

Determination of Accelerated Stability Studies

Practical 11 | Physical Pharmaceutics II

Aim

To determine Accelerated Stability Studies, and interpret the recorded observations.

Principle

- Temperature-dependent rate data can be examined with the Arrhenius model when the degradation mechanism and physical state remain comparable.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.

Materials and Apparatus

- Assigned stability time/concentration records at several temperatures.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

Method

1. Review concentration-time records at the assigned temperatures.
2. Use the appropriate kinetic model to estimate a rate constant at each temperature.
3. Convert all temperatures to kelvin.
4. Plot $\ln(\text{rate constant})$ against reciprocal absolute temperature.
5. Interpret the fitted slope and any extrapolated rate only if the mechanism remains comparable.
6. Report model assumptions and distinguish a classroom estimate from a justified product shelf life.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Temperature in kelvin	_____
Concentration-time readings	_____
Rate constant	_____
Arrhenius plot	_____

Calculations and Interpretation

- $\ln(k) = \ln(A) - E_a/(RT)$.
- Slope of $\ln(k)$ versus $1/T = -E_a/R$.
- For first-order loss, $t_{90} = -\ln(0.90)/k$; extrapolation is conditional and does not itself authorize a shelf life.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

Viva Questions

1. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

2. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

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