



Basaluzzo, October 26th, 2020

To whom it may concern

STORAGE CONDITIONS

We - ICE S.p.A. - Via Novi 78, 15060 Basaluzzo (Al), Italy

hereby declare that

based on the stability data available, the active substance Ursodiol doesn't show any degradation when stored at $25^{\circ}\text{C}\pm 2^{\circ}\text{C}$ and $60\% \pm 5\%$ R.H. (ICH long term storage conditions) and at $40^{\circ}\text{C}\pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ R.H (ICH accelerated studies). According with the new Annex 10, *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* (WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second report, WHO Technical Report Series, No. 1010, 2018), Appendix 2, when testing conditions under which the stability of the API has been demonstrated are $25^{\circ}\text{C}/60\%$ RH (long-term) $40^{\circ}\text{C}/75\%$ RH, the recommended labelling statement is "Do not store above 25°C " (See Table 10A.1).

Then, in considering the above, the controlled Room Temperature & Humidity (Temperature- NMT 25°C with RH- 45% to 60% & Temperature- NMT 25°C with RH- NMT 60%) can be considered the best option. Of course, this shall be considered as a suggestion and not a mandatory condition.

A handwritten signature in blue ink that reads "Paola Alexia Alfano".

ICE S.p.A.
Head of Regulatory Affairs
Paola Alexia Alfano