ZAVIN BIOTECHNOLOGY

Analytical Reference Standards

CERTIFICATE OF ANALYSIS

Document: COA-XT100-2026-R01 | Revision: 01 | Issue Date: 2026-06-23

PRODUCT IDENTIFICATION

Product Name	NT-BT Analytical Reference
Catalog No. (SKU)	XT100
Lot / Batch No.	ZBV-XT100-20260618
Quantity per Vial	100 iu
Manufacture Date	2026-06-18
Analysis Date	2026-06-23
Expiration Date	2028-06-23
Physical Appearance	White to off-white lyophilized powder
Material Form	Lyophilized solid

MOLECULAR CHARACTERIZATION

Chemical Name / Synonyms	NT-BT Analytical Reference
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%	99.7%	In-house HPLC / USP <621>
Identity Confirmation (MS)	Consistent with reference	Conforms	ESI-MS / LC-MS
Water Content (Karl Fischer)	<= 5.0%	3.26%	USP <921> Method Ic
Acetate / Counter-ion	Report value	9.59%	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	20.44 min

Main Peak Area	99.7%
Total Related Substances	0.30%
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	+/- 0.07 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	99.1%	UV 214 nm

STORAGE & HANDLING

Lyophilized / Unopened Solid	Unopened vacuum-dried solid in a refrigerator at 2-8 deg C (up to 36 months or the labeled expiration, whichever is first). Do not freeze. Protect from light. (BOTOX / onabotulinumtoxinA PI)
After Reconstitution (Analytical Solution)	Refrigerate reconstituted solution at 2-8 deg C and use within 24 hours. Discard unused portion. Do not freeze.
Handling	Keep unopened vials at 2-8 deg C. Mix by gentle rotation only; do not shake or foam. Record the date and time of reconstitution. Do not freeze.
Stability Note	Unopened: 2-8 deg C through labeled expiration (label states up to 36 months). After reconstitution: 2-8 deg C for up to 24 hours.

RESEARCH USE ONLY — REGULATORY NOTICE

All products distributed by Zavin Sales LLC are supplied for analytical and in-vitro laboratory research only. No product is intended or approved for human consumption, veterinary use, clinical administration, or therapeutic injection. Purchaser is responsible for laboratory handling and regulatory compliance.