The data are summarized in research reports and stability reports, testing specifications.

The stability reports of the different steps of development are built up and written in the same format. Thus all data can be cross-checked easily, and the final shelf life can be based on all these data.

By presenting all the available stability data in such a comprehensive way, considerable savings can be reached concerning different strengths, different packaging materials, and later with variations.

The derived stability information is based on a broad set of data and assures the quality of the drug product to the patient.

Table 5 gives an overview of the different documents that result during development.

The analytical procedures, the specification and the corresponding testing specifications are developed systematically in steps 1–4.

In step 4 they are transferred to quality control, which elaborates on this basis the testing specifications for quality control.

Therefore the registration application contains two types of testing specifications:

- Those that have been applied during development for release of clinical trial samples and for stability testing and will be applied for on-going stability testing
- Those that will be applied for quality control of running production and follow-up stability testing

The analytical procedures are usually not changed after the transfer into quality controls, but the format may be changed to consider the requirements of different countries.

After an overview of the required capacity (Table 6) and period for analytical statements (Table 7), each step is described in detail, practical examples are given, the required capacity calculated, and the period for analytical statements indicated.

2. Step 1: Stress and Accelerated Testing with the Drug Substance

2.1. Objective

- Elucidation of the intrinsic characteristics of the drug substance with reference to chemical properties (physical properties are investigated separately)
- Establishment of the degradation pathway, leading to identification of degradation products and hence supporting the suitability of the proposed analytical procedure
- Investigation of the following influencing factors: moisture, temperature, moisture + temperature, moisture + temperature + drug substance concentration, pH, ionic strength, oxidation, light

The tests with the drug substance are of general nature and are not specific to any particular dosage form. Consequently the results are generally applicable. These investigations are required by the ICH Stability Guideline. The performance, however, is up to the applicant's discretion.