

Tirzepatide EN

Sterile procedure for reconstituting and dividing a lyophilized peptide

Accessories

- [100 x syringe filter, 0.65+0.22µm, 13mm, sterile](#)
- [100 x syringe, 1ml, sterile](#)
- [100 x syringe, 5ml, sterile](#)
- [100 x needle, 23G, 3/4", sterile](#)
- [100 x needle, 30G, 1/2", sterile](#)
- [100 x bouffant cap, medium](#)
- [35 x respiratory mask, N95, regular](#)
- [100 x surgical glove, size 7, sterile](#)
- [100 x drape, disposable](#)
- [100 x vial, 10ml, evacuated, sterile](#)
- [160 x germicidal wipe](#)
- [10 x bacteriostatic water, 30ml](#)
- [3 x storage bag](#)

Dosage table

Dosage	Initial BAW	Additional BAW	Total BAW	Number of 10ml vials (0.5ml each)
6mg	2ml	3ml	5ml	10 vials
7.5mg	2ml	2ml	4ml	8 vials
10mg	2ml	1ml	3ml	6 vials
12mg	2ml	0.5ml	2.5ml	5 vials
15mg	2ml	0ml	2ml	4 vials

Required materials

Material	Quantity
Lyophilized peptide (60mg)	1 evacuated 3ml vial
BAW (bacteriostatic water) (30ml)	1 vial
1ml sterile syringes	According to dosage table
5ml sterile syringes	2 syringes
23G 3/4" sterile needles	3 needles
30G 1/2" sterile needles	According to dosage table
0.22µm sterile syringe filter	1 filter
10ml sterile evacuated vials	According to dosage table + 1
Alcohol swabs	Sufficient quantity
Germicidal wipes	Sufficient quantity
Disposable sterile field	1 field
Still air box (SAB)	1 unit
Bouffant cap	1 unit
N95 respirator mask	1 mask
Sterile gloves	1 pair
Label maker and labels	1 unit with sufficient labels
Vial storage rack	1 unit
70% isopropyl alcohol (IPA)	Sufficient quantity
Sharps container	1 container

Procedure

1. Initial preparation

1. Wash your hands thoroughly with soap and water for at least 20 seconds. Dry with a clean towel or air dry.
2. Clean the workspace with germicidal wipes.
3. Set up the still air box (SAB) in the workspace.
4. Gather all necessary materials.

2. SAB and material preparation

1. Clean the inside of the SAB with 70% IPA, including a fine spray.
2. Clean all materials with 70% IPA.
3. Install a disposable sterile field in the SAB to create a sterile work surface.
4. Place all cleaned materials inside the SAB.
5. Spray a final fine mist of IPA inside the SAB.
6. Close the SAB and wait 15 minutes for the alcohol to evaporate and suspended particles to settle.

3. Personal protective equipment

1. During the 15-minute waiting time:
 - a. Wash your hands again thoroughly with soap and water for at least 20 seconds. Dry with a clean towel or air dry.
 - b. Put on the bouffant cap:
 - Gather your hair if necessary.
 - Take the cap by the edges.
 - Gently stretch it and place it on your head.
 - Make sure it covers all your hair and ears.
 - c. Put on the N95 mask:
 - Hold the mask in your hand, letting the straps hang freely.
 - Place the mask under your chin with the nosepiece facing up.
 - Pull the top strap over your head and place it above the ears, on the crown of your head.
 - Pull the bottom strap over your head and place it at the base of your neck.
 - Adjust the nosepiece to fit the shape of your nose by pressing with both hands.
 - Check the mask's seal by inhaling and exhaling forcefully. The mask should collapse slightly on inhalation and inflate on exhalation. Adjust if necessary.
2. After the 15-minute waiting period:
 - a. Wash your hands again thoroughly with soap and water for at least 20 seconds. Dry with a clean towel or air dry.
 - b. Put on the sterile gloves:
 - Open the sterile glove package without touching the gloves themselves.
 - Take the first glove by the folded edge, touching only the inside of the glove.
 - Put on the glove by unrolling it onto your dominant hand.

- With the gloved hand, slide your fingers under the folded edge of the second glove.
 - Put on the second glove by unrolling it onto your other hand.
 - Adjust the gloves to be comfortable, touching only sterile surfaces.
3. Once equipped, avoid touching your face or adjusting your protective equipment. If adjustment is necessary, use an aseptic technique or change the equipment if needed.

4. Final preparation

1. Using alcohol swabs, quickly wipe down each piece of equipment in the SAB again before use.

5. Initial reconstitution

1. Disinfect the stopper of the 3ml evacuated peptide vial and the BAW vial with an alcohol swab.
2. Using a 5ml syringe with a 23G 3/4" needle, draw up 2ml of BAW.
3. Before injecting the BAW, pull back slightly on the plunger to equalize pressure in the evacuated vial.
4. Slowly inject the 2ml of BAW into the peptide vial, aiming for the side to avoid disturbing the powder.
5. Gently swirl until completely dissolved. Do not shake.

6. Transfer to the first 10ml vial and additional dilution

1. Disinfect the stopper of the 3ml evacuated peptide vial and the 10ml vial with an alcohol swab.
2. Using the same 5ml syringe and needle, draw up all of the reconstituted solution (2ml) from the 3ml vial.
3. Remove the 23G needle from the syringe and dispose of it properly.
4. Attach the 0.22µm filter to the syringe.
5. Attach a new 23G 3/4" needle to the other end of the filter.
6. Before injecting the solution, pull back slightly on the plunger to equalize pressure in the evacuated 10ml vial.
7. Inject the filtered solution into the sterile 10ml vial.
8. Using a new 5ml syringe and 23G 3/4" needle, draw up the additional BAW according to the dosage table.
9. Inject this additional BAW into the same 10ml vial, again equalizing pressure beforehand.

10. Gently swirl to ensure complete mixing.
11. Remove and properly dispose of the needles and filter.

7. Distribution into 10ml vials

1. Disinfect the stopper of the reconstituted Tirzepatide vial and a new 10ml vial with an alcohol swab.
2. Using a 1ml syringe with a 30G 1/2" needle, draw up 0.5ml of the final reconstituted solution from the 10ml vial.
3. Before injecting, pull back slightly on the plunger to equalize pressure in the evacuated 10ml vial.
4. Inject 0.5ml into the 10ml vial.
5. Repeat steps 1 to 4, using a new 30G 1/2" needle for each vial, until all the solution is transferred.

8. Labeling and storage

1. Label each vial with the substance name, reconstitution date, and expiration date (84 days from reconstitution).
2. Store the vials in a storage rack in the refrigerator (2°C to 8°C), protected from light.