

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2019-02b Version: 30/01/2020	Artesunate / Amodiaquine tablets, manufactured by Guilin Pharmaceuticals Eligibility reinstated for procurement with Global Fund (GF) funds
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Addressees

- All PRs though HPM specialist
- GF Sourcing

Purpose

The GF QA is issuing this information notice to advice on the reinstatement in the Global Fund List of eligible Products of Artesunate/Amodiaquine, tablets, multiple strengths, manufactured by Guilin Pharmaceuticals Co. Ltd.

Identification of the product(s) and manufacturer

Name of Manufacturer	Guilin Pharmaceutical Co Ltd, No. 43 Qilidian Road, Guilin, 541004, Guangxi, China.
Commercial Name(s)	Artesun-Plus
INN	Artesunate/Amodiaquine
Strength	25 mg/67.5 mg 50 mg/135 mg 100 mg/270 mg
Pharmaceutical form	Tablet
Packaging & Pack size & Type	All
Batch(es)	All
Manufacturing Date	All
GF QA Standards	WHO Prequalification Ref. MA083, MA084 & MA085

Background

GF QA received information that one batch of ASAQ manufactured by **Guilin Pharmaceuticals** failed to meet the expected quality criteria. Results show an out of specification for Artesunate related substances testing.

Subsequently and following internal investigations 5 more batches were found out of specifications for the same testing parameters.

WHO PQ has been informed and followed the manufacturers' investigations as the impacted products are prequalified.

While waiting for the outcomes of the investigations the GF QA decided to take the protective measures on 11th April 2019.

Manufacturers Investigation has been reviewed and has been assessed as satisfactory by WHO PQ.

The variation submitted by the manufacturer to WHO PQ in response to the complaint have been accepted.

Nature of defect(s)

N/A

Action/Investigations taken

N/A

Next Steps

Based on confirmation of the closure of the complaint and lately of the acceptance of the variations submitted to WHO PQ, the above identified products will be listed in the next revision of the Global Fund List of eligible Pharmaceutical Product.

Procurement of the above-mentioned products using GF funds can be envisaged without any further notice.

Contacts

This IN does not require specific written response from PR. Please direct the respective answers and any questions about this matter to the technical contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Amelie Darmon, QA Associate Specialist	Amelie.Darmon@theglobalfund.org