HELM

RESEARCH-GRADE COMPOUNDS

DOCUMENT

CERTIFICATE OF ANALYSIS

Report HLM-SMX-2026-001

Issued April 18, 2026 · v1

SAMPLE

This is a **template Certificate of Analysis** representing the format and specification targets for Semax Nasal Spray. A batch-specific, third-party verified COA will replace this document once the first production batch is received and tested by Janoshik Analytical.

01 — SAMPLE INFORMATION & COMPOUND IDENTITY

Product	Semax Nasal Spray
Batch Number	HLM-SMX-2026-001
Manufacturer	Helm Research, LLC
Form	Nasal Spray (metered)
Fill Volume	10 mL
Total Peptide	30 mg
Concentration	3.0 mg / mL (0.3%)

Compound	Semax
Sequence	Met-Glu-His-Phe-Pro-Gly-Pro
Molecular Formula	C37H51N9O10S
Molecular Weight	813.93 g/mol
CAS Number	80714-61-0
Storage	2–8 °C, protect from light
Shelf Life	18 months unopened

02 — ANALYTICAL RESULTS

PARAMETER	METHOD	RESULT	SPECIFICATION	STATUS
Purity (% peak area)	HPLC-UV 220 nm	99.2 %	≥ 98.0 %	Pass
Identity	LC-MS/MS, ESI+	814.91 m/z $[M+H]^+$	Confirmed to theoretical	Pass
Assay (label claim)	HPLC-UV quantitation	100.3 %	95.0 – 105.0 %	Pass
Appearance	Visual	Clear, colorless	Clear, colorless	Pass
pH	Potentiometric	5.4	4.0 – 6.5	Pass
Bacterial Endotoxins	LAL (kinetic)	< 0.5 EU / mL	≤ 5.0 EU / mL	Pass
Microbial Contamination	USP <61>	< 10 CFU / mL	≤ 100 CFU / mL	Pass

03 — TESTING METHODOLOGY

HPLC PURITY & ASSAY

Column: C18 reverse-phase, 4.6 × 150 mm, 5 µm
Mobile Phase A: 0.1% TFA in water
Mobile Phase B: 0.1% TFA in acetonitrile
Gradient: 5 → 60 % B over 20 min
Flow Rate: 1.0 mL/min
Detection: UV 220 nm
Injection Volume: 10 µL
Reference Standard: In-house qualified vs. USP

LC-MS/MS IDENTITY

Ionization: Electrospray, positive mode
Scan Range: 200 – 1200 m/z
Collision Energy: 35 eV
Theoretical $[M+H]^+$: 814.94
Observed $[M+H]^+$: 814.91
Mass Accuracy: ≤ 5 ppm
Testing Laboratory: Janoshik Analytical
Accreditation: ISO/IEC 17025 (planned)

> The above specification conforms to Helm's internal quality standard for research-grade Semax. The represented batch, once produced, will be released for research use only upon successful verification against every parameter listed in Section 02.

QUALITY AUTHORIZATION
Pending — assigned on batch release

RELEASE DATE
Pending

COA VERSION
Template v1 — April 18, 2026