

 **Transval Version 2.0**

**FACTORY RELEASE AND
VALIDATION CERTIFICATE FORM**

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

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

Product Quality was managed by Arlenda (PharmaLex Statistical Solutions).

An **Installation Qualification** demonstrated that *Transval* environment can be installed as described in the installation document (**TRAN2.0-10**) and that the server is able to satisfy *Transval* performance specifications.

An **Operational Qualification** was done using the validation environment on 1 “Release candidate” versions: **Transval V2.0 RC1**.

During these tests,

- No high incident(s) were detected
- 1 medium incident(s) was detected and closed
- 2 low incident(s) were detected:
 - 2 are closed




A **Performance Qualification** was done using the production environment, on version: **Transval V2.0 PROD**.

During this test,

- No incidents were detected

This last Qualification demonstrated that the complete process of *Transval* (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 Arlenda (PharmaLex Statistical Solutions) to ensure that **Transval V2.0 PROD can be released**.

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