SaphoBio

How Sapho Bio Tests for **Peptide Potency**

We correct our reference standards to the **Net Peptide Content** of every peptide API — so your potency result reflects exactly how much peptide is in the vial.

Potency testing answers a deceptively simple question: How much API is in a compounded preparation?

A pharmacy sends us a vial labeled 10 mg/mL of a peptide API. By measuring it against our internal reference standards using **HPLC-UV (USP <621>),** we then report whether it meets its label claim (90.0–110.0%). That result is only as trustworthy as the standard behind it, which is why we correct our standards to the **Net Peptide Content** of the API.

The Problem We Kept Seeing

A common error when compounding peptides is improperly correcting the mass of lyophilized powder using data from the Certificate of Analysis (COA). A batch of lyophilized peptide does not only contain the peptide of interest: counterion salts (such as TFA or acetate) and water can be a substantial fraction of the powder. "HPLC Purity" is usually the highest number on the COA and the easiest to reach for. But it doesn't accurately describe all the impurities in a batch; correcting to HPLC Purity alone can miss a massive shortfall. The result is a preparation that is subpotent, even when the label was followed exactly, and a patient who is under-dosed. We design our testing to detect this problem before it reaches a patient.

What a Certificate of Analysis Tells You

A complete COA reports many values that carry different information. Three matter, and each measures something different.

PEPTIDE CONTENT	The fraction of lyophilized powder's mass that are peptides. Peptide Content removes water, counterion salts, and residual solvents. For a lyophilized peptide this is often 75–90%.
HPLC PURITY	The target API as a fraction of all UV-absorbing species. It separates the correct peptide from off-target peptides, such as off-target sequences and degradation products.
ASSAY (%)	A quantitative measurement of mass against a reference standard. Some suppliers report the "Peptide Content" shortfall here.

No single value is the whole story; each holds valuable information about what is actually in your product. For that reason, all of these values need to be incorporated into your corrections.

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How We Determine **Net Peptide Content**

Net Peptide Content =
Measured Mass × (Peptide Content %)
× (HPLC Purity %) × (Assay %)

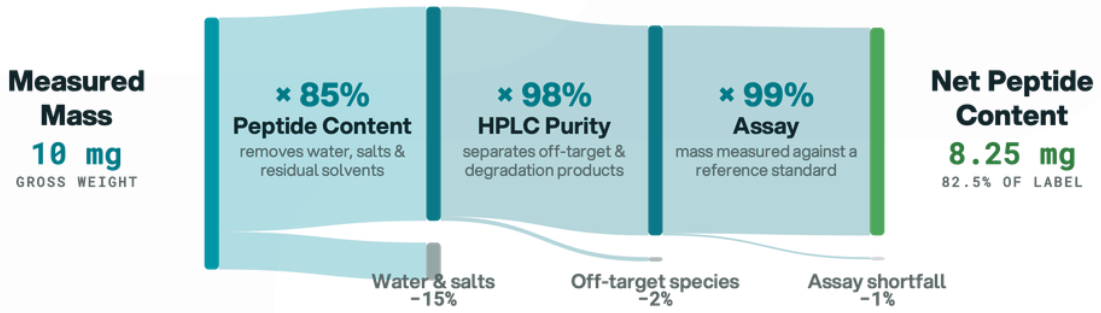
The Net Peptide Content represents the actual amount of peptide API in a formulation and accounts for all of the shortfalls described in a COA.

Other Benefits of using Net Peptide Content:

SIMPLICITY	One standard, one sample, one measurement. Allows us to focus on accuracy and rapid results
CONSISTENCY	We don't have to account for different formulations, APIs, preparations, salts, etc. Our test measures everything to the same specification.
CLARITY	We measure what is on the label, nothing more, nothing less. Pharmacies and patients don't have to wonder what our number represents or perform additional math.

Example Calculation: A peptide standard measured at **10 mg**, with an **85%** Peptide Content, **98%** HPLC Purity, and **99%** Assay.

Net Peptide Content = 10 mg × (0.85) × (0.98) × (0.99) = **8.25 mg**



That is a 17.5% gap from the label — greater than the difference between a preparation that passes and one that fails.

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How Our **Potency Testing** Works

About Sapho Bio
Sapho Bio is a **precision measurement company** offering a comprehensive suite of lot release and stability tests for compounding pharmacies, including USP validated methods for rapid sterility, endotoxin and potency.

You send us the vial, its label claim (e.g. 10 mg/mL), and the Certificate of Analysis of your current lot.

Using validated HPLC-UV methods, we compare your preparation to corrected reference standards.

We report the Net Peptide Content in your formulation and issue a pass or fail against label claim (90.0–110.0%)

Frequently Asked Questions

Why isn't HPLC Purity enough?

HPLC Purity only compares the correct molecule to other molecules the HPLC-UV can detect. It does not account for the water and salt that make up a real share of many powders, and it ignores content shortfalls reported elsewhere on the COA. A material can be highly “pure” on an HPLC and still be well below its labeled concentration.

My COA lists HPLC Purity and Assay, but no separate "Peptide Content" — is that a problem?

Not necessarily. Suppliers differ in how they report information in a COA, and many report the Peptide Content shortfall under "Assay." When this is the case, we apply all the values that are present. When in doubt, it is always best to reach out to your supplier.

My COA reports percentages of acetate, water, and other different substances. Do I need to also account for these values?

No. The Peptide Content value already accounts for all non-peptide substances, including acetate and water. The exception is when your API forms a complex with a metal ion (for example, the Copper ion in GHK-Cu). In this case, the Peptide Content can be replaced with the sum of the percentage of peptide and metal percentages to measure the total mass of the Peptide-Metal complex.

My peptide API is a salt or a hydrate — how is that handled?

The counterion and water are not active product, so they are not measured. We work from the COA's quantitative assay on the basis that matches your dose, just as we remove a peptide's counterion and water.