ALKALI METALS LTD.,
Plot B-5, Block III, IDA, Uppal, Hyderabad - 500 039, India
CIN: L27109TG1968PLC001196.

+91-40-2344 5961/2344 5962
+91-40-2756 2932/2720 1179
info@alkalimetals.com
www.alkalimetals.com

ANISO9001&14001
COMPANY
BUREAU VERITAS Certification

Manufacturers of : Sodium Amide, Sodium Alkoxides, Sodium Hydride, Sodium Azide, Tetrazoles,Amino Pyridines, Pyridine Derivatives, Cyclic Compounds, Fine Chemicals, Intermediates for pharmaceuticals and Active Pharmaceutical Ingredients

AML/SE /20190521 Date: 21.05.2019

To
The General Manager
Department of Corporate Services,
The Bombay Stock Exchange Limited,
PhirozeJeejeebhoy Towers,
Dalal Street,
Mumbai-400001
Ph:022-22721234
Fax:022-22723121
Scrip Code: 533029

To
The Vice President,
Listing Department,
National Stock Exchange of India,
Bandra (East),
Exchange Plaza, BandraKurla Complex,
Mumbai-400051
Ph: 022-26598235/36
Fax: 022-26598237/238/347/348
Symbol: ALKALI, Series :EQ

Dear Sir,

Sub: Receipt of EIR from US FDA – Regulation 30 of SEBI (LODR) Regulations, 2015
Ref: Alkali Metals Ltd.

With reference to the captioned subject and in compliance with Regulation 30 of the SEBI (LODR) Regulations, 2015, we hereby inform you that, Alkali Metals Limited has received an Establishment Inspection Report (EIR) from United States Food and Drug Administration (US FDA) for its Visakhapatnam Unit in Andhra Pradesh.

The Visakhapatnam unit manufactures Active Pharmaceutical Ingredients (APIs) and other Chemical intermediates.

The EIR from USFDA indicates closure of the inspection and that the Unit is in acceptable state of Compliance of Current Good Manufacturing Practice (CGMP).

Kindly take the same on record and oblige.

Thanking You

Yours faithfully,

For Alkali Metals Limited

Y.S.R.VenkataRao
Managing Director
DIN:00345524

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

May 13, 2019

Mr. V.V. Viswanadha Sarma, General Manager
Alkali Metals Limited
Plot 36, 37 & 38, J.N. Pharma City
Thanam, Parawada, Visakhapatnam, 531021-India

Dear Mr. Sarma:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Alkali Metals Limited, FEI 3011971984, located at Plot 36, 37 & 38 J.N. Pharma City; Parawada Mandal, Thanam, Andhra Pradesh, 531021- India from February 11, 2019 to February 15, 2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" (VAI).[1] Based on this inspection, this facility is in a minimally acceptable state of compliance with regard 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 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 applications referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. 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.

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[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm222231.htm.

If you have any questions regarding this letter, you may contact Deyaa Shaheen via telephone at 240-402-0200 or email at deyaa.shaheen@fda.hhs.gov.

Sincerely,

Milind Ganjawala

Milind Ganjawala
Director
Division of Drug Quality II
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research