

DIFAEM-EPN Minilab Network News 1 / 2023

May 2023

Dear Minilab Network partners,

Today you receive an extract from the internal Minilab Network newsletter. We would like to draw your attention to substandard and falsified medicines, which have recently been identified by the DIFAEM-EPN Minilab Network using the GPHF Minilab. These products are harmful for patients and must not be used. In case you encounter one of these products, immediately remove it from the shelf and quarantine or destroy it according to the procedures of your organization/facility. Please do not return these products to the supplier as in this manner they might be resold to other customers. In case of question you may contact us using the email addresses below.


Have a pleasant reading.

Kind regards,

Christine

and

Gabi



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Recent confirmed cases of falsified products reported to WHO

Please note that in all cases batches other than those shown may also be affected.



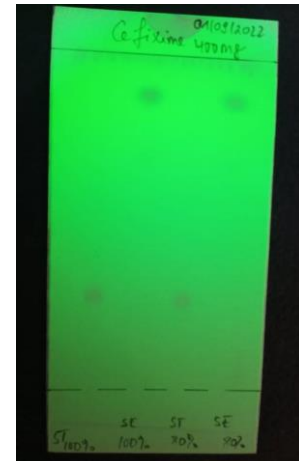
Erythromycin Stearat BP 250mg tabs

- Stated manufacturer: Prm-inter laboratoiresLtd
- Batch: 12M/54
- Mfg. Date: 01/20
- Exp. Date: 12/23
- Result of compendial analysis: 0,6 % Erythromycin, orthographical errors on label
- Detected in DRC in August 2022
- Reported to WHO by Difaem



ASPIRIN Tablets 100 mg

- Stated manufacturer: Shangdong Xier Kangtai Pharmaceutical Co. Ltd
- Batch: 170746
- Exp. Date: 07/2024
- Result of compendial analysis: no API, spots on the tablets
- Detected in DRC in August 2022
- Reported to WHO by Difaem



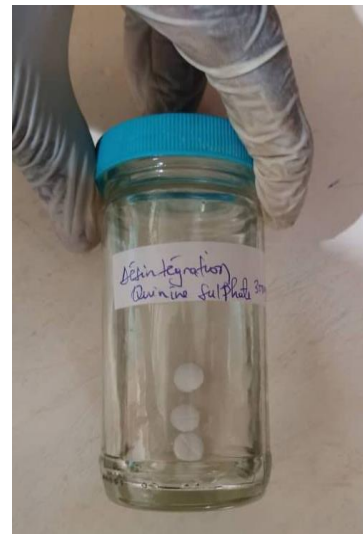
CEFIXIME Tablets 400 mg

- Stated manufacturer: Sterop
- Batch: T1407101
- Mfg. Date: 06 /2022
- Exp. Date: 06/2024
- Result of compendial analysis: no API, unclear label
- Detected in DRC in September 2022
- Reported to WHO by Belgian Medicines Control Agency



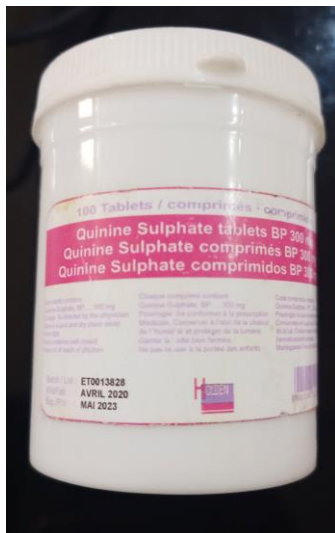
COARTEM Tablets 20/120 mg

- Stated manufacturer: Novartis
- Batch: F2261
- Mfg. Date: 01/2021
- Exp. Date: 06/2024
- Result of compendial analysis: no API
- Detected in DRC in March 2022
- Reported to WHO by Difaem



QUININE Tablets 300 mg

- Stated manufacturer: Holden
- Batch: ET 18323
- Mfg. Date: 04/2021
- Exp. Date: 12/2023
- Result compendial analysis: no API, disintegration non conforme
- Detected in DRC in March 2022
- Reported to WHO by Difaem



QUININE Tablets 300 mg

- Stated manufacturer: Holden
- Batch: second case ET 0013828
- Mfg. Date: 04/2020
- Exp. Date: 05/2023
- Result compendial analysis: no API, disintegration non conforme, Orthographical errors on the label
- Detected in DRC in June 2022
- Reported to WHO by Difaem

WELTRIM and GILTRIM, Cotrimoxazol Tablets 480 mg, two cases



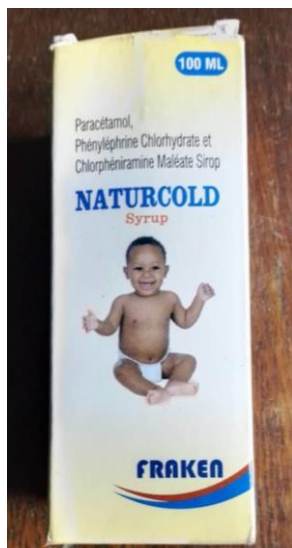
- Stated manufacturer: WELTEC HEALTHCARE
- Batch: WHL 1020
- Mfg. Date: 03/2022
- Exp. Date: 02/2024
- Detected in Nigeria in May 2022
- HPLC analysis, (Tuebingen university): no API
- Reported to WHO by Difaem



- Stated manufacturer: GIL IND.LTD
- Batch: SCT:002
- Mfg. Date: 01/2022
- Exp. Date: 05/2025
- Detected in Nigeria in May 2022
- HPLC analysis, (Tuebingen university): no API, errors on the label (80 mg Sulfa-methoxazole and 80 mg Trimethoprim and other mistakes)
- Reported to WHO by Difaem

All confirmed cases of falsified products were reported to WHO rapid alert system by DIFAEM

NATURCOLD SYRUP (Paracetamol, Phenylephrine, Chlorpheniramin)



- Stated manufacturer: FRAKEN INTERNATIONAL LONDON, ENGLAND
- Batch: E22053
- Mfg. Date: 03/2022
- Exp. Date: 02/2025

On 13 April 2023, we received a warning from Cameroon. Six children under the age of six died in a health facility in Fundong health district. These children who were all brought in from out of the North West Region to seek proper medical care, presented with decreased kidney function after having consumed a suspected substandard cough syrup named NATURCOLD. The syrup seems to be contaminated with ethylene glycol or diethylene glycol. Upon request by WHO, the samples have been handed over to WHO Country office in Yaoundé.