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Description

[0001] The present invention relates to inhalers and, in particular, to inhalers for the delivery of dry powder medicament to the lung.

[0002] Oral or nasal delivery of a medicament using an inhalation device is a particularly attractive method of drug administration as these devices are relatively easy for patients to use discreetly and in public. As well as delivering medicament to treat local diseases of the airway and other respiratory problems, they have more recently been used to deliver drugs to the bloodstream via the lungs, thereby avoiding the need for hyodermic injections.

[0003] For a medicament in particulate form, the provision of an inhalable aerosol requires an inhaler that can produce a repeatable dose of fine particles. In order for the particles of medicament to reach the deep lung area (alveoli) and thus be absorbed into the bloodstream, the particles must have an effective diameter in the range of approximately 1 to 3 microns. The portion of the emitted aerosol which includes this range of particle size is known as the "fine particle fraction" (FPF). If the particles are larger than 5 microns, they may not be transported by the inhaled airflow deep into the lung, because they are likely to be trapped in the respiratory passages before reaching the deep lung. For example, particles of the order of 10 microns are unlikely to progress further than the trachea and particles of the order of 50 microns tend to deposit on the back of the throat when inhaled. Furthermore, if the particles are less than 1 micron in effective diameter, the particles may not be absorbed into the lung, because they are small enough to be expelled from the lung with the exhaled airflow.

[0004] The efficiency of a dry powder inhaler may be measured in terms of the fine particle dose (FPD) or the FPF. The FPD is the total mass of active agent which is emitted from the device following actuation which is present in an aerodynamic particle size smaller than a defined limit. This limit is generally taken to be 5 microns although particles having a diameter less than 3 microns are preferred, for the reasons stated above. The FPD is measured using an impactor or impinger, such as a twin stage impinger (TSI), multi-stage impinger (MSI), Andersen Cascade Impactor (ACI) or a Next Generation Impactor (NGI). Each impactor or impinger has a pre-determined aerodynamic particle size collection cut points for each stage. The FPD value is obtained by interpretation of the stage-by-stage active agent recovery quantified by a validated quantitative wet chemical assay where either a simple stage cut is used to determine FPD or a more complex mathematical interpolation of the stage-by-stage deposition is used.

[0005] The FPF is normally defined as the FPD divided by the emitted or delivered dose which is the total mass of active agent that is emitted from the device following actuation and does not include powder deposited inside or on the surfaces of the device. The FPF may also, however, be defined as the FPD divided by the metered dose which is the total mass of active agent present in the metered form presented by the inhaler device in question. For example, the metered dose could be the mass of active agent present in a foil blister.

[0006] In conventional inhalers, the emitted dose (the amount of medicament that enters the patient's airway) is around 80% to 90% of the dose ejected from the inhaler. However, the FPF may only be around 50% of the emitted dose but the variation in the respirable dose of known inhalers can be +/-20 to 30%. Such variation is generally acceptable in the case of asthma drugs and the like. However, it will be appreciated that for the pulmonary delivery of systemic small molecule and protein and peptide drugs or for the administration of drugs such as insulin, growth hormone or morphine, this amount of variation in respirable dose is unacceptable. This is not only because it is considerably more important to ensure that the patient receives the same intended dose of these types of drugs each time the inhaler is used, so that a predictable and consistent therapeutic effect is achieved, but a relatively low respirable dose represents a significant wastage of what may be an expensive drug.

[0007] It will therefore be appreciated that for systemic pulmonary delivery, the provision of an inhalable aerosol requires an inhaler that can deliver the drug in a highly efficient, accurate and repeatable manner leading to a more predictable and consistent therapeutic effect which minimises any potentially harmful side effects for the patient as well as reducing the amount of costly drug required to deliver a therapeutic dose.

[0008] To ensure that a powdered medicament is delivered with an accurately controlled range of particle sizes in order that they are absorbed effectively in the lung, it is necessary to deagglomerate the particles as they flow through the device prior to entry into the patient's airway.

[0009] It is known to separate particles of medicament by generating shear forces between the particles, for example by providing a substantial velocity gradient across the particles. One way to achieve this is to provide the inhaler with a cyclone chamber having an axial outlet and a tangential inlet. The drug is entrained in an airflow and allowed to enter the cyclone chamber through the tangential inlet. The high shear forces generated between the particles as they spin around the chamber in the airflow are sufficient to break-up agglomerates of particles before they pass out of the chamber through the outlet. An inhaler having a cyclone chamber is known from the Applicant's own earlier patent EP1 191966 B1. A device for the pulverisation of particles or agglomerates of a powdered inhalation medicament is also known from EP0477222 A1. The device disclosed in this document comprises a rotationally symmetrical vortex chamber with spaced inlet and outlet ports. The inlet ports direct drug laden air into the vortex chamber in a direction at a tangent or close to a tangent of the chamber.

[0010] WO 89/007464 discloses a dispenser for powdered medication comprising a housing containing means for piercing a capsule containing powdered medication, a generally cylindrical chamber adapted to receive the capsule and in which the capsule can rotate freely to release the powdered medication, and a mouthpiece through which the powdered medication can be drawn from the chamber, in which the chamber has three air inlets spaced around the cylindrical wall of the chamber.

[0011] EP 1 649 886 discloses a medication capsule for an inhaler comprising apertures to admit air flow and structures in the interior surface to create, in use, cyclonic air flow.

[0012] WO 01/007107 discloses a dry powder inhaler comprising an intake section, a mixing section and a mouthpiece. The mouthpiece is connected by a swivel joint to the mixing section, and may swivel back onto the intake section and be enclosed by a cover.

[0013] US 2003/0188747 discloses an inhalator including a chamber for receiving a powder, a reservoir for temporarily storing an air-powder mixture flowing from the powder receiving chamber, and a passage for introducing a diluent air into the air-powder mixture reservoir. The air-powder mixture is formed within the powder receiving chamber when an air is introduced into the powder receiving chamber. The air-powder mixture within the air-powder mixture reservoir is admixed with a diluent air introduced thereinto through the diluent air passage. The diluted air-powder mixture is discharged from an air-powder mixture outlet intro a user's oral or nasal cavity.

[0014] GB 2 407 042 and its equivalent WO 05/037353 disclose an inhaler comprising a housing to receive a strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and, an actuator operable to sequentially move each blister into alignment with a blister piercing element. The actuator is also operable to cause the blister piercing element to puncture the lid of a blister such that, when the user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister via the mouthpiece into the user's airway.

[0015] The present invention seeks to provide an inhaler which is capable of reliably generating an inhalable aerosol of a powdered medicament with an effective particle size that is sufficiently small for the medicament to be delivered to and absorbed into the lungs of a patient.

[0016] According to the invention, there is provided an inhaler for producing an inhalable aerosol of powdered medicament, the inhaler including a mouthpiece, a piercing device for puncturing the lid of a blister containing a dose of medicament and a base, the piercing device comprising a piercing head having piercing elements depending therefrom, an aerosolising device having a chamber of substantially circular cross-section, inlet and outlet ports at opposite ends of the chamber for the flow of drug laden air through the chamber between said ports and, a bypass air inlet for the flow of clean air into the chamber, said bypass air inlet being arranged so that air enters the chamber through said inlet substantially tangential to the wall of the chamber and being configured so that air entering the chamber through said inlet forms a cyclone in the chamber that interacts with the drug laden air flowing between the inlet and outlet ports, characterised by the piercing device being disposed beneath the mouthpiece on the opposite side of the base and extending from or being connected to the base, the piercing head having clean air inlet flow passages spaced around a central drug laden air outlet passage, the blister piercing elements being configured to puncture the lid of said blister so that, when a patient inhales through the mouthpiece, clean air enters the blister through the air inlet flow passages and entrains the dose contained in the blister, the drug laden air then flowing out of the blister through the central drug laden air outlet passage and the chamber to the mouthpiece.

[0017] In a preferred embodiment, the chamber is configured so that the cyclone interacts with the drug laden air flow so as to cause the drug laden air flow to assume a helical path as it flows from the inlet port to the outlet port.

[0018] Although it is known to provide an inhaler with a bypass air entry inlet, the sole purpose of that inlet or, more specifically, the bypass air which flows into the device through that inlet, is to reduce the overall pressure drop across the device and so make it easier for the patient to inhale. The bypass air inlets are arranged so that the bypass airflow is flowing in the same direction as the drug laden air when the two airflows meet so that there is limited interaction between the bypass air and the drug laden air.

[0019] In one embodiment, the chamber is tapered. However, the walls of the chamber may also be straight, i.e. parallel to the longitudinal axis of the chamber.

[0020] The chamber may be tapered in a direction extending from the outlet port towards the inlet port. However, they may also taper in the opposite direction.

[0021] The inhaler of the invention includes a base and the inlet port is preferably formed in said base.

[0022] A mesh can be formed in the base and the inlet port can be formed from openings in that mesh. The mesh can be formed in a separate component attached to or inserted into an aperture in the base or, it can be formed integrally in the base.

[0023] The inlet port can be coaxial with a longitudinal axis of the chamber. Alternatively, the inlet port may be offset from the longitudinal axis of the chamber.

[0024] Conveniently, the inlet port comprises at least one opening in said base.

[0025] The or each opening may extend at an angle relative to the longitudinal axis of the chamber. However, in a

preferred embodiment, the longitudinal axis of each opening is parallel to, or coaxial with, the longitudinal axis of the chamber.

[0026] Preferably, the chamber comprises an end wall opposite to the base at the other end of the chamber, the outlet port being formed in said end wall.

[0027] The end wall may comprise a mesh and the outlet port can be formed from the openings in the mesh.

[0028] The mouthpiece may have a portion that extends beyond the end wall in a direction away from the inlet port. That portion may taper outwardly away from said end wall to form a diffuser.

[0029] In a preferred embodiment, the bypass air inlet is located at the base of the chamber. Conveniently, the base forms a sidewall of the bypass air inlet.

[0030] In another embodiment, the bypass air inlet is spaced from the base closer to the end wall. In one embodiment, the bypass air inlet is adjacent to the end wall and can be partially formed from the end wall.

[0031] The tangential bypass air inlet may be formed from an arcuately shaped flow path.

[0032] In other embodiments, there can be more than one tangential bypass air inlet. Preferably, there are at least two inlets on diametrically opposite sides of the chamber.

[0033] In a preferred embodiment, the chamber is formed within a mouthpiece. However, in another embodiment, the outlet port of the chamber is connected to a separate mouthpiece. If the chamber is formed within the mouthpiece, it can be a separate component within the mouthpiece. That component may be separable from the mouthpiece.

[0034] Preferably, the inhaler comprises a blister piercing element operable to puncture the lid of a blister containing a dose of medicament to enable a user to inhale said dose through said chamber.

[0035] In one embodiment, the blister piercing member comprises a piercing element upstanding from a surface and clean air inlet and drug laden air outlet flow passages extending through the blister piercing member from said surface in the vicinity of each piercing element, said piercing element being operable to puncture a clean air inlet opening and a drug laden air outlet opening in the blister such that, when a user inhales, clean air can flow through the clean air inlet flow passage in the blister piercing member and clean air inlet opening into the blister to entrain the dose contained in the blister, the drug laden air flowing out of the blister through the drug laden air outlet opening in the blister and drug laden air outlet flow passage in the blister piercing member.

[0036] Preferably, the drug laden air outflow passage is in communication with the inlet port of the chamber.

[0037] In one preferred embodiment, the clean air inlet opening comprises a plurality of peripheral clean air inlet openings that surround the drug laden air outlet opening. Advantageously, the clean air inlet openings are arranged symmetrically around the drug laden air outlet opening.

[0038] In one embodiment, the inhaler further comprises a housing configured to receive a strip having a plurality of blisters, each blister having a puncturable lid and containing a dose of medicament for inhalation by a user, means operable to drive the strip to sequentially move each blister into alignment with the blister piercing member and actuating means operable to cause the blister piercing member to pierce the lid of said aligned blister.

[0039] In another embodiment, the inhaler comprises a housing configured to receive a single blister having a puncturable lid and containing a dose of medicament for inhalation by a user and actuating means operable to cause the blister piercing member to pierce the lid of said blister received in the housing.

[0040] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

FIGURE 1 is a simplified cross-sectional side view of a portion of an inhalation device according to an embodiment of the present invention;

FIGURE 2 is a cross-sectional view of the device shown in Figure 1 taken along line X-X;

FIGURE 3 is a perspective view of the blister piercing head of the inhaler shown in Figure 1; and

FIGURE 4 is a perspective view of the cyclone chamber without the mouthpiece of the inhalation device shown in Figure 1 or 2.

[0041] Referring now to the drawings, there is shown in Figure 1 a portion 1 of an inhalation device according to an embodiment of the present invention having a mouthpiece 2 defining a chamber 3 having a chamber wall 3a, a drug laden air inlet port 4, an outlet port 5 and bypass air inlets 6. A cross-sectional view taken along the line X-X in Figure 1 is also shown in Figure 2.

[0042] The term "bypass" means that the air entering through these inlets 6 is clean air, i.e. air from outside the device 1 which does not have drug entrained in it.

[0043] The device includes a base 7 extending across a lower end of the mouthpiece 2 and closing the chamber 3. The drug laden air inlet port 4 is formed in, and extends through, the base 7. In the illustrated embodiment, the drug laden air inlet port 4 is coaxial with the longitudinal axis (A -A in Figure 1) of the chamber 3, although it will be appreciated that the drug laden air inlet port 4 may be offset or otherwise spaced from the longitudinal axis. The axis of the drug laden air inlet port 4 may also be angled with respect to the longitudinal axis of the chamber 3, although in the preferred

embodiment the axis of the drug laden air inlet port 4 is parallel to the longitudinal axis of the chamber 3. It is also possible that the base 7 may have multiple drug laden air inlet ports 4 positioned around the longitudinal axis of the chamber 3.

[0044] Although the base 7 could be formed integrally with the mouthpiece 2, it is preferably formed as a separate component which is attached to the mouthpiece 2 during assembly. The mouthpiece 2 and base 7 may also be separable from each other by a user to facilitate cleaning of the inside of the chamber 3.

[0045] As can be seen most clearly from Figures 2 and 4, which shows an underside perspective view of the mouthpiece 2 without the base 7, the bypass air inlets 6 are channels formed in the sides of the mouthpiece 2 and the base 7 forms the lowermost wall and encloses the lower end of the chamber (apart from the drug laden air inlet port 4), but also forms the lower surface of the channels 6 so that the channels 6 are open only at each of their ends. In the illustrated embodiment, there are two bypass air inlets 6 so as to direct clean air into the chamber 3. However, there may only be one or several bypass air inlets 6. The bypass air inlets 6 are preferably tangential to the chamber 3, although it will be appreciated that the desired air flow can also be obtained as a result of positioning the bypass air inlets 6 so that they are not at an exact tangent to the chamber 3 but are offset from it.

[0046] In the illustrated embodiment, the bypass air inlets 6 are arcuate in shape, although they may also be straight. They may also be circular in cross-section and/or taper along their length in either direction.

[0047] As the bypass air inlets 6 are arranged tangentially or so as to direct the bypass air in a substantially tangential direction into the chamber 3, the clean air flowing through these inlets 6 into the chamber 3 spins around the chamber so as to form a cyclone or vortex (as indicated by arrow "B" in Figure 1).

[0048] The outlet port 5 may be in the form of a mesh extending across the end of the chamber 3 through which the entrained drug may flow out of the chamber 3 into the patient's airway. Preferably, the mouthpiece 2 incorporates a flow diffuser 5a that extends beyond the outlet port 5 and has a cross-sectional area that gradually increases towards the top edge 2a of the mouthpiece 2. The walls 2b of the diffuser 5a in this region may be curved in shape.

[0049] The chamber 3 may be straight, i.e. the inner curved surface 3a of the chamber 3 may extend parallel to the longitudinal axis of the chamber 3. However, in other embodiments, the chamber 3 may taper in either direction. In particular, it may widen as it extends from the drug laden air inlet 4 towards the outlet port 5.

[0050] The diameter and height of the chamber 3 have been shown to influence the aerosolisation performance. Preferably the diameter of the chamber 3 is between 15 mm and 25 mm and the height is 20 mm or more. However, to be able to package a device into a convenient volume, smaller diameters and heights have also been used to get a sufficient increase in performance with less demanding therapies. In these cases diameters down to 9.5mm and heights down to 5.5mm have been shown to give significant improvements in aerosolisation over a device without cyclonic bypass air.

[0051] Air inlets 6 of dimensions 3.7 mm wide and 5.6 mm high have been shown to work well although, surprisingly, the aerosolisation performance is less sensitive to the cross sectional area of the air inlets 6 which may then be advantageously varied to modify the resistance of the device to suit a particular therapy / patient group with little impact on performance.

[0052] A piercing device 8 is disposed beneath the mouthpiece 2 on the opposite side of the base 7 and may extend from or be connected to the base 7. As can most clearly be seen from Figure 3, the piercing device 8 comprises a piercing head 9 having piercing elements 10 depending therefrom. The piercing head 9 has clean air inlet flow passages 11 spaced around a central drug laden air outlet passage 12 (see Figure 3). In one embodiment, the inhaler 1 is configured to receive a single blister 13 containing a dose of medicament which is located beneath the blister piercing elements 10. The blister piercing elements 10 are configured to puncture the lid 13a of said blister 13 so that, when a patient inhales through the mouthpiece 2, clean air enters the blister 13 through the air inlet flow passages 11 (in the direction of arrow "C" in Figure 1) and entrains the dose contained in the blister 13. The drug laden air then flows out of the blister 13 through the central drug laden air outlet passage 12 (in the direction of arrow "D"). The drug laden air outlet passage 12 is connected to the drug laden air inlet port 4 of the chamber 3 so that it flows in an axial direction into the chamber 3 (in the direction indicated by arrow "E"). At the same time, clean bypass air enters the chamber 3 through the tangential bypass air inlets 6 and spins around the chamber 3 (in the direction of arrow "B") forming a vortex or cyclone.

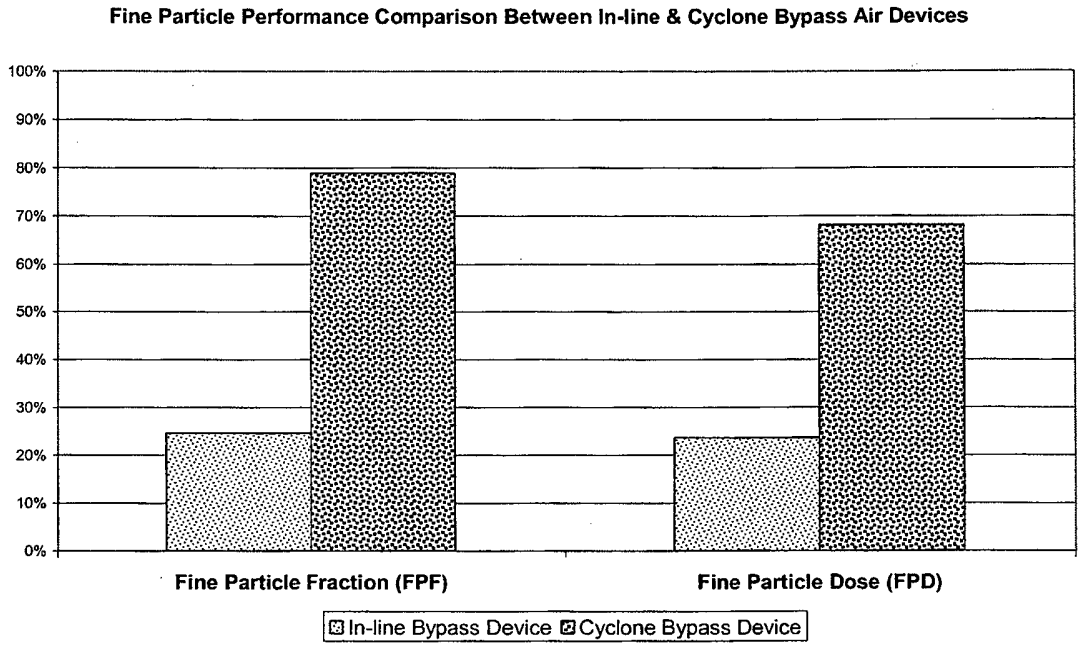
[0053] It will be appreciated from Figure 3, that the air inlet flow passages 11 and drug outlet flow passage 12 are symmetrically arranged so the emitted drug dose has no dependence on the orientation of the inhaler around the chamber axis at the time of inhalation. The blister piercing elements 10 extend over or bridge the air inlet flow passages 11 and drug outlet flow passage 12. The drug outlet flow passage 12 may be larger than the total combined area of the air inlet flow passages to increase flow area and to ensure that as much as possible of the dose is entrained in the airflow and removed from the blister 13.

[0054] Although reference is made to a unit dose device which receives only one blister 13 at a time, the invention is equally applicable to a multi-dose dry powder inhaler. For example, the device may have a housing configured to receive a strip having a plurality of blisters spaced along its length and means which are operable to drive the strip to sequentially move each blister into alignment with the blister piercing member. Such a device may also be provided with an actuator to cause the blister piercing member to pierce the lid of an aligned blister. A device of this type is known, for example,

from the Applicant's own earlier application published as WO05/03735 A1.

[0055] The cyclone interacts with the drug laden air flowing in a generally axial direction between the inlet and outlet ports 4,5 so as to cause the drug laden air flow to twist or follow a helical path towards the outlet port 5. The interaction of the vortex formed from the bypass air spinning around chamber 3 on the drug laden air flowing into the chamber 3 in an axial direction has been found by the Applicant to provide a marked improvement in performance of the inhaler. Experimental results have shown that the drug laden air is accelerated as it flows through the chamber 3 and experiences increased shear forces and differential velocites which further deagglomerates the particles and improves the fine particle fraction of the emitted dose.

[0056] The graph below compares aerosolisation performance, for a typical drug and fill weight, of the cyclone bypass air invention and an otherwise similar device where the bypass airflow is flowing in the same direction as the drug laden air with limited interaction between the bypass air and the drug laden air.



This graph illustrates approximately 200% increase in fine particle fraction with the cyclone bypass device

[0057] In the illustrated embodiment, the chamber 3 is provided within the mouthpiece 2. This has the advantage that the contact area between the device and drug dose is minimised as there is no additional airway to carry the deagglomerated drug into the mouthpiece for delivery to the user and the device is compact. However, it will be appreciated that the mouthpiece 2 could be separate to the chamber 3 in which case a further flow path extends from the outlet 5 of the chamber 3 to the inlet of the separate mouthpiece. The chamber 3 may also be a separate component that is inserted within the mouthpiece 2 and could be detachable therefrom. A separate chamber unit is shown in Figure 4, which locates within the mouthpiece 2, as shown in Figures 1 and 2.

[0058] Many modifications and variations of the invention falling within the terms of the following claims will be apparent to those skilled in the art and the foregoing description should be regarded as a description of the preferred embodiments of the invention only.

Claims

1. An inhaler for producing an inhalable aerosol of powdered medicament, the inhaler including a mouthpiece (2), a piercing device (8) for puncturing the lid of a blister containing a dose of medicament and a base (7), the piercing device (8) comprising a piercing head (9) having piercing elements (10) depending therefrom, an aerosolising device having a chamber (3) of substantially circular cross-section, inlet and outlet ports (4,5) at opposite ends of the chamber (3) for the flow of drug laden air through the chamber (3) between said ports (4,5) and, a bypass air inlet (6) for the flow of clean air into the chamber (3), said bypass air inlet (6) being arranged so that air enters the chamber (3) through said inlet (6) substantially tangential to the wall of the chamber (3) and being configured so that air entering the chamber (3) through said inlet (6) forms a cyclone in the chamber (3) that interacts with the drug laden

air flowing between the inlet and outlet ports (4,5), **characterised by** the piercing device (8) being disposed beneath the mouthpiece (2) on the opposite side of the base (7) and extending from or being connected to the base (7), the piercing head (9) having clean air inlet flow passages (11) spaced around a central drug laden air outlet passage (12), the blister piercing elements (10) being configured to puncture the lid (13a) of said blister (13) so that, when a patient inhales through the mouthpiece (2), clean air enters the blister (13) through the air inlet flow passages (11) and entrains the dose contained in the blister (13), the drug laden air then flowing out of the blister (13) through the central drug laden air outlet passage (12) and the chamber (3) to the mouthpiece (2).

2. An inhaler according to claim 1, wherein the chamber (3) is configured so that the cyclone interacts with the drug laden air flow so as to cause the drug laden air flow to assume a helical path as it flows from the inlet port (4) to the outlet port (5).

3. An inhaler according to any preceding claim, wherein the chamber (3) is tapered.

4. An inhaler according to any preceding claim, wherein the inlet port (4) is formed in the base (7), the base (7) including a mesh portion, the inlet port (4) being formed by the openings in said mesh.

5. An inhaler according to claim 4, wherein the inlet port is coaxial with a longitudinal axis of the chamber (3).

6. An inhaler according to claim 4, wherein the inlet port is offset from the longitudinal axis of the chamber (3).

7. An inhaler according to any of claims 4 to 6, wherein the inlet port (4) comprises at least one opening in said base (7), the or each opening extends through the base (7) at an angle relative to the longitudinal axis of the chamber (3).

8. An inhaler according to any of claims 4 to 7, wherein the chamber (3) comprises an end wall at the other end of the chamber (3) opposite the base (7), the outlet port being formed in said end wall, the end wall comprising a mesh, the outlet port (5) being formed from openings in the mesh.

9. An inhaler according to claim 8, wherein the chamber (3) has a portion that extends beyond the end wall in a direction away from the inlet port (4).

10. An inhaler according to any of claims 4 to 9, wherein the bypass air inlet (6) is located in a wall of the chamber (3) adjacent to the base (7).

11. An inhaler according to claim 10, wherein the base (7) forms a sidewall of the tangential bypass air inlet (6).

12. An inhaler according to any of claims 4 to 9, wherein the tangential bypass air inlet (6) is spaced away from the base towards the end wall and is partly formed from the end wall.

13. An inhaler according to any of claims 10 to 12, wherein the tangential bypass air inlet (6) is formed from an arcuately shaped flow path.

14. An inhaler according to any preceding claim, wherein the chamber (3) is formed within the mouthpiece (2).

Patentansprüche

1. Inhalator zur Herstellung eines inhalierbaren Aerosols aus einem pulverförmigen Medikament, wobei der Inhalator ein Mundstück (2), eine Durchstechvorrichtung (8) zum Durchstechen des Deckels eines Blisters, der eine Arzneimitteldosis enthält, und ein Bodenelement (7) aufweist, wobei die Durchstechvorrichtung (8) einen Durchstechkopf (9) mit Durchstechelementen (10), die davon abgehen, eine Aerosolisierungsvorrichtung, die eine Kammer (3) von im Wesentlichen kreisförmigem Querschnitt aufweist, Einlass- und Auslassöffnungen (4, 5) an gegenüberliegenden Enden der Kammer (3) für den Durchfluss von Arzneimittel-beladener Luft durch die Kammer (3) zwischen den Öffnungen (4, 5) und einen Bypass-Lufteinlass (6) für das Einströmen von sauberer Luft in die Kammer (3) umfasst, wobei der Bypass-Lufteinlass (6) eingerichtet ist, sodass Luft in die Kammer (3) durch den Einlass (6) im Wesentlichen tangential zu der Wand der Kammer (3) eintritt und derart konfiguriert ist, dass Luft, die in die Kammer (3) durch den Einlass (6) eintritt, einen Zyklon in der Kammer (3) bildet, der mit der Arzneimittel-beladenen Luft, die zwischen den Einlass- und Auslassöffnungen (4, 5) strömt, in Wechselwirkung tritt, **dadurch gekennzeichnet, dass** die

Durchstechvorrichtung (8) unterhalb des Mundstücks (2) auf der gegenüberliegenden Seite des Bodenelements (7) angeordnet ist und sich von dem Bodenelement (7) erstreckt oder mit ihm verbunden ist, der Durchstechkopf (9) Einlassströmungskanäle (11) für saubere Luft aufweist, die rund um einen zentralen Auslasskanal (12) für Arzneimittel-beladene Luft beabstandet angeordnet sind, die Blister-Durchstechelemente (10) konfiguriert sind, den Deckel (13a) des Blisters (13) zu durchstechen, sodass, wenn ein Patient durch das Mundstück (2) inhaliert, saubere Luft in den Blister (13) durch die Luft-Einlassströmungskanäle (11) eintritt und die Dosis mitreißt, die in dem Blister (13) enthalten ist, die Arzneimittel-beladene Luft anschließend durch den Auslasskanal (12) für Arzneimittel-beladene Luft und die Kammer (3) aus dem Blister (13) zu dem Mundstück (2) strömt.

2. Inhalator gemäß Anspruch 1, wobei die Kammer (3) derart konfiguriert ist, dass der Zyklon mit der Arzneimittel-beladenen Luft in Wechselwirkung tritt, um zu veranlassen, dass der Arzneimittel-beladene Luftstrom eine spiralförmige Bahn annimmt, wenn er von der Einlassöffnung (4) zu der Auslassöffnung (5) strömt.

3. Inhalator gemäß einem der vorhergehenden Ansprüche, wobei die Kammer (3) sich verjüngt.

4. Inhalator gemäß einem der vorhergehenden Ansprüche, wobei die Einlassöffnung (4) in dem Bodenelement (7) ausgebildet ist, das Bodenelement (7) einen Gitterabschnitt aufweist, wobei die Einlassöffnung (4) durch die Öffnungen in dem Gitter gebildet wird.

5. Inhalator gemäß Anspruch 4, wobei die Einlassöffnung koaxial mit einer Längsachse der Kammer (3) ist.

6. Inhalator gemäß Anspruch 4, wobei die Einlassöffnung zu der Längsachse der Kammer (3) verschoben ist.

7. Inhalator gemäß einem der Ansprüche 4 bis 6, wobei die Einlassöffnung (4) mindestens eine Öffnung in dem Bodenelement (7) umfasst, wobei die oder jede Öffnung sich durch das Bodenelement (7) in einem Winkel relativ zur Längsachse der Kammer (3) erstreckt.

8. Inhalator gemäß einem der Ansprüche 4 bis 7, wobei die Kammer (3) eine Stirnwand an dem anderen Ende der Kammer (3) gegenüber dem Bodenelement (7) aufweist, wobei die Auslassöffnung in der Stirnwand ausgebildet ist, die Stirnwand ein Gitter aufweist, wobei die Auslassöffnung (5) von den Öffnungen in dem Gitter ausgebildet ist.

9. Inhalator gemäß Anspruch 8, wobei die Kammer (3) einen Abschnitt aufweist, der sich über die Stirnwand hinaus in einer Richtung weg von der Einlassöffnung (4) erstreckt.

10. Inhalator gemäß einem der Ansprüche 4 bis 9, wobei der Bypass-Lufteinlass (6) in einer Wand der Kammer (3) benachbart zu dem Bodenelement (7) angeordnet ist.

11. Inhalator gemäß Anspruch 10, wobei das Bodenelement (7) eine Seitenwand des tangentialen Bypass-Lufteinlasses (6) bildet.

12. Inhalator gemäß einem der Ansprüche 4 bis 9, wobei der tangentiale Bypass-Lufteinlass (6) von dem Bodenelement in Richtung der Stirnwand weg beabstandet ist und teilweise durch die Stirnwand gebildet wird.

13. Inhalator gemäß einem der Ansprüche 10 bis 12, wobei der tangentiale Bypass-Lufteinlass (6) aus einer bogenförmig ausgeformten Strömungsbahn gebildet ist.

14. Inhalator gemäß einem der vorhergehenden Ansprüche, wobei die Kammer (3) innerhalb des Mundstücks (2) ausgebildet ist.

Revendications

1. Inhalateur pour produire un aérosol de médicament pulvérulent, l'inhalateur comportant un embout (2), un dispositif de perçage (8) pour percer le couvercle d'une alvéole contenant une dose de médicament et une base (7), le dispositif de perçage (8) comprenant une tête de perçage (9) ayant des éléments de perçage (10) suspendus à celle-ci, un dispositif de brumisation ayant une chambre (3) de section transversale substantiellement circulaire, des orifices d'entrée et de sortie (4, 5) à des extrémités opposées de la chambre (3) pour l'écoulement d'air chargé de médicament à travers la chambre (3) entre lesdits orifices (4, 5) et une entrée d'air de dérivation (6) pour

l'écoulement d'air propre dans la chambre (3), ladite entrée d'air de dérivation (6) étant disposée de telle sorte que de l'air entre dans la chambre (3) à travers ladite entrée (6) substantiellement tangentiellement à la paroi de la chambre (3) et étant configurée de telle sorte que de l'air entrant dans la chambre (3) à travers ladite entrée (6) forme un cyclone dans la chambre (3) qui entre en interaction avec l'air chargé de médicament s'écoulant entre les orifices d'entrée et de sortie (4, 5), **caractérisé en ce que** le dispositif de perçage (8) est disposé sous l'embout (2) sur le côté opposé de la base (7) et s'étend depuis, ou est connecté à, la base (7), la tête de perçage (9) ayant des passages d'écoulement d'entrée d'air propre (11) espacés autour d'un passage central de sortie d'air chargé de médicament (12), les éléments de perçage (10) d'alvéole étant configurés pour percer le couvercle (13a) de ladite alvéole (13) de telle sorte que lorsqu'un patient inspire à travers l'embout (2), de l'air propre entre dans l'alvéole (13) à travers les passages d'écoulement d'entrée d'air (11) et entraîne la dose contenue dans l'alvéole (13), l'air chargé de médicament s'écoulant alors hors de l'alvéole (13) à travers le passage central de sortie d'air chargé de médicament (12) et la chambre (3) jusqu'à l'embout (2).

2. Inhalateur selon la revendication 1, dans lequel la chambre (3) est configurée de telle sorte que le cyclone entre en interaction avec l'écoulement d'air chargé de médicament de manière à conférer à l'écoulement d'air chargé de médicament une forme de chemin hélicoïdal à mesure qu'il s'écoule depuis l'orifice d'entrée (4) jusqu'à l'orifice de sortie (5).

3. Inhalateur selon l'une quelconque des revendications précédentes, dans lequel la chambre (3) est de forme conique.

4. Inhalateur selon l'une quelconque des revendications précédentes, dans lequel l'orifice d'entrée (4) est formé dans la base (7), la base (7) comportant une portion à maillage, l'orifice d'entrée (4) étant formé par les ouvertures dans ledit maillage.

5. Inhalateur selon la revendication 4, dans lequel l'orifice d'entrée est coaxial à un axe longitudinal de la chambre (3).

6. Inhalateur selon la revendication 4, dans lequel l'orifice d'entrée est décalé de l'axe longitudinal de la chambre (3).

7. Inhalateur selon l'une quelconque des revendications 4 à 6, dans lequel l'orifice d'entrée (4) comprend au moins une ouverture dans ladite base (7), la ou chaque ouverture s'étendant à travers la base (7) suivant un angle par rapport à l'axe longitudinal de la chambre (3).

8. Inhalateur selon l'une quelconque des revendications 4 à 7, dans lequel la chambre (3) comprend une paroi d'extrémité à l'autre extrémité de la chambre (3) opposée à la base (7), l'orifice de sortie étant formé dans ladite paroi d'extrémité, la paroi d'extrémité comprenant un maillage, l'orifice de sortie (5) étant formé à partir d'ouvertures dans le maillage.

9. Inhalateur selon la revendication 8, dans lequel la chambre (3) présente une portion qui s'étend au-delà de la paroi d'extrémité dans une direction s'éloignant de l'orifice d'entrée (4).

10. Inhalateur selon l'une quelconque des revendications 4 à 9, dans lequel l'entrée d'air de dérivation (6) est située dans une paroi de la chambre (3) adjacente à la base (7).

11. Inhalateur selon la revendication 10, dans lequel la base (7) forme une paroi latérale de l'entrée d'air de dérivation tangentielle (6).

12. Inhalateur selon l'une quelconque des revendications 4 à 9, dans lequel l'entrée d'air de dérivation tangentielle (6) est espacée de la base vers la paroi d'extrémité et est partiellement formée dans la paroi d'extrémité.

13. Inhalateur selon l'une quelconque des revendications 10 à 12, dans lequel l'entrée d'air de dérivation tangentielle (6) est formée d'un chemin d'écoulement de forme arquée.

14. Inhalateur selon l'une quelconque des revendications précédentes, dans lequel la chambre (3) est formée à l'intérieur de l'embout (2).

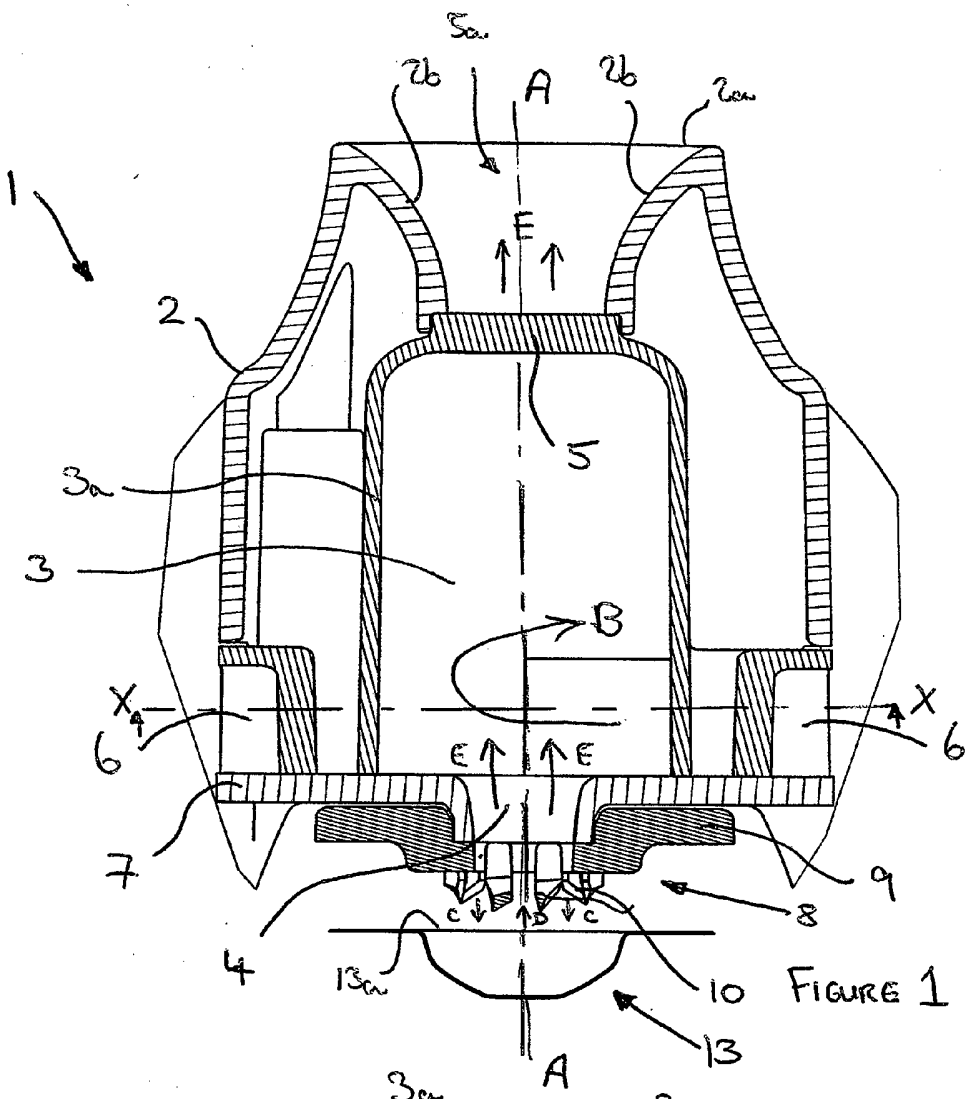


FIGURE 1

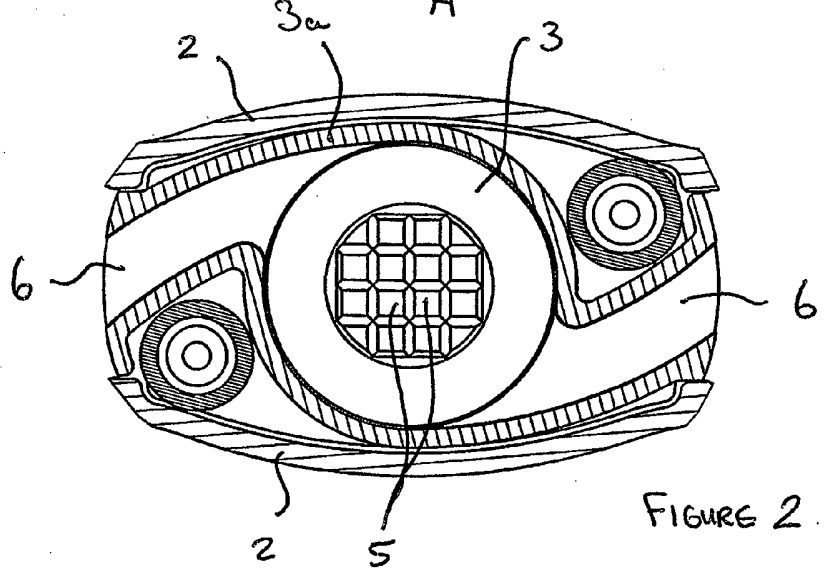


FIGURE 2

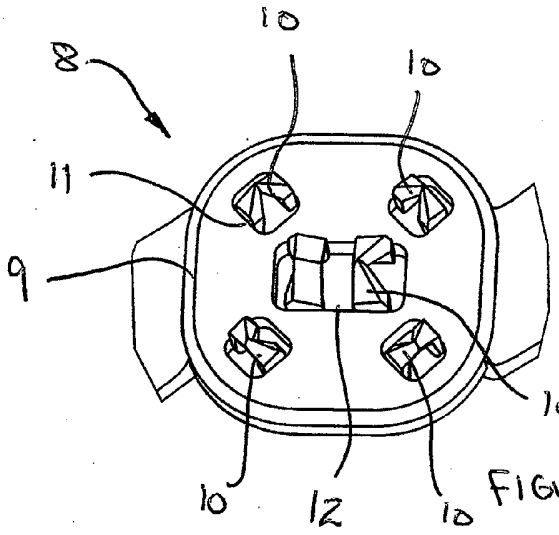


FIGURE 3

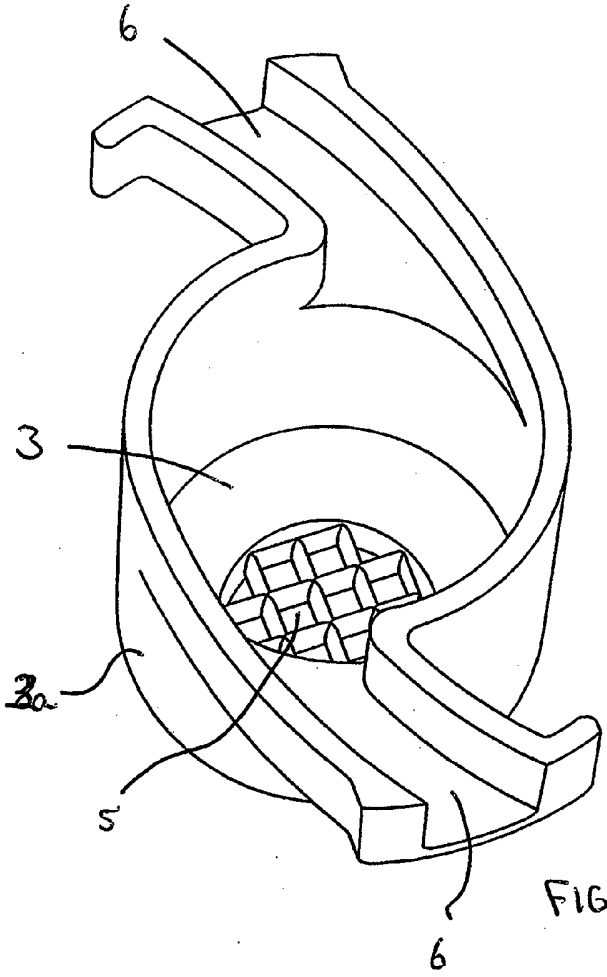


FIGURE 4

REFERENCES CITED IN THE DESCRIPTION

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INHALÁTOR

Szabadalmi igénypontok

1. Inhalátor porított gyógyszer belélegezhető aeroszoljának előállítására, az inhalátor tartalmaz szájrészt (2), lyukasztóeszközt (8) a gyógyszer dózisát tartalmazó bliszter fedelének átlyukasztásához és alapot (7), a lyukasztóeszköznek (8) lyukasztóelemekkel (10) rendelkező lyukasztófeje (9) van, alapvetően kör keresztmetszetű kamrával (3) rendelkező porlasztóeszközt, a kamra (3) szemközti végein beömlő- és kiömlőnyílást (4, 5) gyógyszerhordozó levegőnek a nyílások (4, 5) között a kamrán (3) keresztüli áramlásához, valamint áteresztő légbeömlőt (6) tiszta levegő kamrába (3) áramlásához, az áteresztő légbeömlő (6) úgy van elrendezve, hogy a levegő a kamrába (3) a légbeömlőn (6) át alapvetően a kamra (3) falához képest érintőirányban lép be, továbbá úgy van kiképezve, hogy a légbeömlőn (6) át a kamrába (3) belépő levegő a beömlő- és a kiömlőnyílás (4, 5) között áramló gyógyszerhordozó levegővel a kamrában (3) kölcsönható ciklont képez, **azzal jellemezve**, hogy a lyukasztóeszköz (8) a szájrész (2) alatt az alap (7) átellenes oldalán van elhelyezve és az alapról (7) terjed ki vagy az alaphoz van csatlakoztatva, a lyukasztófejnek (9) központi gyógyszerhordozólevegő-kiömlőjárat (12) körül térközzel elrendezett tisztalevegő-beömlőjáratai (11) vannak, a bliszterlyukasztó-elemek (10) a bliszter (13) fedelét (13a) olyan módon átlyukasztón vannak kiképezve, hogy a páciens szájrészen (2) keresztül történő belégzésekor a levegőbeömlő-járatokon (11) át a bliszterbe (13) tiszta levegő lép be és a bliszterben (13) lévő dózist magával ragadja, ezt követően a gyógyszerhordozó levegő a bliszterből (13) a központi gyógyszerhordozólevegő-kiömlőjáraton (12) és a kamrán (3) át a szájrészbe (2) áramlik.

2. Az 1. igénypont szerinti inhalátor, ahol a kamra (3) a ciklon és a gyógyszerhordozó levegő áramának olyan kölcsönhatását kiváltón van kiképezve, hogy a gyógyszerhordozó levegő a beömlőnyílástól (4) a kiömlőnyíláshoz (5) áramlása során csavarvonal alakú pályán halad.

3. Az előző igénypontok bármelyike szerinti inhalátor, ahol a kamra (3) elkeskenyedően van kiképezve.

4. Az előző igénypontok bármelyike szerinti inhalátor, ahol a beömlőnyílás (4) az alapban (7) van kiképezve, az alap (7) hálórészt tartalmaz, a beömlőnyílást (4) a háló nyílásai képezik.

5. A 4. igénypont szerinti inhalátor, ahol a beömlőnyílás a kamra (3) hossztengelyével egytengelyű.

6. A 4. igénypont szerinti inhalátor, ahol a beömlőnyílás a kamra (3) hossztengelyéről el van tolva.

7. A 4-6. igénypontok bármelyike szerinti inhalátor, ahol a beömlőnyílás (4) az alapban (7) legalább egy nyílást tartalmaz, a legalább egy nyílás az alapon (7) a kamra (3) hossztengelyével szöget bezárón halad át .

8. A 4-7. igénypontok bármelyike szerinti inhalátor, ahol a kamra (3) az alappal (7) szemközti másik végén végfallal rendelkezik, a kiömlőnyílás a végfalban van kiképezve, a végfal hálót tartalmaz, a kiömlőnyílást (5) a háló nyílásai képezik.

9. A 8. igénypont szerinti inhalátor, ahol a kamrának (3) egy a végfalon a beömlőnyílástól (4) elfelé mutató irányban túlnyúló része van.

10. A 4-9. igénypontok bármelyike szerinti inhalátor, ahol az áteresztő légbeömlő (6) a kamra (3) falában az alappal (7) szomszédosan helyezkedik el.

11. A 10. igénypont szerinti inhalátor, ahol az alap (7) képezi az érintőirányú áteresztő légbeömlő (6) oldalfalát.

12. A 4-9. igénypontok bármelyike szerinti inhalátor, ahol az érintőirányú áteresztő légbeömlő (6) az alaptól a végfal irányában távközzel van elrendezve és azt részben a végfal képezi.

13. A 10-12. igénypontok bármelyike szerinti inhalátor, ahol az érintőirányú áteresztő légbeömlőt (6) ívelt alakú áramlási pálya képezi.

14. Az előző igénypontok bármelyike szerinti inhalátor, ahol a kamra (3) a szájrészben (2) van kiképezve.