



Stab•e•lity is software dedicated to the evaluation of long-term stability data. It allows you to determine a retest period or shelf-life for a drug substance or product (pharmaceutical or biological).

Stab•e•lity features:

- Reports one-sided or two-sided confidence intervals for the retest period or shelf-life using either fixed or random batch regression models.
- Able to model analytical method variability via nested errors models.
- Uses statistical methods that are compliant with FDA, ICH and WHO stability guidelines.
- Provides clear graphical representation of the results.
- Statistically compares regression lines using ANCOVA models to determine if data from multiple lots can be pooled.
- Checks the normality of the data.
- Checks for potential outliers in the data.
- Provides batch release limits.
- Can apply the ICH recommended approach for the computation for the shelf-life or retest-period.
- Generates a stand-alone (eCTD compliant) report with results of all statistical analyses.
- Internet based application on a secured web-site ([https://](https://www.arlenda.com)). No installation and maintenance cost. Always the most up to date version available.
- 21 CFR Part 11 compliant.
- SAS based statistical analyses.
- SAS not required on your system.

Available statistical methodologies to estimate the regression models:

- FDA SAS macro-Linear Regression.
- Fixed batches-ANCOVA.
- Fixed batches with nested errors-ANCOVA.
- Random batches.
- Random batches with nested errors.

Available kinetics models:

- Zero-order linear regression.
- Zero-order quadratic regression.
- First-order log linear regression.

Other data transformations:

- Square-root(Y) linear regression.
- Reciprocal-Y regression.

Give it a try, ask for a demo on
<http://www.arlenda.com/login/demoform.html>

EXAMPLE OF SCREENSHOTS

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Shelf-Life long-term study - Project description (1/3)

1. Project description

Name: Francois Moonen
 Department: Management
 Company: Arlenda
 Product name: Product name
 Firm: Firm
 Stability study id: Study ID
 Compound: Compound
 Test type: Test Type
 Storage condition: 25°C - 60RH

2. Data introduction

Load with an Excel file *
 Select the Excel file: [Browse] [Load]

Filename: stability_AUTO.xls
 Checksum (MD5): 55465626476464108020F

* Only if you upload your data using a Stab.e.lity compatible file

Method: Batch Time Level Therap

0 01 0.348 100.0
 0 01 1.36 100.0
 0 01 0.348 100.0
 0 01 6.276 100.0
 0 01 18.396 132.4
 0 01 24.36 100.0
 0 01 36.852 133.8
 0 01 48.888 132.8
 0 02 0.348 100.0
 0 02 1.36 100.0
 0 02 3.364 100.0
 0 02 6.702 100.0
 0 02 13.36 100.0

Time unit: Weeks Months
 Level unit: %
 Decimal separator: Point (.) Comma (,)

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Shelf-Life long-term study - Model selection (4/3)

Methodology	Model	Function	Estimable	Start date	Start date (Ch)	R-Value *	Convergence	Selected
Random batches	Linear regression	Secure	96	02	ND		NA	<input type="checkbox"/>
Random batches	Quadratic regression	Secure	96	02	0.0010		NA	<input type="checkbox"/>
Random batches	SQRT(X) regression	Secure	96	02	0.0041		NA	<input type="checkbox"/>
Random batches	LOG(X) regression	Secure	96	02	0.0040		NA	<input type="checkbox"/>
Random batches	Rational Y regression	Secure	96	02	0.0451		NA	<input type="checkbox"/>
Random batches	Linear regression	NA	96	02	0.173		NA	<input type="checkbox"/>
Random batches	Quadratic regression	NA	ND	ND	ND		NA	<input checked="" type="checkbox"/>
Random batches	SQRT(X) regression	NA	96	02	0.1603		NA	<input type="checkbox"/>
Random batches	LOG(X) regression	NA	96	02	0.1485		NA	<input type="checkbox"/>
Random batches	Rational Y regression	NA	96	02	0.1282		NA	<input type="checkbox"/>

* Estimated Shelf-life in Months
 * R-Value of Shapiro-Wilk test for normality
 * Estimated Shelf-life in Months with the ICH recommendation

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Shelf-Life long-term study - Parameters determination (2/3)

1. Statistical models

Test batches (PCA-SAS Matrix): Linear regression
 Test batches: Quadratic regression
 Test batches: SQRT(X) regression
 Test batches: LOG(X) regression
 Test batches: Rational Y regression
 Random batches: Linear regression
 Random batches: Quadratic regression
 Random batches: SQRT(X) regression
 Random batches: LOG(X) regression
 Random batches: Rational Y regression

2. Statistical parameters

Alpha: 0.05 (Range: 0.01 - 0.99)
 Beta: One-sided Two-sided
 Lower specification limit: 80
 Upper specification limit: 110

The point must be used as the decimal separator
 * Mandatory fields

3. Shelf-life graph parameters

Title: Title
 X label: Time
 X unit: Months
 Y label: Concentration
 Y unit: %
 X range: %
 Y range: %
 Automatic calculation: (minimum & max. maximum is the shelf life + 8 months)
 Manual
 Automatic calculation: (1/30% of all introduced values)
 Manual

The point must be used as the decimal separator

4. Application of the ICH recommendation for the computation of the shelf-life *

Apply for shelf-life computation: Yes No
 Use the product refrigerated: Yes No

* Using decision tree from ICH Topic Q1E Evaluation of stability data, Appendix 1 - 2010

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Name: Francois Moonen
Company: Arlenda
Department: Management
Stability study ID: Study ID

5 SHELF-LIFE GRAPHIC VISUALIZATION

Figure 5-1. Shelf-life prediction

CL = 95% two-sided confidence limits (n=0.05)
 Computed shelf-life = 96 Months
 USL = Upper Specification Limit
 LSL = Lower Specification Limit

The coloured circles represent the introduced measurement results (level) for each batch and are plotted with respect to their corresponding time in the stability study (in months). A line of the same colour with the corresponding measurement results represents the estimated regression model for each batch and has the name of the batch indicated on it.
 The short dashed black lines represent the specification limits.
 The dashed blue lines represent the confidence limits of the regression line corresponding to the batch that gives the estimated shelf-life.
 The estimated shelf-life is indicated by the vertical blue dotted line and clearly stated in the graphic legend.

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