If all the analytical data obtained after manufacture are within the release specifications, the stability information obtained from the stress tests and acceleration tests can be considered generally applicable with a high degree of reliability.

It may be necessary to ensure compliance with the minimum shelf life by marking packs with storage instructions.

It is important to present this information unambiguously (Table 10).

Table 10 How Storage Instructions Should Be Worded

Storage instruction	Reason
Do not store above 30°C	Relevant changes were seen in the samples after storage at 40°C.
Do not store above 25°C	Relevant changes were seen in the samples after storage at 30°C/70%, but not after storage at 25°C/60%.
Store at ≤8°C in a refrigerator	Revelant changes were observed in the samples after storage at 25°C/60%.
2–8°C, store in a refrigerator, do not freeze	Relevant changes were observed in the samples after storage at 25°C/60% and −10°C.

2.12. Reliability of Minimum Shelf Lives

The shelf lives for the batches of clinical samples are established to cover the duration of the clinical trial plus a supplement to allow for logistics and the provision of clinical supplies. The shelf lives determined apply to all the batches of the relevant development stage, although only the batches in the final phase of development originate from a validated manufacturing phase and are therefore representative.

How reliable is shelf life and stability information?

This question can be answered as follows.

The shelf lives for clinical phases I and II (and in some cases III) represent a minimum shelf life, in other words, they still include a "reserve." A shelf life of 3 months for a first clinical trial does not mean that the batch may not be stable for longer periods. The shelf lives may be extended after appropriate storage and tests.

Minimum shelf lives are therefore associated with a lower risk than shelf lives at the end of which the sample may be unstable.

Furthermore, the principle of "semi-coverage" applies to clinical phase I, i,e., half the shelf life (3–6 months) is covered by storage at higher temperatures.

If there are several strengths, bracketing is performed, i.e., two to three strengths are tested simultaneously for stability.

If all two or three strengths exhibit the same stability behavior, a statement can be made regarding the reproducibility or the technological parameters.

If the stability information for two to three batches of different strengths or composition is identical, the information is naturally also applicable to identical batches.