

Storage temperatures

- Controlled room temperature: permissible limits 15-30°C Turkey (25°C)
- Room temperature: the temperature of the room (change.)
- Cool place: 8-15°C
- Cold (refrigerator): 2-8°C
- Freezer: (-25) - (- 10) °C

Uluslararası iklim kuşakları

İklim kuşağı	Hesaplanan veriler				Türetilen türevler		
	$^{\circ}C$	$^{\circ}C$	(MKT)	%RH	Mbar	$^{\circ}C$	%RH
İlman (I) İngiltere,rusya kuzey avrupa	20	20.0	42	9.9	21	45	11.2
Akdeniz-subtropik(II) Amerika, japonya, g.avrupa,türkiye	21.6	22	52	13.5	25	60	19.0
Sıcak,kuru(III) İran,ırad,sudan	26.4	27.9	35	11.9	30	35	15.0
Sıcak,nemli (IV) Brezilya,gana, filipinler,endonezya	26.7	27.4	76	26.6	30	70	30.0

Stability tests

- Long-term
- Accelerated
- Compulsive (stress)

Stability test conditions for countries in the I and II climate zone

❖ Product and active substance recommended to be stored at room temperature

Long term... $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%60 \pm 5$minimum12months

Medium duration.... $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%65 \pm 5$... minimum12months

Accelerated.. $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%75 \pm 5$ minimum6months

❖ refrigerator storage recommended product and drug

Long term ... $5^{\circ}\text{C} \pm 3^{\circ}\text{C} / \%60 \pm 5$ minimum12months

Accelerated ... $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%60 \pm 5$ minimum6months

- ❖ Recommended product and drug for storage in deep freeze
- ❖ Uzun süreli...- 20 ± 5 °C.....min 12 m
- ❖ Separate evaluation should be made for the product and the active substance which should be stored below -20 °C
- ❖ final product test
- ❖ It is carried out under the same test conditions for products stored at room temperature. If the accelerated test fails, the test is repeated for 12 months at 30 ± 2 °C / $60\% \pm 5$ relative humidity.

❖ Test conditions for products stored in semi-permeable packaging

Long term ... $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%40 \pm 5$ min 12m

Medium..... $30 \pm 2^{\circ}\text{C} / \%65 \pm 5$ min12m

Accelerated.... $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%25 \pm 5$ min 6m

❖ For products stored in deep freezing

Long term... $-15^{\circ}\text{C} \pm 5^{\circ}\text{C}$ min12m

Accelerated.... $5 \pm 3^{\circ}\text{C} / \text{ambient humidity}$ min 6m

For climate zone III and IV

- Room temperature
- Long term... $30 \pm 2^{\circ}\text{C} / \%65 \pm 5$ min 12m
accelerated... $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%75 \pm 5$ min 6m
- Semi-permeable packaging
- Long term..... $25^{\circ}\text{C} \pm 2$ / $\%35 \pm 5$...min 12m
- accelerated... $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \%25 \pm 5$ min 6m

Testing periods of samples

First year every 3 months (3, 6, 9 ve 12)

Second year every 6 months(18, 24. months)

Then once a year(36, 48, 60.months)