

概述

您所需的数据及您所期待的决定

分析的目标是准确的定量 (quantify)。认证的目标是实验室和管理机构能保证准确的定量。

e-nova/Seelva软件通过评估和显示分析结果来实现上述目标。

本软件能确保以您们所期望的准确度对样本进行最有效的定量。

e-nova/Seelva能为您们的分析过程提供一个参考的决定。

方法便于使用

e-nova/Seelva是一个以互联网 (<https://>) 为基础的商业服务系统, 它只需一个网络浏览器, 一个分析软件和您们提供的数据。

e-nova/Seelva 软件便与安装、使用并在企业内易于推广。

它的优化的人机对话和图形界面设计, 使其使用方便, 对信息的解释直观, 只需简单的培训。

这是一个充分遵循管理机构的标准并可合法使用的软件


e-nova/Seelva软件不仅是一种统计软件系统和一种网络工具, 也是一个真正可供各实验室使用的工业化工具, 从其开发、确认到资料收集都一一遵循了最严谨的条文规定 (如21CFR-Part 11的规定)。QUALILAB是一个以实验室认证及软件高效著称的公司。

与QUALILAB公司 (www.qualilab.com) 的紧密合作保证了本软件的卓越品质。

最后的成果是一个毋需修正的适合您要求的PDF格式的报告, 并展示出您的结果的权威性。

仅仅几分钟时间, 您即可获得一份清晰易懂并被认可的报告。

Extracts of pages from the report generated by e-nova ▶▶▶



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4. Precision

Precision is the closeness of agreement among measurements from multiple sampling of a homogeneous sample under the recommended conditions. It gives some information on random errors and it can be evaluated at two levels: repeatability and intermediate precision. As can be seen in Tables VI. and VII., precision is expressed in terms of standard deviation (SD) and relative standard deviation (RSD) values for repeatability and intermediate precision. The estimates of variance components are obtained by the iterative approach of restricted maximum likelihood (REML).


Table VI. - Relative Intermediate Precision and Repeatability

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (RSD%)	Intermediate precision (RSD%)
25.4	25.35	4.897	6.262
48.2	48.24	3.701	3.701
437.8	437.8	3.035	4.414
838.6	838.6	2.583	4.622

Table VII. - Absolute Intermediate Precision and Repeatability

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (SD - ng/mL)	Between-series (SD - ng/mL)	Ratio of Variance components	Intermediate precision (s/n)	Upper Confidence Limit Intermediate precision (ng/mL)
25.4	25.35					5.408
48.2	48.2					1.708
						9.57
						11.3

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2. Response function

The response function of an analytical method is, within the range, the existing relationship between the response (signal) and the concentration (quantity) of the analyte sample. The calibration curve is the most appropriate response function. Table III. presents all selected regression models that have been sorted according to the accuracy index (cf. Appendix 2).

Table III. - Sorting of the calibration model

Model	Accuracy index	Lower and upper limits of quantitation (LOQ) (ng/mL)	Dosing Range Index	Precision index	Trueness index
Linear Regression	0.7946	[25.35, 838.6]	1.000	0.5136	0.9769


Explanation of accuracy index, dosing range index, precision index, trueness index can be found in Appendix 5.

The selected calibration model is: **Linear Regression**

The calibration curves obtained from this regression model (cf. Table IV. and Fig. 1.) are represented by the following equation:
 $Y = a + bX$ where Y = Analytical response (in auc) and X = Introduced concentration (in ng/mL)

Table IV. - Regression parameters

Slope	r ²	Residual d.f.
0.9906	0.9906	10
		10
		10



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6. Accuracy

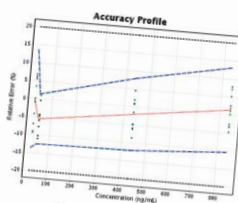
Accuracy refers to the closeness of agreement between the test result and the accepted reference value, namely the conventionally true value. The accuracy takes into account the total error, i.e. systematic and random errors, related to the test result. It is assessed from the accuracy profile illustrated in Figure 2. The acceptance limits have been set at ± 20 %; acceptance limits may differ depending on the concentration level. However, the accuracy profile is obtained by linking on one hand the lower bounds and on the other hand the upper bounds of the β-expectation tolerance limits calculated at each concentration level. The formula for calculating these β-expectation tolerance limits is:

$$\text{bias}(\%) \pm k \cdot \text{RSD}_{1-\beta}(\%)$$

The method is considered as valid within the range for which the accuracy profile is within the accuracy acceptance limits set at 20 %. This approach gives the guarantee that each further measurement of unknown samples is included within the tolerance limits at the 10.0 % level.

Figure 2. - Accuracy profile obtained by considering Linear Regression

The plain line is the relative bias, the dashed lines are the β-expectation tolerance limit and the dotted curves represent the acceptance limit (20 %). The green dots represent the concentration.



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保证您的分析软件符合规定，并对您的软件充满信心

分析家常常要在符合规定或能提供可信结果的软件中做出抉择。

e-nova/Seelva软件在符合规定的前提下，会让您对自己的软件更充满信心。

e-nova/Seelva软件是众多分析和统计领域的学术界及工业界专家超过八年钻研的杰出科研成果。

在**e-nova/Seelva**软件的帮助下，您可以很容易的满足各项规定标准，确保结果的可信度。

使用大量的校准模型来获得精确的结果

最近FDA指南中提出，校准模型应该是参数及其响应值之间最简单的模型。**e-nova/Seelva**软件有更佳的功能！

e-nova/Seelva软件能自动提供获得最准确结果的最简单模型！你们使用了一种可准确量化的方法，而不是单纯的适应简单模型。这是显而易见的，不是吗？

找到最极端的可靠的量化极限 (limits of quantitation)

大多数分析软件的宗旨在于能在较大范围内准确的定量，特别是要在数据很少的情况下仍能维持其准确性。

e-nova/Seelva软件利用新的计算方法能帮助你找到需要的最小(及最大)的数据量，为此你可充分地信任它。

使用**e-nova/Seelva**软件能获得那些效益？

- **e-nova/Seelva**符合ICH、FDA、华盛顿会议和ISO对分析方法的确认。
- **e-nova/Seelva**恰当地分析了分析方法得到的数据的合法性，能确保符合标准，如线性范围、精确性、真实性、准确性、定量限和检测限、配合等级和余差等。
- **e-nova/Seelva**严格的按照21CFR-Part II、GXP和ISO等已被认可的软件要求来开发和被确认的。
- **e-nova/Seelva**不仅仅是一个统计软件，也是一个报告生成器。在20分钟内它不仅能完成你所有统计计算，而且能作出一份完整卓越的PDF报告，包含为确认你的方法的合法性的所有信息。
- 所有**e-nova/Seelva**的计算及传送均使用SAS系统(数据处理的权威性的参照工具)。
- 风险管理
利用 β 期望容许区间 (Tolerance interval)，你可预知常规分析的结果。