PHARMALEX

Seelva

QUICK START GUIDE: POTENCY MODULE

Access and Login

Seelva is accessible by web via the following hyperlink**:** **https://www.arlenda.com/log/** and selecting the corresponding **Demo Version** image 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.

Hover your pointer over the Validation link in the Left-Menu. Two sub-menus will appear:

▶ Content

▶ Potency

Click on the **Potency** sub-menu – this option should be used for the downloadable **Content assay** sample **Excel** data file (**Potency Sample Data.xlsx**) that is available on the **Arlenda** website (https://www.arlenda.com/documents). The **Data Format & Input** page is displayed.

Step 1: Data Format & Input

The following sections will be presented:

▶ Upload Data

▶ 1. Project description

▶ 2. Data Description

▶ 3. Potency Data

Data introduction

Data can be entered in two ways: manually or automatically, using a pre-filled **Excel** template file (also available on the **Data Format & Input** 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 each of the fields on this page with the data contained within the pre-filled **Excel** template file.

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

Step 2: Model Parameters

The following sections will be presented:

▶ 1. Assay Format

▶ 2. Transformation

▶ 3. Specify the acceptance limit(s) for total error

▶ 4. Select the risk level

▶ 5. Warnings and deviations

Scroll down to section 3 and set the **Lower** and **Upper Acceptance Limits** to **-30**% and **+30**% respectively. All other fields can be left at their default value.

Click **Next** to advance to the **Total Error Indexes** screen.

Step 3: Total Error Indexes

A table presenting the accuracy indexes will be presented. A hyperlink (Relative Potency) is pointing towards the **Accuracy Profile** (or **Total Error Profile**) for that method. Use the hyperlink to view the figure.

If the accuracy profile fits the expectations, click **Next** to advance to the **Get report** screen.

Step 4: Get Report

Format and Comment-Entry

Three different report formats are presented:

▶ WordML

▶ Non-secured PDF (eCTD)

▶ Secured PDF

The reports can be downloaded by clicking on the icons available towards the right of each of the report format descriptions (note that the demo version only supports the secured PDF format). The reports are written in **English**.

Users have the option of including comments in the **PDF**-format reports.

Click on one of the **PDF** icons (Secured/Non-secured) to advance to the **Report customization** screen.

Report Download

When any comments have been introduced, click on the **Get Report** button. After several seconds (depending on your internet's connection speed) your report will be generated.

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