A a VV	Dokumentationsblatt/ Documentation Sheet	QA-SOP-00-01.01
AQVIDA		Version 1
Seite 1 von 5	Investigation for falsified product of AqVida product	Gültig ab: 16.07.2018

Investigation of AqVida drug counterfeiting

- Product: Oxaliplatin 5mg/ml concentrate for solution for infusion
- Batch numbers: AF190402 (50mg) and AG190302 (100mg)

[Comparison of Physical Appearance]

1. AqVida uses clear vials, while the falsified vials both are amber vials.



Asyl	Dokumentationsblatt/ Documentation Sheet	QA-SOP-00-01.01
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2. AqVida uses "tubed" vials, with a flat shoulder. The falsified products have a "molded" shape with a round shoulder.

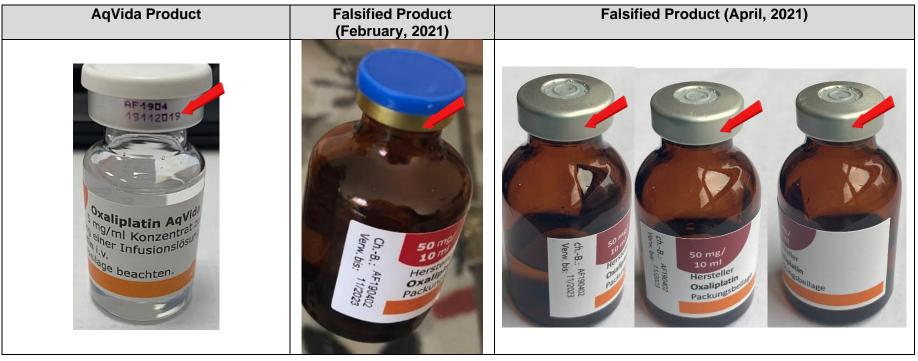


3. AqVida uses white flip-off cap with aluminum part without any coating, while the first falsified vials have blue cap with yellow coating on the aluminum part and the second has a cap, which has the aluminum part without any coating or colour.



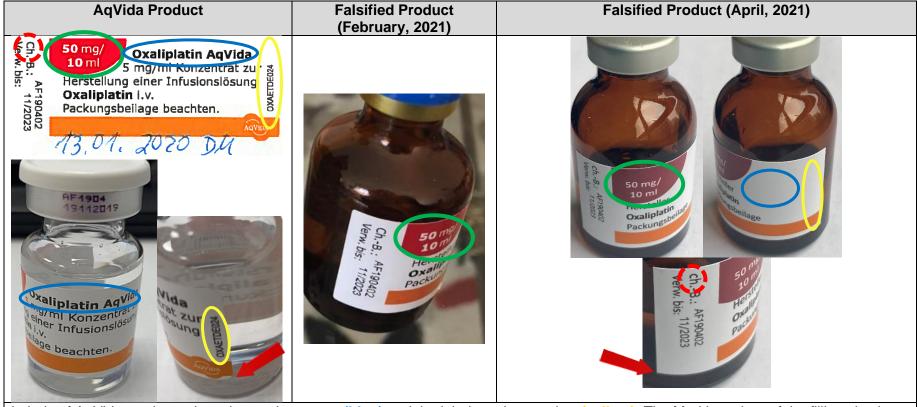
Asyl	Dokumentationsblatt/ Documentation Sheet	QA-SOP-00-01.01
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4. AqVida prints the manufacturing date and bulk batch number on the side of the cap, while the falsified vials do not have any print on the cap.



Action	Dokumentationsblatt/ Documentation Sheet	QA-SOP-00-01.01
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5. The labels of the falsified vials are missing information or a different colouring, which AqVida prints on all its products labels.



Labels of AqVida products show the product name (blue) and the label version number (yellow). The Markingcolour of the filling size is labelled in bright red for the AqVida product (green) and the batch number is writen with capital "C" (red). Furthermore uses AqVida labels with rounded corners (arrow).

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Conclusion:

Based on above observations, the falsified products are clearly not AqVida products.

Physical appearances of the vial, cap, and label are distinctively different. However, there are even differences between the falsified products. The recently received falsified vial of 50mg/10ml (F2) has a different shoulder shape, compared to the shoulder of the falsified vials of the same 50mg/10ml from February (F1) and different caps were used for F1 and F2, as well. In addition, the labels of both counterfeits are not only significantly different than the label of AqVida, but there are several distinctive differences between the falsified products.

This suggests the potential presence of other version(s) of falsified products in the market.

29.04.2021

Dwight You, Head of Production, AqVida GmbH.