

 Version 4.1

**FACTORY RELEASE AND
VALIDATION CERTIFICATE FORM**

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

► **PHARMALEX** Rue Belin, 5 – 1435 Mont-Saint-Guibert (Belgium)

Product Quality was managed by PharmaLex Belgium.

An **Installation Qualification** demonstrated that *Enoval* environment can be installed as described in the installation document (**ENOV4.1-15**) and that the server is able to satisfy *Enoval* performance specifications.

An **Operational Qualification** was done using the validation environment on 1 “Release candidate” version: **Enoval V4.1 RC1**.

During these tests,

- No high incidents were detected and closed
- No medium incidents were detected and closed
- 3 low incidents were detected:
 - All of them are closed

Additional information can be found in **Validation Report, ENOV4.1-18**.

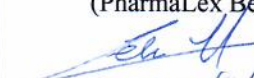


A **Performance Qualification** was done using the production environment, on version: **Enoval V4.1 PROD**.

During this test,

- No incidents were detected

This last Qualification demonstrated that the complete process of *Enoval* (calculation, reporting, and environment) works well in its specified operating environment. Standard Operating Procedures were checked to ensure change control management and traceability, and availability of an up to date user’s guide was also verified.

All these qualification results enable PharmaLex Belgium to ensure that **Enoval V4.1 PROD can be released**.

<p>CELIS Jean-Yves System Owner (PharmaLex Belgium)</p>  09-NOV-2018	<p>HUBIN Pierre Product Project Manager (PharmaLex Belgium)</p>  09-NOV-2018	<p>MARTIN Gaëlle Quality Assurance Manager (PharmaLex Belgium)</p>  09-NOV-2018
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V02 : change Company name and logo and Product Project Manager