

CERTIFICATE OF ANALYSIS

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Product Identification			
Product Name	NP-OT Acetate Analytical Standard		
Catalog No. (SKU)	OT10		
Lot / Batch No.	ZBV-OT10-20260301		
Quantity per Vial	10 mg		
Manufacture Date	2026-03-01		
Analysis Date	2026-03-04		
Expiration Date	2028-03-04		
Physical Appearance	White to off-white lyophilized powder		
Material Form	Lyophilized solid		
Molecular Characterization			
Chemical Name / Synonyms	Oxytocin acetate; nonapeptide hormone reference		
Molecular Formula	C43H66N12O12S2		
Molecular Weight (Calc.)	1007.19 Da		
Primary Structure	CYIQNCPLG (disulfide bridge Cys1-Cys6; supplied as acetate salt)		
CAS Registry No.	50-56-6		
Summary of Analytical Results			
Analytical Test	Specification	Result	Method Reference
HPLC Purity (area %)	>= 98.0%	99.0%	In-house HPLC / USP <621>
Identity Confirmation (MS)	Consistent with reference	Conforms	ESI-MS / LC-MS
Water Content (Karl Fischer)	<= 5.0%	3.43%	USP <921> Method 1c
Acetate / Counter-ion	Report value	10.04%	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	21.51 min		

Main Peak Area	99.0%
Total Related Substances	1.00%
System Suitability	N >= 2000 plates; tailing factor <= 1.5 (USP <621>)

MASS SPECTROMETRY IDENTITY CONFIRMATION

Ionization Mode	ESI-Positive
Theoretical Mass	1007.19 Da
Observed Mass (M+H)+	1007.26 Da
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	98.3%	UV 214 nm

STORAGE & HANDLING

Lyophilized / Unopened Solid	Lyophilized oxytocin acetate at -20 deg C (prefer -80 deg C for long-term), desiccated, protected from light and atmospheric oxygen. Disulfide nonapeptide.
After Reconstitution (Analytical Solution)	Solution is short-lived. Working stock: 2-8 deg C up to 1 week (Sigma peptide handling). For longer hold, freeze single-use aliquots at -20 deg C or colder. Do not store at alkaline pH. Protect from light.
Handling	Equilibrate the sealed vial to ambient temperature before opening to avoid condensation on the solid. Keep desiccated and protected from light. Do not shake. Aliquot solutions so each tube is thawed once. Minimize oxygen exposure. Do not leave solutions at pH greater than 8.
Stability Note	Solid: -20 deg C or -80 deg C, sealed and dry. Solution: Sigma handling up to 1 week at 2-8 deg C, or frozen aliquots; Cys-containing peptides are unstable in solution.

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