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 *Stabelity V3.1* release (see *STAB3.1-17.V01 Stabelity User guide*).

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

CELIS Jean-Yves System Owner (PharmaLex Belgium) 09-NOV2018	**HUBIN Pierre** Project Leader (PharmaLex Belgium) 09-NOV-2018	**MARTIN Gaëlle** QA Manager (PharmaLex Belgium) 09-NOV-2018

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.