# ZAVIN BIOTECHNOLOGY

Analytical Reference Standards

# CERTIFICATE OF ANALYSIS

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## PRODUCT IDENTIFICATION

| | |
|---|---|
| **Product Name** | GHRH-TS Analytical Standard |
| **Catalog No. (SKU)** | TSM10 |
| **Lot / Batch No.** | ZBV-TSM10-20260602 |
| **Quantity per Vial** | 10 mg |
| **Manufacture Date** | 2026-06-02 |
| **Analysis Date** | 2026-06-06 |
| **Expiration Date** | 2028-06-06 |
| **Physical Appearance** | White to off-white lyophilized powder |
| **Material Form** | Lyophilized solid |

## MOLECULAR CHARACTERIZATION

| | |
|---|---|
| **Chemical Name / Synonyms** | GHRH-TS 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% | 99.1% | In-house HPLC / USP <621> |
| Identity Confirmation (MS) | Consistent with reference | Conforms | ESI-MS / LC-MS |
| Water Content (Karl Fischer) | <= 5.0% | 2.16% | USP <921> Method Ic |
| Acetate / Counter-ion | Report value | 6.58% | 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** | 13.32 min |

| | |
|---|---|
| **Main Peak Area** | 99.1% |
| **Total Related Substances** | 0.90% |
| **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** | +/- 0.04 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 | 98.6% | 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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