



**e.noval** is a software dedicated to the validation of physico-chemical method both relative (LC, GC, EC, AAS,...) and absolute (titration, UV,...).

**e.noval** allows you to assess the trueness, the precision and the accuracy of your analytical method. In addition, it helps to evaluate a potential matrix effect in the calibration. **e.noval** generates Accuracy Profiles that are the keys to take a decision about the way for calibrating (which regression model, within or without matrix) and about the validity of your method.

- **e.noval** is the validation software for your laboratory that guarantees that your methods will be compliant to regulatory documents such as ICH, FDA and ISO.
- **e.noval** is a statistical software using SAS for the computation of your data
- **e.noval** will also generate a stand-alone report. In a couple of minutes you get the final report of your validation (see an example on [www.arlenda.com](http://www.arlenda.com))
- **e.noval** is based on the Total Error approach.
- **e.noval** is a decision tool: one graph = one decision.
- **e.noval** makes the statistic easy to understand and to interpret; Accuracy Profile is summarising all the information you need to know.
- **e.noval** proposes you 10 statistical models to compute your calibration data. A ranking will be proposed to help you in the decision (Accuracy Index)
- **e.noval** gives you the possibility to analyse the matrix effect for the calibration. You will introduce 2 set of data (without matrix, within matrix) for the calibration, and the software will propose you the accuracy profile using the best calibration model (within or without matrix) based on the more accurate back-calculated results.
- **e.noval** will help you to manage your RISK. Through the  $\beta$ -expectation Tolerance Interval, you simulate how your method will behave in routine.
- **e.noval** is an Internet based application on a secured website (<https://>). No installation and maintenance cost. Always the last version available.

**Calibration Models available:**

- Linear regression through 0 using the highest level
- Linear regression through 0 using a specified level
- Linear regression
- Weighted (1/X) linear regression
- Weighted (1/X<sup>2</sup>) linear regression
- Linear regression after (base 10) LOGARITHM transformation of both concentration and response
- Linear regression after SQUARE ROOT transformation of both concentration and response
- Quadratic regression
- Weighted (1/X) Quadratic Regression
- Weighted (1/X<sup>2</sup>) Quadratic Regression

If you want to try it for 1 month, just fill the application form on <http://www.arlenda.com/login/demoform.html>

◀◀ Example of screenshots from e.noval

**Validation form (using responses) - Step 1 of 4**

**Data Format and Input**

**Project Description**

Project title: Validation of A11254 method

Method to be validated: [ ]

Reference material: [ ]

Compound name: [ ]

Matrix: [ ]

Reference numbers: [ ]

Validation: [ ]

Prepared by: [ ]

Checked by: [ ]

**Data Description**

**Select the statistical models to fit on calibration data**

Use all current models

Linear regression through fitting the highest level

Linear regression through fitting the lowest level

PLS regression

Weighted (1/X^2) linear regression

Weighted (1/X) linear regression

Linear regression after data LOB/LOQ/LOD transformation of both concentration and response

Linear regression after 100 and 500% transformation of both concentration and response

Quadratic regression

Weighted (1/X) quadratic regression

Weighted (1/X^2) quadratic regression

**Specify the acceptance limit (%) for accuracy:**

Full range

Intermediate only

Standard only

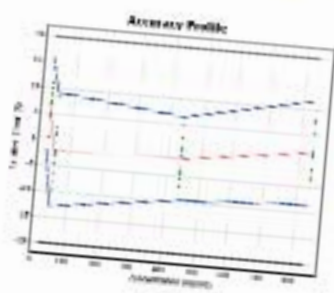
Others: [ ] % at level of [ ] mg/L (mg/mL) and standard error

**Model selection for reporting - Step 3 of 4**

Model	Standard Error	Weighted Error	Residual Error	Standard Error	Weighted Error	Residual Error
Standard (1/X^2) Linear Regression	0.004	0.000	0.000	0.004	0.000	0.000
Linear Regression after LOB/LOQ/LOD transformation	0.004	0.000	0.000	0.004	0.000	0.000
Weighted (1/X^2) Linear Regression	0.004	0.000	0.000	0.004	0.000	0.000
Weighted (1/X) Linear Regression	0.004	0.000	0.000	0.004	0.000	0.000
Linear Regression after 100 and 500% transformation	0.004	0.000	0.000	0.004	0.000	0.000
Quadratic Regression	0.004	0.000	0.000	0.004	0.000	0.000
Weighted (1/X) Quadratic Regression	0.004	0.000	0.000	0.004	0.000	0.000
Weighted (1/X^2) Quadratic Regression	0.004	0.000	0.000	0.004	0.000	0.000

**Weighted (1/X^2) Linear Regression - without matrix**

**Accuracy Profile**



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Name: Francis Moens  
Company: Arlenda  
Department: -  
Phase: Validation  
Reference number: 2006022

**Validation of A11254 method**

Method: Proteinase M  
Company: Arlenda  
Department: -  
Phase: Validation  
Reference number: 2006022  
Method ID: A11254  
Protocol ID:  
Prepared by: Francis Moens  
Compound Name:  
Matrix:

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**Table 6 - Overview**

Concentration level (mg/mL)	Mean Instrumental Concentration (mg/mL)	Mean Bias: individual and overall (mg/mL)	Absolute Error (mg/mL)	Relative Error (%)	Accuracy (%)
10.0	10.00	0.00	0.00	0.00	100.0
100.0	100.0	0.00	0.00	0.00	100.0
1000.0	1000.0	0.00	0.00	0.00	100.0