



SOLARA
Active Pharma Sciences

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November 4, 2019

The BSE Limited

Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai – 400 001

Scrip Code: 541540

The National Stock Exchange of India Limited

Exchange Plaza, Bandra-Kurla Complex
Bandra (E), Mumbai – 400 051

Scrip Code: SOLARA

Dear Sir / Madam,

Sub: Announcement under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulation, 2015

Please find attached press release issued by the Company titled:

"Updates on Ranitidine Hydrochloride & Nizatidine API"

Thanking you,

Yours faithfully,

For Solara Active Pharma Sciences Limited

S. Murali Krishna
Company Secretary



Encl:- as above

Updates on Ranitidine Hydrochloride & Nizatidine API

- ▶ **USFDA releases testing results of Ranitidine and Nizatidine samples and sets the acceptable NDMA limits for the products**
- ▶ **Majority of the marketed products that were found within the acceptable limits were manufactured with the APIs supplied by Solara**

Bangalore, India – November 04, 2019:

Solara Active Pharma Sciences Ltd (Solara) (NSE: SOLARA; BSE: 541540) today shared additional updates on its Ranitidine and Nizatidine APIs.

The USFDA on November 01, 2019¹ posted the results of laboratory tests conducted to investigate the presence of the N-Nitrosodimethylamine (NDMA) impurity levels in all Ranitidine and Nizatidine samples it tested. USFDA has set the acceptable daily intake limit for NDMA at 0.096 micrograms or 0.32 ppm for Ranitidine which it considers reasonably safe for human ingestion based on lifetime exposure. Basis the outcomes, USFDA will recommend manufacturers to recall all the products with NDMA levels above these acceptable daily intake limit.

Amongst the samples tested for Ranitidine and Nizatidine, the Company is pleased to note that majority of the marketed products in the US that were found within the acceptable limits were manufactured with the APIs supplied by Solara. The company is a key supplier of Ranitidine Hydrochloride & Nizatidine API and partners with global pharmaceutical companies for their formulations.

The Company is engaging with its formulation partners to understand the next steps and will provide an update in the next few days.

About Solara

Solara Active Pharma Sciences Ltd (BSE-541540, NSE-SOLARA) headquartered in Bengaluru, India offers a basket of diversified, high-value Commercial APIs and Contract manufacturing services in over 75 countries. It has a manufacturing base comprising five globally compliant API facilities, with approvals including the USFDA, EU GMP and PMDA in Japan.

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Statutory and corporate affairs

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¹ <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine>