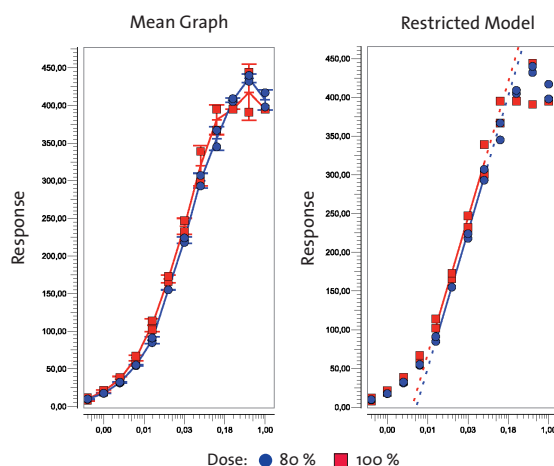


Rituximab Binding Assay (FACS) using Raji cells

Assay setup and evaluation

- Standard was used with 100% and 80% potency level as sample
- Titration by factor 2 was performed over 12 steps in duplicate starting from 100 µg/mL
- The mean fluorescence intensity (MFI) of PE labelled Raji cells by secondary antibody is shown on graph as response (linear)
- Rituximab conc. shown on graph as relative dose (log)
- 4 points in linear range were chosen for parallel line analysis
- Assay was „passed“ according to Eu. Pharm. Chapter 5.3
- Estimated vs. stated potency: 83.5% vs. 80%



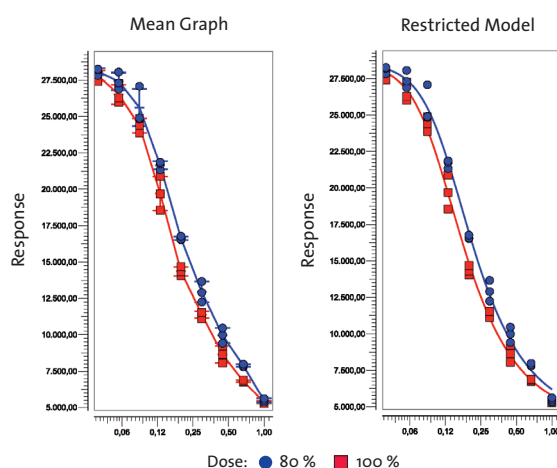
Potency Estimation 80% vs. 100%

- Potency Ratio (without Pre-Dilution Factors): 0.835
- 95.0% Confidence Interval: 0.731 – 0.953
- Relative Confidence Interval: 87.5% – 114.0% (26.5%)

Rituximab CDC Potency Assay using Ramos cells

Assay setup and evaluation

- Standard was used with 100% and 80% potency level as sample
- Titration was performed over 9 steps in triplicate
- Alamar Blue fluorescence is shown on graph as response (linear)
- Rituximab conc. shown on graph as relative dose (log)
- A 5-PL fit was used for potency determination
- Assay was „passed“ according to Eu. Pharm. Chapter 5.3
- Estimated vs stated potency: 83.0% vs 80%



Potency Estimation 80% vs. 100%

- Potency Ratio (without Pre-Dilution Factors): 0.830
- 95.0% Confidence Interval: 0.796 – 0.867
- Relative Confidence Interval: 95.8% – 104.4% (8.6%)