# Linearity analysis

1. Open the table containing the linearity study

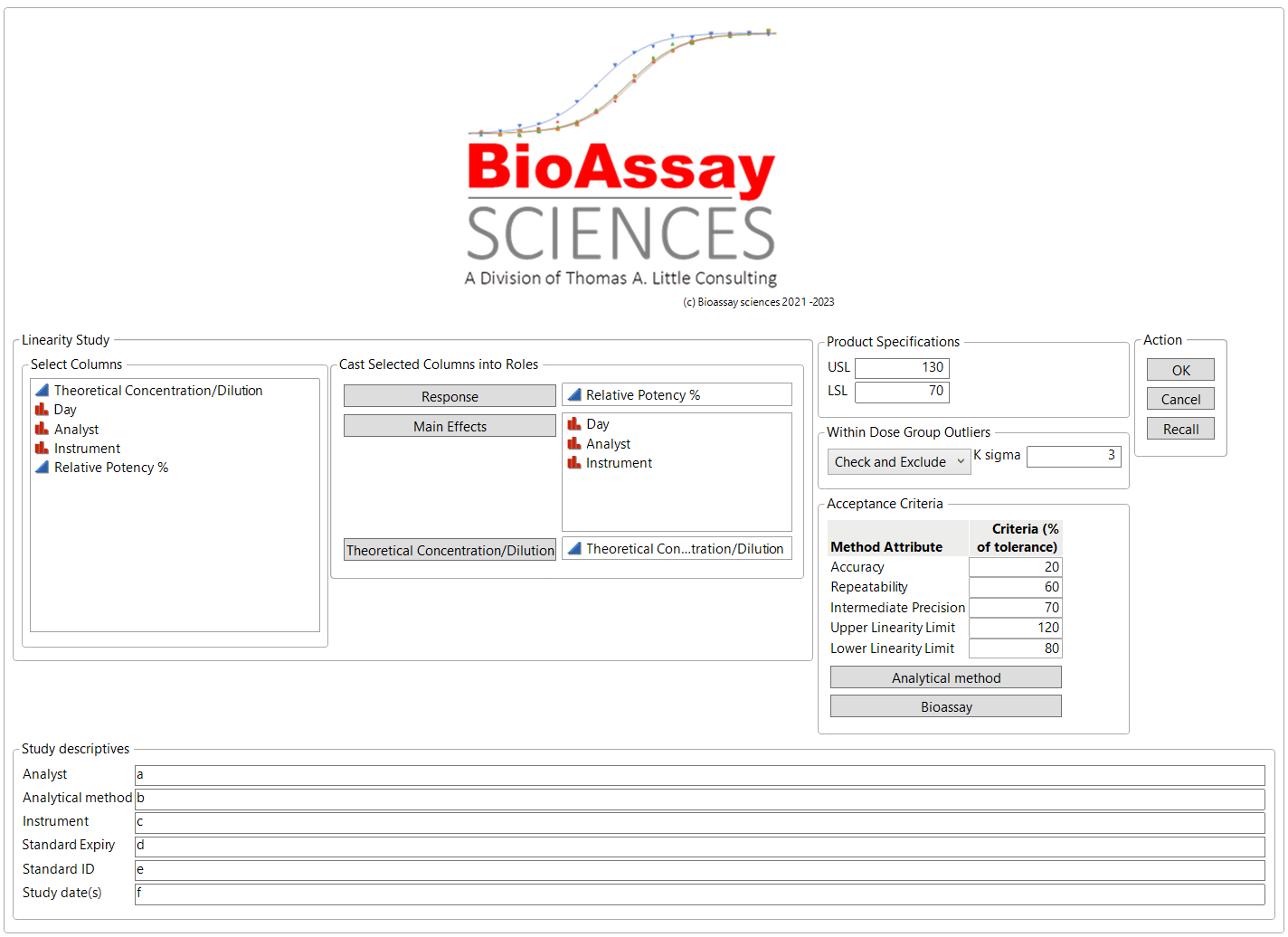
## Example Data Table linearity study

Five concentrations of a reference standard by six independent determinations for each concentration covering 80% of the lower specification limits and 120% of the upper specification limit for a two-sided product specification limit.

| **Theoretical Concentration/Dilution** | **Day** | **Analyst** | **Instrument** | **Relative Potency %** |
| --- | --- | --- | --- | --- |
| 150 | D1 | A1 | I2 | 153.6 |
| 50 | D1 | A2 | I2 | 47.1 |
| 150 | D2 | A2 | I1 | 156 |
| 125 | D2 | A1 | I2 | 128.2 |
| 50 | D1 | A1 | I1 | 52 |
| 50 | D1 | A1 | I1 | 47.6 |
| 100 | D2 | A2 | I2 | 97.9 |
| 75 | D2 | A2 | I1 | 76.7 |
| 75 | D1 | A1 | I2 | 79.9 |
| 100 | D1 | A1 | I1 | 99.5 |
| 100 | D1 | A1 | I1 | 99.4 |
| 150 | D1 | A1 | I2 | 153.7 |
| 50 | D2 | A1 | I2 | 41.3 |
| 100 | D2 | A2 | I2 | 99 |
| 150 | D1 | A2 | I1 | 168.9 |
| 125 | D2 | A1 | I1 | 129.6 |
| 125 | D2 | A1 | I1 | 127.8 |
| 150 | D2 | A1 | I2 | 155.5 |
| 75 | D1 | A2 | I2 | 80.1 |
| 50 | D2 | A2 | I1 | 53.9 |
| 100 | D2 | A2 | I2 | 101.7 |
| 75 | D2 | A1 | I2 | 73.4 |
| 150 | D2 | A2 | I1 | 159 |
| 125 | D1 | A2 | I1 | 117.1 |
| 75 | D2 | A1 | I1 | 81.2 |
| 75 | D1 | A2 | I1 | 81.4 |
| 50 | D2 | A2 | I2 | 52.2 |
| 125 | D1 | A2 | I2 | 126.3 |
| 100 | D1 | A1 | I1 | 101.1 |
| 125 | D1 | A2 | I2 | 125.3 |

1. Launch the linearity analysis from the Method Validation menu

## Launch dialog Linearity



* The response is the measured concentration/potency or other quantitation of the method
* The main effects are the study factors, each in a separate column coded as nominal
* The theoretical concentration or dilution is the 'truth' that we want to see if the method can pick up
* The product specifications in combination with the acceptance criteria set the requirements for the method. Tolerance is USL - LSL
* Within dose group outliers allows you to choose how to handle outlier detection. If 'Detect only' or 'Check and Exclude' is selected, the K sigma value determines the spec for what is flagged as an outlier
* The study descriptives are not used in the analysis but added to the report on the title page

# Limit of Detection (LOD) and Limit of Quantitation (LOQ)

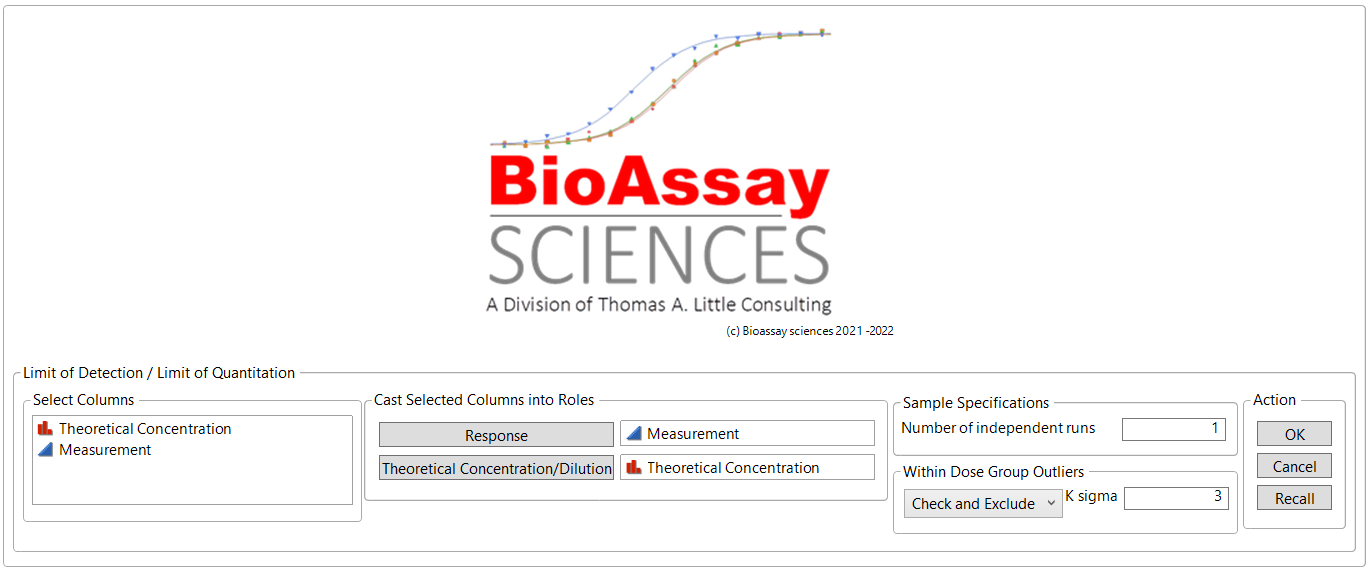
## Example data table LOD & LOQ

Two concentrations of a reference standard by six independent determinations for each concentration at or near the estimated LOD and LOQ limit.

| **Theoretical Concentration** | **Measurement** |
| --- | --- |
| 4 | 3.953 |
| 4 | 4.014 |
| 4 | 4.000 |
| 4 | 4.042 |
| 4 | 3.981 |
| 4 | 4.028 |
| 2 | 1.986 |
| 2 | 1.994 |
| 2 | 1.996 |
| 2 | 2.014 |
| 2 | 1.981 |
| 2 | 2.019 |

1. Launch the LOD/LOQ analysis from the Method Validation menu

## Launch dialog LOD & LOQ



* Response and theoretical concentration/dilution are the same observation as used in the linearity study
* Number of independent runs can be used if the observed response is based on multiple measurements. In this example it is based on 3 repeat measurements from a batch.
* Within dose group outliers allows you to choose how to handle outlier detection. If 'Detect only' or 'Check and Exclude' is selected, the K sigma value determines the spec for what is flagged as an outlier

1. Press ok to run the analysis

The report is saved as a journal and a pdf in the same folder as the study data table is located. The file name is formatted as “data table name yyyy.mm.ddThh.mm.ss.(jrn/pdf)”

# Specificity Interference analysis

1. Open the table containing the Specificity interference study

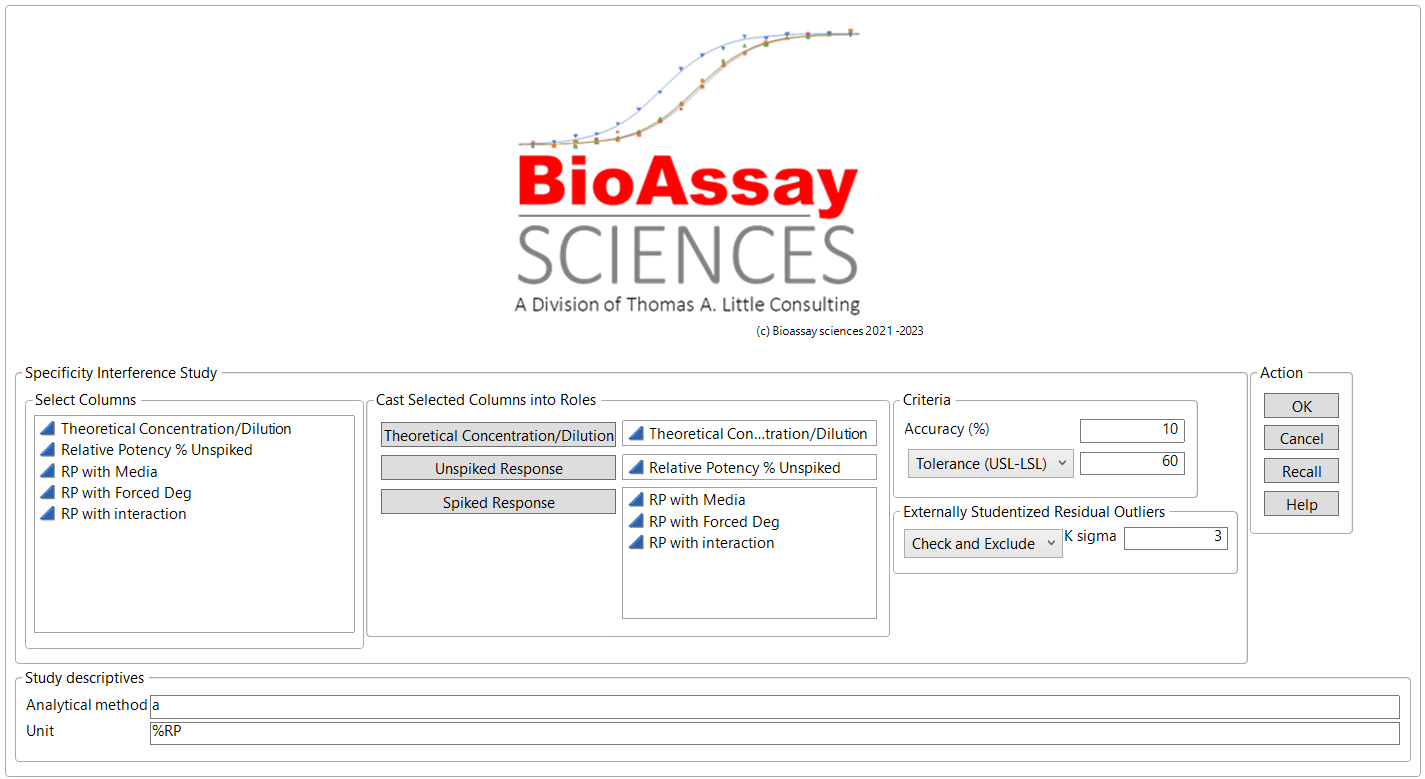
## Example data table specificity interference study

Three concentrations of the reference standard for every interfering compound spike in representative concentrations of the interfering compound.

| **Theoretical Concentration/Dilution** | **Relative Potency % Unspiked** | **RP with Media** | **RP with Forced Deg** | **RP with interaction** |
| --- | --- | --- | --- | --- |
| 125 | 128.2 | 131.6 | 133.0 | 160.25 |
| 125 | 129.6 | 133.4 | 135.1 | 162 |
| 125 | 127.8 | 133.8 | 131.3 | 159.75 |
| 125 | 117.1 | . | . | 146.375 |
| 125 | 126.3 | . | . | 157.875 |
| 125 | 125.3 | . | . | 156.625 |
| 100 | 97.9 | 103.0 | 100.0 | 97.9 |
| 100 | 99.5 | 106.1 | 104.4 | 99.5 |
| 100 | 99.4 | 103.1 | 101.9 | 99.4 |
| 100 | 99 | . | . | 99 |
| 100 | 101.7 | . | . | 101.7 |
| 100 | 101.1 | . | . | 101.1 |
| 75 | 76.7 | 81.0 | 79.0 | 57.525 |
| 75 | 79.9 | 85.2 | 83.1 | 59.925 |
| 75 | 80.1 | 83.9 | 82.6 | 60.075 |
| 75 | 73.4 | . | . | 55.05 |
| 75 | 81.2 | . | . | 60.9 |
| 75 | 81.4 | . | . | 61.05 |

1. Launch the specificity interference analysis from the Method Validation menu

## Launch dialog



* The concentrations are the concentrations at which the study is done
* The unspiked response is the measurement of the pure material under study
* The spiked responses are the measurements (one per column) of the pure material but changed with materials or methods that need to be validated for their impact on the method
* Accuracy is the percentage of tolerance that is allowable for the spiked material to impact the quantitation
* The study descriptives are not used in the analysis but added to the report on the title page

1. Press ok to run the analysis

The report is saved as a journal and a pdf in the same folder as the study data table is located. The file name is formatted as “data table name yyyy.mm.ddThh.mm.ss.(jrn/pdf)”

# Specificity ID analysis

1. Open the table containing the Specificity ID study

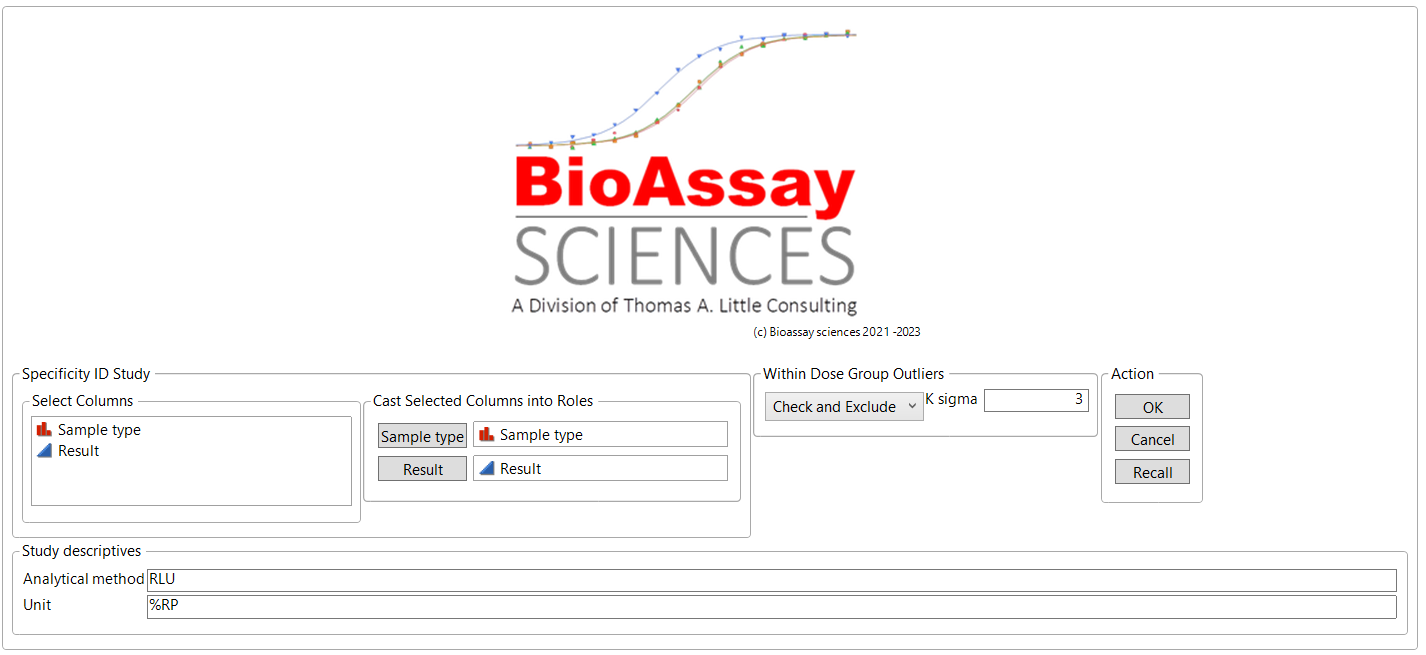
## Example data table specificity interference study

Three concentrations of the reference standard for every interfering compound spike in representative concentrations of the interfering compound.

| Sample type | Result |
| --- | --- |
| Positive control | 106 |
| Positive control | 102 |
| Positive control | 104 |
| Negative control | 2 |
| Negative control | 3 |
| Negative control | 2.6 |

1. Launch the specificity ID analysis from the Method Validation menu

## Launch dialog



* Sample type identifies the sample
* Result is the measurement on each sample type

1. Press ok to run the analysis

The report is saved as a journal and a pdf in the same folder as the study data table is located. The file name is formatted as “data table name yyyy.mm.ddThh.mm.ss.(jrn/pdf)”

# Stability analysis

1. Open the table containing the stability study

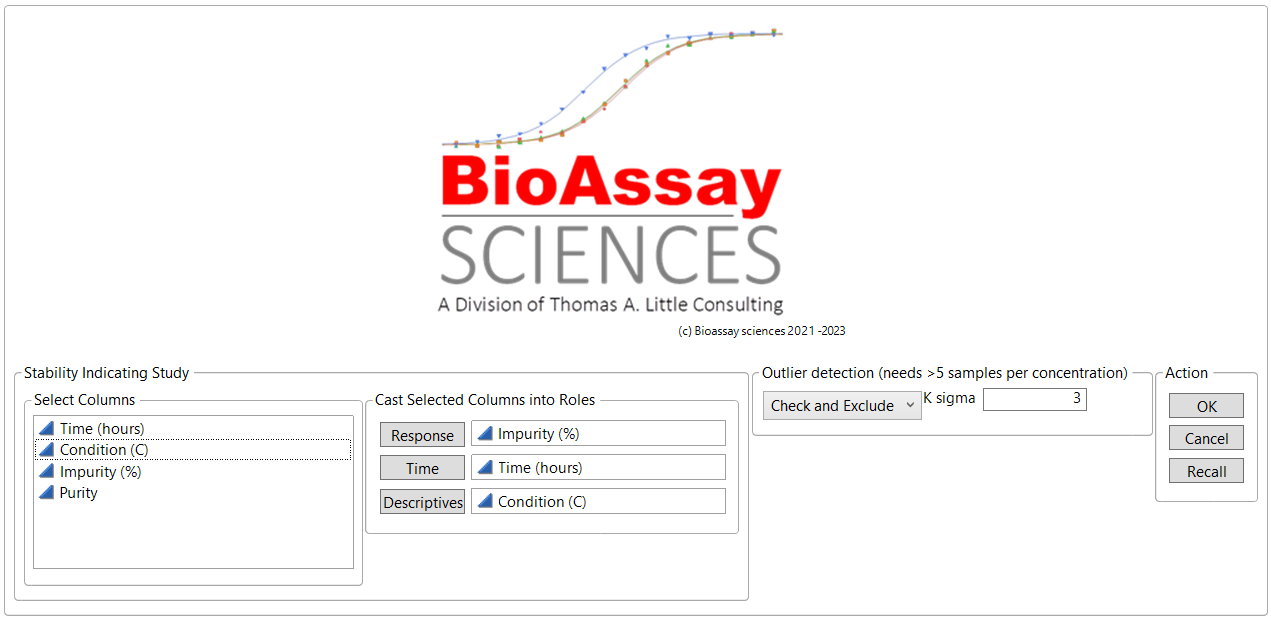
## Example data table stability study

One standard concentration under stressed conditions (temperature or pH) at five time points.

| **Time (hours)** | **Condition (C)** | **Impurity (%)** | **Purity** |
| --- | --- | --- | --- |
| 0 | 40 | 2 | 98 |
| 2 | 40 | 2.2 | 97 |
| 6 | 40 | 2.7 | 99 |
| 12 | 40 | 3.5 | 98.5 |
| 24 | 40 | 4.8 | 97.5 |
| 48 | 40 | 5.6 | 98 |

1. Launch the stability analysis from the Method Validation menu

## Launch dialog



* The response is the measured concentration/potency or other quantitation of the method
* Time is the column that contains the time in units at which the measurements were taken
* Descriptives is a column that contains text that describe the conditions of the study (for example the temperature in degrees C at which the study was conducted)
* Outliers detection allows you to choose how to handle outlier detection. If 'Check and Exclude' is selected, the K sigma value determines the spec for what is flagged as an outlier

1. Press ok to run the analysis

The report is saved as a journal and a pdf in the same folder as the study data table is located. The file name is formatted as “data table name yyyy.mm.ddThh.mm.ss.(jrn/pdf)”