

Summary of Matrixed Stability Program

Condition	Batch	Time point (month)		
		0	1.5	3
5 ± 3°C	Batch 1	1 (A,B)		1 (A,B)
	Batch 2	1 (A,B)		1 (A,B)
	Batch 3			
	Batch 4			
	Batch 5		1(A)	
	Batch 6			
	Batch 7	<i>Contingency</i>		
	Batch 8			
	Batch 9	1 (A,B)		1 (A,B)
25 ± 2°C/60 ± 5 %RH	Batch 1	See 5 ± 3°C		
	Batch 2			
	Batch 3			
	Batch 4			
	Batch 5		1 (A)	
	Batch 6			2 (A,B,C)
	Batch 7			
	Batch 8	<i>Contingency</i>		
	Batch 9			
12,000 lux hrs*	Batch 1	N/A	N/A	N/A
	Batch 2	N/A	N/A	N/A
	Batch 3	1(A) ^{1a}	1(A) ^{1b}	N/A
	Batch 4	1(A) ^{2a}	1(A) ^{2b}	N/A
	Batch 5	N/A	N/A	N/A
	Batch 6	N/A	N/A	N/A
	Batch 7	N/A	N/A	N/A
	Batch 8	N/A	N/A	N/A
	Batch 9	N/A	N/A	N/A

A = Physiochemical Tests, B= Microbiological Tests, C= CCIT

* 12,000 lux hours, an integrated near ultraviolet energy of not less than 200-watt hours/square meter, at ambient temperature and humidity.

X = represents 1 single bag from that batch

1 exposed to light, 2 dark control

a T=0, b Tested at the completion of the photostability study exposure, 12,000 lux hours