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Table 9.1ICH storage conditions for general, refrigerated and frozen drug substances and
products (ICH Guideline Q1A).

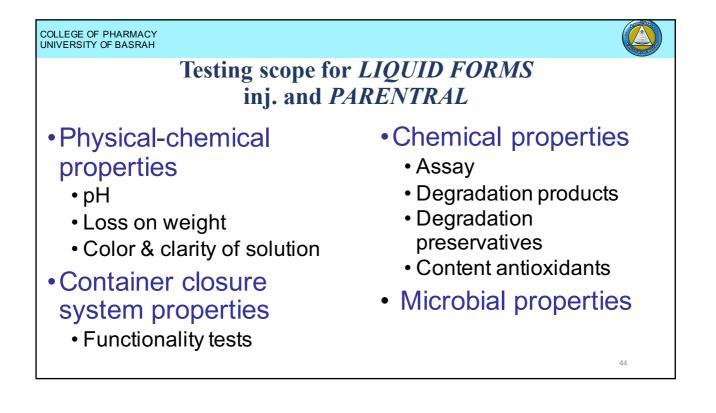
Study	Storage condition	Minimum data required before regulatory submission				
General						
Long-term	25 \pm 2 °C and 60 \pm 5% RH 30 \pm 2 °C and 65 \pm 5% RH	12 months				
Intermediate	30 \pm 2 °C and 65 \pm 5% RH	6 months				
Accelerated	40 \pm 2 $^\circ$ C and 75 \pm 5% RH	6 months				
Refrigerated						
Long-term	5 \pm 3 °C	12 months				
Accelerated	25 \pm 2 °C and 60 \pm 5% RH	6 months				
Frozen						
Long-term	$-$ 20 \pm 5 $^\circ$ C	12 months				

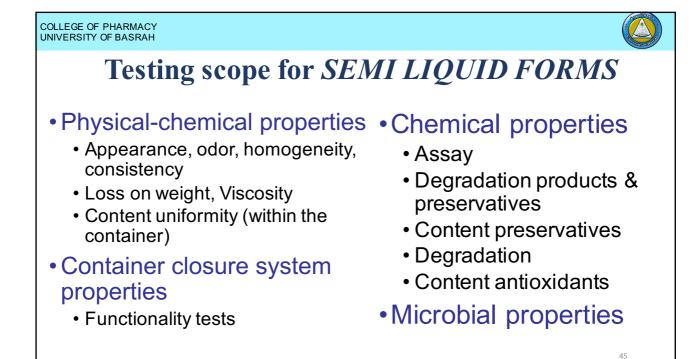
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Table 9.2 ICH climatic zones and their associated long-term storage conditions.									
Climatic zone	Definition	Long-term storage conditions							
I	Temperate	21 °C, 45% RH							
II	Subtropical and Mediterranean	25 °C, 60% RH							
III	Hot and dry	30 °C, 35% RH							
IVA	Hot and humid	30 °C, 65% RH							
IVB	Hot and very humid	30 °C, 75% RH							
		40							

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Table 49.3 Examp	ples of recommend	led minimum stability testing s	chedules for pharmaceutical pr	oducts			
Storage time (months)	Products inter refrigerator	nded to be stored in a	Product intended to be stored in ambient conditions				
	Long-term 5°C	Accelerated Zone II 25°C/60% RH Zone IVA 30°C/65% RH Zone IVB 30°C/75% RH	Long-term Zone II 25 °C/60% RH Zone IVA 30 °C/65% RH Zone IVB 30 °C/75% RH	Accelerated 40°C/75% RH			
0	\checkmark	\checkmark	\checkmark	\checkmark			
3	\checkmark	\checkmark	\checkmark	\checkmark			
6	\checkmark	\checkmark	\checkmark	\checkmark			
9	\checkmark		\checkmark				
12	\checkmark		\checkmark				
18			\checkmark				
24			\checkmark				
36			\checkmark	41			

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Testing scope for Solid dosage <i>Tablet & Capsule</i>								
 Physical-chemical properties Appearance Elasticity Mean mass 	 Chemical properties Assay Degradation Microbial properties 							
 Moisture Hardness Disintegration Dissolution 	 Container closure system properties Functionality tests (e.g. extraction from blister) 							

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Testing scope for Oral liquid form									
 Physical-chemical properties pH Color & clarity of solution Viscosity Particle size distribution (for oral suspensions only) Microbial properties 	 Chemical properties Assay Degradation products Degradation preservatives Content antioxidants Container closure system properties Functionality tests 								





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Suggested anal drug:	yticc	al me	əthc	ods fo	or v	various	do	sage fo	rms, c	depe	endir	ng upon the	active
DOSAGE ANALYTICAL METHOD													
FORM	WT	VOL	PH	OSM	RI	SP GR	MP	UV/VIS	HPLC	GC	IR	STERIL	ENDO
Bulk substances	_		*		*	_	*	*	*	*	*	_	_
Powders	*	_	_	_	_	_	_	_	*	*	_	_	
Capsules	*	_		_	_	_	_	_	*	*	_	_	
Tablets	*	_			_	_	_	_	*	*	_	_	
Lozenges	*	_			_	_	_	_	*	*	_	_	_
Suppositories	*	_	_	_	_	*	*	_	*	*	_	_	_
Sticks	*	—	—	_	_	*	*	_	*	*	—	—	
Solutions	*	*	*	*	*	*	—	*	*	*		—	
Suspensions	*	*	*	—	_	*	—	_	*	*	_	—	
Emulsions	*	*	*		_	*	—	—	*	*		—	
Semisolids	*				—	*	*	—	*	*		—	
Gels	*	*	*	_	*	*	_	—	*	*		—	
Ophthalmics, Otics, and Nasals	*	*	*	*	*	*	—	*	*	*	—	*(Ophthalmic only)	—
Inhalations	*	*	*	*	*	_	_	*	*	*	_	*	_
Injections	*	*	*	*	*	*	_	*	*	*	_	*	*