

To test for permeation and sorption, the filled plastic tubes are stored for 3 months at 40°C.

When selecting the packaging material, the climatic zone in which the product is to be introduced must also be taken into account.

Because of the problems arising with plastic tubes, aluminum tubes are preferred.

If the final packaging material has been selected, the investigations on photostability are performed.

The samples with and without container are irradiated with a Xenon lamp (Suntest 250 W/m<sup>2</sup>) for 24 hours.

The test criteria are appearance, drug substance decomposition and assay.

### 3.2.6. Evaluation

If the results of the test for organoleptic and physicochemical stability are within the shelf life specifications, the stability prediction is only determined by the chemical and microbial stability. Content uniformity within a container and possible interactions with the packaging material must also be considered. Generally, stability predictions are most difficult for semisolid dosage forms, and this applies particularly to the use of reaction kinetics. It may also be necessary to ensure compliance with the minimum shelf life by marking packs with storage instructions.

### 3.2.7. Stability Information

This is as for solid dosage forms.

## 3.3. Solutions, Ampoules

### 3.3.1. Selection of Batches

This is as for solid dosage forms.

### 3.3.2. Test Criteria

Organoleptic and physicochemical stability: Appearance, clarity, pH.

Chemical and microbial stability: Drug substance decomposition and assay preservative decomposition and assay.

### 3.3.3. Storage conditions, storage period, testing frequency, packaging material (Tables 20 and 21)

### 3.3.4. Number of Batches

This is as for solid dosage forms.

### 3.3.5. Selection of Packaging Material for Liquid Dosage Forms

*Packaging:* ampoule, injection vial with rubber stopper, glass bottle or plastic bottle with screw closure or pilferproof closure and liner.

*Problems:* pH, leakage, desorption, sorption, permeation, interaction with rubber stopper, interaction with liner.

*Tests packaging material—dosage form:* To test for sorption, permeation, pH, and leakage, the final formulation solution is filled in the container, and for desorption placebo solution is used. The samples are stored vertically and inverted