

Manual 048

5.2.2 Testing Schedules

API Stability Testing Schedules New Product Introduction (1st three batches)	
Months	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> 25°C/60% RH (Climate zone I and II) </div> <div style="width: 30%;"> 40°C/75%RH (Note 2) </div> <div style="width: 30%;"> 30°C/65% RH (Note 3) </div> </div> <div style="text-align: center;"> 30°C/65% RH (Climate zone III and IV) (Note 1) </div>
Initial (Note 1)	
3	L A A
6	L A A
9	L A A
12	L A
18	L
24	L
36	L
48	L
60	L

5.3.2 Testing Schedule

API Stability Annual Maintenance Stability Testing Schedule	
25°C/60%RH or 30°C/65%RH	
<i>API retest period ⇒</i>	<i>18 24 36 48 60</i>
<u>Pull Month</u> <i>Initial (Note 1)</i>	
6	L
12	L L L L L
18	L L
24	L L L L
36	L L L
48	L L
60	L