

To whom it may concern

Vienna, 03-Jul-2019

Formal Temperature Deviations due to not Stopping the Logger

Any formal temperature deviation that can be traced back to not sufficiently stopping the logger, can be considered uncritical.

In such a case it has to be proven unambiguously, that root cause of the observed alarm is that the logger has not been stopped. This can be done by comparison of the receipt time (e.g. shipping documents, tracking list) against the beginning time of the temperature excursion. It is important that no temperature deviation is observed within the time of shipping. If those prerequisites are fulfilled no temperature deviation report has to be processed at AOP Orphan and documentation can be done directly at the recipient on the logger printout or the shipping documents.

Example of Justification:

"The temperature deviation is considered formal only, because shipment arrived at xxx. During the time frame of the shipment no excursion is observed. Hence, the shown alarm is considered uncritical and the material can be further used."

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Date



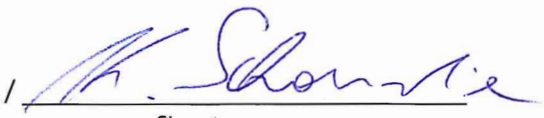
Signature

Approved by:

DI (FH) Katharina Schornsteiner
Qualified Person
AOP Orphan Pharmaceuticals AG

03 JUL 2019

Date



Signature