oil allows the stopper to slide easily within the barrel when administering a dose, which may ensure the full dosage is administered.

[0004] The use of silicone in a pre-filled syringe, auto-injector, or pen is a concern in the industry because the oil may degrade the medicament and/or because an amount of silicone may be injected with it. The use of silicone in a pre-filled syringe, auto-injectors, and pens may be of particular concern with regard to biopharmaceuticals because it may cause aggregation of certain proteins.

[0005] In addition, some fluid compositions in pre-filled syringes auto-injectors, and pens are oxygen-sensitive and may oxidize or otherwise be adversely impacted by coming into contact with oxygen. Such oxygen sensitivity can present an issue for pre-filled syringes, auto-injectors, and pens, which typically permit a small amount of air to infiltrate into the syringe during storage. As a result, oxygen sensitive drugs or drug formulations may require additional excipients, packaging, and/or manufacturing steps for stability enhancement and degradation prevention. These approaches, however, add complexity to the overall construction of the device or drug formulation.

[0006] Thus, there exists a need for silicone free pre-filled syringes, auto-injectors, and pens that are configured to inhibit or prevent oxygen permeation into the barrel of the syringe, auto-injector, or pen.

SUMMARY

[0007] In an aspect of the disclosure, there is a medical delivery device comprising:

a lubricant-free barrel having a proximal end, a distal end, and an interior surface defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface of the barrel; and a plunger rod connected to the elastomeric stopper,

wherein the barrel has a region of reduced diameter located at least at the proximal end thereof to enhance an interference fit between the elastomeric stopper and the interior surface of the barrel, and, wherein the elastomeric stopper includes at least one rib in abutting contact within the region of reduced diameter while the elastomeric stopper is in an undepressed state; wherein at least one insert is in contact with the interior surface of the barrel to form the region of reduced diameter, said at least one

insert being a gas barrier to inhibit oxygen infiltration into said barrel,

optionally wherein at least one of:

said insert is affixed to the interior surface of the barrel via an adhesive;

said insert is integrally formed on the interior surface of the barrel;

the insert comprises a solid polymer tube that is bonded to the interior surface of the barrel the insert comprises a laminate including one or more fluoropolymer membranes attached to the interior surface of the barrel.

[0007A] In an example, there is a medical delivery device comprising: a lubricant-free barrel having a proximal end, a distal end, and an interior surface defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface of the barrel, wherein the elastomeric stopper comprises a plurality of ribs, each pair of ribs having a valley therebetween; and at least one ring member positioned within at least one valley, wherein the at least one ring member comprises an oxygen-absorbing material, an oxygen-adsorbing material, or a combination thereof.

[0007B] In an example, there is a medical delivery device comprising: a silicone-free barrel having a proximal end, a distal end, and an interior surface defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface;

a plunger rod attached to the stopper and mounted within the barrel for moving the stopper distally within the barrel; and

a barrier coating positioned on at least a portion of the elastomeric stopper, wherein the barrier coating comprises an oxygen barrier material.

[007C] In an example, there is a medical delivery device comprising: a lubricant-free barrel having proximal and distal ends and an interior surface defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface; a plunger rod attached to the elastomeric stopper and mounted within the syringe barrel for moving the elastomeric stopper distally within the barrel; and a coating material positioned on a portion of the interior surface of the barrel adjacent to the proximal end of the barrel to form a region of reduced diameter, said region of reduced diameter having a diameter that is less than a diameter of an uncoated region of the barrel, and an expanded polytetrafluoroethylene film having a first side and a second side, said first side being secured to said outer surface of said elastomeric

stopper, wherein the stopper includes at least one rib in abutting contact within the coating material while the stopper is in an undepressed state, and wherein at least one rib is in contact with the uncoated region of the interior surface while the stopper is in a depressed state.

[0007D] In an example, there is a medical delivery device comprising: a barrel having a proximal end, a distal end, and an interior surface having thereon a lubricant, said barrel defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface of the barrel; and a plunger rod connected to the elastomeric stopper, wherein the barrel has a region of reduced diameter located at least at the proximal end thereof to enhance an interference fit between the elastomeric stopper and the interior surface of the barrel, and, wherein the elastomeric stopper includes at least one rib in abutting contact within the region of reduced diameter while the elastomeric stopper is in an undepressed state; optionally wherein the medical delivery device is a syringe, an auto-injector, or a pen.

[0007E] In an example, a medical delivery device comprises: a barrel having a proximal end, a distal end, and an interior surface having thereon a lubricant, said barrel defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface of the barrel, wherein the elastomeric stopper comprises a plurality of ribs, each pair of ribs having a valley therebetween; and at least one ring member positioned within at least one valley, wherein the at least one ring member comprises an oxygen-absorbing material, an oxygen-adsorbing material, or a combination thereof; optionally wherein the medical delivery device is a syringe, an auto-injector, or a pen.

[0007F] In an example, a medical delivery device comprises: a barrel having proximal and distal ends and an interior surface having thereon a lubricant, said barrel defining a fluid chamber for containment of at least one therapeutic; an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface; a plunger rod attached to the elastomeric stopper and mounted within the syringe barrel for moving the elastomeric stopper distally within the barrel; and a coating material positioned on a portion of the interior surface of the barrel adjacent to the proximal end of the barrel to form a region of reduced diameter, said region of reduced diameter having a diameter that is less than a diameter of an uncoated region of the barrel, and an expanded polytetrafluoroethylene film having a first side and a

second side, said first side being secured to said outer surface of said elastomeric stopper, wherein the stopper includes at least one rib in abutting contact within the coating material while the stopper is in an undepressed state, and wherein at least one rib is in contact with the uncoated region of the interior surface while the stopper is in a depressed state; optionally wherein the medical delivery device is a syringe, an auto-injector, or a pen.

[0007G] In an example, the present disclosure is directed to medical delivery devices (e.g., syringes, auto-injectors, and pens) that include a silicone free barrel having proximal and distal ends and an interior surface that defines a fluid chamber for the containment of at least one therapeutic, an elastomeric stopper that has an outer surface that forms a fluid-tight seal with the interior surface of the barrel, and a plunger rod or actuation mechanism to displace the stopper within the barrel. The barrel has a region of reduced diameter located at the proximal end of the barrel to enhance an interference fit between the elastomeric stopper and the interior surface of the barrel. The stopper includes at least one rib in abutting contact with the region of reduced diameter while the stopper is in an undepressed state. The region of

What is claimed is:

1. A medical delivery device comprising:

a lubricant-free barrel having a proximal end, a distal end, and an interior surface defining a fluid chamber for containment of at least one therapeutic;

an elastomeric stopper having an outer surface forming a fluid-tight seal with the interior surface of the barrel; and

a plunger rod connected to the elastomeric stopper,

wherein the barrel has a region of reduced diameter located at least at the proximal end thereof to enhance an interference fit between the elastomeric stopper and the interior surface of the barrel, and,

wherein the elastomeric stopper includes at least one rib in abutting contact within the region of reduced diameter while the elastomeric stopper is in an undepressed state; wherein at least one insert is in contact with the interior surface of the barrel to form the region of reduced diameter, said at least one insert being a gas barrier to inhibit oxygen infiltration into said barrel,

optionally wherein at least one of:

said insert is affixed to the interior surface of the barrel via an adhesive;

said insert is integrally formed on the interior surface of the barrel;

the insert comprises a solid polymer tube that is bonded to the interior surface of the barrel the insert comprises a laminate including one or more fluoropolymer membranes attached to the interior surface of the barrel.

2. The medical delivery device of claim 1, wherein at least one of:

the barrel contains the region of reduced diameter, a region of greater diameter positioned at the distal end of the barrel, and a transition section positioned therebetween to provide a gradual transition between the region of reduced diameter and the region of greater diameter;

two or more ribs are in abutting contact with the region of reduced diameter while the elastomeric stopper is in the undepressed state.

3. The medical delivery device of claims 1 or 2, wherein a coating material is provided on a portion of the interior surface of the barrel to form the region of reduced diameter;

optionally wherein one of:

the coating material comprises at least one member selected from the group consisting of fluorinated ethylene propylene, expanded fluorinated ethylene propylene, epoxy resins and acrylics;

at least one rib is in contact with the coating material when the syringe is in the undepressed state;

the coating material further comprises an oxygen-absorbing material, an oxygen-adsorbing material, or a combination thereof.

4. The medical delivery device of any one of claims 1-3, wherein the elastomeric stopper is at least partially covered with an expanded polytetrafluoroethylene membrane or a densified expanded polytetrafluoroethylene membrane.

5. The medical delivery device of any one of claims 1-4, wherein at least one of:

said at least one therapeutic is selected from DNA fragments of Target genes or DNA Target receptors genes of a group consisting of genes Coagulation Factors, Cytokines, Epigenetic protein families, Growth Factors, Hormones, Peptides, Signal Transduction molecules, Vaccines, and combinations thereof;

said at least one therapeutic is selected from mutations of DNA fragments of Target genes or DNA Target receptors genes;

the therapeutic is factor VII;

the medical delivery device is configured to be used for treatment of ocular disease;

the medical delivery device is a syringe, an auto-injector, or a pen.