Table 24 Time to Availability of Prediction of Minimum Shelf Life

Stage of development	Storage period		Analysis and evaluation	Stability report	Total period	
	Stress[a]	Accelerated			Preliminary*	Final
Phase I	—	6 weeks	1 week	2 weeks	—	9 weeks
Phase I	—	12 weeks	1 week	2 weeks	—	15 weeks
Phase II	12 weeks	24 weeks	1 week	2 weeks	15 weeks	27 weeks
Phase III	12 weeks	24 weeks	1 week	2 weeks	15 weeks	27 weeks
Registration batches	12 weeks	24 weeks	1 week	2 weeks	—	27 weeks

[a] In clinical phases II and III a preliminary prediction can be made based on the data of samples stored at stress conditions.

In Table 25 estimations for phases I, II, and III are given.

Table 25 Estimated Capacities for the Stress Investigations of Clinical Samples

Test sample batch	Dosage form	Analytical procedures, validation (weeks)	Analysis of test samples no. of dosages			Total required capacity no. of dosages		
			1 (week)	2–4 (weeks)	>4 (weeks)	1 (week)	2–4 (weeks)	>4 (weeks)
Phase I	Solid	6	5	10	15	11	16	21
	Semisolid	3	2	4	6	5	7	9
	Liquid	3	1	2	4	4	5	7
Phase II	Solid	6	9	17	25	15	23	31
	Semisolid	3	4	8	12	7	11	15
	Liquid	3	2	5	7	5	8	10
Phase III, final formulation	Solid	7	16	31	47	23	38	55
	Semisolid	3	6	11	17	9	14	20
	Liquid	3	5	10	15	8	13	18

8. SUMMARY

The stability program for clinical samples as presented in this chapter is based on the principles of the ICH Guideline "Stability Testing for New Drug Substances and Drug Products."

However, these principles have been adapted to suit the complex circumstances arising during ongoing development, as exemplified by the transition from clinical Phase I to III.

Storage conditions, storage periods, and the derived minimum shelf lives correspond to the duration of clinical trials in Phases I to III.

Shelf lives are established on the basis of stress and acceleration tests. Only with this approach can shelf lives be established rationally and all batches provided with an open expiration date. By consistently separating the storage conditions for organoleptic, physicochemical, and chemical-microbial test criteria, all stability-indicating test criteria can be integrated in the stability information.