

Note: COA located on Page 3

## **Beyond Purity: Why Comprehensive Testing Matters**

Peptidology products undergo rigorous testing to ensure they're safe for research use. While many understand the importance of product purity, less known but equally crucial are sterility and endotoxin testing. This document explains these testing methods and why they all matter for your safety.

## **Understanding the Tests**

### **Purity Testing**

Purity testing measures how much of the desired compound is present compared to other related substances. Using techniques like High-Performance Liquid Chromatography (HPLC), laboratories measure the "peak area percentage" to determine purity. A pharmaceutical with 99% purity means 99% of the substance contains the active ingredient, with 1% being related compounds. Purity above 95% is considered pharmaceutical grade.

#### **Assay Testing**

While purity focuses on related substances, assay testing determines the exact amount of active ingredient by comparing it to a reference standard. This test confirms the correct dosage is present in your research peptides, ensuring effectiveness.

#### **USP 71 - Sterility Testing**

USP 71 refers to the United States Pharmacopeia standard for sterility testing. This test verifies products are free from living microorganisms. Using either membrane filtration or direct inoculation methods, laboratories confirm no bacteria, fungi, or other organisms are present in products labeled "sterile".

#### **USP 85 - Bacterial Endotoxin Testing**

Even when bacteria are killed during manufacturing, they can leave behind toxic fragments called endotoxins. USP 85 testing detects these fragments, which can cause serious reactions even in sterile products.



## The Limitations of Purity Testing Alone

While high purity is essential for pharmaceutical quality, it doesn't tell the complete safety story. A product can be 99.9% pure yet still contain dangerous contaminants:

- 1. Purity tests don't detect viable microorganisms that could cause infections
- 2. Purity analysis doesn't identify bacterial endotoxins, which remain toxic even after sterilization

## Why Sterility and Endotoxin Testing Are Critical

### **Sterility Testing (USP 71)**

If sterility testing isn't performed or fails:

- Patients could receive products contaminated with living microorganisms
- Infections ranging from mild to life-threatening could develop, especially in immunocompromised patients
- Multiple organ system failures could occur in severe cases

#### **Endotoxin Testing (USP 85)**

If endotoxin testing isn't performed or fails:

- Human or animal models could experience fever, inflammation, and potentially septic shock
- Endotoxin levels as low as 0.5 EU/mL can trigger serious immune responses
- Effects can be particularly dangerous for children, elderly, or immunocompromised patients
- Even sterile products can cause harm if endotoxin levels are high

## **The Complete Picture**

The pharmaceutical industry uses a multi-layered approach to ensure safety.

Purity testing confirms the right ingredient is present, assay testing verifies the correct amount, sterility testing ensures no living organisms remain, and endotoxin testing confirms no toxic bacterial fragments are present. Only when all tests are passed can a product be considered truly safe. This comprehensive approach protects researchers from both visible and invisible threats, ensuring compounds are safe for research use.

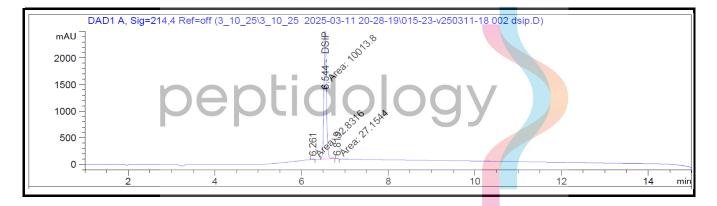


Vanguard Laboratory 2635 Parkmont Ln Olympia, Wa 98502 360-967-7010

## Certificate of Analysis

DSIP 5 mg

Report To: **Peptidology** 1111 N Scottsdale Rd STE 205 Scottsdale, AZ 85254 480-974-4660 Compound: DSIP Amount: 5 mg Laboratory ID: V250311-18 002 Date Reported: 3/26/2025 Lot Number: 1200013-1352



Analysis	Method	Result
Chromatographic Purity	HPLC-UV/VIS	99.21% + 0.18%
Assay	HPLC-UV/VIS	4.98 mg



Report By: Dustin Newman, Laboratory Director on 3/26/2025

Approved By: Tori Johnson, Operations Manager on 3/26/2025



Please consult A2LA Certificate #6377.01.01 for a list of accredited tests. Samples were received in acceptable condition. The result(s) in this report relate only to the portion of the sample(s) tested. All analyses were performed consistent with the Vanguard Laboratory Quality Management System. Vanguard Laboratory and its staff did not observe or participate in the sample selection process, and cannot confirm the authenticity of the sample or its representativeness of the associated lot/batch.

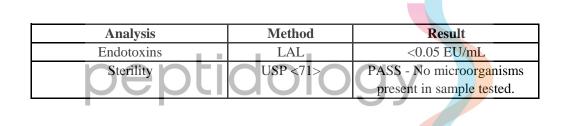


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ND: Non-Detect LOD: Limit of Quantification



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