Some of these elements, such as selection of samples and batches, number of batches, storage conditions, testing frequency, and storage periods are firmly established, while others, such as test criteria, analytical procedures with validation, and specifications undergo further development. Combining the six stages and the eleven basic principles yields a systematically structured stability study schedule.

1.2. Specific Requirements for Stability Testing of Clinical Samples

Similarly to the requirements for proprietary medicinals, the aim of stability testing in this area of clinical samples is to maintain the quality and safety of these materials up to the end of phase I, II, and III clinical trials.

This means that all relevant test results must remain within the minimum shelf life specifications up to the end of the clinical trial.

In systematically structured stability programs, stability tests are carried out on clinical samples in steps 2 and 3.

Stability testing accompanies phase I to III clinical trials.

At first, neither the dosage formulation nor the dosage form is definitely established; they are gradually defined during the course of development.

The same applies to analytical procedures and specifications.

The effort and scope of stability testing must be tailored to the specific problem.

The stability program will always differ from that required to generate stability information (expiration date, etc.) for marketing authorization application documents for proprietary medicinals. This stability information is based on the results obtained with three representative pilot plant batches put into storage after the end of development. The stability information is then applicable to all production batches.

The stability information for clinical samples is required only for a small number of batches and for the duration of the respective clinical trial.

The shelf life determined is thus not a maximum shelf life ($\leq$5 years) at the end of which the acceptance criteria of the shelf life specifications for individual test parameters are reached, but a minimum shelf life at the end of which the tolerance limits usually have not been reached.

There are no defined official regulations stipulating effort, scope, and implementation, which are left to the manufacturer's discretion.

In the USA (6), in each phase of the investigation sufficient information should be submitted to ensure the proper identification, quality, purity, and strength of the investigational drug; the amount of information needed to achieve that assurance will vary with the phase of the investigation, the dosage form, and the amount of information otherwise available.

Therefore, although stability data are required in all phases of the IND to demonstrate that the new drug substance and drug product are within acceptable chemical and physical limits for the planned duration of the proposed clinical investigation, if very short term tests are proposed, the supporting stability data can be correspondingly very limited. It is recognized that modifications to the method of preparation of the new drug substance and dosage form, and even changes in the dosage form itself, are likely as the investigation progresses.