

(USFDA FEI No.: 3017085815)

## STABILITY TESTING OF PHARMACEUTICALS

Stability Study as per ICH, EMA, FDA & WHO Guidelines

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| <ul style="list-style-type: none"> <li>1 Accelerated Stability Testing</li> <li>2 Real Time stability Testing</li> <li>3 Photo stability Testing</li> <li>4 Force Degradation Studies</li> </ul> | <ul style="list-style-type: none"> <li>5 Container Closure Integrity Testing</li> <li>6 Freeze-Thaw Testing</li> <li>7 Transportation Studies</li> <li>8 All Zones stability Testing</li> </ul> |
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### ALL FOUR ZONE STABILITY STUDY

Long Term Testing Conditions As per ICH Q1A (R2)				Accelerated and Intermediate Testing Conditions As per ICH Q1A (R2)			
Climatic Zone	Temperature	Humidity	Minimum Duration	Climatic Zone	Temperature	Humidity	Minimum Duration
Zone I	21°C ± 2°C	45% RH ± 5% RH	12 Months	Accelerated Ambient	40°C ± 2°C	75% RH ± 5% RH	6 Months
Zone II	25°C ± 2°C	60% RH ± 5% RH	12 Months	Accelerated Refrigerated	25°C ± 2°C	60% RH ± 5% RH	6 Months
Zone III	30°C ± 2°C	35% RH ± 5% RH	12 Months	Accelerated Frozen	5°C ± 3°C	No Humidity	6 Months
Zone IVa	30°C ± 2°C	65% RH ± 5% RH	12 Months	Intermediate	30°C ± 2°C	65% RH ± 5% RH	6 Months
Zone IVb	30°C ± 2°C	75% RH ± 5% RH	12 Months				
Refrigerated	5°C ± 3°C	No Humidity	12 Months				
Frozen	-15°C ± 5°C	No Humidity	12 Months				

With Best Compliments From

<p><b>Shri.Mulubhai Kandoriya</b> (Managing Director)</p>	<p><b>Dr.Rina Gokani</b> (Director &amp; CSO) +91 90996 16769</p>	<p><b>Dr.Manish Rachchh</b> (Director &amp; CEO) +91 90999 81023</p>	<p><b>Mr.Mayur Kandoriya</b> (Director &amp; CMO) +91 99099 19545</p>
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Email Your Inquiry On : [info@accuprec.com](mailto:info@accuprec.com)



**NORTH AMERICA OFFICE:**  
Pittsburgh, PA, USA  
**CANADA OFFICE:**  
Sudbury, ON, Canada

**REGISTERED OFFICE:**  
Opp. Zydus Pharmez, Changodar-Bavla Highway,  
Near Matoda Patiya, Po. : Matoda, Ahmedabad  
382 213, Gujarat, INDIA.

