An overview of the most important packaging materials for stability testing for clinical samples is given in Table 7.

2.10. Evaluation

A systematic approach should be adopted in the evaluation and presentation of the analytical results.

Tests for significant changes with the aid of statistics, reaction kinetics calculations, or linear regression analysis are valuable tools. The stress and accelerated test results are evaluated for each clinical phase taking into account the specific objective of the respective storage conditions.

On the one hand, there is the test for organoleptic and physicochemical stability, on the other hand for chemical or microbial stability. If, for example, discoloration, a decrease in hardness, an increase in dissolution, or phase separation is observed after 3 months's storage at 70°C, these changes will be recorded, but they are only of limited relevance for predicting stability. If there are no significant changes in the test for organoleptic and physicochemical stability, stability can be predicted by means of reaction kinetics calculations that are based mainly on the results obtained after storage at stress temperatures.

Considering these facts, all test criteria can be included in the stability prediction. A critical examination is conducted to determine whether relevant changes have occurred and whether the proposed minimum shelf life tolerance limits have been reached or exceeded.

Stability studies for clinical samples are based on stress and acceleration tests with the aim of speeding up, especially, chemical decomposition by storing samples at elevated temperatures. The results are then used to calculate the stability behaviour at 25°C/60% r.h. based on the laws of reaction kinetics.

The equations for a first-order reaction and the Arrhenius model are used. If decomposition levels are available for only one temperature (4,5), the expression ΔE: 83 kJ mol^{-1} is used for the activation energy.

Table 8 shows decomposition levels for 25°C/60% r.h. calculated from values obtained after storage at 40°C to 70°C. Reported in Table 6 are the decomposition determined after storage at accelerated and stress temperatures, and the decomposition for 25°C derived from these data.

After evaluating the data of one batch it is assessed whether the strengths or the dosage forms exhibit different stability behavior or whether the results of the batches can be combined to produce uniform stability information.

The packaging material and possible interactions have to be included in the evaluation.

The general stability information, the period of use, and if necessary storage instructions are based on

Primary data
: The results of the stress and accelerated investigations and later the results of the long-term testing for confirmation.

Supportive data
: Drug substance stability profile, which also includes orientational predictions regarding the chemical stability of the drug substance in solid, semisolid, and liquid dosage forms.