The number of analyses can be reduced by bracketing if phases I and II are performed using several dosages.

Stability predictions based on stress and acceleration tests are supported by long-term tests conducted under the storage conditions representing climatic zone II, i.e., 25°C/60% r.h. The packaging material planned for commercial use is always included.

The analytical procedures and the specifications to be derived from the results also undergo a process of development.

For example, at the outset the validation has a preliminary character and includes specificity, linearity, recovery, and limit of quantitation, whereas on completion there is the completely validated specification for clinical samples and stability testing. In the same way, the specifications initially serve as a general guide that becomes increasingly specific. This flexible approach makes it possible to obtain reliable stability information while ensuring the rational use of resources.

Not carrying out stress and acceleration tests and replacing them by long-term tests would either cause major delays in clinical development or make it impossible to state an open expiration date.

An alternative would be to include all batches in stability testing, running the serious risk of having to replace batches during the clinical trial and, in addition to the great analytical effort involved, of always having to keep up-to-date stable batches available in order to safeguard the continuity of the clinical trial.

Summarizing, it can be stated that the systematic approach of proceeding in logically coordinated steps represents the best way of supporting the clinical trial by stability testing.

Furthermore, stability testing of clinical samples is a central factor for generating comprehensive stability information, i.e., an overall assessment of the quality of the finished medicinal product.

By applying the same principles to the stability testing of clinical samples and the finished medicinal product, the marketed drug, it is ensured that the results of the clinical trial can be considered applicable to the finished medicinal product; both products have similar stability and therefore quality.

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