



RWANDA FDA

Rwanda Food and Drugs Authority

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18 JUN 2019

Kigali

Ref N° 0638/Rwanda FDA/2019

District Pharmacy (All)
District Hospital (All)
Referral Hospital (All)
Pharmaceutical Wholesalers (All)
Retail Pharmacies (All)
Private clinics/ (All)

Title: Recall of medical products due to Quality issues

The role of the Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the law N° 003/2018 of 09/02/2018 to health professionals and to other concerned organs. The Authority takes into considerations every serious information from Partners to ensure safe and quality products.

Reference made to the Laboratory quality control rapport in its routine Post marketing surveillance activities, we regret to notify the following batches revealed substandard:

DESCRIPTION	BATCH	Exp. date	Manufacturer	Quality issue
Albendazole 400 mg Tablets	BN: 370420	Exp. date: 08/2022	GlaxoSmithKline South Africa (Pty) Ltd.	Failed the Dissolution test QC results: Average: 75% of the labelled amount is dissolved in 30 minutes. Specifications Not less than (NLT) 80%(Q) of the labelled amount dissolved in 30 minutes
Silver Sulfadiazine Cream USP 1% (Agoburn)	BN: K82001	Exp. date: 02/2021	Agog Pharma Ltd., India	Failed the Assay tests QC results: (82.2%) of the labelled amount

				Specifications: 90.0%-110.0% of the labeled amount
Biperiden.HCl Sterop Tablets 2 mg	BN: 18B05	Exp. date: 01/2023	Lab. STEROP NV, Belgium	Failed the test on Related substances (impurities). QC results Impurity A: 22.06% vs Not more than (NMT) 0.50% Impurity B: 1.77% vs NMT 0.50% Any other impurity: 1.12% vs NMT 0.1% Total of impurities A, B&C: 23.8% vs NMT 1.0% Total of impurities other than A, B&C: 25.35% vs NMT 0.5%
Chloramphenicol 0.5% w/v Eye Drops B.P	BN: 131936	Exp. date: 01/2021	Abacus Parenteral Drugs Ltd., Uganda	Failed the Assay test and the degradation product content. QC result: Assay: 77.1% Specifications: 90.0%-110.0% of the labeled amount Content in 2-amino-1-(4-nitrophenyl) propane-1,3-diol: 14.1% Specifications: NMT 8%

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Action to be taken

Rwanda Food and Drug Authority instruct all wholesalers, District Pharmacies, retailers, Public and Private Health Facilities to stop the distribution and dispensing of the above incriminated batches for the above mentioned products and return them to suppliers for suitable management.

Sincerely,



Dr. Charles KARANGWA
Ag. Director General of Rwanda FDA

CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**
- **Permanent Secretary/MOH**

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