


e.noval Version 3.0
21 CFR PART 11 FORM

e.noval software provides calculations and reports dedicated to Analytical Validation.

This is a product of:

ARLEND A

Rue de l'Hôpital 1, CHU Bat B36 - 4000 LIEGE 1 (Belgium)

This quality product was managed by Qualilab and Arlenda (creation of a Validation Committee):

QUALILAB

1121, Rue de la Bergeresse - 45160 OLIVET (France)

The statistics for the validation of analytical procedures are required by the GxP (Good Practices). The software providing those statistics must then also respect the applicable regulatory documents. It must be validated (*see e.noval "ENOV3.0-43 Factory Release Form" for information on validation process*).

e.noval and Electronic records:



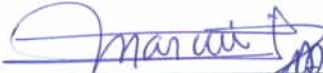
No electronic data are recorded by **e.noval** after 30 minutes of inactivity or after logoff. Data necessary for the computations are only saved during user's connection. No traces of these data are kept once the connection ends. In the same way, reports obtained from these data are not saved. The user can choose to print or download them, but when the session closes, they are deleted from the e.noval server. **We can therefore consider that e.noval works as a "Typewriter system" (comments IV-22 of 21 CFR Part 11) and that "Electronic records" requirements do not apply to e.noval.**

Nevertheless, **e.noval** implements technical solutions that guarantee confidentiality and integrity of data exchanged between server and client computers (*see "ENOV3.0-54 Security & Confidentiality form" for details on this point*).

e.noval and Electronic signatures :

e.noval does not manage any electronic signature, so "Electronic signatures" requirements of 21 cfr part 11 do not apply to e.noval.

However, for security reasons **e.noval** identifies each user by a unique combination of a login and a password. For traceability reasons reports generated by e.noval are identified by a unique identifier. They also indicate the name of the user responsible for this reporting and date & time of issuing.

<p style="text-align: center;">Nadia MERCIER Quality Product Manager (QUALILAB)</p> <p style="text-align: center;"><i>21-oct-03</i></p> 	<p style="text-align: center;">François MOONEN Product Project Manager (ARLEND A)</p> <p style="text-align: center;"><i>21-oct-2003</i></p> 	<p style="text-align: center;">Eric ROZET Quality Assurance Manager (ARLEND A)</p> <p style="text-align: center;"><i>P.O. Roland MARINI 21/10/2003</i></p> 
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