DRUG DELIVERY DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the priority of U.S. Provisional Application No. 62/908,504, filed September 30, 2019, entitled, "Drug Delivery Device," U.S. Provisional Application No. 62/961,006, filed January 14, 2020, entitled, "Drug Delivery Device," and U.S. Provisional Application No. 62/961,014, filed January 14, 2020, entitled, "Drug Delivery Device," each of which is incorporated by reference.

FIELD OF DISCLOSURE

[0002] The present disclosure relates to drug delivery devices, and, more particularly, devices for automatically injecting a drug into a patient.

BACKGROUND

[0003] A general aversion to exposed needles, as well as health and safety issues, have led to the development of drug delivery devices which conceal a needle or other insertion member prior to use and which automate various aspects of an injection process. Such devices offer a variety of benefits as compared with traditional forms of drug delivery including, for example, delivery via a conventional syringe.

[0004] Many injector systems use coil and other spring structures to provide actuation energy for functions such as needle insertion and/or fluid delivery. The use of springs can offer benefits of simplicity and low cost, but it may have certain limitations. For example, there is a linear relationship between force and displacement in spring actuators. To provide sufficient energy for drug delivery at the end of plunger stroke, an excessive amount of energy may be input to the system as drug delivery commences. As another example, as higher viscosity drugs are delivered via autoinjectors, the requisite spring forces will likely increase. Springs with higher spring constants may transmit more force to the drug product and primary container. Because kinetic energy is proportional to velocity squared, even incremental increases in the spring constant can result in large changes in the net kinetic energy applied to the drug and primary container. Forces generated by excessive energy can cause catastrophic effects, such as damage or breakage of the primary container and drug product. Accordingly, it may be desirable or advantageous to provide a drug delivery device that can maintain the intended spring force load while reducing such undesirable effects.

[0005] Although autoinjectors may offer these operational differences over a non-automatic drug delivery device, such as a traditional syringe, autoinjectors may still utilize the same or a similar primary container as a syringe. For example, autoinjectors may include a syringe, a syringe barrel, and/or other syringe components to serve as the drug storage container component(s). As a result, it may be desirable or advantageous for the remaining components of the autoinjector to be compatible with the syringe component(s), both during assembly and during operation of the device.

[0006] The present disclosure sets forth drug delivery devices embodying advantageous alternatives to existing drug delivery devices, and that may address one or more of the challenges or needs mentioned herein.

SUMMARY

[0007] According to a first aspect of the present disclosure, there is provided a drug delivery device including a housing defining a longitudinal axis and having an opening and a drug storage container having a body portion with a proximal end and a distal end and a delivery member extending from the distal end of the body portion. The device may further include a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member and a plunger biasing member configured to urge the plunger toward the distal end of the drug storage container. The device may also include a container holder configured to support the drug storage container with respect to the housing such that a resultant force acting on the drug storage container from the plunger biasing member is at least substantially borne by the distal end of the body portion of the drug storage container. The device also includes a plunger guide configured to receive at least a

portion of the plunger biasing member, the plunger guide including a flexible arm configured to support the proximal end of the body portion of the drug storage container.

[0008] The container holder may support the drug storage container with respect to the housing such that a resultant force acting on the drug storage container from the plunger biasing member is at least substantially completely borne by the distal end of the body portion of the drug storage container. For example, the container holder may support the drug storage container with

respect to the housing adjacent to (e.g., proximal to) at least a portion of the distal end of the body portion of the drug storage container such that a resultant force acting on the drug storage container from the plunger biasing member is at least substantially completely borne by the distal end of the body portion of the drug storage container.

[0009] The container holder may include at least two inwardly protruding flanges configured to receive the distal end of the drug storage container body portion. The flanges may be separated from each other by at least two gaps.

[0010] The container holder may include a resilient portion configured to absorb at least a portion of the resultant force. The resilient portion may include an elastomer component. Additionally or alternatively, the resilient portion may include at least two inwardly protruding flanges configured to receive the distal end of the drug storage container body portion.

[0011] The container holder may be positioned within the housing and coupled with the housing such as to substantially prevent relative movement between the container holder and the housing. The housing may include an inner surface defining at least two slots and the container holder may be coupled with the housing by the slots. The container holder may include at least two or four lock ridges configured to be received within the slots and the housing inner surface may define at least two or four slots for receiving the lock ridges.

[0012] The container holder may be defined by features of the housing and configured to substantially prevent relative movement between the drug storage container and the housing.

[0013] The drug storage container may include at least one outwardly protruding flange at the proximal end of the body portion and the drug storage container may be coupled with the container holder such that the resultant force acting on the drug storage container is not significantly borne by the at least one outwardly protruding flange. The container holder may define at least one opening configured to receive the at least one outwardly protruding flange.

[0014] The device may include a flexible arm configured to support the proximal end of the drug storage container body portion. For example, the device may include a plunger guide configured to receive at least a portion of the plunger biasing member, where the plunger guide includes a proximal end coupled with the housing and a distal end configured to abut the container holder. The plunger guide may define the flexible arm.

[0015] The container holder may include an open position for receiving the drug storage container and a closed position for securing the drug storage container. The container holder may include at least two arms configured to be selectively secured with each other.

[0016] The container holder may include at least one arm movable between an open position and a closed position.

[0017] The container holder may include at least two arms movable with respect to each other between the open position and the closed position. The arms may extend generally along the longitudinal axis. The container holder may further include an annular ring supporting the at least two arms. The annular ring may be adjacent to a distal portion of the container holder and the at least two arms may extend proximally along the longitudinal axis.

[0018] The container holder may include at least one or at least two locking components configured to secure the container holder in the closed position. The at least two locking components may each include a pair of mating connectors configured to secure the container holder in the closed position. The container holder may include at least two inwardly protruding flanges configured to receive a distal end of the drug storage container. The container holder may include at least two proximal inwardly protruding flanges configured to define a proximal opening for receiving the drug storage container when the container holder is in the open position.

[0019] According to a second aspect of the present disclosure, there is provided a drug delivery device including a housing defining a longitudinal axis and having an opening and a drug storage container having a body portion with a proximal end and a distal end and a delivery member extending from the distal end of the body portion. The device may further include a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member and a plunger biasing member configured to urge the plunger toward the distal end of the drug storage container. The device may also include

a container holder configured to substantially support the drug storage container with respect to the housing by the distal end of the body portion of the drug storage container. The device also includes a plunger guide configured to receive at least a portion of the plunger biasing member, the plunger guide including a flexible arm configured to support the proximal end of the body portion of the drug storage container.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the drawings may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some drawings are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. Also, none of the drawings is necessarily to scale.

[0021] Fig. 1A is a perspective view of an exemplary drug delivery device in accordance with various embodiments;

[0022] Fig. 1B is a perspective view of the drug delivery device in Fig. 1A, with a cap removed therefrom;

[0023] Fig. 1C is a perspective view of the drug delivery device in Fig. 1A, in a pre-injection configuration;

[0024] Fig. 1D is a perspective view of the drug delivery device in Fig. 1A, in an injection configuration;

[0025] Fig. 2 is cross-sectional view of the drug delivery device in Fig. 1;

[0026] Fig. 3A is an exploded assembly view of a portion, namely the drive mechanism, of the drug delivery device in Fig. 2;

[0027] Fig. 3B is an exploded assembly view of the drug delivery device in Fig. 2;

[0028] Fig. 4A is a perspective view of an exemplary drug storage container for use with a drug delivery device in accordance with various embodiments;

[0029] Fig. 4B is a perspective view of an exemplary container holder for use with a drug delivery device in accordance with various embodiments, where the container holder is in an open position;

[0030] Fig. 4C is a perspective view of the container holder in Fig. 4B coupled with the drug storage container in Fig. 4A, where the container holder is in a closed position;

[0031] Fig. 4D is a perspective view of an exemplary container holder for use with a drug delivery device in accordance with various embodiments, where the container holder is in a closed position;

[0032] Fig. 4E is a perspective view of an exemplary housing for use with a drug delivery device in accordance with various embodiments;

[0033] Fig. 4F is a partial cross-sectional view of the container holder and the drug storage container, taken around line 4F-4F in Fig. 4C;

[0034] Fig. 5A is a partial cross-sectional view of the container holder, the drug storage container, taken around line 5A-5A in Fig. 4C, as well as a partial cross-sectional view of a distal portion of an exemplary plunger guide coupled with the container holder and the drug storage container;

[0035] Fig. 5B is a perspective view of an exemplary plunger guide in accordance with various embodiments;

[0036] Fig. 5C is a perspective, partial cross-sectional view of the plunger guide in Fig. 5B;

[0037] Fig. 6A is a perspective view of an exemplary guard member in accordance with various embodiments;

[0038] Fig. 6B is a perspective view of an exemplary guard extension in accordance with various embodiments;

[0039] Fig. 6C is a perspective, partial cross-sectional, view of the guard extension, the releaser, and the plunger guide, wherein the components are in a pre-injection position;

[0040] Fig. 7A is a perspective view of an exemplary releaser member in accordance with various embodiments;

[0041] Fig. 7B is another perspective view of the releaser member in Fig. 7A;

[0042] Fig. 8 is a perspective view of the plunger guide from Fig. 5B, the releaser member from Fig. 7A, and the plunger 26 shown in Fig. 2, wherein the guide member is shown in translucent form for illustrative purposes;

What is claimed is:

1. A drug delivery device comprising:

a housing defining a longitudinal axis and having an opening;

a drug storage container having a body portion with a proximal end and a distal end and a delivery member extending from the distal end of the body portion;

a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member;

a plunger biasing member configured to urge the plunger toward the distal end of the drug storage container;

a container holder configured to support the drug storage container with respect to the housing such that a resultant force acting on the drug storage container from the plunger biasing member is at least substantially borne by the distal end of the body portion of the drug storage container, and

a plunger guide configured to receive at least a portion of the plunger biasing member, the plunger guide including a flexible arm configured to support the proximal end of the body portion of the drug storage container.

2. The drug delivery device of claim 1, wherein the distal end of the body portion of the drug storage container includes an end surface, the delivery member extends from the end surface, and the container holder is configured to support the drug storage container with respect to the housing adjacent to the end surface.

3. The drug delivery device of any of claims 1 or 2, wherein the container holder includes at least two inwardly protruding flanges configured to receive the distal end of the drug storage container body portion.

4. The drug delivery device of claim 3, wherein the at least two inwardly protruding flanges are separated from each other by at least two gaps.

5. The drug delivery device of any of claims 2 through 4, wherein the container holder includes a resilient portion configured to absorb at least a portion of the resultant force.

6. The drug delivery device of claim 5, wherein the resilient portion includes an elastomer component.

7. The drug delivery device of claim 6, wherein the resilient portion includes at least two inwardly protruding flanges configured to receive the distal end of the drug storage container body portion.

8. The drug delivery device of any of claims 1 or 2, wherein the container holder is positioned within the housing and coupled with the housing such as to substantially prevent relative movement between the container holder and the housing.

9. The drug delivery device of claim 8, wherein the housing includes an inner surface defining at least two slots and the container holder is coupled with the housing by the slots.

10. The drug delivery device of claim 9, wherein the container holder includes at least two lock ridges configured to be received within the slots.

11. The drug delivery device of claim 8, wherein the housing includes an inner surface defining at least four slots and the container holder is coupled with the housing by the slots.

12. The drug delivery device of claim 11, wherein the container holder includes at least four lock ridges configured to be received within the slots.

13. The drug delivery device of any of claims 1 or 2, wherein the container holder is defined by features of the housing and configured to substantially prevent relative movement between the drug storage container and the housing.

14. The drug delivery device of claim 13, wherein the housing includes an inner surface defining at least two inwardly protruding flanges configured to receive the distal end of the drug storage container body portion.

15. The drug delivery device of any of claims 1 through 14, wherein the drug storage container includes at least one outwardly protruding flange at the proximal end of the body portion, and wherein the drug storage container is coupled with the container holder such that the resultant force acting on the drug storage container is not significantly borne by the at least one outwardly protruding flange.

16. The drug delivery device of claim 15, wherein the container holder defines at least one opening configured to receive the at least one outwardly protruding flange.

17. The drug delivery device of any of claims 1 through 16, wherein the container holder includes a flexible arm configured to support the proximal end of the drug storage container body portion.

18. The drug delivery device of any of claims 1 through 17, wherein the plunger guide including a proximal end coupled with the housing and a distal end configured to abut the container holder.

19. The drug delivery device of any of claims 1 through 18, wherein the container holder includes at least two arms configured to be selectively secured with each other.

20. The drug delivery device of any of claims 1 through 19, wherein the container holder includes an open position for receiving the drug storage container and a closed position for securing the drug storage container.

21. The drug delivery device of any of claims 1 through 19, wherein the container holder includes at least one arm movable between an open position and a closed position.

22. The drug delivery device of any of claims 20 or 21, wherein the container holder includes at least two arms movable with respect to each other between the open position and the closed position.

23. The drug delivery device of claim 22, wherein the at least two arms extend generally along the longitudinal axis.

24. The drug delivery device of claim 23, wherein the container holder further includes an annular ring supporting the at least two arms.

25. The drug delivery device of claim 24, wherein the annular ring is adjacent to a distal portion of the container holder and the at least two arms extend proximally along the longitudinal axis.

26. The drug delivery device of any of claims 20 through 25, wherein the container holder includes at least one locking component configured to secure the container holder in the closed position.

27. The drug delivery device of claim 26, wherein the container holder includes at least two locking components configured to secure the container holder in the closed position.

28. The drug delivery device of claim 27, wherein the at least two locking components each include a pair of mating connectors configured to secure the container holder in the closed position.

29. The drug delivery device of any of claims 20 through 28, wherein the container holder includes at least two inwardly protruding flanges configured to receive a distal end of the drug storage container.

30. The drug delivery device of any of claims 20 through 29, wherein the container holder includes at least two proximal inwardly protruding flanges configured to define a proximal opening for receiving the drug storage container when the container holder is in the open position.

31. A drug delivery device comprising:

a housing defining a longitudinal axis and having an opening;

a drug storage container having a body portion with a proximal end and a distal end and a delivery member extending from the distal end of the body portion;

a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member;

a plunger biasing member configured to urge the plunger toward the distal end of the drug storage container;

a container holder configured to substantially support the drug storage container with respect to the housing by the distal end of the body portion of the drug storage container; and

a plunger guide configured to receive at least a portion of the plunger biasing member, the plunger guide including a flexible arm configured to support the proximal end of the body portion of the drug storage container.

32. The drug delivery device of claim 1, wherein the container holder is configured to support the drug storage container with respect to the housing such that a resultant force acting on the drug storage container from the plunger biasing member is completely borne by the distal end of the body portion of the drug storage container.

33. The drug delivery device of claim 31, wherein the container holder is configured to completely support the drug storage container with respect to the housing by the distal end of the body portion of the drug storage container.

34. The drug delivery device of claim 1, wherein the drug storage container is filled or pre-filled with the drug, and wherein the drug comprises one of: a drug containing a human IgG1 kappa antibody, a drug containing a small interfering RNA

(siRNA) that lowers lipoprotein(a), a drug containing erenumab, etanercept, Tezepelumab, efavaleukin alfa, evolocumab, and a drug containing a gastric inhibitory polypeptide receptor (GIPR) antagonist and a GLP-1R agonist.

35. The drug delivery device of claim 31, wherein the drug storage container is filled or pre-filled with the drug, and wherein the drug comprises one of: a drug containing a human IgG1 kappa antibody, a drug containing a small interfering RNA (siRNA) that lowers lipoprotein(a), a drug containing erenumab, etanercept, Tezepelumab, efavaleukin alfa, evolocumab, and a drug containing a gastric inhibitory polypeptide receptor (GIPR) antagonist and a GLP-1R agonist.