Certificate of Analysis

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Publish Date:	2025-08-08
Client & Sample ID:	Allen GBH T30 07-25
Sample Name & Mfg:	Tirzepatide 30 mg 1 Vial Allen Bio



Photo of Sample:



Results

Sample ID	SPL-1479
TM-1001 Tirzepatide Assay	36.603 mg
TM-1001 Tirzepatide Purity	99.949 %
TM-1001 Tirzepatide ID by RT	1.00
TM-1001 Tirzepatide ID by Spectral	1000
TM-1001 Coelution Control	1000
TM-1001 System Suitability	0.2 %RSD

Created by

Reviewed by

Ashlee Lust President

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- Sample Assay: This is the amount of the compound in the vial we tested determined by HPLC analysis.
- **Sample Purity:** This is purity of the sample, calculated including peaks around the compound that may be impurities.
- **ID by RT:** This is an identification test in which the retention time of the sample is compared to the average retention time of five reference standard injections.
- **ID by Spectral** This is an identification test in which the UV spectrum of the sample is compared to the UV spectrum of the standard.
- System Suitability: This value shows that the HPLC system was running properly throughout your testing. The %RSD of the standard injections performed before your sample and the standard injection performed after your sample is calculated to ensure there were no system errors during your run. Although system errors such as leaks, a line running dry, air bubbles, etc. are rare, it's important that we demonstrate no errors occurred during analysis.
- **Coelution Control: NOTE:** This value is not purity of the compound the peak is pure compound as it was separated out by the HPLC. This value demonstrates that there is no co-elution occurring during analysis. We receive samples from a multitude of manufacturers and each has their own recipe (stabilizers, solubilizers, fillers, etc) in their process. This measurement ensures that none of these other components interfere with the analysis. In short, this number confirms that the method is working properly and only analyzing the target compound.

Important Testing Notice

The analytical results detailed herein pertain solely to the presence of the specified compounds in the samples as submitted. These results are generated by our independent partner laboratory. It is acknowledged that all prepared lyophilized peptide products and any other tested material may include stabilizers, solubilizers, fillers, and other excipients and ingredients, which are not tested for unless explicitly noted in the testing agreement and this Certificate of Analysis (COA). The results provided do not imply suitability for any specific use or purpose, and testing is limited to the listed compounds unless noted herein. Clients and other users are advised that the responsibility for determining the applicability of these results for any use rests entirely with them. It is imperative that any users of this information consult with a physician prior to using any peptide or other compound. Peptides or other compounds sold for "research purposes" may not be suitable for human use. Any liability for the provided analytical results is confined to the procedural adherence of our partner laboratory to recognized professional standards during the testing process.

Microbiological analyses are in accordance with USP 71 Sterility (total viable bacteria) using two non-selective broth media. Results reported are provided *as-is* and relate only to samples tested. A satisfactory result only indicates that no contaminating microorganism has been found in the sample examined under the conditions of the test.

Our sterility testing methods adhere to USP 71 guidelines to maintain compliance with industry standards. However, the samples tested are provided directly by the client and may or may not fully represent the entire production batch due to the limitations in obtaining batch-wide samples. While our testing follows USP 71 procedures, the client is solely responsible for ensuring that their sampling process aligns with USP 71 standard, as we have no visibility or control over the production batch from which the samples are drawn.