Stab·e·lity

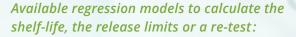**stab·e·lity** is a software dedicated to the evaluation of the long-term stability of your product and to the determination of its shelf-life. **stab·e·lity** also allows you to define release limits, define an optimal experimental design, set up a standard re-test period for your product, predict 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:

o *Simple linear regression*

o *Quadratic regression*

o *Linear regression after square root transformation*

o *Linear regression after logarithmic transformation*

o *Linear regression after inverse transformation*

o *Non-linear mono-exponential decay*

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Example of screenshots from **stab·e·lity**