NORTHCHAIN
ANALYTICS

CERTIFICATE OF ANALYSIS

REPORT #: SB-2026-80865 **PASS**

Client	SynovaBiotech	**Analysis date**	9/15/26
Report #	SB-2026-80865	**Certified date**	9/15/26

SAMPLE INFORMATION

Product	Tesamorelin	**Form**	Lyophilized Powder
Lot / batch	T301	**Labeled qty**	10mg
Cap color	Orange	**Crimp color**	Silver

TEST RESULTS

Analysis / method	Reference standard	Result	Review
Purity (HPLC)	>98%	99.71%	PASS
Net content	10mg	10.74mg	PASS
Identity (LC-MS)	(Tesamorelin)	Tesamorelin	PASS
Bacterial endotoxin	<0.5EU/ml	PASS	PASS
Microbial growth screen	no growth	no microbial growth detected	PASS

HEAVY METAL SCREENING

Analyte	Result	Status
Arsenic (As)	negative	PASS
Cadmium (Cd)	negative	PASS
Lead (Pb)	negative	PASS
Mercury (Hg)	negative	PASS

BATCH CONFORMITY RESULTS / ONE VIAL TESTED

Sample	Purity (%)	Net content (mg)
Vial 1	99.71	10.74

One submitted vial tested. These findings describe this vial; batch-wide variation was not measured.

CHROMATOGRAPHIC RECORD / TRACEABILITY

Method	RP-HPLC	**Run / data ID**	TS1-20260918-003
Column	C18	**Detector / wavelength**	DAD at 214nm

AUTHORIZATION

Reviewed by	Paul Molina	**Review date**	9/15/26
Issued by	Paul Molina	**Verification key**	SBPTS10



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BACTERIAL ENDOTOXIN ANALYSIS

REPORT #: SB-2026-80865 **PASS**

ASSAY / METHOD AS PERFORMED

CLIENT & SAMPLE INFORMATION

Client	SynovaBiotech	**Report ID**	SB-2026-80865
Product name	Tesamorelin	**Strength**	10mg
Lot / batch	T301	**Condition**	Lyophilized Powder
Report date	9/15/26	**Access key**	SBPTS10

TEST METHODOLOGY

Test performed	Quantitative Bacterial Endotoxin Test	**Compendial reference**	USP<85>
Assay type	Kinetic Turbidimetric	**Detection wavelength**	660nm
Detection range	0.01-1.0EU/ml	**Endotoxin standard**	E.coli 0111:B4
Dilution volume	2.0ml	**Matrix**	LAL Reagent Water

QUANTITATIVE RESULTS

Parameter	Result	Controls	Status
Endotoxin level	<0.05 EU/ml	Positive control	PASS
Acceptance limit	≤0.5EU/ML	Negative control	PASS
Sample CV (%)	3.00%		
Spike CV (%)	4.80%		
Spike recovery (%)	98%		
Final determination	PASS		

INTERPRETATION

Endotoxin content was quantitatively determined using a kinetic turbidimetric LAL assay in accordance with USP <85>. Result reported as below quantitation threshold. The measured endotoxin level meets the specified acceptance criteria. The sample passes the endotoxin limit test.

AUTHORIZATION

Reviewed by	Paul Molina	**Review date**	9/15/26
Issued by	Paul Molina	**Method record ID**	TSM1051G



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HEAVY METALS ANALYSIS

REPORT #: SB-2026-80865 **PASS**

ICP-MS / METHOD AS PERFORMED

CLIENT & SAMPLE INFORMATION

Client	SynovaBiotech	**Report ID**	SB-2026-80865
Product name	Tesamorelin	**Strength**	10mg
Lot / batch	T301	**Condition**	Lyophilized Powder
Report date	9/15/26	**Access key**	SBPTS10

TEST METHODOLOGY

Test performed	Elemental Impurities Analysis	**Instrument**	ICP-MS
Sample preparation	HNO^3/H^20^2 matrix	**Calibration**	Multi-element standard curve
Internal standards	Sc,Ge,In,Bi	**Material type**	Raw Material

ELEMENTAL IMPURITIES RESULTS

Element	Result / unit	Acceptance limit	Status
Lead (Pb)	0.5	≤10	PASS
Arsenic (As)	0.15	≤1.5	PASS
Cadmium (Cd)	0.05	≤0.5	PASS
Mercury (Hg)	0.3	≤3	PASS

METHOD SUITABILITY / SPIKE RECOVERY

Element	Spike level	Recovery (%)	Criteria
Lead (Pb)	4ppm	98%	70-150%
Arsenic (As)	0.70ppm	96%	70-150%
Cadmium (Cd)	0.25ppm	98%	70-150%
Mercury (Hg)	1.0ppm	100%	70-150%

QUALITY CONTROL & INTERPRETATION

Method blank	PASS	**CCV / calibration**	PASS
Duplicate RPD	≤20%	**Method run ID**	TS1054

AUTHORIZATION

Reviewed by	Paul Molina	**Review date**	9/14/26



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ANALYTICS

MICROBIAL GROWTH SCREENING

REPORT #: SB-2026-80865

INCUBATION METHOD AS PERFORMED

CLIENT & SAMPLE INFORMATION

Client	SynovaBiotech	**Report ID**	SB-2026-80865
Product name	Tesamorelin	**Strength**	10mg
Lot / batch	T301	**Condition**	Lyophilized Powder
Report date	9/29/26	**Access key**	SBPTS10

TEST METHODOLOGY

Test performed	14 Day Microbial Growth Screening	**Culture system**	Aerobic and anaerobic bottles
Incubation period	14 days	**Detection principle**	Colorimetric CO_2 detection
Sample requirement	1 vial (destructive)	**Condition as received**	Sealed

TEST RESULTS

Parameter	Result / observation
Aerobic microbial growth	No microbial growth detected
Anaerobic microbial growth	No growth detected
Final determination	No microbial growth detected during 14 day incubation period

METHOD OVERVIEW

The submitted sample was aseptically introduced into BacT ALERT culture bottles designed to support microbial growth detection. The BacT ALERT system continuously monitors each bottle during incubation. If microorganisms are present and grow, they may produce carbon dioxide which interacts with the colorimetric sensor in the bottle; the instrument detects this change photometrically. If growth is detected, the system automatically flags the bottle as positive and records the time to detection. If no growth is detected during the full incubation period, the final result is reported as no microbial growth detected.

INTERPRETATION

No microbial growth was detected in the submitted sample during the 14 day BacT ALERT incubation period. The result indicates that no detectable microbial growth was observed under the conditions of this screening method. The result should not be interpreted as a guarantee of sterility for the entire batch lot or product line.

AUTHORIZATION

Reviewed by	Paul Molina	**Review date**	9/29/26

