

### 3.1.9. Stability Information

All the results and the stability information are compiled in a Stability Report. Correspondingly three Stability Reports are available.

Stress Testing and Long-Term Testing phase I  
 Stress Testing and Long-Term Testing phase II  
 Stress Testing and Long-Term Testing phase III

If the data of the different stress investigations are comparable, it can be concluded that the quality of the clinical trial batches is comparable with the quality of the registration batches; the patient after marketing authorization will get the same quality as the patient during the clinical trials.

Furthermore, packaging materials can be recommended for the registration batches as in Table 17.

Storage instructions should be given if required.

**Table 17**

Packaging material	Climatic zones		
	I + II	III	IV
PVC/PVDC blister	x	x	—
Polypropylene tubes with polyethylene closure	x	x	x
Polyethylene bottle	x	x	x
Glass bottle with screw cap	x	x	x
Aluminum blister	x	x	x

## 3.2. Semisolid Dosage Forms: Creams, Ointments

### 3.2.1. Selection of Batches

This is as for solid dosage forms.

### 3.2.2. Test Criteria

Organoleptic and physicochemical stability; appearance, odor, homogeneity, consistency, pH, particle size (if active ingredient is in suspension), recrystallization.

chemical and microbial stability: Appearance, homogeneity, content uniformity within the container (tubes stored vertically are cut open, samples are taken from the beginning, middle and end of the tube and analyzed), drug substance decomposition and assay, preservative decomposition, assay

### 3.2.3. Storage Conditions, Storage Period, Testing Frequency, Packaging Material

Although the samples are stored differently for organoleptic/physicochemical and chemical/microbial stability, the tests overlap; see Tables 18 and 19.