Table 12 The Objective Is to Extend the Shelf Life by 30%

Derived minimum shelf life (months)	Extension by 30% to (months)
3	4
6	9
12	16
18	24
24	32
36	48

The Stability Report comprises the stability data of stress investigations with the active ingredient it represents the stability profile of the NME.

The following influencing factors were investigated: Moisture, temperature, moisture + temperature, moisture + temperature + drug substance concentration, pH, ionic strength, oxidation, and light.

The following stability information is derived.

For drug substance,

Test criteria for accelerated and long-term testing with the registration batches
Analytical procedures
Selection of packaging materials
Preliminary retest period
Storage instructions, if required

For drug product,

Solid, liquid and semiliquid dosage forms can be developed concerning chemical stability.

From the investigations of step 2, performulation and formulation finding for clinical trial samples, information is available on the additional influence of the excipients on the stability of the drug substance.

On the base of this comprehensive information, the stress and accelerated testing is planned and performed.

3.1. Solid Dosage Forms: Tablets, Capsules

3.1.1. Selection of Batches and Samples

Phase I: Experimental laboratory batches from the development laboratory
Phase II: Clinical batches, pilot scale from manufacturing clinical supplies
Phase III: Pilot plant batches, final formulation from pilot plant

3.1.2. Test Criteria

Organoleptic and physicochemical stability
Tablets: appearance, hardness, average mass, disintegration time, dissolution rate
Capsules: appearance, elasticity, average mass, average mass of content, average mass of filling, disintegration time, dissolution rate