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To whom it may concern

Vienna, 06-Jun-2017

Temperature control

We confirm that any measured temperature has to be rounded commercially (also see Ph. Eur. 1. *General Notices*) to the significant digits shown by the respective limit. The rounded value is the one to be compared against the specified limit.

This is applicable for temperature monitoring of shipping and storage of any material with specified temperature range (e.g. IMP, commercial products, reference standards, etc.)

Example:

The measured value of 8.3 °C is rounded to 8 °C, which is within the specified limit 2-8 °C.

Prepared by:	P	re	pa	re	d	b	v:
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DI (FH) Iris Koller QM Manager AOP Orphan Pharmaceuticals AG 0 6 JUN 2017

Date

Signature

Approved by:

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

0 6 JUN 2017

Signature