DESCRIPTION

Dry Powder Inhaler

Background of the Invention

Field of the Invention

The field of the invention is inhalers. More specifically, the invention relates to dry powder inhalers for delivering drugs in a finely divided dry powder or fluid form.

Inhalers are used to deliver drugs into a patient's lungs. Typically, an inhaler contains or provides a mixture of drugs and air or propellants. The mixture is delivered via the patient inhaling from a mouthpiece on the inhaler, for treatment of various conditions, for example, bronchial asthma. However, delivery of drugs via inhalation can be used for many other treatments, including those unrelated to lung conditions.

One well known inhaler, described in PCT application No. PCT/US93/09751 contains individual medicine doses stored within a plurality of apertures in a medicine containing cartridge. The cartridge is manually advanced to successive doses by rotating the medicine containing cartridge. However, while the above-described device has met with varying degrees of success, disadvantages still remain in indexing or advancing the cartridge within the inhaler, and in reliably delivering a precise quantity of drug from the cartridge.

U.S. Patent Nos. 5,327,883, and 5,577,497, both incorporated herein by reference, describe an inhaler having a spinning impeller. The motor for spinning the impeller is switched on by a sail-switch. In the above design, the sail switch has a sail or flap which is moved by the flow of air caused by the patient inhaling. The mechanical movement of the flap closes the switch, thereby turning on the motor. The motor spins an impeller within a mixing chamber, resulting in drug/air mixing and drug particle deagglomeration. As the inhaler is substantially flow rate independent, and may be used at very low flow rates, the switch must be very sensitive to air flow. Although the sail-switch has performed well in the past, improvements remain to be made in switch performance.

Inhalers have also used various techniques for storing drugs to be delivered. Some inhalers have used bulk drug storage reservoirs and mechanisms for dividing out individual doses with each use. Other inhalers have used separately packaged drug doses, such as in U.S. Patent Nos. 4,778,054 and 5,327,883. Still, reliable and consistent delivery of doses of dry powder drugs has remained as an elusive objective.

Accordingly, it is an object of the invention to provide an improved inhaler.

Statement Of The Invention

To these ends, the present inhaler includes a housing containing a mixing or aerosolizing chamber. A multi-dosage medicine containing cartridge is advantageously attached on the top of the housing. The cartridge has individual dosages radially spaced apart in a cartridge ring. A lid is advantageously pivotally attached to the housing and is used to index or advance the cartridge ring to a next aperture for delivery of successive drug dosages.

Also to these ends, a dry powder inhaler includes a venturi air passageway contained within an inhaler housing. The venturi air passageway preferably has a tapered inlet section, a throat section, and a tapered outlet section. A pressure switch is advantageously contained within the inhaler housing and actuates a motor which spins an impeller. When a patient inhales from a mouthpiece on the inhaler, a pressure differential develops across the venturi air passageway. When the pressure within the venturi reaches a predetermined value, the motor is turned on by the pressure switch. Accordingly, the inhaler accurately and reliably senses inhalation and switches the motor on.

Other and further objects will appear hereinafter.

Brief Description Of The Drawings

In the drawings, wherein similar reference characters denote similar elements throughout the several views:

Figure 1(a) is a perspective view of the inhaler with the detachable mouthpiece portion removed;

Figure 1(b) is a front perspective view of the detachable mouthpiece used in the inhaler shown in Fig. 1(a);

Figure 1(c) is a perspective view of the back side of the detachable mouthpiece shown in Fig. 1(b);

Figure 2(a) is a perspective view of the inhaler shown in Fig. 1(a) with the lid of the inhaler in the open position, and the mouthpiece covered;

Figure 2(b) is a perspective view of the inhaler shown in Fig. 2(a), wherein the lid is in a partially opened position;

Figure 3 is an exploded perspective view of the inhaler of Figs. 2(a) and 2(b);

Figure 4 is an exploded perspective view of the medicine containing cartridge assembly shown in Fig. 2A;

Figure 4A is a section view of the outer ring of the cartridge shown in Fig. 4;

Figure 4B is an enlarged section view of a single hole in the center ring shown in Fig. 4;

Figure 4C is an enlarged top perspective view of the bottom seal plate shown in Fig. 4;

Figure 4D is a bottom perspective view thereof;

Figure 4E is an enlarged top perspective view of the top seal plate shown in Fig. 4;

Figure 4F is a bottom perspective view thereof;

Figure 4G is an enlarged top perspective view of the bottom spring plate shown in Fig. 4;

Figure 4H is a bottom perspective view thereof;

Figure 4I is an enlarged top perspective view of the top spring plate shown in Fig. 4; and

Figure 4J is a bottom view thereof;

Figure 5(a) is a perspective view of the venturi air passageway assembly shown in Fig. 3;

Figure 5(b) is a geometric construction of the venturi shown in Fig. 5(a); and

Figure 6 is a partial section view taken along the line 2-2 of Fig. 2(a).

Detailed Description Of The Embodiments

Turning now in detail to the drawings, as shown in Figs. 1-3, a dry powder inhaler 1 includes a lid 20 pivotally mounted via hinge 7 a housing 5. Lid 20 includes a transparent window 22 for viewing individual drug dosages 67 within a medicine containing cartridge 60 supported on the housing 5. A slide groove assembly 24 located on the underside of the lid 20 includes a groove G located between a first vertical face 26 and a second vertical face 28, as shown in Fig. 2(a) and 3. Both the first vertical face 26 and the second vertical face 28 extend at an angle with respect to the longitudinal centerline of the inhaler. Ribs 29 and a vertical support wall 30 support the vertical face 28 and, a vertical support wall 31 supports the first vertical face 26. Extensions 21 help to hold a cartridge 60 down onto the housing 5, when the lid 20 is closed.

Turning now to Figs. 1(a), 1(b), 1(c) and 3, the housing 5 includes a mixing, or aerosolizing chamber 8. Mixing chamber 8 is formed on the back side by a rear wall 9 molded in the housing 5, and on the front by the rear wall 101 of a removable mouthpiece 100, as

shown in Fig. 1(c). As shown in Fig. 3, a drug port 10 on the top of the housing 5 extends into the mixing chamber 8. An opening 11 in the rear wall 9 within mixing chamber 8, allows air flow into the mixing chamber during patient inhalation. An impeller 13 within the mixing chamber 8 is attached to a shaft of an electric motor 15.

Referring still to Fig. 3, the housing 5 further includes a pair of light emitting diodes (LEDs) 16 and 17 on its top surface. LED 16 is advantageously red in color and when lit indicates to the patient that batteries (not shown) used in powering the dry powder inhaler need replacement. LED 17 is preferably a different color than LED 16, e.g., green, and indicates that the battery power is sufficient and that the number of inhalation cycles of the device (e.g., 1500 cycles) has not been exceeded. A blinking light indicates that the inhaler has sufficient battery power and remaining life cycles to deliver drug doses from two more cassettes. A circuit board 65 attached to the bottom of the housing 5 is linked to the LEDs 16 and 17, and to the batteries and to the motor, to control these functions.

Continuing to refer to Fig. 3, a lever recess 21 is located within the top surface of the housing 5. A vertical post 23 extends up from the top surface of housing 5, and is a pivot point for ratchet lever 70. The rachet lever 70 includes a forked end 71, a cylinder end 73, and a tooth 75. The ratchet lever 70 is pivotable about the vertical post 23. Its movement is limited by the edges of lever recess 21. A leaf spring 72 on the housing 5 pushes the ratchet lever 70 radially inwardly and keeps the forked end 71 against the post 23. The ratchet lever 70 slides along the leaf spring as the lid is opened and closed.

A pressure switch 19 is located on the underside of housing 5, for actuating the impeller 13 via electric motor 15. The pressure switch 19, shown in phantom in Fig. 3, preferably is an MPL-502-0.15 V available from Micro Pneumatic Logic, Inc., Ft. Lauderdale, Florida. The pressure switch 19 is linked to the motor 15.

Referring now to Figs. 3, 5(a), and 5(b), the dry powder inhaler includes a venturi air passageway assembly 40 preferably as a separately molded component. When the dry powder inhaler is assembled, as shown in Figs. 2(a) and 2(b), the venturi air passageway assembly 40 is attached e.g., adhered or, heat sealed ultrasonically welded, to the underside of housing 5, forming a generally air-tight passageway from inlet holes 85 to the mixing chamber 8.

The venturi passageway assembly 40 allows for consistent and reproducible actuation of pressure switch 19. Referring to Fig. 5(b), the venturi section of the assembly 40 includes a tapered section 42 that initially receives atmospheric air when a patient inhales on the mouthpiece 100. The tapered inlet section 42 preferable has a converging angle λ within the

range of approximately 20-30°, preferably about 25°. The tapered inlet section 42 can have a variety of cross-sectional profiles, including circular, semi-circular, parabolic, and the like.

The venturi air passageway further includes a throat section 44 that is continuous with tapered inlet section 42 and has a constant axial cross-sectional area. Like the inlet section 42, the throat section 44 may have a variety of cross-sectional profiles. Preferably, the throat section 44 has throat diameter as in the range of about 2-3mm and preferably approximately 2.5mm. The throat section may have a variable length within the range of approximately 0.8 to 1.8mm, preferably about 1.3mm. A pressure tap 48 is located within throat section 44, where pressure switch 19 measures the pressure in throat section 44 during inhalation.

Continuing to refer to Fig. 5(b), venturi air passageway assembly 40 includes a tapered outlet section 46 that is continuous with mixing chamber 8. The tapered outlet section 46 preferably has a diverging angle ϕ within the approximate range of 5-10°, preferably 7°. The tapered outlet section 46 can have a variety of cross-sectional profiles, including circle, semi-circular, parabolic and the like. In the preferred embodiment, the inlet, throat, and outlet are semi-circular.

Preferably, the maximum internal diameters of both the tapered outlet section 46 and the tapered inlet section 42 are equivalent. The ratio β, defined as the ratio of the throat section diameter to the maximum diameter of the tapered inlet section, should vary between 1/4 and 1/2, and is preferably approximately 1/2. When β falls within the above-specified range, the pressure switch 19 can reliably and consistently activate the motor 15 under operational flow conditions.

Referring now to Figs. 3 and 4 a medicine containing cartridge 60 includes a cartridge ring 63 having sawtooth edges 65 located circumferentially around its perimeter. Holes 67 in the ring 63 are filled with dry powder medication. The cartridge ring 63 is sandwiched between a top seal plate 68 and a bottom seal plate 69. Both the top and bottom seal plates 68, 69 are preferably made of transparent plastic and largely prevent contamination or leakage of the powder from apertures 67. A top spring plate 110 having a slotted central hub 112 is positioned on top of the seal plate 68. A bottom spring plate 114 having a receptacle 116 is positioned under the bottom plate 69. The receptacle 116 is adapter to receive and snap-lock onto the hub 112 of the receptacle 116, to hold the ring and plates together in a sandwich construction. Anti-rotation holes 62 and 64 extend throughout the entire medicine containing cartridge 60, preventing the plates 110, 68, 69, and 114 from moving during indexing.

The bottom seal plate 69 has a hole 118 and two through - plate posts 120 which engage the anti rotation holes in the bottom spring plate 14, and maintain the hole 118 aligned over the opening 66. The top surface 124 of the bottom seal plate 69 also has two short blind posts 128 which extend up from the top surface 124, but do not protrude below the bottom seal plate 69. The top surface 124 is otherwise flat and smooth. The receptacle 116 extends up through a large clearance hole 126 in the bottom seal plate 69. A third short blind post 129 extends above and below the plate 69. A chute opening 66 in the bottom plate 69 is provided so that the apertures 67 can be accessed when brought into alignment with drug port 10 during use.

The posts 120 on the bottom seal plate 69 extend through holes 62 and 64 in the top plate 68. A step post 130 extends up from the top surface of the top plate and engages a hole 132 in the top outer plate 110, thereby aligning the plates 110, 68, 69 and 114.

The cartridge ring 63 preferably is made of Delrin. The top plate 68 and bottom plate 69 are preferably made of polycarbonate. These materials provide appropriate lubricity between their sliding surfaces as the ring 63 turns within the sandwiched plates, and better prevent migration of powder out of the drug storage holes 67.

As shown in Figs. 4A and 4B, the ring 63 has a recess 101 on its top and bottom, with a diameter D. The seal plates have a matching (nominally smaller) diameter and center themselves on the ring 63 when assembled. A lip or rim R is formed around each hole 67, as shown in Fig. 4B. The holes 67 are sealed via the seal plates engaging the rims R, which rise above the base ring surface B by a distance H, about 0.2mm (.008 in). The width W of the rim R is also about 0.2mm. The rim R acts as a wiper or scraper on the seal plates, and helps to seal the powder in the holes 67, before, during, and after each movement of the ring.

The spring plates 110 and 114 are independent of the seal plates. The spring plates exert a clamping or normal force on the seal plates, to hold the seal plates flat against the ring 63, and specifically against the rims R, on top and bottom. This force is created and maintained by the snap engagement of the hub 112 into the receptacle 116, during assembly. The 5-layer sandwich cartridge can therefore reliably contain and deliver accurate doses of drug powder.

Referring now to Fig. 3, to load the medicine containing cartridge 60, the patient aligns anti-rotation holes 62 and 64 over slotted anti-rotation pegs 25 and 26 and presses the cartridge down. Tabs on the ends of pegs 25 and 26 spring outwardly after clearing the top spring plate 110 of the cartridge 60, and securely fasten the cartridge 60 to the housing 5.

Referring still to Fig. 3, a housing cover assembly 80 is attached to the under-side of housing 5, enclosing the motor 15, the venturi air passageway assembly 40, the batteries and

the circuit board 65. An ejection button recess 82 containing an ejection button 90 is located on the bottom surface of the housing cover assembly 80. The ejection button 90 includes a pair of ejection prongs 92 for ejecting the cartridge assembly 60 from the housing. To eject cartridge 60, a patient merely presses the ejection button 90 with sufficient force to release the cartridge 60 from pegs 25 and 26. The prongs 92 push against the solid flat bottom surface of the bottom spring plate 114.

Referring now to Figs. 1(a), 1(b), and 1(c), a detachable mouthpiece 100 includes a tapered mouth portion 103. The rear-wall 101 is located on the back of the detachable mouthpiece 100. A plurality of holes 105 in the rear-wall 101 allow the air-drug mixture to flow from the mixing chamber 8 into the mouthpiece 100 during inhalation. Radial holes 107 are positioned circumferentially around the back portion of the detachable mouthpiece 100. Referring briefly to Figs. 2(a) and 2(b), a removable mouthpiece cover 108 is press-fit on the mouthpiece 100 when the inhaler is not in use.

Radial pins 109 on the back of mouthpiece 100, which engage grooves 30 on housing 5, enable a patient to easily remove and re-attached mouthpiece 100 to housing 5, for cleaning.

To advance, or index the cartridge 60 to a next, successive dose, a patient simply first opens, then closes lid 20 of the dry powder inhaler. Referring to Figs. 2(a), 2(b), and 3, when a patient begins to open the lid 20 to a position shown in Fig. 2(a), the ratchet lever 70 begins to pivot around vertical post 23 on the housing 5 due to the mechanical engagement of the cylinder end 73 with the slide-groove assembly 24 contained in the lid 20. As the lid is opened, the cylinder end 73 is progressively pushed in the direction of arrow A in Fig. 3 by the sliding contact with the first vertical face 26 of lid 20. The ratchet lever 70 simultaneously moves radially outwardly against the inward acting force of the spring 72, as the tooth 75 rides up and over a sawtooth on the cartridge ring. The forked end 71 allows radial movement away from the post 23. Friction prevents the ring from moving with the tooth 75 on the ratchet lever 70.

When lid 20 is fully opened to a position shown in Fig. 2(a), the tooth 75 has passed over a sawtooth and moved back radially inwardly to form a mating, or matching fit with a sawtooth edge 65 of cartridge ring 63. The spring 72 drives the tooth portion inwardly behind the sawtooth after it has cleared the sawtooth. Once the matching connection has been made, the patient closes the lid 20, to the position shown in Fig. 1(a). When pivoting lid 20 towards the closed position, the tongue 73 of ratchet lever 70 is progressively pushed in the direction of arrow B due to the sliding contact with the second vertical face 28.

As the tooth 75 of the lever ratchet 70 is now in mating contact with sawtooth edge 65, the sawtooth edge 65 and cartridge ring 63 likewise rotate in the direction of arrow B driven by the interaction of the tongue 73 in the slide groove 24. The plates 68, 69, 110 and 114 of the cartridge 60 remain fixed at all times on the pegs 25 and 26. When the lid 20 has closed to the position shown in Fig. 1(a), cartridge ring 63 has indexed, or advanced one aperture 67, so the next dose can be delivered to the patient.

In use, the dry powder inhaler is held in an upright position as shown in Fig. 1(a). Prior to inhalation, a patient advances, or indexes the medicine containing cartridge 60 to move the next dose into the delivery position by opening and closing the lid 20. A new aperture 67 containing powdered drug is moved into alignment over drug port 10. The aperture 67 and powdered drug containing therein are no longer sandwiched between the top plate 68 and bottom plate 69 because chute hole 66 in the bottom plate 69 allows access to mixing chamber 8.

After advancing the cartridge, the user places the tapered mouthpiece 103 of detachable mouthpiece 100 into the mouth and inhales. As the user inhales, air is drawn through inlet holes 85 into the venturi air passageway assembly 40. The velocity of air flowing through the throat section 44 increases, causing a corresponding decrease in pressure in throat section 44 consistent with Bernoulli's principle.

Figures 5(a) and 6 illustrate the path of air through the inhaler and venturi 40. Arrow C in Fig. 5(a) shows the air path from the atmosphere through the venturi air passageway assembly 40. Figure 6 illustrates this same flow path by arrow D, only this view shows a cross-sectional view of the flow in the entire inhaler.

The reduced pressure in the throat section 44 is detected via a pressure tap 48 or tube connecting the throat section 44 to the pressure switch 19. Accordingly, when the pressure drop across throat section 44 reaches a sufficient magnitude, the pressure switch 19 closes, thereby turning on motor 15. The spinning impeller attached to a shaft of motor 15 begins spinning within mixing chamber 8. Preferably, the pressure switch 19 closes when the flow rate in mouthpiece 100 exceeds the approximate range of 4-8 liters/minute, a very low threshold which virtually all patients can meet or exceed using the inhaler. The design of the venturi allows independent selection of the flow rate which actuates the motor 15. The venturi also serves as a control point for the flow resistance of the inhaler, preferably creating a resistance of about 0.1 - 0.2 $(cm\ H_2O)^{1/2}$. The value of the pressure drop at the venturi may also

be used to determine the inhalation flow rate. This information can be recorded, displayed or used to tell the patient if the proper rate was achieved.

Both inhalation and turbulence created from spinning impeller 13 pull air exiting the tapered outlet section 46 into mixing chamber 8 via an opening 11 located on the rear-wall 9 of the mixing chamber 8. In addition, the same inhalation and turbulence causes powdered drug stored within aperture 67 to transfer to mixing chamber 8 via drug port 10. Air and drug are mixed in the mixing chamber by the spinning impeller.

Referring now to Fig. 1(c), powder laden air passes out of the mixing chamber 8 through outflow holes 105 located in the rear-wall 101 of mouthpiece 100 and into the interior of the mouthpiece 100 and from there into the patients lungs.

Thus, a novel inhaler has been shown and described. Various changes and modifications can of course be made and various equivalents and substitutions can be used, without departing from the spirit and scope of the present invention. The invention, therefore, should not be restricted, except by the following claims.

Claims

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1. An inhaler comprising:
a housing;
a mixing chamber in said housing;
a pressure switch within said housing;
a venturi air passageway within said housing; and
a pressure tap on the venturi connecting to the pressure switch.

2. The inhaler according to claim 1, further comprising an electric motor contained within said housing actuated by said pressure switch.

3. The inhaler according to claim 2, further comprising an impeller fixedly attached to a shaft of the electric motor, wherein the impeller is located within said mixing chamber.

4. The inhaler according to claim 1, wherein said pressure switch contained within said housing is a pressure transducer.

5. The inhaler according to claim 1, further comprising a cartridge ring rotatably mounted on said housing, wherein the cartridge ring contains a plurality of powder filled apertures.

6. The inhaler according to claim 5, further comprising an ejector button within said housing for ejecting the cartridge ring.

7. The inhaler according to claim 1, further comprising a light emitting diode in said housing, wherein the light emitting diode indicates to a user when a battery needs replacement.

8. The inhaler according to claim 1, further comprising a mouthpiece, the mouthpiece being removably attached to said housing over said mixing chamber.

9. The inhaler according to claim 8, wherein said pressure switch closes when a flow rate in the mouthpiece exceeds approximately 4.0 liters/minute.

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10. An inhaler comprising:

a housing;

a mixing chamber in said housing;

a pressure switch contained within said housing;

a cartridge ring rotatably mounted on said housing; said cartridge ring containing a plurality of powder filled apertures;

means for advancing said cartridge ring from a first powder filled aperture to an adjacent powder filled aperture.

11. The inhaler of claim 10 wherein the means for advancing the cartridge ring comprises:

a ratchet lever having a first end and a second end with the first end pivotably attached to the housing and having a tooth engaging the cartridge ring; and

a lid pivotably attached to the housing and including first and second spaced apart curved walls, with the second end of the ratchet lever positioned between the first and second walls.

12. The inhaler of claim 10 wherein the cartridge ring has a sawtooth edge and the ratchet lever has a tooth portion for engaging the sawtooth edge.

13. The inhaler of claim 10 further comprising:

a top plate and a bottom plate slidably positioned on the cartridge ring; and

an anti-rotation post on the housing extending through the top and bottom plates.

14. A dry powder inhaler comprising:

a housing;

a mixing chamber in said housing;

a pressure switch contained within said housing; and

a venturi air passageway contained within said housing for actuating said pressure switch, said venturi air passageway comprising:

(a) a tapered inlet section;

(b) a throat section; and

(c) a tapered outlet section.

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15. The inhaler according to claim 14, wherein said throat section of said venturi air passageway has an internal diameter between the range of approximately 0.08" to 0.13".

16. The inhaler according to claim 14, wherein said tapered inlet section and said tapered outlet section have a maximum diameter of approximately twice that of the internal diameter of said throat section.

17. The inhaler according to claim 14, further comprising an electric motor contained within said housing, wherein the electric motor is actuated by said pressure switch.

18. The inhaler according to claim 14, further comprising a cartridge ring rotatably mounted on said housing, wherein the cartridge ring contains a plurality of powder filled apertures.

a plurality of spaced apart holes in the cartridge ring for holding a dry powder;
a top seal plate on the top side of the cartridge ring ;
a bottom seal plate on the bottom side of the cartridge ring;
a top spring plate overlying the top seal plate; and
a bottom seal plate underlying the bottom seal plate.

19. A medicine containing cartridge for use with an inhaler, comprising:
a cartridge ring having a top side and a bottom side;
a plurality of spaced apart holes in the cartridge ring for holding a dry powder;
a top seal plate on the top side of the cartridge ring ;
a bottom seal plate on the bottom side of the cartridge ring;
a top spring plate overlying the top seal plate; and
a bottom seal plate underlying the bottom seal plate.

20. The cartridge of claim 19 further comprising sawtooth edges located circumferentially around the perimeter of the cartridge ring.

21. The cartridge of claim 19 wherein the top and bottom seal plates and spring plates are made of transparent plastic.

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22. The cartridge of claim 19 wherein one of the top and bottom spring plates has a hub and the other has a receptacle adapted to snap lock onto the hub, to hold the cartridge ring, seal plates, and spring plates together in a sandwich construction.

23. The cartridge of claim 19 further comprising a pair of anti-rotation holes extending through the seal plates and the clamp plates.

24. The cartridge of claim 19 further comprising a delivery hole in the bottom seal plate and a chute opening in the bottom spring plate.

25. The cartridge of claim 19 wherein the cartridge ring comprises Delrin and the top and bottom seal plates comprise polycarbonate, to provide an appropriate lubricity between their sliding surfaces.

26. The cartridge of claim 19 wherein the cartridge ring includes a top recess and a bottom recess adapted to receive the top and bottom seal plates.

27. The cartridge of claim 25 further comprising lip formed around each hole on the top side and the bottom side of the cartridge ring.

28. The cartridge of claim 27 wherein the lip has a height of about 0.2mm and a width of about 0.2 mm.

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