

New Features in EasyStat 5.0

We proudly present the new version 5.0 of our user-friendly Excel Add-In EasyStat! As all previous versions, EasyStat is **validated for the pharmaceutical industry**.

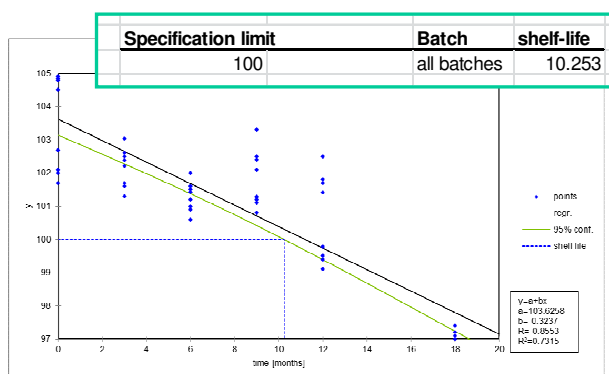
We have added some methods which you hopefully also will find very useful. Nevertheless EasyStat of course remains „easy“: just select your data, click on the icon, and look at the results – including as much support by the software tool as possible when selecting the method and interpreting the analysis.

Besides the current functionality for visualising data, for linear regressions, for control charts and for statistical tests, EasyStat 5.0 newly offers you the following methods:

- **Stability analysis according to ICH Q1E**

Using the new EasyStat 5.0, you can perform a **complete stability analysis** without any final adaption or manual editing. In particular, it is very helpful that EasyStat automatically tests the investigated batches for poolability, and then fits the most suitable model.

We have directly implemented the **guidelines of the ICH**, i.e. we start with testing the poolability of the slopes in the ANCOVA (SS type I), and the poolability of the batches is checked with a significance level of 0.25 instead of the usual 0.05. You do not have to spend many thoughts on that, but you just select your data, click on the „stability“ icon and then you get the result – separately by batches, with pooled slopes, or all batches pooled.



- **ANCOVA**

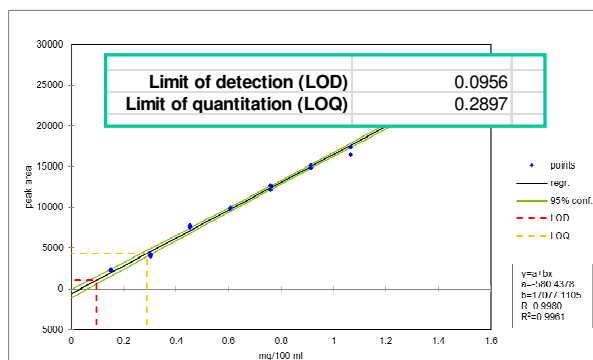
The ANCOVA (C is for „co“variance analysis) allows investigating a **categorical and a continuous parameter** (the „co“-variable) **simultaneously**. This is very similar to the stability analysis, but there are more fields of application, for instance if you want to find out whether the effects of increasing the dosage differ depending on the chosen dosage form. As in general there is no reason to assume that one parameter is more important than the other, we here use the so-called SS type III. Here, as well as in the stability analysis, EasyStat also can cope with **missing values** (unbalanced data).

- **Enhanced functionality for the linear regression**

Up to now, in addition to using EasyStat, you had to resort to the standard Excel linear regression method if you wanted to assess information on the residuals (model deviations) for the normality check using the quantile plot and for the residual plot. Now you get everything **on a single click**: your usual analysis, but also the model diagnostics.

- **Determination of LOD / LOQ**

The determination of the LOD (limit of detection) and the LOQ (limit of quantitation) is an important point in the validation of analytical methods when small amounts are to be measured. Now you can use EasyStat to **automatically determine LOD and LOQ**. Of course, the underlying formulas correspond to the recommendations of the ICH Q2(R1).



Moreover, we have implemented a number of **smaller improvements**, mainly in the representation of the results.