INJECTOR AND METHOD OF ASSEMBLY

Background

[0001] This patent is directed to an injector and a method of assembling the injector, and, in particular, to a prefilled injector and a method of assembling the prefilled injector.

[0002] Injectors are used to deliver medical fluids, such as liquid drugs, to a patient. In particular, the injector will provide the fluid to the patient through a needle, cannula or catheter that defines a flow path into the patient. Certain injectors have a reservoir that is assembled by the manufacturer already connected to the flow path. However, these reservoirs are typically provided empty by the manufacturer to the patient or healthcare provider (e.g., doctor, nurse, healthcare assistant, etc.), and then the reservoir is filled at the time of use. Alternatively, the injector may be used in combination with a reservoir that is provided to the patient or healthcare provider prefilled.

[0003] In either case, the injector must be prepared prior to use. For example, if the reservoir is provided empty, then the reservoir must be filled. To do this, a syringe is filled with the drug to be delivered, and then the drug is injected into the reservoir through an inlet port. Prior to the injection, the inlet port must be sterilized by swabbing the outer surface with an alcohol wipe, for example. Similarly, before the prefilled reservoir is connected to the flow path in the alternative injector, the mating connectors must be sterilized, by swabbing the surface with an alcohol wipe.

[0004] In either event, the use of the injector requires additional material and time.

[0005] As set forth in more detail below, the present disclosure sets forth an improved injector embodying advantageous alternatives to the conventional devices and methods discussed above.

Summary

[0006] In one aspect, there is provided an injector comprising: a container including a wall with an interior surface defining a bore, at least one stopper having an interior surface and being received within and moveable along the bore and a seal assembly with an interior surface, at least the stopper and the interior surfaces of the wall and the seal assembly defining a closed sterile reservoir filled with a drug product; a fluid delivery system comprising a sterile

container needle having a point disposed only partially through the seal assembly in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the interior surface of the seal assembly into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir; and an actuator that is adapted to move the container needle from the storage state to the delivery state; wherein the seal assembly comprises a flexible wall having an interior surface that defines the interior surface of the seal assembly, the seal assembly comprises a barrier separate from and spaced from the flexible wall such that the barrier and the flexible wall define an enclosed space between the flexible wall and the barrier, and the point of the sterile container needle is disposed through the barrier into the enclosed space in the storage state. Disclosed is an injector may include a container having a wall with an interior surface defining a closed sterile reservoir filled with a drug product. The injector may also include a sterile fluid delivery system which may or may not be in fluid communication with the sterile reservoir in a

storage state, but is in fluid communication with the reservoir in the delivery state. The injector further includes other clean elements (e.g., an actuator) that are assembled with the container and the needle.

[0007] The wall of the container may be a rigid wall or a flexible wall.

[0008] If the fluid delivery system is not in fluid communication in a storage state, the injector may include an actuator that is adapted to changes the state of the fluid delivery system from the storage state to the delivery state.

[0009] In such an injector, the actuator is adapted to change the state of the fluid delivery system repeatedly between the storage state and the delivery state.

[0010] In such an injector, the actuator may be adapted to delay change in state of the fluid delivery system from the storage state to the delivery state after an input is received.

[0011] In such an injector, the injector may include a mechanical, electro-mechanical, or electrical input device coupled to the actuator.

[0012] According to any of the foregoing, the drug product may include a volume of an erythropoiesis stimulating agent, a granulocyte colony-stimulating factor, a TNF blocker, a pegylated granulocyte colony-stimulating factor, interleukin-receptor specific antibody, IGF-receptor (Insulin Growth Factor receptor) specific antibody, TGF-specific antibody, or PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) - specific antibody.

[0013] In yet another aspect, there is provided a method of assembling an injector, the method comprising: filling a sterile reservoir of a container with a drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container and including a bore; disposing at least one stopper having an interior surface in the bore under sterile conditions such that the stopper is movable along the bore and defines a portion of the reservoir; attaching a sterile fluid delivery system to the container under sterile conditions by inserting a point of a sterile container needle partially through a seal assembly, wherein the seal assembly comprises a flexible wall and a barrier separate from and spaced from the flexible wall such that the barrier and the flexible wall define an enclosed space between the flexible wall and the barrier, the sterile container needle not in fluid communication with the reservoir with a point of the sterile container needle disposed through the barrier into the enclosed space when the fluid delivery system is in the storage state, and the point of the sterile container needle disposed through the interior surface of the seal assembly into the sterile reservoir in a delivery state such that the sterile container needle is in fluid

communication with the reservoir; and assembling the remainder of the injector under clean room conditions.

Also disclosed is a method of assembling an injector may include filling a sterile reservoir of a container with a drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container. The method may also include attaching a sterile fluid delivery system to the container under sterile conditions to define a storage state in which the fluid delivery system may or may not be in fluid communication with the sterile reservoir, and a delivery state in which the fluid delivery system is in fluid communication. The method may include assembling the remainder of the injector under clean room conditions.

[0014] The method may also include attaching the fluid delivery system to an actuator under clean room conditions, the actuator adapted to change the state of the fluid delivery system from the storage state to a delivery state wherein the fluid

CLAIMS

1. An injector comprising:

a container including a wall with an interior surface defining a bore, at least one stopper having an interior surface and being received within and moveable along the bore and a seal assembly with an interior surface, at least the stopper and the interior surfaces of the wall and the seal assembly defining a closed sterile reservoir filled with a drug product;

a fluid delivery system comprising a sterile container needle having a point disposed only partially through the seal assembly in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the interior surface of the seal assembly into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir; and

an actuator that is adapted to move the container needle from the storage state to the delivery state;

wherein the seal assembly comprises a flexible wall having an interior surface that defines the interior surface of the seal assembly, the seal assembly comprises a barrier separate from and spaced from the flexible wall such that the barrier and the flexible wall define an enclosed space between the flexible wall and the barrier, and the point of the sterile container needle is disposed through the barrier into the enclosed space in the storage state.

2. The injector of claim 1, wherein the wall of the container comprises a rigid wall.

3. The injector of claim 1, wherein the wall of the container comprises a flexible wall.

4. The injector of claim 1, wherein the wall of the container defines a bore with an opening and the flexible wall defines a septum disposed across the opening and fixedly attached to the wall of the container.

5. The injector of claim 3, wherein the stopper comprises the flexible wall of the seal assembly.

6. The injector of claim 5, wherein the wall of the container defines a closed end opposite the stopper and an open end in which the stopper is disposed.

7. The injector of claim 1, wherein the bore has a first end defining an opening, and the flexible wall defines a septum disposed across the opening and fixedly attached to the wall of the container, the container further comprising a piston defining the stopper, the stopper being disposed within a second end of the bore and moveable along the bore.

8. The injector of claim 1, wherein the stopper comprises the flexible wall defining a first stopper and the barrier defining a second stopper each stopper being moveable along the bore.

9. The injector of claim 1, wherein the container comprises a vent in fluid communication with the enclosed space between the barrier and the flexible wall.

10. The injector of claim 9, wherein the vent is formed in the barrier.

11. The injector of claim 9, wherein the vent is formed within the interior surface of the wall of the container.

12. The injector of claim 9, wherein the wall of the container defines a closed end opposite the first and second stoppers and an open end in which the first and second stoppers are disposed.

13. The injector of claim 1, wherein the bore includes a first end with an opening, and the flexible wall and the barrier each defines a septum disposed across the opening and fixedly attached to the wall of the container, the container further comprising a piston defining the stopper and being disposed within a second end of the bore and moveable along the bore.

14. The injector of any one of the preceding claims, wherein the fluid delivery system comprises sterile flexible tubing connected at a first end to the container needle and a second end to a sterile injection needle received within a sterile cover that closes off the sterile injection needle.

15. The injector of any one of the preceding claims, wherein the actuator is adapted to delay movement of the container needle from the storage state to the delivery state after an input is received.

16. The injector of any one of the preceding claims, further comprising a mechanical, electro-mechanical, or electrical input device coupled to the actuator.

17. The injector of any one of the preceding claims, wherein the drug product comprises a volume of an erythropoiesis stimulating agent.

18. The injector of any one of claims 1-16, wherein the drug product comprises a volume of a granulocyte colony-stimulating factor.

19. The injector of any one of claims 1-16, wherein the drug product comprises a volume of a TNF blocker.

20. The injector of any one of claims 1-16, wherein the drug product comprises a volume of a pegylated granulocyte colony-stimulating factor.

21. The injector of any one of claims 1-16, wherein the drug product comprises a volume of interleukin-receptor specific antibody.

22. The injector of any one of claims 1-16, wherein the drug product comprises a volume of IGF-receptor (Insulin Growth Factor receptor) specific antibody.

23. The injector of any one of claims 1-16, wherein the drug product comprises a volume of TGF-specific antibody.

24. The injector of any one of claims 1-16, wherein the drug product comprises a volume of PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) - specific antibody.

25. A method of assembling an injector, the method comprising:

filling a sterile reservoir of a container with a drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container and including a bore;

disposing at least one stopper having an interior surface in the bore under sterile conditions such that the stopper is movable along the bore and defines a portion of the reservoir;

attaching a sterile fluid delivery system to the container under sterile conditions by inserting a point of a sterile container needle partially through a seal assembly, wherein the seal assembly comprises a flexible wall and a barrier separate from and spaced from the flexible wall

such that the barrier and the flexible wall define an enclosed space between the flexible wall and the barrier, the sterile container needle not in fluid communication with the reservoir with a point of the sterile container needle disposed through the barrier into the enclosed space when the fluid delivery system is in the storage state, and the point of the sterile container needle disposed through the interior surface of the seal assembly into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir; and

assembling the remainder of the injector under clean room conditions.

26. The method of claim 25, wherein assembling the remainder of the injector comprises: attaching the fluid delivery system to an actuator under clean room conditions, the actuator adapted to change the state of the fluid delivery system from the storage state to a delivery state.