STORAGE SYSTEM AND METHOD FOR STORING AND TRANSPORTING MEDICAMENT

CROSS-REFERENCE TO RELATED APPLICATION

[0001] Priority is claimed to U.S. Provisional Patent Application No. 63/028,875, filed May 22, 2020, the entire contents of which are hereby incorporated herein by reference.

FIELD OF DISCLOSURE

[0002] The present disclosure generally relates to drug products and, more particularly, to packaging, storing, and transporting approaches for medicament.

BACKGROUND

[0003] Medicaments (also referred to as drugs or pharmaceutical drugs) are administered to treat a variety of conditions and diseases. Many drugs must be kept cold (e.g., at temperatures between approximately 2°C and approximately 8°C), frozen, and/or lyophilized (e.g., at temperatures below approximately -20°C) prior to use to ensure effectiveness of the drug upon administration. Accordingly, these drugs often must remain cold during transportation and distribution. In some environments, drugs may be transported via air freight. Such shipments typically include a passive container cooled by a passive cooling element such as dry ice. Because air freight typically involves relatively smaller volumes of cargo, these shipment systems typically may be loaded and unloaded relatively quickly. Accordingly, the drug may not be exposed to warmer environments such as warehouses where the drug does not receive cooling for extended periods. Accordingly, so long as the passive container is used within the qualified duration of use, the drug may be safely stored and/or transported. However, shipping via air freight may result in increased shipping costs and may not be suitable for larger freight sizes. As another example, shipping via air freight may be difficult to schedule during times of high-demand for flight cargo space. Further, in some scenarios, air freight may involve delays during the loading and/or unloading stages in addition to flight delays, such delays may extend longer than the duration that the passive cooling element may be capable of maintaining reduced temperatures of the drug, and as a result, the drug may be exposed to potentially damaging temperatures.

[0004] In other environments, drugs may be transported via ocean freight shipments, where a large quantity of product is placed in a reefer (i.e., refrigerated) containers. These reefer containers may be cooled via active cooling systems that maintain the interior volume of the container at a desired temperature level. Such active cooling systems are typically electrically powered. During the packaging and transporting process, the reefer containers may undergo transition periods when an electrical source is disconnected and/or unavailable. For example, this may occur during packaging, palletizing, labeling, loading, and/or unloading of the reefer container. In these instances, the drug may again be exposed to environmental temperatures where the drug may be at risk of warming to potentially hazardous levels. Further, during shipping, the reefer container may experience an unplanned, unscheduled, or last minute “power off” situation where the active cooling system does not maintain temperatures within the interior volume due to, for example, a loss of electrical power. These situations may also lead to the drug experiencing potentially hazardous environmental temperatures.

[0005] As described in more detail below, the present disclosure sets forth systems and methods for storage of drugs embodying advantageous alternatives to existing systems and methods, and that may address one or more of the challenges or needs mentioned herein, as well as provide other benefits and advantages.

SUMMARY

[0006] In one aspect, the present disclosure provides a storage system for storing a drug, the storage system comprising: a container including an interior volume to accommodate at least one drug; at least one passive cooling system disposed within the container, the at least one passive cooling system including a phase change material; and an active cooling system operably

coupled with the container and, when in an operational mode, adapted to maintain a desired temperature within the interior volume of the container.

[0006a] In another aspect, the present disclosure provides a method of shipping a drug, the method comprising: disposing at least one passive cooling system in a container having an interior volume, the at least one passive cooling system including a phase change material; placing the drug in the interior volume of the container; coupling an active cooling system with the container; and transporting the shipping container to a different location.

[0006b] In accordance with a first ~~aspect~~example, a storage system for storing a drug includes a container, at least one passive cooling system, and an active cooling system. The container includes an interior volume to accommodate at least one drug. The at least one passive cooling system is disposed within the container and includes a phase change material. The active cooling system is

operably coupled with the container and, when in an operational mode, maintains a desired temperature within the interior volume of the container.

[0007] In some examples, the phase change material is transitionable between a solid state and a liquid state. In these examples, the phase change material is configured in the solid state prior to placing the at least one drug within the interior volume of the container.

[0008] In some examples, the storage system may additionally include at least one drug container disposed within the interior volume of the container. The at least one drug container is dimensioned to store the at least one drug. Further, in some examples, the at least one drug container may include a number of sidewalls, an upper surface, and a lower surface. The at least one passive cooling system may be operably coupled with at least one of the plurality of sidewalls, the upper surface, or the lower surface. In some examples, the at least one passive cooling system is removably disposed within an opening formed in the at least one drug container. In other forms, the at least one passive cooling system is removably disposed within a pocket formed in the at least one drug container. The pocket may be on an interior and/or an exterior surface of the at least one drug container.

[0009] In some examples, the at least one drug container may further include at least one of an expanded polystyrene member or a molded polyurethane member. In some examples, the storage system may transition to a passive cooling state where the at least one passive cooling system maintains a desired temperature within the interior volume of the container. Further in some examples, the storage system may include an electrical connector operably coupled with the active cooling system to provide electrical power thereto.

[0010] In accordance with a second ~~aspect~~example, an approach for shipping a drug includes disposing at least one passive cooling system in a container having an interior volume, placing the drug in the interior volume of the container, coupling an active cooling system with the container, and transporting the container to a different location. The at least one passive cooling system includes a phase change material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The above needs are at least partially met through provision of the packaging and storage for a drug described in the following detailed description, particularly when studied in conjunction with the drawings, wherein:

[0012] Fig. 1 illustrates a schematic of an example storage system for a drug having an example drug container in accordance with various embodiments;

[0013] Fig. 2 illustrates a perspective view of the example drug container of Fig. 1 in accordance with various embodiments;

[0014] Fig. 3 illustrates a schematic of the example drug container of Figs. 1 and 2 accommodating additional passive cooling systems in accordance with various embodiments;

[0015] Fig. 4 illustrates a perspective view of the example drug container of Fig. 3 in accordance with various embodiments;

[0016] Fig. 5 illustrates a schematic of a second example storage system for a drug having an example drug container in accordance with various embodiments; and

[0017] Fig. 6 illustrates a graph depicting surface temperatures of a drug being stored in an example drug container over time in accordance with various embodiments.

[0018] Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions and/or relative positioning of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of various embodiments of the present invention. Also, common but well-understood elements that are useful or necessary in a commercially feasible embodiment are often not depicted in order to facilitate a less obstructed view of these various embodiments. It will further be appreciated that

What is claimed is:

1. A storage system for storing a drug, the storage system comprising:

a container including an interior volume to accommodate at least one drug;

at least one passive cooling system disposed within the container, the at least one passive cooling system including a phase change material; and

an active cooling system operably coupled with the container and, when in an operational mode, adapted to maintain a desired temperature within the interior volume of the container;

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2. The storage system of claim 1, wherein the phase change material is transitionable between a solid state and a liquid state.

3. The storage system of claim 2, wherein the phase change material is configured in the solid state prior to placing the at least one drug within the interior volume of the container.

4. The storage system of any one of claims 1-3, further comprising at least one drug container adapted to be disposed within the interior volume of the container, the at least one drug container being dimensioned to store the at least one drug.

5. The storage system of claim 4, wherein the at least one drug container includes a plurality of sidewalls, an upper surface, and a lower surface, wherein the at least one passive cooling system is operably coupled with at least one of the plurality of sidewalls, the upper surface, or the lower surface.

6. The storage system of claim 5, wherein the at least one passive cooling system is removably disposed within an opening formed in the at least one drug container.

7. The storage system of claim 5, wherein the at least one passive cooling system is removably disposed within a pocket formed in the at least one drug container.

8. The storage system of claim 7, wherein the pocket is formed on at least one of an interior surface of the at least one drug container or an exterior surface of the at least one drug container.

9. The storage system of any one of claims 5-8, wherein the at least one drug container further includes at least one of an expanded polystyrene member or a molded polyurethane member.

10. The storage system of any one of claims 1-9, wherein the storage system is further configured to transition to a passive cooling state whereby the at least one passive cooling system maintains a desired temperature within the interior volume of the container.

11. The storage system of any one of claims 1-10, further including an electrical connector operably coupled with the active cooling system to provide electrical power thereto.

12. A method of shipping a drug, the method comprising:

disposing at least one passive cooling system in a container having an interior volume, the at least one passive cooling system including a phase change material;

placing the drug in the interior volume of the container;

coupling an active cooling system with the container; and

transporting the shipping container to a different location.

13. The method of claim 12, wherein the phase change material is transitionable between a solid state and a liquid state.

14. The method of claim 13, wherein the phase change material is configured in the solid state prior to placing the at least one drug within the interior volume of the container.

15. The method of any one of claims 12-14, further comprising cooling, via the active cooling system, the container prior to placing the drug into the interior volume thereof.

16. The method of any one of claims 12-15, further comprising disposing at least one drug container within the interior volume of the container, the at least one drug container being dimensioned to store the at least one drug.

17. The method of claim 16, wherein the at least one drug container includes a plurality of sidewalls, an upper surface, and a lower surface, wherein the at least one passive cooling system is coupled with at least one of the plurality of sidewalls, the upper surface, or the lower surface.

18. The method of claim 17, wherein the step of coupling at least one passive cooling system with the at least one drug container includes removably disposing the at least one passive cooling system within an opening formed in the at least one drug container.

19. The method of claim 17, wherein the step of coupling at least one passive cooling system with the at least one drug container includes removably disposing the at least one passive cooling system within a pocket formed in the at least one drug container.

20. The method of claim 19, wherein the pocket is formed on at least one of an interior surface of the at least one drug container or an exterior surface of the at least one drug container.

21. The method of any one of claims 16-20, further including disposing at least one of an expanded polystyrene member or a molded polyurethane member in the at least one drug container.

22. The method of any one of claims 16-21, further comprising transitioning to a passive cooling state whereby the at least one passive cooling system maintains a desired temperature within the interior volume of the container.

23. The storage system of claim 1, further comprising the at least one drug in the interior volume of the container, wherein optionally the at least one drug comprises a drug product which has undergone completion of mixing and/or other finishing steps or a drug substance which is intended to be mixed and/or finished after shipping.

24. The method of claim 12, wherein placing the drug in the interior volume of the container comprises placing a drug in the interior volume of the container, wherein optionally the drug comprises a drug product which has undergone completion of mixing and/or other finishing steps or a drug substance which is intended to be mixed and/or finished after shipping.