March 29, 2016

To

BSE Limited
Department of Corporate Services,
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai Samachar Marg,
Mumbai - 400 001.

National Stock Exchange of India Ltd.,
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Sub: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Dear Sir/Madam,

In connection with the note published by IIFL Capital, relating to the observations made by the US FDA during the course of audit of our Mandideep facilities and in continuation to the comments made by the Company today afternoon, for the benefit of all the stakeholders, we wish to provide, as under, further clarity on each observation: -

API unit at Mandideep

Observation no.	Details	IIFL takeaways	Management Comment
1.	Rejected batches of intermediates were used to manufacture sterile APIs. These APIs which used rejected intermediates were distributed / formulated into finished products for 4 years from 2012 to 2015.	Very serious observation. Especially because it has been repeated over the years.	Relates to 1 sterile product which is a small contributor to sales. The observation relates to an unknown impurity which didn't impact the end product. The company is in the process of filing a 'PAS' application with the USFDA which will allow them to re-process the intermediate (the practice was to allow reprocessing as a recorded deviation in 2015, which was since discontinued). As a precautionary measure, they are also recalling the batches of the above-mentioned product on the market that pertain to the pre-2015 period.
2.	Deficiencies in cleaning validation studies.	Relates to sterile area and that's why serious	Relates to user's contact time with the hand sanitizer. The company was able to demonstrate to USFDA that the contact time (30 seconds) required for sanitization is being followed adequately.

... 2.

Formulation unit at Mandideep

Observation no.	Details	IIFL takeaways	Management Comment
1	Equipment used in manufacture of drug products is not of appropriate design. Specific example includes capsule checkweigher.	Serious	Checkweigher is used to sort out the overweight/ underweight Capsules. The machine was qualified for one capsule size (size zero, 500mg) and not qualified for the other (size two, 250mg). The company was able to qualify for the other size on the spot and demonstrated the results to the inspector on the site.
2	Deficiencies in cleaning SOPs.	Although such observations are manageable, similar observations have been highlighted at Lupin's Goa facility raising concerns whether this is a firm-wide issue for the company.	Same as Observation 2 in the API unit

You are requested to note the above.

Thanking You,

Yours faithfully,
For LUPIN LIMITED

LUPIN LIMITED MUMBAI INDIA

R. V. SATAM
COMPANY SECRETARY