

Quality Assurance (QA) for Health Products
QA Information Notice

IN N° 2020-05 Version:24/06/2020	VOLUNTARY RECALL of 20 Batches of Isoniazid Tablets BP 100mg, supplied by Lupin Ltd India.
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Addressees

- Any person having products in stock (pharmacies, retailer) in transit or under custom clearance
- Any procurers, buyers with a pending order
- All PRs

Purpose

The GF QA is issuing this information notice to provide information that was transmitted by Lupin regarding a voluntary recall (level II Class) initiated on 08th of May 2020 for the below mentioned product.

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer	Lupin
INN Name	Isoniazid
Commercial Name(s)	Isoniazid Tablets BP 100mg
Pharmaceutical form	Tablet
Strength	100 mg
Packaging & Pack size	Bottle HDPE: 100x1, 1000x1; Blister Alu/PVC/PVdC: 10x10
Batch(es)	Several (see annex 2)
Expiry Date	Several (see annex 2)

Background

On the 14th of May 2020, GF QA received information from its procurement agent GDF, of a voluntary recall initiated by the manufacturer Lupin, Ltd India (see annex 1). This recall is initiated based on an impact assessment of Out of Specification (OOS) results observed for the dissolution test at 48Months, 30°C/75%RH condition in the annual stability batch for the year-2016. Based on the health Hazard assessment and risk assessment performed, the manufacturer, Lupin decided to initiate a Class II level recall.

Nature of defect(s)

Details of defect or problem.	OOS results observed in dissolution test in annual stability batch.
Is there any evidence or suspicion of a risk to public health?	No concrete evidence of risk for patient. Potential decrease in efficacy.
Extent of the problem (eg. how many batches).	20 Batches (see annex 2)
Extent of distribution of the product / batch (es).	Several (see annex 2)
Number of patients potentially impacted	No impacted patients known

Action/Investigations taken

- Manufacturer identified the countries which were impacted by the OOS and provided the list to GF QA;
- The procurement service agent in charge for TB medicines has supported the recall in sending out the information to the involved recipients.

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by GF QA:

- Not to recall at user level;
- To put immediately in quarantine conditions the impacted products at pharmacy and retail level of the supply chain and send it back to wholesaler/regional or central distributors;
- To immediately stop any shipment and further distribution of the impacted product within the supply chain (wholesaler/regional or central distributors);
- To report or confirm to the supplier/procurer the stock put in quarantine conditions;

Contacts

This IN requires a specific written response from the PR.

PRs should copy GF QA Team on any correspondence regarding the matter for follow-up purposes.

Please direct the respective answers and any questions about this matter to the technical contacts listed below:

Organisation	Name / Function	E-mail address
Global Fund	Amelie Darmon, Associate QA Specialist	Amelie.Darmon@theglobalfund.org
Global Drug Facility	Nigorsulton Muzafarova, Lead Product Quality Officer	nigorsultonm@stoptb.org

Annex 1: Manufacturer's recall letter



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Annexure-11
SOP No.: CQA-019

PRODUCT / BATCH RECALL/MARKET WITHDRAWAL NOTICE
(For Products Marketed in Overseas)

Part A: (To be filled by Site QA)

To	Mr. Mohul Jeeath	Recall /Market withdrawal Ref No.:	RCL/AVR/20/02
		Date:	08/05/20

Please stop further distribution/sale of below mentioned product/batches with immediate effect. Kindly recall/withdraw the stocks of these batch/es from the market. All unsold goods in the warehouse and recalled/withdrawal goods to be quarantined till further advice from QA. Inform site QA and CQA about the stock in hand and returns from the market on a weekly basis for the next 4 weeks.

Manufacturing site: Aurangabad Mfg. Lic. No.: 633

Product Details (Name/ Strength/Dosage Pack)	Batch / Lot No.	Mfg. Date / Expiry	Batch Size	Quantity Released for Sale
Isoniazid tablets BP 100mg 10 x 10 T	-	Refer Attachment-I	-	-
-	-	-	-	-

Reason for Recall/Market withdrawal:
Recall initiated for 20 finished product batches against impact assessment of OOS results observed in dissolution test at 48M, 30°C/75%RH condition in annual stability batch for year 2016. (Reference OOS Number: OOS/c/20/AVR/08/003)


Site QA Head (Name, Sign & Date)
08/05/20 S.D. Gujareathi


SP
27/12/2019

13/01/2020

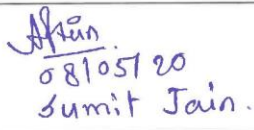
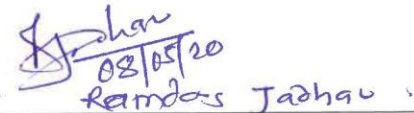
Hulu
27/12/2019

Annex 2: Manufacturer's distribution list

 ATTACHMENT - I								
LIST OF IMPACTED BATCHES								
Title		Investigation report for observed out of specification results in Dissolution test of Isoniazid Tablets BP 100 mg						
Name of Product		Isoniazid Tablets BP 100 mg		Reference Document No.		OOS/C/20/AUR/SS/003		
Batch Size		140.400 Kg = 1,200,000 Tablets		Mfg. Lic. No.		633		
Sr. No.	Product Details (Name/ Strength/ Dosage Pack)	Batch / Lot No.		Mfg. Date / Expiry		Quantity to be released for Sale (Box)	Batch Size	Market
		SFG Batch No.	FG Batch No.	Mfg. Date	Exp. Date			
1	Isoniazid 100mg 10X10T GDF	A601119	A601150	Feb-16	Jan-21	290	1,200,000 Tablets	Mozambique
						345		Togo
						150		Ghana
						839		Sri Lanka
						2,400		Uruguay
						7,676		Nigeria
2	Isoniazid 100mg 10X10T GDF	A602498	A602597	Apr-16	Mar-21	11,341	Mozambique	
3	Isoniazid 100mg 10X10T GDF	A602499	A602598	Apr-16	Mar-21	11,645	Mozambique	
4	Isoniazid 100mg 10X10T GDF	A602500	A602599	Apr-16	Mar-21	11,830	Mozambique	
5	Isoniazid 100mg 10X10T GDF	A602501	A602763	Apr-16	Mar-21	11,863	Mozambique	
6	Isoniazid 100mg 10X10T GDF	A602588	A602779	Apr-16	Mar-21	973	1,200,000 Tablets	Moldavia
						165		Kosovo
						4,836		Afghanistan
						180		Congo
						2,063		Togo
7	Isoniazid Tablets 100mg 10 X 10T - ROW	A602588	A602780	Apr-16	Mar-21	3,500	Camroon	
8	ISONIAZID 100MG 10X10T GDF	A604418	A604487	Aug-16	Jul-21	10,144	Afghanistan	
9	Isoniazid Tablets 100mg 10 X 10T - ROW		A604514	Aug-16	Jul-21	1,200	France	
10	Isoniazid 100mg 10X10T GDF	A604419	A604488	Aug-16	Jul-21	22	1,200,000 Tablets	Ivory Coast
						150		Ghana
						1,097		Malawi
						10,095		Afghanistan
11	Isoniazid 100mg 10X10T GDF	A604420	A604735	Aug-16	Jul-21	880	1,200,000 Tablets	Malawi
						10,629		Cambodia
12	Isoniazid 100mg 10X10T GDF	A604421	A604736	Aug-16	Jul-21	5,539	1,200,000 Tablets	Haiti
						6,371		Cambodia
13	Isoniazid 100mg 10X10T GDF	A604699	A604883	Aug-16	Jul-21	11,685	Haiti	
14	Isoniazid 100mg 10X10T GDF	A604700	A604884	Aug-16	Jul-21	50	1,200,000 Tablets	Burundi
						150		Bhutan
						200		Israel
						5,435		Haiti
						1,292		Burkina Faso
						684		TCHAD
						100		Congo
						2,690		Haiti
						10		Maldives
						1,100		East Timor

 ATTACHMENT - I			
LIST OF IMPACTED BATCHES			
Title	Investigation report for observed out of specification results in Dissolution test of Isoniazid Tablets BP 100 mg		
Name of Product	Isoniazid Tablets BP 100 mg	Reference Document No.	OOS/C/20/AUR/SS/003
Batch Size	140.400 Kg = 1,200,000 Tablets	Mfg. Lic. No.	633

Sr. No.	Product Details (Name/ Strength/ Dosage Pack)	Batch / Lot No.		Mfg. Date / Expiry		Quantity to be released for Sale (Box)	Batch Size	Market
		SFG Batch No.	FG Batch No.	Mfg. Date	Exp. Date			
15	Isoniazid 100mg 10X10T GDF	A606000	A606200	Oct-16	Sep-21	11,545	1,200,000 Tablets	Haiti
16	Isoniazid 100mg 10X10T GDF	A606001	A606201	Oct-16	Sep-21	104		Jordan
						1,959		Malawi
						161		Burundi
						986		Guinea
						2,937		Haiti
						998		Cameroon
17	Isoniazid Tablets 100mg 10 X 10T - ROW	A606001	A606218	Oct-16	Sep-21	2,000		MSF France
18	Isoniazid 100MG Tabs (DEM EXP)	A606001	A606338	Oct-16	Sep-21	2,457		Mednext Pharma Delhi Deemed Export
19	Isoniazid 100mg 10X10T GDF	A607454	A700230	Dec-16	Nov-21	285		Soloman Islands
						303		North Korea
						1,100		East Timor
						2,333		Ivory Coast
						919		North Korea
						1,146		Sri Lanka
						1,775		Djibouti
1,229	Burundi							
20	Isoniazid Tablets 100MG 10 X 10T - ROW	A607454	A700231	Dec-16	Nov-21	2,500		MSF France

 08/05/20 Sumit Jain.	 08/05/20 Ramdas Jadhav.
Prepared By	Reviewed By