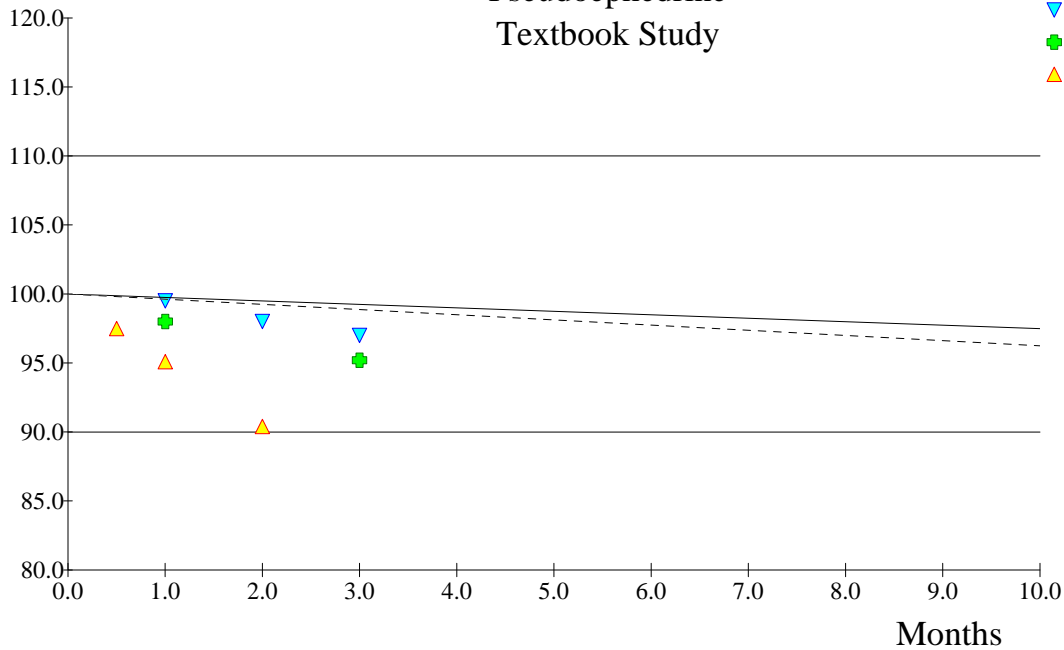


# Shelf Life Projection

Chow and Liu  
Pseudoephedrine  
Textbook Study

Condition

Potency



Arrhenius Projection (Zero-Order) at 25.0° C = 40 Months. Shelf life = 26 Months. (95.0% CI)

Test Category: Assay High Spec: 110.0 Low Spec: 90.0

Test Data

File: C:\Program Files\SLIM\Accelerated Conditions.SST User: Craig Hamilton

Zero-Order fit substituted into the Arrhenius equation.

Initial Purity = 100.0 Potency.

Original Raw Data:

Condition 1	35		
Time :	1.0	2.0	3.0
Results:	99.50	98.00	97.00

Condition 2	45		
Time :	1.0	3.0	
Results:	98.00	95.20	

Condition 3	55		
Time :	0.5	1.0	2.0
Results:	97.50	95.10	90.40

Original Raw Data Treatment:

- Less than (<) results are ignored.
- Greater than (>) results are ignored.
- Values that are not between 0.0 and 100.0 are ignored.

Data Points used in Calculations:

Condition 1	35		
Time :	1.0	2.0	3.0
Results:	99.50	98.00	97.00

Condition 2	45		
Time :	1.0	3.0	
Results:	98.00	95.20	

Condition 3	55		
Time :	0.5	1.0	2.0
Results:	97.50	95.10	90.40

## STATISTICAL ANALYSIS

LOWER ONE-TAILED CONFIDENCE INTERVAL

PROBABILITY LEVEL = 95.0% (equivalent to two-tail 90.0% probability)

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ANOVA Table Under Model  $D(h) = \sum_{ij} \text{Beta}(h)X(h) + e$

Order of reaction	Source of variation	df	Sum of squares	Mean squares	F value	p-value	R
0	Regression	3	162.31814	54.10605	690.37975	0.00000	99.75917
	Residual	5	0.39186	0.07837			
	Total	8	162.71000				
1	Regression	3	0.01750	0.00583	778.29613	0.00000	99.78631
	Residual	5	0.00004	0.00001			
	Total	8	0.01754				

Zero Order : Product degrades at a constant rate which is independent of concentration.

The Arrhenius equation is  $K = A * \exp(-E/RT)$ , where:

K : Rate Constant                      E : Activation Energy  
A : Frequency Factor                  R : Gas Constant (8.31441 J/(K mol))  
T : Absolute Temperature

Initial estimates using Simple Linear Regression:

A = 7.01506E+012      E = 76479.088

Refined estimates using Taylor series expansion:

A = 3.20451E+013      E = 80545.898

Using the refined estimates, let  $\alpha = \ln(A)$ ,  $\beta = -E/R$ , and  $X = 1/T$ . The Arrhenius equation can be rewritten as  $K = \exp(\alpha + \beta * X)$ , where  $\alpha = 31.098167$  and  $\beta = -9687.506180$ .

Summary of Residuals for Lack of Fit for the Arrhenius Equation

Source of variation	df	Sum of squares	Mean squares	F value	p-value
Residual from Arrhenius	6	2.09523			
Residual from Model	5	0.39186	0.07837		
Lack of Fit	1	1.70337		21.73461	0.00552

Additional Statistics...

Sum of Squares of the Error = 0.341060  
Variance of A = 4.583206  
Variance of b = 489670.277601  
Variance in K = 0.042960

Zero Order Results:

(By convention, projections are rounded and expiration dates are truncated.)  
Arrhenius Projection at 25.0° C = 40 Months.  
Expiration Date (95.0% CI) at 25.0° C = 26 Months.

First Order: Product degrades at a constant rate that is proportional to the log of the concentration.

The Arrhenius equation is  $K = A * \exp(-E/RT)$ , where:

K : Rate Constant                      E : Activation Energy  
A : Frequency Factor                  R : Gas Constant (8.31441 J/(K mol))  
T : Absolute Temperature

Initial estimates using Simple Linear Regression:

A = 9.81508E+010      E = 77317.544

Refined estimates using Taylor series expansion:

A = 4.76832E+011      E = 81551.079

Using the refined estimates, let  $\alpha = \ln(A)$ ,  $\beta = -E/R$ , and  $X = 1/T$ . The Arrhenius equation can be rewritten as  $\ln(K) = \alpha + \beta * X$ , where  $\alpha = 26.890430$  and  $\beta = -9808.402460$ .

Summary of Residuals for Lack of Fit for the Arrhenius Equation

Source of variation	df	Sum of squares	Mean squares	F value	p-value
Residual from Arrhenius	6	0.00021			
Residual from Model	5	0.00004	0.00001		
Lack of Fit	1	0.00017		23.11188	0.00485

Additional Statistics...  
Sum of Squares of the Error = 0.000033  
Variance of A = 4.291514  
Variance of b = 458610.844716  
Variance in K = 0.040308

First Order Results:

(By convention, projections are rounded and expiration dates are truncated.)  
Arrhenius Projection at 25.0° C = 42 Months.  
Expiration Date (95.0% CI) at 25.0° C = 28 Months.

Analysis Complete.

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HISTORY INFORMATION

File Version: 0  
File Status : ACTIVE  
File Name : C:\Program Files\SLIM\Accelerated Conditions.SST  
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