PHARMALEX

e·noval

e·noval **Version 4.1**

21 CFR PART 11 FORM

Enoval software provides calculations and reports dedicated to the validation of Analytical methods.
This is a product of:

PHARMALEX
Rue E. Belin, 5 – 1435 Mont-Saint-Guibert (Belgium)

This quality product was managed by PharmaLex Belgium's Quality Assurance team:
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 **ENOV4.1-16.V02 Factory Release Form** for information on the validation process).

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

Nevertheless, **Enoval** implements technical solutions that guarantee confidentiality and integrity of data exchanged between server and client computers *(see* **ENOV4.1-17.V02 Security & Confidentiality Form** for details on this point).

Software and Electronic signatures :
Enoval does not manage any electronic signature, so the "Electronic signatures" requirements of 21 CFR part 11 do not apply to **Enoval**.
However, for security reasons **Enoval** identifies each user by a unique combination of a login and a password. For traceability reasons, reports generated by **Enoval** are identified by a unique identifier. They also indicate the name of the user responsible for this reporting and date & time of issuing.

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V02 : change Company name and logo and Product Project Manager