Amino Acid Analyzer LA8080 AminoSAAYA

Application Test Report 11 – October 2026

Characterizing Peptides in Therapeutics and Pharmaceutical Applications

Executive Summary

Peptide therapeutics have revolutionized modern medicine through structural engineering that enhances their stability, efficacy, and half-life. The success of blockbuster drugs has highlighted the growing need for robust analytical techniques capable of characterizing increasingly complex peptide molecules. Consequently, regulatory agencies require reliable methods for peptide-identity verification, amino-acid-composition analysis, and accurate content determination throughout the peptide therapeutics life cycle. These advances have expanded the role of amino acid analysis throughout peptide drug development.

The Hitachi LA8080 AminoSAAYA supports amino acid identification, quantification, quality control, research and development, and regulatory compliance.

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Analytical Solution

The Hitachi LA8080 Amino Acid Analyzer combines the robustness and quality of liquid-chromatography products with the performance of a post-column ninhydrin application. Based on components of Hitachi HPLC instruments, and cation-exchange chromatography, the LA8080 gives scientists new possibilities in their analysis workflow.

The use of the TDE^3 (Thermodynamic Efficiency) Reactor delivers a high degree of sensitivity, achieving a detection limit of 2.5 pmol. The TDE^3 Reactor also provides improved thermal conductivity with respect to large molecules, such as di- and tr-peptides.

The benchtop design was developed with operator ergonomics and workflow in mind. Daily tasks such as reagent replacement, sample setup, and maintenance are quick and comfortable to perform.

Key benefits of using LA8080

- Characterize up to 50 amino acids
- High sensitivity for detection limits as low as 2.5 pmol
- Software compliance with FDA 21 CFR Part 11
- Uses commercially available reagents, avoiding the need for special preparation
- Capacity for one hundred 1.5 mL sample vials
- Automatic cleaning function for stable operation

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Background

Amino acid analysis is the reference method of peptide and protein characterization and is recognized in pharma guidelines. Amino acid composition is a unique signature for confirming the identity of peptides and proteins. It enables accurate calculation of peptide content, potency, and recovery. This analysis monitors batch-to-batch consistency and verifies process performance, and detects deamination, oxidation, and other degradation-related changes.

In biomedicine production, cells act as living factories to produce therapeutic proteins and monoclonal antibodies once disease-related genes have been identified. To function efficiently, these cells depend on carefully designed culture media, which supply the nutrients required for growth and productivity. For cultures to operate as true factories, not only must temperature, pH, and oxygen be controlled, but the supply of amino acids is equally critical, as it drives cell growth, metabolism, and overall protein quality. This makes amino acid monitoring essential for ensuring high-quality protein and biomedicine production across all process stages.

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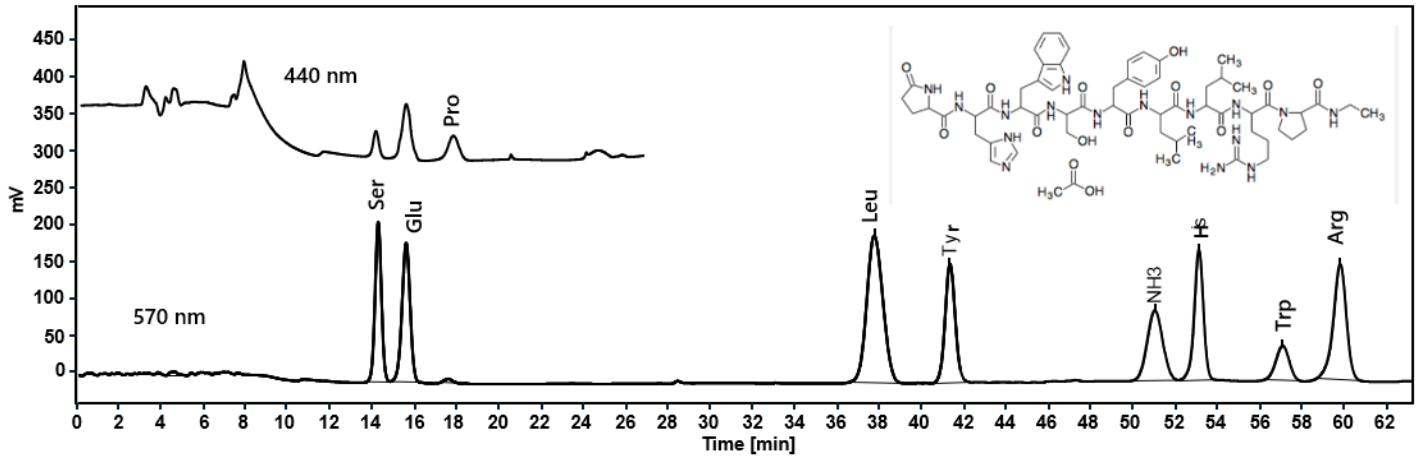
Analysis Data

Leuprolide Acetate Amino Acid Analysis : Compliance with USP Monograph Criteria

Leuprolide acetate presents unique analytical challenges that require informed interpretation of AAA data.

- pGlu Hydrolysis Conversion: N-terminal pyroglutamic acid (pGlu) is converted to glutamic acid during acid hydrolysis, requiring careful interpretation of the Glu signal.
- Trp during acid hydrolysis: Detection and quantification of acid stable analysis of Trp.
- Terminal Ethylamide Modification: Accurate analysis of Proline modified during acid hydrolysis.
- The experimentally determined amino acid composition closely matched the theoretical Leuprolide sequence with Net Peptide Content 93.8 % (w/w, AAA) .
- Total leucine content was consistent with the presence of Leu and D-Leu residues.
- Amino acid analysis successfully verified the identity of this structurally modified nonapeptide.



Amino Acid	Conc. (nmol/20 µL)	Calculated Count (Conc./6.21)	Acc.Criteria
Ser	5.433	**0.87**	**Present**
Glu (from pGlu)	5.978	**0.96**	**0.85 -1.1**
Leu (L-Leu + D-Leu)	12.072	**1.94**	**1.8 - 2.2**
Tyr	6.031	**0.97**	**0.85 – 1.1**
His	5.669	**0.91**	**0.85 – 1.1**
Trp	4.207	**0.68**	**Present**
Arg	6.681	**1.09**	**0.85 – 1.1**
Pro	6.084	**0.98**	**0.85 – 1.1**

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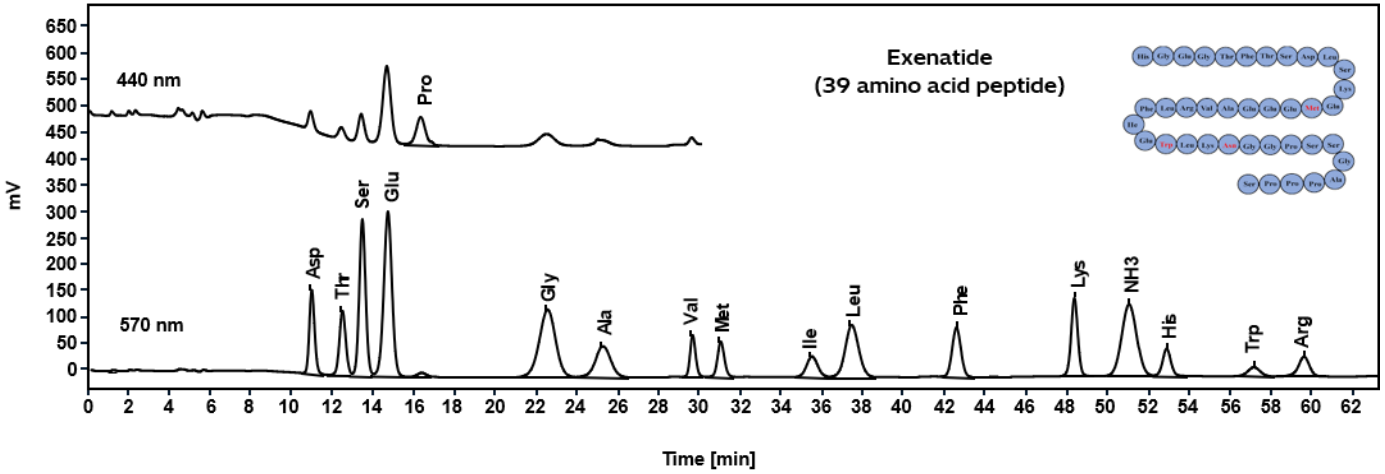
Analysis Data

Exenatide Amino Acid Analysis: Compliance with USP Monograph Criteria

Following acid hydrolysis, the amino acid composition was compared with the theoretical sequence and evaluated against the USP acceptance criteria. The observed amino acid ratios showed excellent agreement with the expected values, confirming peptide identity. These results highlight the capability of the Hitachi LA8080 to support USP-compliant identity testing and accurate quantitative analysis of therapeutic peptides.

Amino Acid	nmol Found	Cal.Count	USP Acceptance
Asp (Asx)	3.61	**1.94**	**1.5–2.5**
Thr	3.41	**1.84**	**1.5–2.5**
Ser	8.13	**4.38**	**4.2–5.5**
Glu (Glx)	10.93	**5.88**	**5.2–6.8**
Gly	9.13	**4.91**	**4.5–5.5**
Ala	3.66	**1.97**	**1.5–2.5**
Val	1.73	**0.93**	**0.5–1.5**
Met	1.79	**0.96**	**0.5–1.5**
Ile	1.72	**0.93**	**0.5–1.5**
Leu	5.46	**2.94**	**2.5–3.5**
Phe	3.46	**1.86**	**1.5–2.5**
Lys	3.74	**2.01**	**1.5–2.5**
His	1.76	**0.95**	**0.5–1.5**
Trp	1.46	**0.79**	**0.5–1.5**
Arg	1.74	**0.94**	**0.5–1.5**
Pro	7.34	**3.95**	**3.5–4.5**



Peptide Recovery	
Parameter	**Result**
Sum of amino acid concentration (20 µL injection)	**68.02 nmol**
Final dilution volume	10 mL (10,000 µL)
Peptide length	39 amino acids
Molecular weight	4186.6 Da
Total amino acids in final volume	**34.01 µmol**
Exenatide recovered	**0.871 µmol**
Peptide mass recovered	**3.64 mg**
Sample weight taken	4.00 mg
Net Peptide Content (AA)	**91.1%**

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Summary

The LA8080 is an invaluable tool for amino acid analysis, supporting critical applications from peptide characterization to quality control and biopharmaceutical production.

Questions?

Contact **Hitachi High-Tech America Inc.** at hta-marketing@hitachi-hightech.com. You can find more information on our website : Amino Acid Analyzer | AAA | HPLC | LA8080 AminoSAAYA | Hitachi High-Tech

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