[05] The syringe may be pre-filled with the medicament during manufacture. Pre-filled syringes are advantageous with respect to safety, accurate dosing and simplicity of use.

[06] Some medicaments exhibit low stability in liquid form. Desiccating these medicaments, as by lyophilization, yields a dry form with higher stability. Syringes manufactured containing such dry medicament and in which the liquid injectable form can be timely reconstituted for delivery, combine the advantages of pre-filled syringes with enhanced shelf-life.

[07] To obtain the dry form of medicament *in situ* within the syringe or within a syringe part (such as a tube), a medicament-containing interior of the syringe or of the syringe part is exposed to a desiccation process. Typically, the desiccation process proceeds within a setting (for example, a closed chamber) in which temperature and pressure are carefully regulated. Manufacturing syringes pre-filled with desiccated medicament is complicated by re-exposure of the medicament to airborne humidity following the desiccation process and prior to the interior being sealed off from surroundings outside the regulated setting.

[08] It would be desirable, therefore, to provide apparatus and methods for reducing the exposure to humidity of medicament desiccated within a syringe or within a syringe part.

SUMMARY OF INVENTION

[08a] An aspect of the present invention provides a stopper for a medicament delivery device, the stopper comprising:

a resilient material;

a sealing base for sealing an opening of the device, the base having a central axis; and

a plurality of elongated members extending away from the base in a direction parallel to the axis, the members set radially away from the axis and defining:

a portion of a central well coaxial with the axis, the well tapering continuously toward the base; and,

between circumferentially adjacent members, a void defined by adjacent surfaces of the members exterior to the stopper merging, adjacent surfaces of the members interior to the stopper merging to form part of a webbing surface of the well, the void partitioned from the well;

wherein:

in a first operational configuration, the elongated members engage an inner wall of the device to support the base away from the opening such that the void provides exchange of gas between an interior and an exterior of the device; and,

in a second operational configuration, the base engages the inner wall to seal the opening.

[08b] Another aspect of the present invention provides a stopper for a medicament delivery device, the stopper comprising:

a resilient material;

a sealing base for sealing an opening of the device, the base having a central axis; and

an elongated member extending away from the base in a direction parallel to the axis, the member set radially away from the axis and defining:

a portion of a central well coaxial with the axis, the well tapering continuously toward the base; and

a void extending in a circumferential direction between adjacent portions of the member, the portions merging and partitioning the void from the well;

wherein:

in a first operational configuration, the elongated member engages an inner wall of the device to support the base away from the opening such that the void provides exchange of gas between an interior and an exterior of the device; and

in a second operational configuration, the base engages the inner wall to seal the opening.

BRIEF DESCRIPTION OF THE DRAWINGS

[09] FIG. 1 is a perspective view of apparatus in accordance with the principles of the invention;

WHAT IS CLAIMED IS:

1. A stopper for a medicament delivery device, the stopper comprising:

a resilient material;

a sealing base for sealing an opening of the device, the base having a central axis; and

a plurality of elongated members extending away from the base in a direction parallel to the axis, the members set radially away from the axis and defining:

a portion of a central well coaxial with the axis, the well tapering continuously toward the base; and,

between circumferentially adjacent members, a void defined by adjacent surfaces of the members exterior to the stopper merging, adjacent surfaces of the members interior to the stopper merging to form part of a webbing surface of the well, the void partitioned from the well;

wherein:

in a first operational configuration, the elongated members engage an inner wall of the device to support the base away from the opening such that the void provides exchange of gas between an interior and an exterior of the device; and,

in a second operational configuration, the base engages the inner wall to seal the opening.

2. The stopper of claim 1 further comprising a flange orthogonal to the axis.

3. The stopper of claim 2 wherein the flange is configured to abut, in the second operational configuration,

a terminal surface of the device, the terminal surface surrounding the opening.

4. The stopper of claim 3 wherein the base comprises the flange.

5. The stopper of claim 1 wherein the resilient material bears a lubricious coating.

6. The stopper of claim 1 wherein the resilient material is penetrable by a needle and self-sealing around an outer wall of the needle.

7. The stopper of claim 6 wherein, in the second operational configuration, the needle extends from the exterior of the device through the base into the central well.

8. The stopper of claim 1 wherein the base comprises a peripheral ridge configured to sealingly engage the inner wall of the device.

9. The stopper of claim 1 wherein, in the first operational configuration, the gas comprises a lyophilization byproduct.

10. The stopper of claim 9 wherein, in the second operational configuration, the stopper seals a lyophilized product within the device between the stopper and a plunger that is sealingly engaged with the inner wall of the device.

11. A method of lyophilizing and sealing a medicament within a medical delivery device using a stopper according to any one of the preceding claims, the method comprising:

placing the medicament into the device;

through an opening of the device, engaging an inner wall of the device with the plurality of resilient elongated members that are fixed to the sealing base;

advancing the members relative to the opening until the base is set apart from the opening by a predetermined offset, the base held in place relative to the device only by the members;

lyophilizing the medicament to produce a vapor that escapes between the inner wall, the members and the base through the voids; and,

then, further advancing the members until the base seals against the inner wall.

12. A stopper for a medicament delivery device, the stopper comprising:

a resilient material;

a sealing base for sealing an opening of the device, the base having a central axis; and

an elongated member extending away from the base in a direction parallel to the axis, the member set radially away from the axis and defining:

a portion of a central well coaxial with the axis, the well tapering continuously toward the base; and

a void extending in a circumferential direction between adjacent portions of the member, the portions merging and partitioning the void from the well;

wherein:

in a first operational configuration, the elongated member engages an inner wall of the device to support the base away from the opening such that the void provides exchange of gas between an interior and an exterior of the device; and

in a second operational configuration, the base engages the inner wall to seal the opening.

13. The stopper of claim 12 further comprising a flange orthogonal to the axis.

14. The stopper of claim 13 wherein the flange is configured to abut, in the second operational configuration, a terminal surface of the device, the terminal surface surrounding the opening.

15. The stopper of claim 14 wherein the base comprises the flange.

16. The stopper of claim 12 wherein the resilient material bears a lubricious coating.

17. The stopper of claim 12 wherein the resilient material is penetrable by a needle and self-sealing around an outer wall of the needle.

18. The stopper of claim 17 wherein, in the second operational configuration, the needle extends from the exterior of the device through the base into the central well.

19. The stopper of claim 12 wherein the base comprises a peripheral ridge configured to sealingly engage the inner wall of the device.

20. The stopper of claim 12 wherein, in the first operational configuration, the gas comprises a lyophilization byproduct.

21. The stopper of claim 20 wherein, in the second operational configuration, the stopper seals a lyophilized product within the device between the stopper and a plunger that is sealingly engaged with the inner wall of the device.

22. A method of lyophilizing and sealing a medicament within a medical delivery device using a stopper according to any one of the claims 12 to 21, the method comprising:

placing the medicament into the device;

through an opening of the device, engaging an inner wall of the device with the resilient elongated member that is fixed to the sealing base;

advancing the member relative to the opening until the base is set apart from the opening by a predetermined offset, the base held in place relative to the device only by the member;

lyophilizing the medicament to produce a vapor that escapes between the inner wall, the member and the base through the void; and,

then, further advancing the member until the base seals against the inner wall.