

GLP-1 Receptor Agonists Potency Assay Development

Potency Determination of GLP-1 Receptor Agonists

- Luminescence-based analytical method
- Measurement of cAMP after activation of GLP-1 receptor
- Robust and precise assay, optimized by testing a wide variety of parameters
- Available assay format: 2 test samples + assay control sample, 8 dose steps, triplicates per dose step
- Suitable for batch release and stability evaluation under GMP conditions
- Time-efficient due to established 2 days protocol
- Adaptable to GLP-1 Receptor Agonists

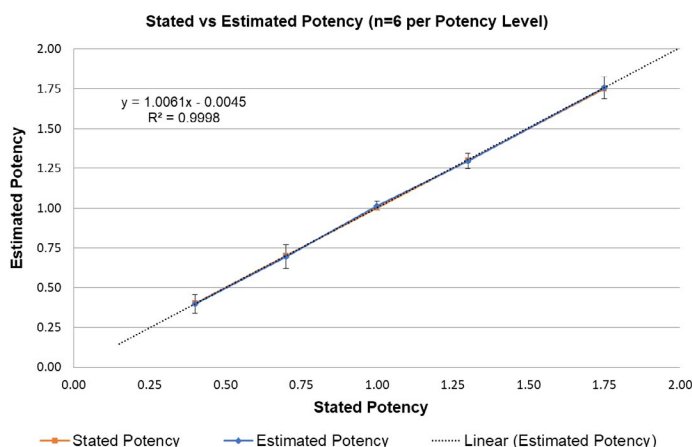
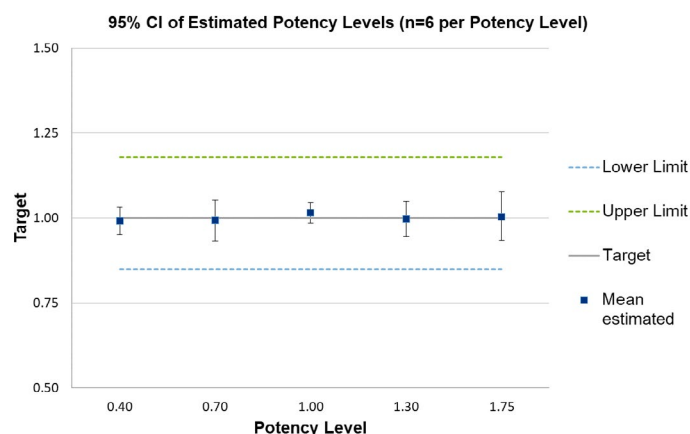
Potency Assay

Method Validation for Batch Release

Method validation performed with acceptance criteria according to international guidelines (ICH Q2, USP <1033>), covering:

- Accuracy, precision, linearity, assay range, repeatability
- Specificity (e.g. buffer/ matrix spiking, stability-indicating properties)
- Robustness (including critical reagents, WCB homogeneity, DoE)

Results – Accuracy and Linearity



Potency Assay Example

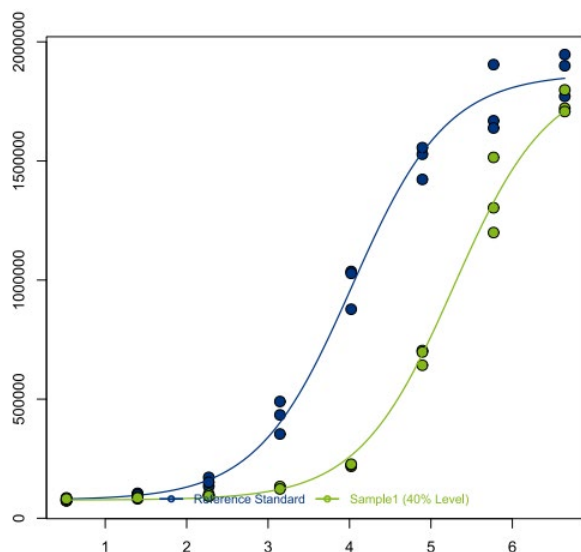
Assay Setup and Evaluation

- Reference standard was used with 40% and 175% potency level as sample
- Titration was performed over 8 steps in triplicate
- Relative Light Units are depicted on graph as response

- A 4-PL fit was used for potency determination
- Assays „passed“ according to Equivalence Margins (USP <1032>)
- GLP-1R agonist concentration depicted on graph as relative dose (log base 2)

Potency Estimation 40% vs. 100%

- Estimated vs Stated Potency: 39.7% vs. 40.0% (weighted mean)
- 95.0% Confidence Interval: 0.3588 – 0.4403 (weighted mean)
- Relative Confidence Interval: 92.46% – 108.15% (15.69%)



Potency Estimation 175% vs. 100%

- Estimated vs Stated Potency: 178.4% vs. 175.0% (weighted mean)
- 95.0% Confidence Interval: 1.7002 – 1.8711 (weighted mean)
- Relative Confidence Interval: 94.89% – 105.39% (10.50%)

