



Laboratoire Central d'Analyses des Contrefaçons /
Anti-Counterfeiting Laboratory
Sanofi Winthrop Industrie
30-36, Avenue Gustave Eiffel
BP 27166 - 37071 Tours Cedex 2

LCAC STATEMENT (Version 2) SUSPECTED COUNTERFEIT

| | |
|-------------------|------------------------------|
| Local trademark | CLOFARABINE |
| Dosage strength | 20 MG/20 ML |
| Dosage form | INJECTION, LIQUID (SOLUTION) |
| CaseID | CLOF - IR - 0001 |
| PTC number | N/A |
| Sien number | 2023-09-1645 |
| Evidence property | N/A |
| Type of origin | Alert |
| Origin | Medical representative |

Statement

[Approved]

Edited by: LCAC
Sign off : [TALLET Nathalie][I am approving this statement]
Date : [26/10/2023 12:41 CEST]

Distributed to: To whom it may concern.

Conclusions and sign off

| Simplified Verdict | Counterfeit/Falsified |
|---|---|
| LCAC Responsible (reviewed and validated) | Sign off : [PIEDALLU Charline] [I am approving the verdict regarding analytical results] Date: [25/10/2023 10:25 CEST] |

Sample Details

| | |
|--------------------------------|---|
| Sample received | Photos |
| Batch number(s) | WC290831 |
| Packaging material (s) studied | BOX VIAL LABEL |
| Drug form | INJECTION, LIQUID (SOLUTION) |
| Sample received was | Incomplete |
| Sample comment | Presentation : 1 Vial (1Box x 1Vial) Incomplete : Only photos of box and vial with label received |

Details

According to traceability and pictures evaluation, this case is falsified.
The batch number "WC290831" does not exist and does not correspond to batch number format used in Northborough site. The last batch "CY0243" of clofarabine packaged was in 2022 with an expiry date in May 2024 whereas this case has an expiry date in January 2025.
Furthermore, the presentation looks like one used for US market but shows a lot of discrepancies compared to the original :

- the text and font are different
- there are several typing errors
- the layout of the text on label is different
- the form of the septum seems to be different
- the variable mentions are printed on another part of the box
- there is no Datamatrix and Serialization doesn't match.