Press Release *For Immediate Release*

Granules Pharmaceuticals, Inc. issues clarification on media reports of recall of 4.78 lakh bottles of Metformin Hydrochloride Extended-Release(ER) tablets USP, 750mg

Hyderabad, 27th July 2020: Over the past weekend, there were several media sources that claimed that Granules India recall 4.78 lakh bottles of diabetes drug in the US. Granules Pharmaceutical Inc. (GPI), Chantilly, VA, a wholly owned subsidiary of Granules India Limited, would like to clarify that there has been no additional recall post the press release, dated July 3rd, 2020, also attached herewith. As mentioned in that press release, Granules did a voluntary recall of 12 batches of 750mg of the generic Metformin ER. Only 1 (One) batch out of a total of 12 (Twelve) did not meet the specifications, but all the batches of 750mg were pulled out on abundance of caution. The 750mg constitutes less than 8% of the total volume of Generic Glucophage ER (Reference Listed Drug) as per IQVIA data and constituted 0.3% of the total revenue of the company as per the year ended FY 20.

About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India is a growing pharmaceutical manufacturing company with best in class facilities and is committed to operational excellence, quality, and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. The Company has 6 manufacturing facilities out of which 5 are located in India and 1 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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Safe Harbor

This document includes certain forward-looking statements. These statements are based on management's current expectations or beliefs and are subject to uncertainty and changes in circumstances. Actual results may vary materially from those expressed or implied by the statements herein due to changes in economic, business, competitive, technological and/or regulatory factors. Granules India Ltd., its directors and any of the affiliates or employee is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events, or otherwise

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Dated July 03, 2020

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES; BSE: 532482

Sub: Press Release

Dear Sir,

We are herewith enclosing the press release given by Granules Pharmaceuticals, Inc. , a wholly owned subsidiary of the Company.

This is for your information and dissemination to the members of the exchange.

Thanking You.

Yours sincerely,

For GRANULES INDIA LIMITED

CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)
Encl as above

Granules Pharmaceuticals, Inc. issues Voluntary **Nationwide** Recall of **Metformin Hydrochloride Extended-Release Tablets USP, 750 mg Due** to the Detection of N-Nitrosodimethylamine (NDMA) Impurity.

FOR IMMEDIATE RELEASE – July 3, 2020

Granules Pharmaceuticals, Inc., Chantilly, VA , a wholly owned subsidiary of Granules India Limited, is voluntarily recalling twelve (12) lots of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, 100 and 500 count bottles within expiry to the consumer level due to the detection of N-Nitrosodimethylamine (NDMA) levels above the Acceptable Daily Intake Limit.

Granules' test results showed NDMA levels above the FDA acceptable limit in **one (1) out of the twelve (12) batches distributed to the US market**. All other batches continue to remain within the specifications. Out of abundance of caution Granules Pharmaceuticals, Inc. has decided to voluntarily recall all twelve (12) of the distributed lots within expiry of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg from the market.

Granules Pharmaceuticals, Inc. has not received any reports of adverse events that have been confirmed to be directly related to this recall as of the date of this letter.

Granules India's Metformin Hydrochloride Immediate-Release Tablets USP, 500 mg, 850 mg & 1000 mg and Metformin Hydrochloride ExtendedRelease Tablets USP, 500 mg are not affected by this recall.

Granules' Metformin 750mg constituted about 0.3% of Granules India's revenue for FY 20.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Metformin Hydrochloride Extended-Release Tablets USP, 750 mg are indicated as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus. The Metformin Hydrochloride Extended-Release Tablets USP, 750 mg lots subject to the recall is identified in the table below.

Metformin Hydrochloride Extended-Release Tablets USP, 750 mg

NDC	Bottle Count	Lot/Expiration
70010-492-01	100 count bottles	4920003A/May-21 4920004A/Jun-21 4920005A/Jun-21 4920009A/Nov-21 4920010A/May-22 4920011A/Jun-22 4920012A/Jun-22 4920013A/Jul-22 4920014A/Jul-22 4920015A/Aug-22 4920016A/Jan-23
70010-492-05	500 count bottles	4920005B/Jun-21

The affected Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, lots were distributed nationwide in the USA directly to Distributors, and Retailers. Granules Pharmaceuticals, Inc. is in the process of notifying its distributers and customers affected by this recall via mail (FedEx standard overnight) by mailing a recall notification letter and is arranging for return of the entire recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers and patients with questions regarding this recall or wishing to return product may contact Inmar Pharmaceutical Services product recall processor to obtain instructions and a return kit for returning their medication:

- Contact Inmar at 888-985-9117 (Hours of Operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: rxrecalls@inmar.com.
- Inmar will provide the materials needed to return their medication and instructions for reimbursement.

If you would like to report any adverse reactions or quality problems experienced with the use of this product you may contact Granules Drug Safety by phone at 1-877-7703183 Monday - Friday, 8:00 am EST to 8:00 pm EST, or via e-mail at drugs.safety@granulesindia.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

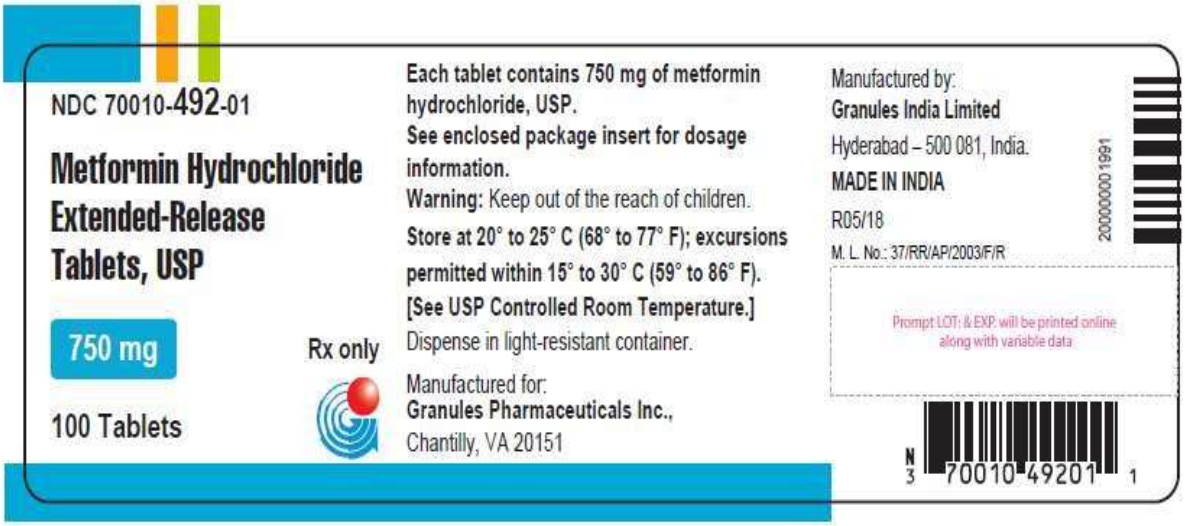
- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Product Photos:

Product Name: Metformin Hydrochloride Extended-Release Tablets USP, 750 mg.

Pack Mode: 100 Tablets



Product Name: Metformin Hydrochloride Extended-Release Tablets, USP 750 mg.

Pack Mode: 500 Tablets

NDC 70010-492-05

Metformin Hydrochloride Extended-Release Tablets, USP

750 mg

500 Tablets

Rx only

Each tablet contains 750 mg of metformin hydrochloride, USP.

See enclosed package insert for dosage information.

Warning: Keep out of the reach of children.

Store at 20° to 25° C (68° to 77° F); excursions permitted within 15° to 30° C (59° to 86° F). [See USP Controlled Room Temperature.]

Dispense in light-resistant container.

Manufactured for:
Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

Manufactured by:
Granules India Limited
Hyderabad – 500 081, India.

MADE IN INDIA

RD5/18

M. L. No.: 37/RR/AP/2003/F/R

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Prompt LOT & MFD will be printed online along with variable data