



**e.noval** is a software dedicated to the validation of physicochemical method such as LC, GC, EC, AAS, titration, UV...

**e.noval** allows you to assess the trueness, the precision and the accuracy of your analytical method. **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 Q2, FDA, ISO, EMA, MHLW, USP 1210, USP 1225 and EDQM.
- **e.noval** generates an e-CTD compliant report within minutes, in full compliance with authority expectations.
- **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.
- **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 validated according to the GAMP5 guidelines and is 21 CFR part 11 compliant.
- **e.noval** 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.

#### **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 ( $1/X^2$ ) 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 ( $1/X^2$ ) Quadratic Regression





**Home page**

**Purpose of the application**

Enoval is a web-based application with the objective of validating Physico-Chemical methods. It generates information on trueness, precision and accuracy in compliance with the international guidelines. An evaluation of a potential matrix effect and on the risk encountered during future routine analysis is also provided.

**Connection information**

User ID: thomas.demarche  
Connection date: 25 Aug 2017  
Connection time: 17:24:39

**Validation design**

Before starting the validation phase it is possible - and recommended - to determine the optimal number of experiments to perform (number of series and number of replicates by series). Those optimal numbers will be based on the results - Precision and accuracy - obtained in the prevalidation phase. Indeed, performing too few experiments could lead to rejection of an acceptable analytical method. Conversely, too much experiments, leading to an excessive power, will make the prevalidation phase longer than necessary. Between these two extremes, exists an optimal number of experiments that can be found in table here below:

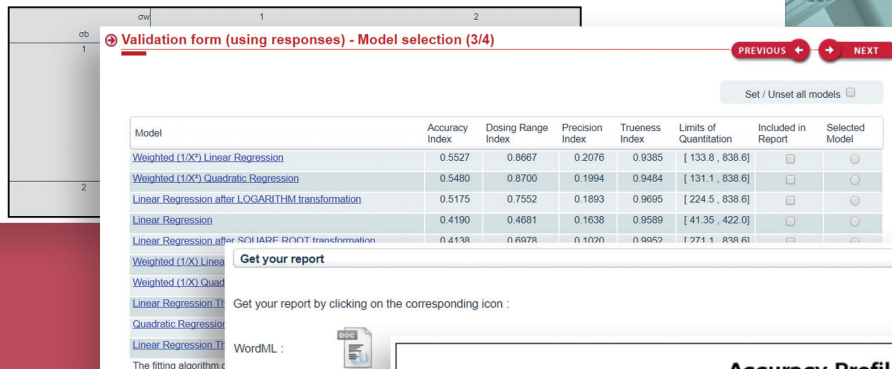
The following tables give you the minimal Recommended Sample to achieve the success in 95% of the case in the validation stage using the Total Error or  $\beta$ -Expectation Tolerance Interval with less than 5% risk that future measurements will fall outside the acceptance Limits:

Please select your parameters :

Acceptance limit: 5  
Expected Bias: 0

**Submit**

Recommended number of Series I and replicates J by series as a function of the expected values for the Between-Series  $\sigma_b$  and the Within-Series  $\sigma_w$  Standard Deviations when acceptance limits are set to 5% and expected bias is about 0%.



**Validation form (using responses) - Model selection (3/4)**


PREVIOUS + + NEXT


Set / Unset all models ☐


Model	Accuracy Index	Dosing Range Index	Precision Index	Trueness Index	Limits of Quantitation	Included in Report	Selected Model
<a href="#">Weighted (1/X) Linear Regression</a>	0.5527	0.8667	0.2076	0.9385	[133.8 , 838.6]	<input type="checkbox"/>	<input type="radio"/>
<a href="#">Weighted (1/X<sup>2</sup>) Quadratic Regression</a>	0.5480	0.8700	0.1994	0.9484	[131.1 , 838.6]	<input type="checkbox"/>	<input type="radio"/>
<a href="#">Linear Regression after LOGARITHM transformation</a>	0.5175	0.7552	0.1893	0.9695	[224.5 , 838.6]	<input type="checkbox"/>	<input type="radio"/>
<a href="#">Linear Regression</a>	0.4190	0.4681	0.1638	0.9589	[41.35 , 422.0]	<input type="checkbox"/>	<input type="radio"/>
<a href="#">Linear Regression after SCHAEFER ROOT transformation</a>	0.4138	0.6478	0.1020	0.9050	[271.1 , 838.6]	<input type="checkbox"/>	<input type="radio"/>

**Get your report**


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WordML : 

Non-secured PDF : (eCTD) 

Secured PDF : 

Remark: Doc report is a Word



Name: Thomas de Marchin  
Company: Arlenda  
Department: Analytical Development  
Phase: Validation  
Reference Number: Template Reference Number

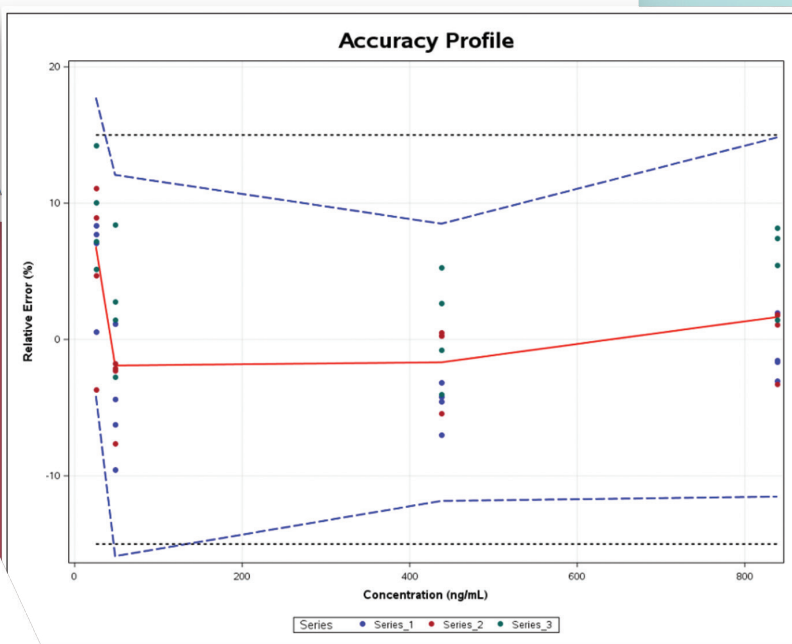
**TEMPLATE TITLE**

Name: Thomas de Marchin  
Company: Arlenda  
Department: Analytical Development  
Phase: Validation  
Reference number: Template Reference Number  
Method ID: Template ID  
Protocol ID: Template Protocol ID  
Product Name: Template Product Name  
Compound Name: Template Compound Name  
Matrix: Template Matrix

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Conditional  
ENOVVAL 4.0a  
PR00-20170221173010



← Example of screenshots from e.noval