

Typical examples of stability testing of drug substance for various storage conditions:

Storage on shelf	Storage condition	Time period
Long term	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH	12 months
Intermediate	30°C ± 2°C/65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months
Storage in a refrigerator	Storage condition	Time period
Long term	5°C ± 3°C	12 months
Accelerated	25°C ± 2°C/60% RH ± 5% RH	6 months
Storage in a freezer	Storage condition	Time period
Long term	- 20°C ± 5°C	12 months