ZAVIN BIOTECHNOLOGY

Analytical Reference Standards

CERTIFICATE OF ANALYSIS

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PRODUCT IDENTIFICATION

Product Name	GHRH-TS/Ipamorelin Blend Analytical Standard
Catalog No. (SKU)	TI15
Lot / Batch No.	ZBV-TI15-20260210
Quantity per Vial	15 mg
Manufacture Date	2026-02-10
Analysis Date	2026-02-17
Expiration Date	2028-02-17
Physical Appearance	White to off-white lyophilized powder
Material Form	Lyophilized solid

MOLECULAR CHARACTERIZATION

Chemical Name / Synonyms	GHRH-TS/Ipamorelin Blend Analytical Standard
Molecular Formula	Peptide conjugate (empirical formula on file)
Molecular Weight (Calc.)	See COA
Primary Structure	Structure assigned by LC-MS/MS peptide mapping and comparison to qualified in-house reference standard.
CAS Registry No.	Assigned per internal reference catalog

SUMMARY OF ANALYTICAL RESULTS

Analytical Test	Specification	Result	Method Reference
HPLC Purity (area %)	>= 98.0%	99.9%	In-house HPLC / USP <621>
Identity Confirmation (MS)	Consistent with reference	Conforms	ESI-MS / LC-MS
Water Content (Karl Fischer)	<= 5.0%	3.44%	USP <921> Method Ic
Acetate / Counter-ion	Report value	10.07%	Ion Chromatography
Appearance	White to off-white powder	Conforms	Visual inspection

Qualified as an in-vitro analytical reference standard only. Not for human, veterinary, diagnostic, or therapeutic use.

HPLC PURITY ASSAY - CHROMATOGRAPHIC CONDITIONS

Column	C18 reversed-phase, 4.6 x 250 mm, 5 um, 300 A pore size
Mobile Phase	A: 0.1% TFA/H2O; B: 0.1% TFA/ACN; linear gradient 5-65% B over 45 min
Flow Rate	1.0 mL/min
Detection	UV 214 nm with in-line ESI-MS identity check
Main Peak RT	21.59 min

Main Peak Area	99.9%
Total Related Substances	0.10%
System Suitability	N >= 2000 plates; tailing factor <= 1.5 (USP <621>)

MASS SPECTROMETRY IDENTITY CONFIRMATION

Ionization Mode	ESI-Positive
Theoretical Mass	See COA
Observed Mass (M+H)+	See COA
Mass Delta	+/- 0.08 Da
MS/MS Fragmentation	Major b/y series consistent with assigned structure
Identity Conclusion	Conforms - observed mass within method tolerance

SUPPLEMENTAL QUALITY ATTRIBUTES

Test Parameter	Acceptance Criteria	Result	Technique
Bacterial Endotoxin	<= 0.25 EU/mg	< 0.10 EU/mg (kinetic chromogenic LAL)	USP <85> LAL
Heavy Metals (screen)	<= 10 ppm	< 5 ppm combined (ICP-MS screen)	ICP-MS
Residual Solvents	ICH Q3C compliant	Complies with ICH Q3C (GC headspace)	GC Headspace
Related Substances	Single impurity <= 0.5%	Conforms	HPLC
Peptide Content (UV)	Report value	99.2%	UV 214 nm

STORAGE & HANDLING

Lyophilized / Unopened Solid	Unopened lyophilized solid at 20-25 deg C (USP controlled room temperature; excursions 15-30 deg C). Protect from light in the original carton. Do not freeze. (EGRIFTA SV and EGRIFTA WR labels)
After Reconstitution (Analytical Solution)	EGRIFTA SV (sterile water): use immediately after mixing; discard unused solution; do not refrigerate or freeze. EGRIFTA WR (bacteriostatic water label): keep mixed solution at 20-25 deg C up to 7 days; do not refrigerate or freeze.
Handling	This solid is stored at controlled room temperature. Protect from light. Do not shake. Do not freeze the unopened vial. After mixing, do not refrigerate or freeze the solution.
Stability Note	Use by the labeled expiration when stored sealed at 20-25 deg C protected from light. After mixing: discard unused SV solution immediately; discard WR solution 7 days after mixing.

RESEARCH USE ONLY — REGULATORY NOTICE

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