Bioassay
Bioanalytical Contract Laboratory
A Reaction Biology Company

Obesity Therapeutics

GLP-1/GLP-2/GIP Receptor Agonist Potency Assays

Cell-based potency determination via cAMP detection using validated TR-FRET methodology. Designed for biosimilar development, batch release testing, and stability evaluation under GMP conditions with seamless transition from proof-of-concept to regulatory submission.

Validated Compounds

- **GLP-1R Agonists:** Liraglutide (adaptable to Semaglutide)
- **GLP-2R Agonists:** Teduglutide
- **GIP-R Agonists:** Tirzepatide (adaptable to other dual GLP-1/GIP agonists)

Regulatory-Ready Infrastructure

ICH Q2(R2)-qualified methods with seamless development-to-GMP pathway. Licensing fees included, eliminating validation gaps and hidden costs.

Integrated Service Offering

Transition from proof-of-concept to FDA-ready data without rebuilding your methodology or managing licensing fees and internal validation.

Proven Performance

Proprietary cell lines optimized for GLP-1/GLP-2/GIP targets delivering 7-8% GCV precision with established success across leading obesity therapeutics.

Technical Specifications

- 3-hour established protocol
- 8 dose steps, triplicates per step
- 2 test samples + assay control
- 4-PL fit for potency determination
- USP <1032> equivalence margins

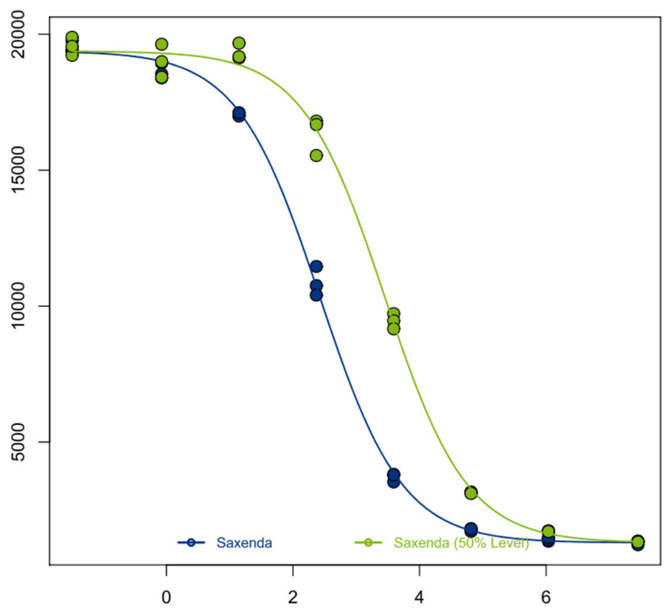
Applications

- Biosimilar characterization
- Batch release and stability testing
- Method validation and transfer
- Regulatory submission support
- Clinical trial material testing

Potency Assay Example – GLP-1R

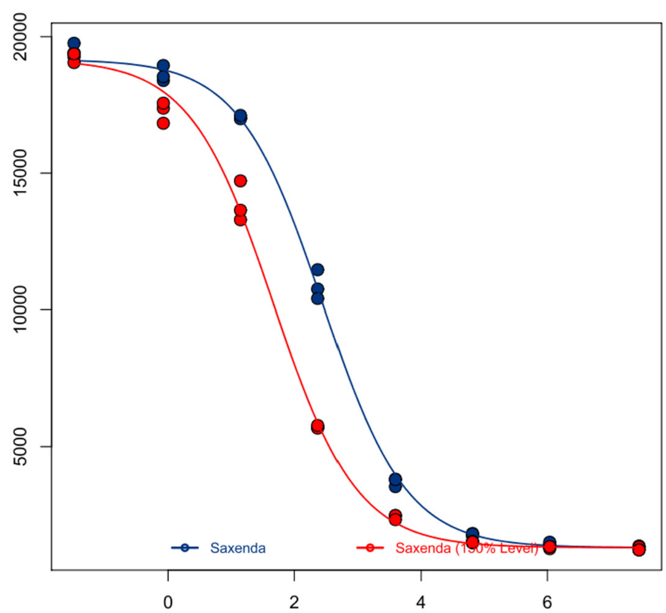
Assay Setup and Evaluation

- Reference standard was used with 50% and 150% potency level as sample
- Titration was performed over 8 steps in triplicate
- Acceptor Counts 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 50% vs. 100%

Estimated vs Stated Potency	51.5% vs. 50.0% (weighted mean)
95.0% Confidence Interval	0.49775 – 0.53358 (weighted mean)
Relative Confidence Interval	95.74% – 104.45% (8.71%)



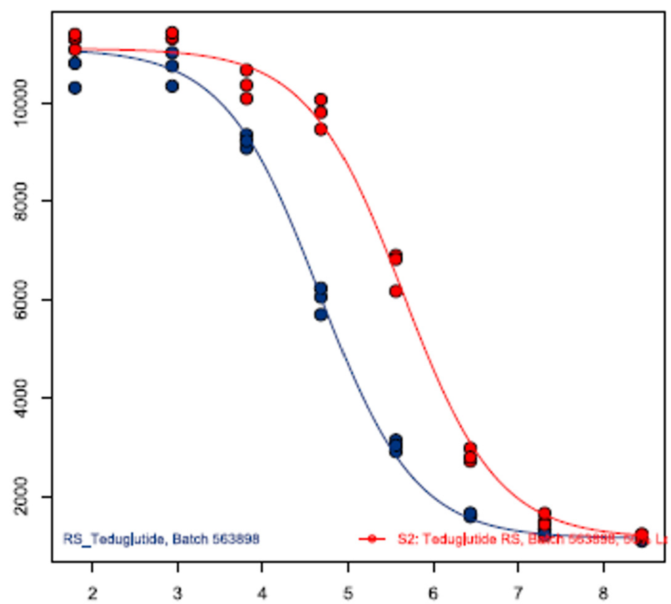
Potency Estimation 150% vs. 100%

Estimated vs Stated Potency	151.1% vs. 150.0% (weighted mean)
95.0% Confidence Interval	1.44503 – 1.56849 (weighted mean)
Relative Confidence Interval	96.20% – 103.95% (7.75%)

Potency Assay Example – GLP-2R

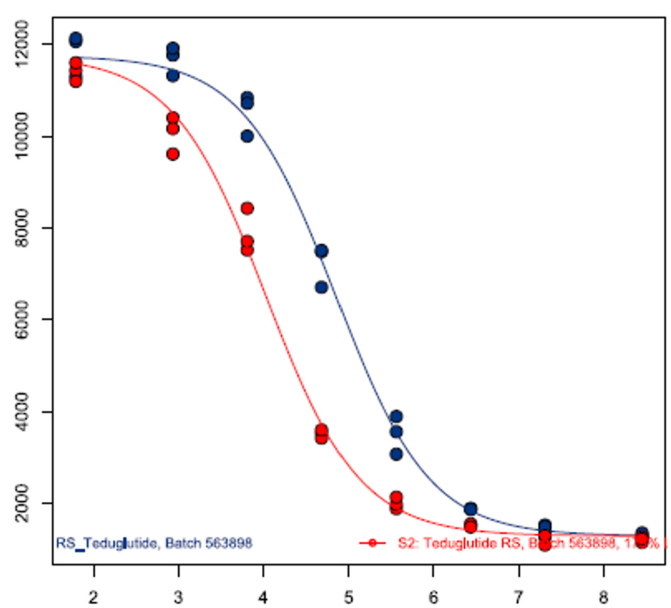
Assay Setup and Evaluation

- Reference standard was used with 50% and 175% potency level as sample
- Titration was performed over 8 steps in triplicate
- Acceptor Counts are depicted on graph as response
- A 4-PL fit was used for potency determination
- Assays “passed” according to Equivalence Margins (USP <1032>)
- GLP-2R agonist concentration depicted on graph as relative dose (log base 2)



Potency Estimation 50% vs. 100%

Estimated vs Stated Potency	50.8% vs. 50.0% (weighted mean)
95.0% Confidence Interval	0.48552 – 0.53248 (weighted mean)
Relative Confidence Interval	95.49% – 104.72% (9.24%)



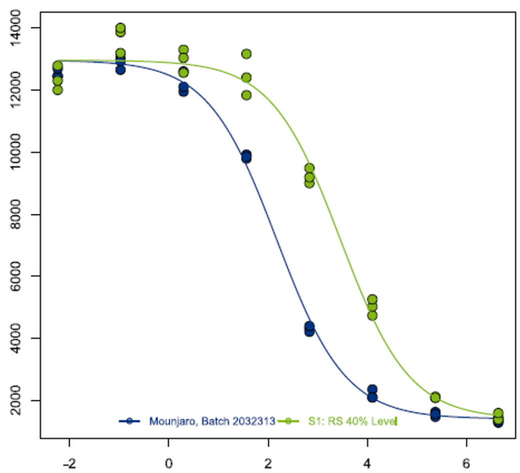
Potency Estimation 175% vs. 100%

Estimated vs Stated Potency	176.7% vs. 175.0% (weighted mean)
95.0% Confidence Interval	1.67228 – 1.86647 (weighted mean)
Relative Confidence Interval	94.66% – 105.65% (10.99%)

Potency Assay Example – GIP-R

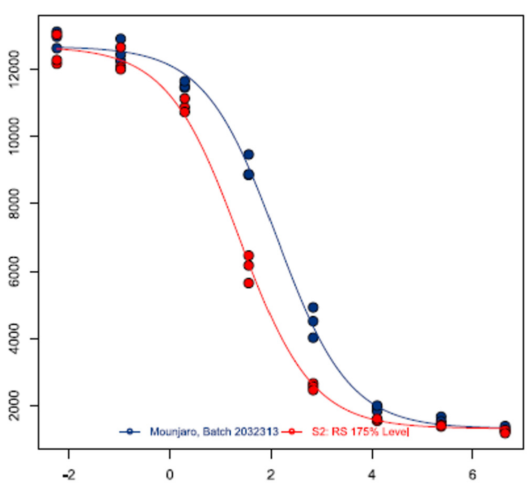
Assay Setup and Evaluation

- Reference standard was used with 40% and 175% potency level as sample
- Titration was performed over 8 steps in triplicate
- Acceptor Counts are depicted on graph as response
- A 4-PL fit was used for potency determination
- Assays “passed” according to Equivalence Margins (USP <1032>)
- GIP-R agonist concentration depicted on graph as relative dose (log base 2)



Potency Estimation 40% vs. 100%

Estimated vs Stated Potency	41.0% vs. 40.0% (weighted mean)
95.0% Confidence Interval	0.38439 – 0.43813 (weighted mean)
Relative Confidence Interval	93.67% – 106.76% (13.10%)



Potency Estimation 175% vs. 100%

Estimated vs Stated Potency	177.0% vs. 175.0% (weighted mean)
95.0% Confidence Interval	1.66892 – 1.87870 (weighted mean)
Relative Confidence Interval	93.92% – 106.48% (12.56%)

Let’s Discover Together.

Take your obesity drug development to the next level. Speak with an expert.

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