

## **Information about compounded GLP-1's from the FDA**

### **Can semaglutide be compounded?**

When a drug is in shortage, compounders may be able to prepare a [compounded](#) version of that drug if they meet certain requirements in the Federal Food, Drug, and Cosmetic (FD&C) Act. As of May 2023, Ozempic and Wegovy are both listed on FDA's [Drug Shortages list](#).

### **Are there concerns with compounded semaglutide?**

FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality.

Additionally, FDA has received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than is used the approved drugs, which contain the base form of semaglutide. The agency is not aware of any basis for compounding using the salt forms that would meet the FD&C requirements for types of active ingredients that can be compounded.

## **Information about Compounded GLP-1s from Cascadia Pharmacy Wallingford for Healthcare Providers**

### **What is the current BUD on Semaglutide and Tirzepatide?**

Currently Semaglutide and Tirzepatide have 6 months BUD from date compounded. Customers can typically expect the product to have 3-5 month dating and should be ordering 1 month supply at a time

### **Does the compounding facility perform stability studies on Semaglutide and Tirzepatide?**

Yes, our partner FDA-registered cGMP compounding facility performs stability studies on all drug products including Semaglutide and Tirzepatide. All stability studies are performed by a qualified third-party lab and adhere to cGMP requirements.

### **Does the compounding facility test for potency and sterility on Semaglutide and Tirzepatide?**

Yes, every batch is tested independently by an independent lab for sterility and potency.

### **Where does your facility source their APIs from, and are the API sources FDA registered?**

For GLP-1s, the FDA-registered cGMP compounding facility that we work with collaborates with the API manufacturer directly, or the manufacturer's US based vendor. Each lot of API received at their facility is sent to a validated third-party lab using validated test methods to confirm the identity of the API.

### **What are the storage requirements of both products prior to dispensing and after?**

Both Semaglutide and Tirzepatide should be stored at refrigerated temperature prior to and after dispensing. However, there is data to support there is no negative effect to the potency of the product if left at room temperature for up to 15 days (about 2 weeks).

**Why does your partner compounding facility use pure Semaglutide base and not the salt, or acetate form?**

The salt and acetate form of Semaglutide are not a component of an FDA approved drug product, and therefore cannot be used for compounding.

**How can I place an order with your pharmacy?**

Prescriptions can be called in, e-scripted, faxed or written and brought into the pharmacy. You may write for the generic OR the brand name on the hard copy, however, you must indicate **“Compounded Version OK”** directly on the prescription notes.

Please specify the desired strength for the prescription, and we will handle any necessary conversions before dispensing it to the patient.

**Pricing List**

Prices will begin at \$199 per month and increase depending on dosage.

**Can the pharmacy inject the medication each week?**

Yes, the pharmacy can provide weekly injections to the patient for a \$25 administration fee.