



FDA's Take on Compounded GLP-1s

Can Semaglutide Be Compounded?

When a drug is in short supply, compounders might step in to create a version, but only if they stick to the Federal Food, Drug, and Cosmetic (FD&C) Act rules. As of May 2023, Ozempic and Wegovy are on the FDA's Drug Shortages list so that compounding could be on the table.

Concerns About Compounded Semaglutide?

The FDA has received reports of adverse events linked to compounded semaglutide. If there's an approved drug available, that's your safest bet. The FDA doesn't review compounded medications for safety, effectiveness, or quality. There's also a concern about some compounders using salt forms of semaglutide, like semaglutide sodium or semaglutide acetate. These aren't the same as the base form used in approved drugs, and the FDA hasn't found any legitimate reason for using these salt forms in compounding.

Information for Healthcare Providers from Peninsula Compounding Pharmacy

What's the Current Beyond-Use Date (BUD) for Semaglutide and Tirzepatide?

Semaglutide and Tirzepatide have a BUD of 6 months from the date they're compounded. Typically, customers can expect a shelf life of 3-5 months and should order a month's supply at a time.

Does the Facility Perform Stability Studies on Semaglutide and Tirzepatide?

Absolutely. Our partner compounding facility, FDA-registered and cGMP compliant, conducts stability studies on all drug products, including Semaglutide and Tirzepatide. A qualified third-party lab conducts these studies.



Is Each Batch Tested for Potency and Sterility?

Yes, every batch undergoes independent testing for both sterility and potency.

Where Are the Active Pharmaceutical Ingredients (APIs) Sourced From, and Are They FDA-Registered?

Our facility collaborates directly with the API manufacturer or their U.S.-based vendor, all of whom are FDA-registered. Every lot of API received undergoes validation by a third-party lab to confirm its identity.

Storage Requirements Before and After Dispensing?

Semaglutide and Tirzepatide must be stored at refrigerated temperatures before and after dispensing. However, data suggests that potency remains unaffected if the product is left at room temperature for up to 15 days.

Why Use Pure Semaglutide Base Instead of the Salt or Acetate Forms?

The salt and acetate forms aren't part of any FDA-approved drug, so they're a no-go for compounding.

How to Place an Order with Our Pharmacy?

Prescriptions can be called in, e-scripted, or faxed. You can write for the generic or brand name, but note "Compounded Version OK" directly on the prescription. Specify the desired strength, and we'll handle any necessary conversions.

Pricing

Prices start at \$199 per month and may vary based on dosage.

Where can the patient get an injection?

We can provide weekly injections to the patient for a \$25 administration fee.