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To whom it may concern

Vienna, 13 August 2020

Declaration

The study medication for the STRESS-L study (EudraCT 2017-001785-14) is to be stored between 2-8 °C according to the study protocol.

Regarding temperature excursions AOP Orphan can give the following confirmation:

According to existing stability data we can confirm that temperature excursions up to 25 °C for a maximum duration of 1 week do not pose any negative impact on the product quality or safety.

As a consequence, temperature excursions falling in the above definition (1 week up to max. 25 °C) do not have to be reported and can be handled with this statement.

For the sake of clarity, deviations below 2 °C must be reported.

AOP Orphan Pharmaceuticals AG
Dr. Klaus Hofstaedter
Qualified Person