



krause analytical

Methods Summary

Purity/Potency/Identification

USP/NF 621

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted to contain approximately 500 mg/L of the peptide.
- The diluted sample is analyzed by HPLC-UV-MS.
- The mass spectrum obtained is compared to an authentic standard of the peptide for identification.
- The total area of all of the peaks in the chromatogram is calculated, and the area of the peak of the peptide is divided by the total area to obtain the chromatographic purity value, reported in percent.
- The area of the peptide is compared to the area of the peptide peak in the known standard to obtain a concentration in the solution. This concentration is used to calculate the total mass of peptide in the vial, which is compared to the stated mass (label claim) and reported as both total mass in the vial and as a percent of the label claim.

Endotoxins

USP/NF 86

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted in endotoxin-free water.
- The diluted sample is analyzed for endotoxins using the LAL method.

Metals

USP/NF 233

- 2 mL of purified water is added to the lyophilized powder in the vial, and the contents mixed to dissolve the lyophilized powder.
- An aliquot is taken from the vial and diluted in deionized water.
- The diluted aliquot is analyzed against known standards by ICP-MS

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