



stab•e•lity is a software dedicated to the evaluation of the long-term stability of your product and to the determination of its shelf-life. **stab•e•lity** also allows you to define release limits, define an optimal experimental design, set up a standard re-test period for your product, predict the long-term stability based on accelerated studies and identify out-of-trend results or batches.

- **stab•e•lity** generates statistics in compliance with regulatory documents such as WHO, ICH Q1A, ICH Q1B, ICH Q1C, ICH Q1E, ICH Q6A, ICH Q6B, ICH Q5C, ICH Q5E and ICH M4Q.
- **stab•e•lity** generates e-CTD compliant reports within minutes, in full compliance with authority expectations, reporting in particularity one- or two-sided confidence intervals for batch release limits, shelf-life and re-test period.
- **stab•e•lity** is a decision tool: one graph = one decision.
- **stab•e•lity** makes the statistic easy to understand and to interpret.
- **stab•e•lity** allows you to use of either fixed or random batch regression models to calculate the shelf-life, the release limits or a re-test period.
- **stab•e•lity** allows you to use of Bracketing or Matrixing designs to define the total number of experiments and the relevant time-points, avoiding to test all combinations of stability factors.
- **stab•e•lity** is validated according to the GAMP5 guidelines and is 21 CFR part 11 compliant.
- **stab•e•lity** is a Software as a Service (SaaS) application. No installation: no need to validate the software on site. No maintenance costs. Always the latest version available.

Available regression models to calculate the shelf-life, the release limits or a re-test:

- Simple linear regression
- Quadratic regression
- Linear regression after square root transformation
- Linear regression after logarithmic transformation
- Linear regression after inverse transformation
- Non-linear mono-exponential decay





Stab.e.lity

Home page

Purpose of the application

The objectives of Stab.e.lity are to handle the evaluation of stability data generated on New Drug Substances or Products and generate the associated information in compliance with international guidelines.

Connection information

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Shelf-Life study design (1/2)

Based on the recommendation of ICH Q1E and ICH Q1D, when different factors (for example, different strengths and/or packaging) are existing for the same drug substance, you have the possibility not to test all combinations of factors. For this, bracketing or matrixing design can be used.

This section of Stab.e.lity will help you to generate a design based on tables containing the different scenario.

Shelf-Life study design

Study design: ☒ Bracketing design ☐ Matrixing design

Factors parameters

Shelf-Life long-term study - Model selection (4/5)

Methodology	Models	Pooled	Shelf-life ¹	P-Value ²	Computable	Convergence	Selected
fixed batches (FDA SAS macro)	Linear regression	Separate intercept, separate slope	27	ND	✓	NA	<input type="radio"/>
fixed batches	Linear regression	Separate intercept, separate slope	28	0.7092	✓	NA	<input type="radio"/>
	Quadratic regression	NA	23	0.2594	✓	NA	<input type="radio"/>
	SQRT(Y) regression	Separate intercept, separate slope	29	0.7304	✓	NA	<input type="radio"/>
	LOG(Y) regression	Separate intercept, separate slope	29	0.7499	✓	NA	<input type="radio"/>
	Box-Cox transformation	Separate intercept, separate slope	30	0.7954	✓	NA	<input type="radio"/>

Shelf-Life longterm study - Get report (5/5)

Get your report by clicking on the corresponding icon :

WordML : 

Non-secured PDF : (eCTD) 

Secured PDF : 

Remarks:

Doc report is a WordML (MS Word) in order to be compliant with eCTD

Molecule A
All batches for the Linear regression model



Concentration (µg/ml)

Time (Months)

Batch: 1 2 3 4 5

LSL=90

Computed shelf-life = 28 Months

LSL = 95% one-sided confidence limit ($\alpha=0.05$)

Computed shelf-life = 28 Months

LSL = Lower Specification Limit

← Example of screenshots from **stab.e.lity**