Quality Assurance (QA) for Health Products

QA Notice

IN Nº 2022-02 **Version 2 :** **23 March 2022**	**Release of the quarantined batches and removal of the precautionary measures for Isoniazid 100mg tablet manufactured by Lupin, India.**

Addressees

- All PRs through HPM specialist.
- Any entity or health facility having the listed product batches in stock (central store, pharmacies, retailer), in transit or under custom clearance.
- Any procurers, buyers with a pending order.

Purpose

Based on new information obtained by the manufacturer Lupin and by the WHO Prequalification Unit (PQT) regarding the potential quality issue of the Finished Pharmaceuticals Products (FPP) Isoniazid 100mg tablet manufactured by Lupin, India, **TGF QA do not object to the release of the quarantined batches proposed by the supplier and remove all precautionary measures that were initially recommended.**

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 Ltd, Rifa & Non-Rifa Facilities, Block No 1 & 2, A-28/1 MIDC Industrial Area, Chikalthana, Aurangabad, 431 210, India
INN Name	Isoniazid
Pharmaceutical form	Tablets
Strength	100 mg
Packaging & Pack size	100 tablets blister pack
Batch(es)	Multiple
Expiry Date	Multiple

Background

- On the 12th of January 2022, GF QA received information from the Global Drug Facility (GDF), of a safety notification issued by one of their qualified manufacturer Lupin, concerning quality issue for Isoniazid tablet 100mg manufactured at the Lupin manufacturing site Ltd, Rifa & Non-Rifa Facilities, Block No 1 & 2, A-28/1 MIDC Industrial Area, Chikalthana, Aurangabad, 431 210, India. The manufacturer recommended to quarantine the available warehouse stock of several batches of the product Isoniazid Tablets 100 mg.
- Similar OOS concerning the same product had been reported in December 2021 on the batch No. A905559 resulting in request for quarantine.
- As a result of their investigation, Lupin considered that there is no impact of observed description failure on the batch quality, and a proposal for the revision of product description from "white to off white" to “White to yellowish tablets" was submitted to WHO PQT.
- On the 11th of March 2022, WHO PQT approved the variation and supported the release of the quarantined batches.

Nature of defect(s)

Details of defect or problem.	N/A
Is there any evidence or suspicion of a risk to public health?	N/A
Extent of the problem (eg. how many batches).	N/A
Extent of distribution of the product / batch (es).	N/A
Number of patients potentially impacted	N/A
Other products potentially impacted	N/A

Action/Investigations taken

Next Steps

The following actions are recommended by GF QA:

- To resume procuring and distributing the Finished Pharmaceutical Product **Isoniazid tablet 100mg** manufactured by Lupin.
- To release all quarantined batches of **Isoniazid tablet 100mg** at central storage level, regional as well at peripheral level (pharmacy and retail level) of the supply chain.
- To contact and liaise on the same with National Regulatory Authority.

Contacts

PRs should copy GF QA Team and GDF on any correspondence regarding the actions taken concerning Isoniazid **tablet 100mg** manufactured by Lupin.

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

Organization	**Name / Function**	**E-mail address**
Global Fund	Sandrine Cloëz, QA Pharmaceuticals Products Specialist	Sandrine.Cloez@theglobalfund.org
Global Drug Facility Team	Nigorsulton Muzafarova, Lead Product Quality Officer	nigorsultonm@stoptb.org