

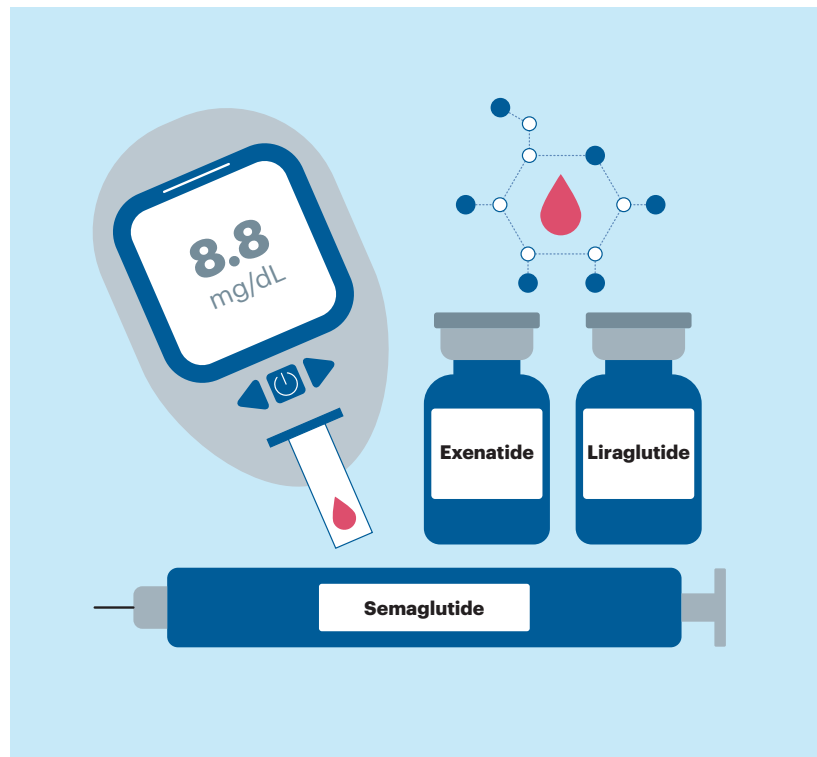
Empowering quality & confidence in GLP-1 development



A trusted set of Reference Standards and Analytical Reference Materials (ARMs) for Exenatide, Semaglutide and Liraglutide

Why it matters

Peptide-based drugs like GLP-1 receptor agonists are reshaping treatment for diabetes, obesity, and metabolic disorders. Ensuring structure, purity and amino acid sequence through robust peptide characterization is critical, as regulators require comprehensive profiling of known and unknown impurities to maintain product quality and compliance.



Facing challenges with the identification of complex GLP-1 impurities

▶ Structural complexity

The presence of conjugated fatty acid chain and/or artificial amino acids, creates addition complexity making impurity analysis analytically demanding.

▶ Epimer and isomer resolution

GLP-1 analogs often contain epimeric and positional isomers (e.g., at Aib or D-Ala positions), which are difficult to resolve but can affect receptor binding and biological activity.

▶ Advanced analytical requirements or high analytical complexity

Detecting and resolving co-eluting and structurally similar impurities in GLP-1 analogs requires advanced techniques, expert method development, and substantial time and infrastructure investments.

▶ Degradant/truncated impurities

Failing to detect impurities like truncated peptides or degradation products, potentially causing immune reactions, toxicity, or reduced efficacy.

▶ Immunogenic impurity risk

Undetected low-level impurities in long-acting GLP-1 therapies may increase immunogenicity risk, making sensitive impurity profiling essential for ensuring safety and consistency.

▶ Availability of impurity RS

The availability of well-characterized reference standards for all peptide-related impurities is often limited, hindering accurate identification and quantification.

How our GLP-1 solutions help

Leverage USP Impurity ARMs to strengthen analytical rigor, enhance confidence in impurity profiling, and meet global quality expectations for GLP-1 therapies.



Providing well-characterized Reference Standards (RS) and Analytical Reference Materials (ARMs) to support consistency and reliability in analytical testing.



Supports lifecycle management through consistent impurity profiling, aiding comparability studies and post-approval changes.



Enabling accurate impurity profiling for method development and validation and supporting identity, purity, and potency testing with orthogonal analytical techniques, including 1H-NMR, 13C-NMR, 2D-NMR, LC-MS, and MS/MS.



Facilitates ICH Q14 and Q2(R2) compliance by supporting impurity spiking studies, linking ATP to CQAs, and enabling the development of robust analytical methods.



Aligned with ICH Q6A/Q6B to reduce regulatory risk by enabling accurate impurity characterization.



Enables early identification of impurity, helping define appropriate specifications and support regulators across regions.

Available resources and products

API name	Item	Item number	Type
Exenatide	Exenatide		DS
	Exenatide Injection		DS
	Exenatide	1269105	RS
	[Glu13]-Exenatidet	1268998	RS
	[Met(O)14]-Exenatide	1269009	RS
	[N-Acetyl-His1]-Exenatide	1269045	RS
	[D-His1]-Exenatide	1181415	RS
	C-OH Exenatide	1800035	ARM
Liraglutide	[Kyn]31-Liraglutide	1800249	ARM
	Formaldehyde adduct-Liraglutide	1800250	ARM
	α -Glu(side Chain)-Liraglutide	1800251	ARM
	D-allo-Thr(11)-Liraglutide	1800252	ARM
	D-allo-Thr(13)-Liraglutide	1800253	ARM
Semaglutide	[Beta-Asp]15-Semaglutide	1800243	ARM
	[Beta-Hydroxybenzyl)-Trp]25-Semaglutide	1800245	ARM
	α -Glu(side chain)-Semaglutide	1800246	ARM
	Des-AEEA-Semaglutide	1800254	ARM

DS: Documentary standard; RS: Reference standard; ARM: Analytical reference material



Start your GLP-1 impurity program with confidence!

Questions: uspbiologics@usp.org

Ordering information: store.usp.org

More information: www.usp.org/biologics/peptides/glp1s

