DUAL CAP SYSTEM FOR CONTAINER-CLOSURES TO MAINTAIN TIP STERILITY DURING SHELF STORAGE

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RELATED APPLICATION

This application claims the benefit of U.S. Provisional application serial number 61/675,909, filed July 26, 2012, the disclosures of which are hereby incorporated in their entirety herein by reference.

SUMMARY

Embodiments of the disclosure are directed to container-closure systems and drug delivery systems that include a vented cap and an over cap.

In one aspect, there is provided an apparatus for dispensing a therapeutic liquid, comprising:

a container configured to hold the therapeutic liquid and having a dispensing tip configured to dispense a dose of the therapeutic liquid;

a vented cap configured to fit over at least a portion of the container including the dispensing tip and having one or more vents that allow air to pass into and out of a cavity defined between the vented cap and the dispensing tip;

a second cap configured to fit over at least a portion of the vented cap; and

a tamper evident seal coupled to the second cap and one or both of the container and the vented cap.

According to some embodiments, a container-closure system includes a container configured to hold a therapeutic liquid and having a dispensing tip configured to dispense a dose of the therapeutic liquid. A vented cap is configured to fit over at least a portion of the container including the dispensing tip and having one or more vents that allow air to pass into and out of a cavity defined between the vented cap and the dispensing tip. A second cap is configured to fit over at least a portion of the vented cap. A tamper evident seal is coupled to the second cap and one or both of the container and the vented cap.

According to various ~~aspects~~embodiments, the container is configured to dispense a plurality of single doses of the therapeutic liquid in the form of an

ophthalmic solution, emulsion or suspension. In some embodiments, the therapeutic agent is selected from the group consisting of bimatoprost, brimonidine, timolol, cyclosporine, gatifloxacin, ocufloxacin, prednisolone, carnitine and ketorolac. In some cases, one or more vents in the vented cap are configured to allow passage of air into and out of the cavity sufficient to accelerate drying of residual therapeutic liquid at the dispensing tip of the container after dispensing the therapeutic liquid dose.

In some cases, the second cap is configured to be twisted and removed from the apparatus, and the tamper evident seal is configured to break in response to the twisting of the second cap. According to various implementations, the vented cap and the second cap define an integral structure, and the tamper evident seal is configured to

break away from the second cap. In accordance with some embodiments, the vented cap, the second cap, and the tamper evident seal define an integral structure, and the tamper evident seal is configured to break away from the vented cap and the second cap. According to some ~~aspects~~embodiments, the second cap defines a second vented cap, and twisting the second vented cap relative to the container causes vents of the vented cap and the second vented cap to overlap.

According to some implementations, the vented cap comprises a protrusion arranged on the vented cap to establish contact with the dispensing tip of the container when the vented cap is fitted on the container. In some cases, the protrusion is configured to seal the dispensing tip of the container when the vented cap is fitted on the container.

According to various implementations, the second cap comprises a desiccant system. In some cases, one or both of the dispensing tip of the container and the vented cap comprise an antimicrobial. In accordance with various embodiments, the therapeutic liquid is a preservative-free therapeutic liquid. In some cases, the container comprises a uni-directional valve situated at the dispensing tip and configured to prevent fluid return into the container. According to some embodiments, the uni-directional valve is configured to prevent contamination of the therapeutic liquid from a source external to the container. In some cases, the container and the dispensing tip are formed of one or more polymers selected from the group consisting of low-density polyethylene, high-density polyethylene, and high-impact polystyrene.

In one aspect, there is provided a method, comprising:

storing a therapeutic liquid in a reservoir of a container configured to hold the therapeutic liquid, the container comprising:

a dispensing tip configured to dispense a dose of the therapeutic liquid;

a vented cap configured to fit over at least a portion of the container including the dispensing tip and having one or more vents that allow air to pass into and out of a cavity defined between the vented cap and the dispensing tip;

a second cap configured to fit over at least a portion of the vented cap; and

a tamper evident seal coupled to the second cap and one or both of the container and the vented cap.

According to further embodiments, a method involves storing a therapeutic liquid in a reservoir of a container configured to hold the therapeutic liquid. The container comprises a dispensing tip configured to dispense a dose of the therapeutic liquid. A vented cap is configured to fit over at least a portion of the container including the dispensing tip and having one or more vents that allow air to pass into and out of a cavity defined between the vented cap and the dispensing tip. A second cap is configured to fit over at least a portion of the vented cap. A tamper evident seal is coupled to the second cap and one or both of the container and the vented cap. In some embodiments, the container is configured to dispense a plurality of single doses of the therapeutic liquid in the form of an ophthalmic solution, emulsion or suspension.

In one aspect, there is provided a method, comprising:

removing a cap from a container configured a hold the therapeutic liquid, the container comprising a dispensing tip configured to dispense a dose of the therapeutic liquid, the cap comprising:

a vented cap configured to fit over at least a portion of the container including the dispensing tip and having one or more vents that allow air to pass into and out of a cavity defined between the vented cap and the dispensing tip; and

a second cap configured to fit over at least a portion of the vented cap; and

dispensing the therapeutic liquid from the container.