </table>				Investigation #	Date Open	Date Closed	# days open				
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SEE REVERSE OF THIS PAGE	(EMPLOYEE'S) SIGNATURE Linda F Murphy, Consumer Safety Officer Anastasia M Shields, Generic Drug User Fee Amendments (GDUFA)		DATE ISSUED 1/24/2017 X Linda F Murphy Linda F Murphy Consumer Safety Officer Signed for Linda F. Murphy, O								
FORM FDA 483 (09-08)		PREVIOUS EDITION OBSOLETE									
INSPECTIONAL OBSERVATIONS		PAGE 1 OF PAGE									

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

1401 Rockville Pike, Ste 200N (HFM-650)
Rockville, MD 20852-1448
(301)827-6220 Fax: (301)827-1944

DATE OF INSPECTION

1/16/2017-1/24/2017*

FEI NUMBER

3004540906

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Bhimavarapu Rami (B.R.) Reddy , Director - Formulations

FIRM NAME

NATCO Pharma Limited

STREET ADDRESS

Kothur Village, Mahaboob Nagar District

CITY, STATE, ZIP CODE, COUNTRY

Mahaboob Nagar, Telangana, 509 228 India

TYPE ESTABLISHMENT INSPECTED

Manufacturer

IR/IV/15/079			
IR/IV/15/086			
IR/IV/15/137			
IR/IV/15/164			
IR/IV/15/210			

C. The Quality Unit did not initiate or implement CAPAs as required by SOP GQA/043-02, "Corrective and Preventive Action (CAPA)". For example, CAPAs were not initiated regarding:

- 1) Repeated incidents regarding [REDACTED] samples tested outside their required timeframe.
- 2) Market Complaint N/IV/MC/16/027, dated 26Jul16, regarding incorrect barcode labels on shipping cartons of [REDACTED]
- 3) Laboratory investigations N/V/OOS/15/006, dated 17Apr15, and N/V/OOS/15/035, dated 27Aug15, in which the assigned cause for both investigations was [REDACTED] during related substance testing of [REDACTED] stability samples.

D. Complaint investigations are not completed within the timeframe required by SOP IVQA/001-06, "Handling of Complaints". For example, the SOP requires a final complaint investigation report to be sent to the customer within 20 business days; however, complaint investigation report N/IV/MC/15/030 regarding a literature review of [REDACTED] was not finalized until [REDACTED] after receipt.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

The written stability testing program is not followed.

Specifically,

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Linda F Murphy, Consumer Safety Officer
Anastasia M Shields, Generic Drug User Fee
Amendments (GDUFA)

INITIALS

X Linda F Murphy
Linda F Murphy
Consumer Safety Officer
Signed by Linda F. Murphy -C

DATE ISSUED

1/24/2017

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1401 Rockville Pike, Ste 200N (HFM-650) Rockville, MD 20852-1448 (301) 827-6220 Fax: (301) 827-1944		DATE OF INSPECTION 1/16/2017-1/24/2017* FBI NUMBER 3004540906
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Bhimavarapu Rami (B.R.) Reddy, Director - Formulations		
FIRM NAME NATCO Pharma Limited	STREET ADDRESS Kothur Village, Mahaboob Nagar District	
CITY, STATE, ZIP CODE, COUNTRY Mahaboob Nagar, Telangana, 509 228 India	TYPE ESTABLISHMENT INSPECTED Manufacturer	

- A. Five (5) incident reports dated between 31 Mar 15 and 17 Jul 15 show [REDACTED] samples were not tested at the required time point. Furthermore, samples were removed from the stability chamber and maintained in a cabinet located within the QC laboratory prior to analysis.

The following table shows the dates samples were removed from the long term condition (25°C, 60%RH) stability chamber and the dates they were tested:

Product	Lot Number	Stability Interval (Month)	Date pulled from chamber	Date test complete	# Days past required test date
[REDACTED]	402841	36 M	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	404570	12 M	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	404585	12 M	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	405061	6 M	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	405062	6 M	[REDACTED]	[REDACTED]	[REDACTED]

- B. Records of stability sample quantities are not accurately maintained. For example, I discovered a discrepancy in the quantity of [REDACTED] remaining in the 40°C/75% RH stability sample chamber as compared with the quantity recorded on the Stability Study Samples Log. According to the log, [REDACTED] of [REDACTED] lot [REDACTED] in the chamber; however, actual count of the samples revealed [REDACTED] were present.

Ygm
24 Jan 17

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, labeling and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

- A. Master label specifications are not maintained in the QC Laboratory for [REDACTED] the approved primary labels were found in the AR&D office in a separate building. In addition, the Quality Unit

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Linda F Murphy, Consumer Safety Officer Anastasia M Shields, Generic Drug User Fee Amendments (GDUFA)	DATE ISSUED 1/24/2017
	☒ Linda F Murphy ☐ Anastasia M Shields ☐ [REDACTED]	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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has not approved master labels for shipping cases, which include information such as product name, storage conditions, NDC number and barcoded NDC number.

- B. According to SOP GQC/083-04, "Procedure for Management of Empower Chromatography Data Station in Quality Control", a single standard may be injected prior to the assessment of system suitability; however, failed "pre-system suitability injections" are not entered into the quality management system for tracking, trending, or root cause analysis.
- C. Placebo powder formulations used during related substance testing of finished products have not been tested for stability; however, the formulations have assigned expiration dates based on the expiration date of excipients used in the preparation, or three (3) years, whichever is earlier.
- D. System suitability testing of [REDACTED] is insufficient in that the Related Substances test procedure, STP K/STP/RMS/594-00, does not require replicate standard injections for evaluation of HPLC system precision during system suitability testing.

PACKAGING AND LABELING SYSTEM

OBSERVATION 4

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning an incident that caused a drug product or its labeling to be applied to another article.

Specifically,

The Quality Unit failed to submit an NDA field alert form when they learned that shipping cartons of ten (10) batches of [REDACTED] 100 count bottles, were barcode labeled with the incorrect NDC number. The cartons were labeled with the barcode for 1000 count bottles of [REDACTED], NDC # 01 5 03 16571 16111 4 instead of the barcode for 100 count bottles, NDC # 01 5 03 16571 16110 7.

According to market complaint N/TV/MC/16/027, on 26Jul16, the Quality Unit was notified the barcode did not match the human-readable NDC number for lot 406795. The investigation revealed case labels were incorrect for the following lots of [REDACTED] pack style: 100 count bottles:

SEE REVERSE OF THIS PAGE	PREPARED BY SIGNATURE Linda F Murphy, Consumer Safety Officer Anastasia M Shields, Generic Drug User Fee Amendments (GDUFA)	DATE ISSUED 1/24/2017
	[Signature of Linda F. Murphy] Linda F. Murphy Consumer Safety Officer Checked by: Linda F. Murphy, C.	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT RELIES Dr. Bhimavarapu Rami (B.R.) Reddy, Director - Formulations		FIR NUMBER 3004540906	
FIRM NAME NATCO Pharma Limited	STREET ADDRESS Kothur Village, Mahaboob Nagar District		
CITY STATE, ZIP CODE COUNTRY Mahaboob Nagar, Telangana, 509 228 India	TYPE ESTABLISHMENT INSPECTED Manufacturer		
• 406437 • 406795 • 406796 • 406797 • 407049 • 407050 • 407056 • 407057 • 407058 • 407059			
Although the investigation was closed on 09Aug16, an NDA field alert form was never submitted. Section 7.1 of SOP GRA/002-03, titled "Field Alerts", includes the following example of an issue requiring initiation of a Field Alert Form (FAR): "any incident that causes the drug product or its labeling to be mistaken for or applied to another article."			
PRODUCTION SYSTEM			
OBSERVATION 5 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed. Specifically, SOP#VPD/106-02, titled, "Entry and Exit Procedure for Aseptic Processing Area" which is applicable to all areas utilized in the manufacturing of pharmaceuticals destined for the U.S. market, including the drugs: [REDACTED] and [REDACTED] requires use of sterile garments and goggles prior to entry into the clean room area. However, the QA department has not validated the number of cleaning and sterilization cycles through which the garments or goggles can be processed without compromising the integrity of the sterile equipment. Additionally the firm is reusing numbers to identify the goggles and garments instead of a unique numbering system. Garments are numbered 1-28 and goggles are numbered 1-50; once a garment or set of goggles is taken out of service the number on that piece of equipment is reassigned to the replacement piece of equipment. Numbering of garments and tracking of these numbers is not covered in any SOP.			
FACILITIES AND EQUIPMENT SYSTEM			
OBSERVATION 6			
SEE REVERSE OF THIS PAGE	EMPLOYER(S) SIGNATURE Linda F Murphy, Consumer Safety Officer Anastasia M Shields, Generic Drug User Fee Amendments (GDUFA)		DATE ISSUED 1/24/2017
X Linda F Murphy Consumer Safety Officer		DATE ISSUED 1/24/2017	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 5 OF 5 PAGES			

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Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the storage of drug products after release. Specifically, the disposition status of approved and quarantined drug product is not well controlled or identified prevent a mix-up. For example, finished goods in quarantine status are stored in the designated areas of the warehouse allocated for "Finished Goods" and the disposition status labels are not always identified.					
*DATES OF INSPECTION 1/16/2017(Mon), 1/17/2017(Tue), 1/18/2017(Wed), 1/19/2017(Thu), 1/20/2017(Fri), 1/23/2017(Mon), 1/24/2017(Tue)					
1/24/2017 ☒ Anastasia M Shields Anastasia M Shields Generic Drug User Fee Amendments (GDUFA) Signed by Anastasia M. Shields -S					
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