Certificate of Analysis Sterility & Endotoxin

Tested by: ISO 17025:2017 accredited, and FDA-registers lab:

Client: Peptide Systems, 50 Iron Point Cir, Ste 140, Folsom, CA 95630

Description: Semax

Lot Number: 20240724SX

Date Received: 08/08/2024 **Date Analyzed:** 08/16/2024

Test	Method	Specification	Results	Pass/Fail
Sterility	MBI-144	Sterile	no growth @14D	PASS
Endotoxin	USP <85>	NMT 2333 EU/mL	423 EU/mL	PASS

SPECFICATIONS Sterility by MBI-144

Tests for a broad range of contaminating microorganisms including aerobic, anaerobic, and spore forming bacteria as well as fungal microorganisms, including yeasts and molds. MBI-144 sterility tests adhere to USP <71> guidelines. A "PASS" indicates the product being examined complies with the test for sterility and no contaminating microorganisms have been found.

USP <85> Bacterial Endotoxin Assay

Uses the kinetic turbidimetric method described in USP <85> Bacterial Endotoxins Test. This test detects toxins released from the cell wall of gram-negative bacteria. A harmonized standard for <85> Bacterial Endotoxins Test has been approved by the Pharmacopeial Discussion Group and has been formally approved by the USP General Chapters Microbiology Expert Committee in accordance with the Rules and Procedures of the 2010–2015 Council of Experts.

	08/16/2024	
Analytics Technician II	Date	