

QUICK START GUIDE: COMMERCIAL (OOT – OOS) MODULE

Access and Login

Stab-e-lity is accessible by web via the following hyperlink: <https://www.arlenda.com/log/> and clicking on the corresponding **Demo Version** or on the corresponding **Production Version** link.

Enter the **User ID** and **Password** in the fields provided and click on the **Login** button. If the **User ID** and **Password** combination are valid, the **Homepage** will be displayed.

Three modules are available:

- ▶ Shelf-life Computation
- ▶ Accelerated Testing
- ▶ Commercial (OOT – OOS)

Click the Commercial (OOT – OOS) link, this option should be used for the downloadable **Commercial (OOT-OOS) stability** sample **Excel** data file (cmc.xls) that is available on the **Arlenda** website (<https://www.arlenda.com/documents>). The **Project description** page is displayed.

Step 1: Project description

The following sections will be presented:

- ▶ 1. Project description
- ▶ 2. Data introduction

Data introduction

Data can be entered in two ways: manually or automatically, using a pre-filled **Excel** template file (also available on the **Project description** page). We will use the latter in this guide.

Click on the **Browse** button to select the file, followed by **Upload**. This will auto-fill the data text area of the page with the data contained within the pre-filled **Excel** template file. The other fields are not completed.

Fill those with the same values as their names (i.e. enter Product Name for the **Product Name**).

Click **Next** to advance to the **Data selection** screen.

Step 2: Data selection

Specify the batch you would like to assess, as well as a timepoint and a corresponding sample ID.

Two tables are presented:

- ▶ Data
- ▶ Summary

The first one lists all the values entered by the user.

The second contains a summary of the data entered by the user.

Click **Next** to advance to the **Parameters determination** screen.

Step 3: Parameters determination

The following sections will be presented:

- ▶ 1. Analyses
- ▶ 2. Statistical models,
- ▶ 3. Statistical parameters,
- ▶ 4. Graph parameters,
- ▶ 5. Report parameters.

Enter a **Registered shelf-life** of 36 months and a **Lower specification limit** of 90. The other editable fields can be left at their default value.

In the fourth section, fill the text fields with the same values as their names (i.e. enter X label for the **X label**).

Click **Next** to advance to the **Get report** screen.

Step 4: Get report

Format and Comment-Entry

The available report format are:

- ▶ WordML
- ▶ Non-secured (eCTD) PDF
- ▶ Secured PDF

The reports can be downloaded by clicking on the icon available towards "Secured PDF".

Only the Secured PDF format is available in demo version.

Report Download

When any comments have been introduced, click on the **Get Report** button.

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The complete User Guide is available by clicking on User's Guide option in the Left-Menu.