

Manual 055

5.2.3.1 Solid Dosage Forms

	New Product Introduction (three 1st, or early, batches)			
Frozen	-20°C	-20°C	5°C	N/A
Refrigerated	5°C	5°C	25°C/60%RH	N/A
Room Temperature	25°C/60% RH	30°C/75% RH	40°/75% RH	30°C/65% RH
Zones/Months	I & II	III & IV	I & II III & IV	I & II
Initial (Note 1)				
1				
2				
3	L	L	A	A
6	L	L	A	A
9	L	L		A
12	L	L		A
18	L	L		
24	L	L		
36	L	L		
48	L	L		

5.2.3.2 Liquids and Semi-solids

	New Product Introduction (three 1st, or early, batches)			
Freezer	-20°C	-20°C	5°C	N/A
Refrigerated	5°C	5°C	25°C	N/A
Room Temperature	25°C/40% or 25°C/60% RH ¹	30°C/75% RH	40°/25% RH ¹	40°C/75% RH
Zones/Months	I & II	III & IV	I & II	III & IV
Initial (Note 1)				
3	L	L	A	A
6	L	L	A	A
9	L	L		
12	L	L		
18	L	L		
24	L	L		
36	L	L		
48	L	L		

5.2.3.3 Bulk Package Stability

	Bulk Package Stability			
Market	Other Climatic Zone I & II Primary Packs	Climatic Zone III & IV Primary Packs		Accelerated Zones I - VI
Frozen	-20°C	-20 °C		5°C
Refrigerated	5 ± 3°C	5 ± 3 °C		25°C/60% RH
Room Temperature	25°C/60% RH	30°C/75% RH		40°C/75% RH
Product Shelf Life	12	18	24	36 48
Pull Month Initial (Note 1)	<i>AS</i>			
3				<i>FOR OTHER CLIMATIC ZONE ZONE I & II PRIMARY PACKS</i>
6	L	L	L	L L A
12	L	L	L	L L
18			L	
24				L

5.3.3.1 Solid Dosage Forms

	Annual Maintenance Schedule ¹				
Market	Other Climatic Zone I & II Primary Packs	Climatic Zone III & IV Primary Packs			
Frozen	-20°C	-20°C			
Refrigerated	5°C	5°C			
Room Temperature ²	25°C/60%RH	30°C/75%RH ³			
Product Shelf Life ⇒	18	24	36	48	60
Pull Month Initial (Note 1)	<i>AS</i>				
3	<i>FOR OTHER CLIMATIC ZONE ZONE I & II PRIMARY PACKS</i>				
6	L				
9					
12	L	L	L	L	L
18	L	L			
24		L	L	L	L
36			L	L	L
48				L	L
60 ⁴					L

5.3.3.2 Liquids and Semi-solids

	Annual Maintenance Schedule ¹							
Market	Other Climatic Zone I & II Primary Packs		Climatic Zone III & IV Primary Packs					
Frozen	-20°C		-20°C					
Refrigerated	5°C		5°C					
Room Temperature ²	25°C/40%RH or 25°C/60% RH ³		30°C/75%RH ⁴					
Product Shelf Life ⇒	18	24	36	48				
Pull Month Initial (Note 1)	AS FOR OTHER CLIMATIC ZONE ZONE I & II PRIMARY PACKS							
3								
6					L			
9								
12					L	L	L	L
18					L	L		
24						L	L	L
36							L	L
48				L				

5.5.3 Schedule

Shelf-life ¹	Long Term (as defined by ICH for product type; e.g. 25°C/60% RH, 25°C/40% RH)							Accelerated (as defined by ICH for product type; e.g. 40°C/75% RH or 40°C/25% RH)	
Months	0	12	18	24	36	48	60	3	6
18	X	X	X					X	X
24	X	X		X				X	X
36	X	X		X	X			X	X
48	X	X		X	X	X		X	X
60	X	X		X	X	X	X	X	X

¹ The shelf life should be the expected or desired shelf life of the product