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 and a seal assembly with an interior surface, 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, and disposed through the interior surface of the seal assembly into the sterile reservoir in a delivery state; and an actuator that is adapted to move the container needle from the storage state to the delivery state. In another aspect, there is provided an injector comprising: a container including a wall with an interior surface defining a closed sterile reservoir filled with a drug product; a sterile fluid delivery system in fluid communication with the sterile reservoir in a delivery state, the fluid delivery system either in fluid communication or not in fluid communication in a storage state; and a clean assembly comprising a remainder of the injector in which the container and the fluid delivery system are disposed. ~~According to an aspect of the present disclosure,~~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; attaching a sterile fluid delivery system to the container under sterile conditions, the fluid delivery system in fluid communication with the reservoir in a delivery state and either in fluid communication or not in fluid communication with the reservoir in a storage state; and assembling the remainder of the injector under clean room conditions. 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 attached to a sterile fluid delivery system, the fluid delivery system in fluid communication with the reservoir in a delivery state and either in fluid communication or not in fluid communication with the reservoir in a storage state; and assembling the remainder of the injector under

clean room conditions. ~~According to another aspect of the present disclosure,~~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