

 Stab.e.lity Version 3.2

**FACTORY RELEASE FORM**

Stab.e.lity is a software application that manages the evaluation of stability data acquired from new drug substances and generates the associated information in compliance with international guidelines for both biological and non-biological products.

Stab.e.lity is a product of:

PharmaLex Belgium  
 Rue Edouard Belin, 5  
 1435 Mont-Saint-Guibert  
 Belgium  
 (Head office)

This product's quality was managed by the Quality Assurance team of PharmaLex Belgium.

An **Installation Qualification** demonstrated that Stab.e.lity's environment can be installed as described in the installation document (see STAB3.0-04.V01 Installation Procedure) and that the server is able to satisfy Stab.e.lity's performance specifications.

An **Operational Qualification** was done using the **validation** environment on 1 release candidate version: Stab.e.lity V3.2 RC1.

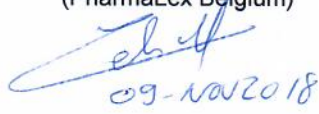

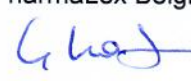
During these tests 0 incidents were detected (see STAB3.2-11.V01 Quality Report).

A **Performance Qualification** was done using the **production** environment, on Stab.e.lity V3.2 PROD. This last qualification demonstrated that the complete process of Stab.e.lity (calculation and reporting) works well in its specified operating environment.

Standard operating procedures applicable to this project were listed in STAB3.2-01.V01 Project Charter - Part 2 to ensure adherence to specific elements of PharmaLex Belgium's internal quality system (e.g., change control, traceability, bug-tracking, project management, etc.).

According to the results of a risk analysis (see STAB3.2-08.V01 Risk Management) no updates were required to be made to the user guide which will remain unchanged from the one updated during the Stab.e.lity V3.1 release (see STAB3.1-17.V01 Stab.e.lity User guide).

These qualification results enable the validation committee to ensure that Stab.e.lity V3.2 PROD can be released.

<p><b>CELIS Jean-Yves</b>                  System Owner                  (PharmaLex Belgium)</p>  09-NOV-2018	<p><b>HUBIN Pierre</b>                  Project Leader                  (PharmaLex Belgium)</p>  09-NOV-2018	<p><b>MARTIN Gaëlle</b>                  QA Manager                  (PharmaLex Belgium)</p>  09-NOV-2018
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V02: Change Head office address and Project Leader  
 V03: Change Company name and logo, project leader name and replacement of Qa associate by the System Owner.