Table 21 Storage Conditions for Organoleptic and Physicochemical Stability

Clinical phase	Packaging material	Storage condition	Storage period
I	Ground-glass-stoppered bottle Glass ampoules	5°C	1 week
II–III	Injection vial with rubber stopper Plastic bottle	≥−10°C	4 weeks

under the following conditions: 30°C/70% r.h., 40°C, and 50°C for up to 12 weeks. Testing intervals: 0, 1, 2, 3 months.

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

The samples in colorless glass and the original packaging material are indicated with a Xenon lamp (Suntest 250 W/m^2) for 24 hours.

The test criteria are appearance (colour of solution), clarity of solution, drug substance decomposition and assay.

3.3.6. Evaluation

If the results of the organoleptic and physicochemical tests are within the shelf life tolerance limits, reaction kinetics prediction presents few problems.

The influence of the packaging materials also has to be considered, especially when elastomers are used.

3.3.7. Stability Information

This is as for solid dosage forms.

4. STABILITY INFORMATION FOR COMPARATOR OR REFERENCE PRODUCTS

When an investigational medicinal product is compared with a marketed product, attention should be paid to ensure the integrity and quality of the comparator product (final dosage form, packaging materials, storage conditions, etc.). If significant changes are to be made to the product, data should be available (e.g., stability, comparative dissolution, bioavailability) to prove that these changes do not significantly alter the original quality characteristics of the product.

Because the expiry date stated on the original package has been determined for the medicinal product in that particular package and may not be applicable to the product where it has been repackaged in a different container, it is the responsibility of the sponsor, taking into account the nature of the product, the characteristics of the container, and the storage conditions to which the article may be subjected to determine a suitable use-by date to be placed on the label. Such a date is not later than the expiry date of the original package. In the absence of stability data or if stability is not followed during the clinical trial, such a date should not exceed 25% of the remaining time between the date of repackaging and the expiry date