(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 January 2008 (17.01.2008)

PCT

(10) International Publication Number
WO 2008/008021 A1

(51) International Patent Classification:
A61M 15/00 (2006.01)

(21) International Application Number:
PCT/SE2007/000682

(22) International Filing Date: 12 July 2007 (12.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/831,145 14 July 2006 (14.07.2006) US

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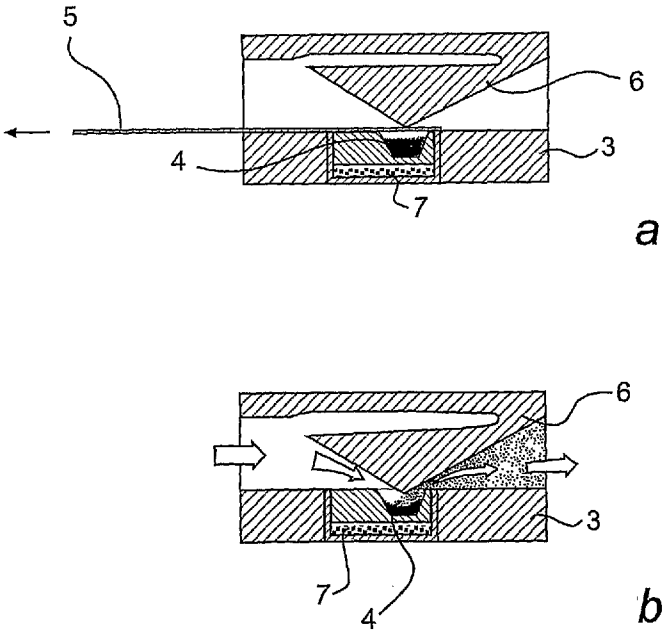
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** INHALATION SYSTEM AND DELIVERY DEVICE FOR THE ADMINISTRATION OF A DRUG IN THE FORM OF DRY POWDER.



(57) **Abstract:** The present invention relates to an inhalation system for the administration of a drug in the form of dry powder by inhalation through an airflow path. The system comprises a delivery device, having a mouthpiece through which the powder is inhaled, a dose cassette comprising at least one drug cavity for each dose, comprising a dose to be delivered. The cassette being sealed by a lid. A resilient member is introduced into the air flow path to guide/direct the air flow into the drug cavity after the lid is removed from the cassette.

WO 2008/008021 A1

Inhalation system and delivery device for the administration of a drug in the form of dry powder

Technical Field

The present invention relates to an inhalation system for the administration of a drug/medicament in the form of dry powder by inhalation through an air flow path. The system comprises a delivery device, having a mouthpiece through which the powder is inhaled, a dose cassette comprising at least one drug cavity for each dose, comprising a dose to be delivered. The dose cassette is sealed by a lid.

The present invention further relates to a single dose disposable delivery device, having a mouthpiece through which a drug/medicament is inhaled from a single dose cassette comprising at least one drug cavity, comprising the dose to be inhaled.

Background of the Invention

The present invention relates to a system and a single dose disposable dry powder inhalation device. The system comprises an inhalation unit and a pre-filled drug cassette. The cassette comprises doses to be inhaled, stored in separately sealed cavities. The system may be used for early clinical studies but can also be used for other production in large scale for regular use of a patient suffering from a respiratory disorder or, if desired, treating a systematic disease through administration of a drug via inhalation.

Available devices with separate doses are capsule based devices e.g. Spinhaler®, Rotahaler®, FlowCaps® and Cyclohaler®. A capsule is fragile and moisture sensitive and must be stored in individual blister packs. When opening the capsule, the walls are ruptured and fragments of the capsule might be inhaled.

In WO98/34661 a single dose disposable inhaler for administering powder by inhalation is described. The known inhaler comprises a channel through which a stream of air may be drawn by inhalation of a user; and a powder dispenser for providing said powder in said stream of air for inhalation by the user. The channel includes at least one deagglomeration section with a section inlet, a section outlet downstream of said section

inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider. The divider has a surface opposite said section inlet and said surface is oriented at an angle substantially perpendicular to the flow of said stream of air passing through said section inlet.

The Object of the Invention

The object of the present invention is to provide an inhalation system for the administration of a drug in the form of dry powder delivered in separate doses that provides an alternative to the known inhaler mentioned above.

Summary of the Invention

According to a first aspect of the invention, a system for the administration of a drug in the form of dry powder by inhalation through an air flow path is provided. The system comprises a delivery device, having a mouthpiece through which the powder is inhaled, and a dose cassette. The dose cassette comprises at least one drug cavity for each dose, comprising a dose to be delivered, and is sealed by at least one lid. The system further comprises a resilient member, which is introduced into the airflow path to direct the airflow into the drug cavity after the lid is removed from the cassette.

The system provides high compliance and low cost per dose. Due to the use of a drug cassette, the system is both durable and robust. Further, the cassette is suitable for labelling. With the system according to the present invention, fine particle fraction and low retention is achieved.

The system according to the present invention is suitable for low volume (<1k units) manual filling and assembly. The exactly same system is also suitable for production in high volumes (>1M units) using a fully automated production line.

According to at least one embodiment of the invention, the resilient member protrudes into the drug cavity. By introducing the resilient member into the drug cavity, the cavity is efficiently emptied when the user inhales.

According to at least one embodiment of the invention, the resilient member is adapted to create a turbulent airflow in the drug cavity to efficiently retract the powder there from. The thus created turbulent airflow ensures that the cavity is completely emptied in a fast and efficient manner.

According to at least one embodiment of the invention the said delivery device is a single dose disposable delivery device.

According to at least one embodiment of the invention said at least one drug cavity is at least partly embraced by moisture absorbent material.

According to at least one embodiment of the invention said resilient member is provided with a triangular shaped end.

According to at least one embodiment of the invention said resilient member is formed integrally with the inhalation device.

According to at least one embodiment of the invention said system is provided with at least two drug cavities, containing drug to be inhaled simultaneously. By using several drug cavities from which drug is inhaled simultaneously, a flexible dosing range from a few μg to several mg of drug is achieved. The two or more drug cavities may be covered by a common lid or, alternatively, each cavity may be covered with its respective lid.

According to at least one embodiment of the invention each of said drug cavities is at least partly embraced by moisture absorbent material. For extra high moisture protection, moisture protection of the type describes in WO2006/00758 can be used.

With such moisture protection, each moisture permeable region of the structure is protected against the ingress of moisture by locating a moisture absorbing sink between that region and the ambient air outside the structure. When using cassettes with such moisture protection, the system can be stored for long time without risk that the drugs will be damaged by moisture entering the cavities.

According to at least one embodiment of the invention said at least two drug cavities contains drug of the same type.

According to at least one embodiment of the invention said at least two drug cavities contains drug of different type.

According to at least one embodiment of the invention said drugs are being incompatible with each other. Thus, the drugs of different type should be kept separated from each other in order to e.g. avoid one drug adversely affecting the other before they are inhaled. Nevertheless, the drugs may have a combinatory effect in the human body when they have been inhaled.

According to at least one embodiment of the invention said at least two drug cavities are of the same size.

According to at least one embodiment of the invention said at least two drug cavities are of different size.

According to at least one embodiment of the invention said resilient member is a first resilient member which is introduced into the air flow path to guide/direct the air flow into a first drug cavity, the delivery device further comprising a second resilient member which is introduced into the air flow path to guide/direct the air flow into a second drug cavity after the at least one lid is removed from the cassette.

According to at least one embodiment of the invention the first and second resilient members are introduced substantially simultaneously into the air flow path, whereby the drug in the first drug cavity and in the second drug cavity are inhalable substantially simultaneously.

According to a second aspect of the present invention a single dose disposable delivery device having a mouthpiece through which a drug is inhaled from a single dose cassette is provided. The delivery device comprises at least one drug cavity, comprising the dose to be inhaled, said cassette being sealed by at least one lid. The delivery device also comprises a resilient member introduced into the air flow path to direct the air flow into the drug cavity after the lid is removed from the cassette.

According to at least one embodiment of the invention, the delivery device comprises a key, said key being adapted to fit a specific cassette being coupled to a specific delivery device.

According to at least one embodiment of the invention, the delivery device comprises an auxiliary spacer.

According to at least one embodiment of the invention, said spacer is a ventilator.

According to at least one embodiment of the invention said spacer is a holding chamber.

According to at least one embodiment of the invention, the delivery device comprises an auxiliary bellow arranged to discharge drug aerosol into the spacer.

Furthermore, similar to what has been described above, according to at least some embodiments, the delivery device comprises said first and second resilient members and said first and second cavities.

According to a third aspect of the present invention, an inhalation system for the administration of at least one drug in the form of dry powder by inhalation through an air flow path is provided. The inhalation system comprises a delivery device having a mouthpiece through which the powder is inhaled. The inhalation system also comprises a dose cassette comprising for each dose at least at least a first and a second drug cavity containing drug to be inhaled simultaneously, said cassette being sealed by at least one lid. At least one directing member is present in the air flow path to guide/direct the air flow into the drug cavities after the at least one lid is removed from the cassette.

According to a fourth aspect of the present invention, a single dose disposable delivery device having a mouthpiece through which at least one drug is inhaled from a single dose cassette is provided. The delivery device comprises at least at least a first and a second drug cavity comprising the dose to be inhaled, said cassette being sealed by at least one lid. The delivery device also comprises a directing member introduced into the air flow path to direct the air flow into the drug cavities after the at least one lid is removed from the cassette.

The third and the fourth aspects of the invention may enable a user to select whether to inhale the drug from just one cavity or from both cavities. The drug in the two cavities may either be the same or different. To provide the user with the above selecting options, the cavities are suitably covered by a respective lid. However, the invention according to the third and fourth aspects of the invention are not limited to multiple lids, but additionally encompass the possibility of having a single lid covering both cavities. Furthermore, even though the directing member may optionally be a resilient member as has been described above in connection with the first and second aspects of the invention, the directing

member may, as an alternative, be non-resilient. It should also be understood that any other feature described in connection with the first and second aspects of the invention may also be comprised in an inhalation system or delivery device according to the third and fourth aspects of the invention.

The delivery device of the present invention may be used with any suitable form of powder, including powders introduced into the air stream in the raw state or as agglomerate, micronised or carrier based formulation. Furthermore, the active ingredient or ingredients of the powder may be diluted with one or more substances such as lactose and may include substances for the treatment of various conditions, not necessarily respiratory conditions. Indeed, the powder can include genetic material and need not be restricted to human use only.

Drugs suitable for administration by the powder inhaler of the present invention are any which may be delivered by inhalation and include for example β2-adrenoreceptor agonists, for example, salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators, for example, ipratropium bromide and the like; glucocorticosteroids, for example, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone and the like, and their pharmacologically acceptable esters and salts; antiallergic drugs, for example, sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic drugs; tranquilisers; cardiac glycosides; hormones; antihypertensive drugs; antidiabetic drugs; antiparasitic drugs; anticancer drugs; sedatives; analgesic drugs; antibiotics; antirheumatic drugs; immunotherapies; antifungal drugs; antihypotension drugs; vaccines; antiviral drugs; proteins; polypeptides and peptides, for example, peptide hormones and growth factors; polypeptide vaccines; enzymes; endorphines; lipoproteins and polypeptides involved in the blood coagulation cascade;

vitamins; and others, for example, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

Suitable glucocorticosteroids include budesonide, fluticasone (e.g. as propionate ester), mometasone (e.g. as furoate ester), beclomethasone (e.g. as 17-propionate or 17,21-dipropionate esters), ciclesonide, loteprednol (as e.g. etabonate), etiprednol (as e.g. dicloacetate), triamcinolone (e.g. as acetonide), flunisolide, zoticasone, flumoxonide, rofleponide, butixocort (e.g. as propionate ester), prednisolone, prednisone, tipredane, steroid esters according to WO 2002/12265, WO 2002/12266 and WO 2002/88167 e.g. 6α,9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, 6α,9α-difluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxy-androsta-1,4-diene-17β-carbothioic acid S-(2-oxo-tetrahydro-furan-3S-yl) ester and 6α,9α-difluoro-11β-hydroxy-16α-methyl-17α-[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, steroid esters according to DE 4129535, steroids according to WO 2002/00679, steroids according to WO 2005/041980, steroids GSK 870086, GSK 685698, GSK 799943 and the like.

Preferably the bronchodilator is a long-acting β_2-agonist. Suitable long-acting β_2-agonists include salmeterol, formoterol, bambuterol, TA 2005 (chemically identified as 2(1H)-Quinolone, 8-hydroxy-5-[1-hydroxy-2-[[2-(4-methoxy-phenyl)-1-methylethyl]-amino]ethyl]-monohydrochloride, [R-(R*,R*)] also identified by Chemical Abstract Service Registry Number 137888-11-0 and disclosed in U.S. Patent No 4.579.854 (= CHF-4226, carmoterol)), QAB149 (CAS no 312753-06-3; indacaterol), GSK 159797, formanilide derivatives e.g. 3-(4-{[6-({(2R)-2-[3-(formylamino)-4-hydroxyphenyl]-2-hydroxyethyl}amino)hexyl]oxy}-butyl)-benzenesulfonamide as disclosed in WO 2002/76933, benzenesulfonamide derivatives e.g. 3-(4-{[6-({(2R)-2-hydroxy-2-[4-hydroxy-3-(hydroxy-methyl)phenyl]ethyl}amino)-hexyl]oxy}butyl)-benzenesulfonamide as disclosed in WO 2002/88167, aryl aniline receptor agonists as disclosed in WO 2003/042164 and WO 2005/025555, indole derivatives as disclosed in WO 2004/032921 and the like.

Among the anticholinergic compounds may be mentioned ipratropium (e.g. as bromide), tiotropium (e.g. as bromide), oxitropium (e.g. as bromide), tolterodine, AD-237 (Arakis), quinuclidine derivatives as disclosed in US 2003/0055080 and the like. Several of these compounds could be administered in the form of pharmacologically acceptable esters, salts, solvates, such as hydrates, or solvates of such esters or salts, if any. Both racemic mixtures as well as one or more optical isomers of the above compounds may be used with the present invention.

Brief Description of the Drawings

Fig. 1 is a schematic overview illustrating a single dose disposable delivery device, here in the form of an inhalation unit.

Figs. 2a and 2b illustrate details of the inhalation unit.

Figs. 3a-3d illustrate various cassette configurations.

Fig. 4 illustrates the cassettes placed in a row.

Figs. 5a-5c show a sequence in which the lidding material is removed from a cassette that has been torn off from the row of cassettes illustrated in Fig. 4.

Figs. 6a and 6b schematically illustrate details of at least one embodiment of an inhalation unit as an alternative to the one illustrated in Figs. 2a and 2b.

Fig. 7 schematically illustrates details of at least another embodiment of an inhalation unit.

Detailed Description of the Drawings

Fig. 1 is a schematic overview illustrating a single dose disposable delivery device 1, here in the form of an inhalation unit, according to at least one embodiment of the present invention. The device comprises a mouthpiece 2 through which the user inhales. The inhalation channel is configured to give good performance in terms of fine particle fraction (FPF) around 30% and low retention. The delivery device 1 is a single injection moulded component. A cassette 3 with prefilled drug cavities 4 is loaded into the device. The cassette is injection moulded and comprises one or more drug cavities 4 holding the

formulation, and a lidding material 5 e.g. Al foil. If needed, inhalation units can be coded to only work with a certain cassette.

Figs. 2a and 2b illustrate details of the inhalation unit, with a resilient member 6 located above a loaded cassette 3 with a drug cavity 4. In Fig. 2a an arrow indicates that the lidding material 5 covering the drug cavity 4 is to be peeled off. Thereafter, a user may inhale the drug contained in the drug cavity 4. Before the lidding material 5 is peeled off, a portion of the resilient member 6, here illustrated as a tip of the resilient member 6, rests or is biased against the lidding material 5. As shown in Fig. 2b the resilient member 6 is allowed to protrude into the drug cavity 4 after the lidding has been peeled off. The airflow created when the user inhales is thus led into the open drug cavity, enabling the cavity to be emptied of powder, as indicated by the arrows in Fig. 2b. The resilient member 6 is preferably designed to create a turbulent airflow when air enters the drug cavity 4. This is to achieve an efficient emptying of the drug cavity 4. The inhalation unit can accommodate any suitable cassette filled with any suitable formulation, drug, dose size etc. If needed the inhalation units can be coded to only work with a certain cassette, e.g. the inhalation unit may comprise a key which is adapted to fit a specific cassette.

Figs. 3a-3d illustrate details of various cassette configurations, with different shape and size of drug cavities 4. The cassettes 3 are injection moulded and comprise one or more drug cavities holding the drug to be inhaled, and a lidding material, e.g. Al foil, which is folded in two layers. When the cassette has more than one drug cavity, several chemically incompatible drugs can be inhaled simultaneously to provide a combinatory effect. The cassettes 3 can be filled either manually or by using commercial dosating fillers. A simple bench top filling equipment can be used for small series down to about 1 g of formulation. The preferred formulation is a carrier-based formulation but also a pure micronised powder can be used. After the cassettes are filled with the drug, the cassettes are sealed using conventional heat sealing. The cassettes can now be distributed and stored separate from the inhalation unit. The cassette 3 can have dual walls with a desiccant 7 in between. For extra high moisture protection, cassettes with moisture protection of the type described in WO2006/00758 can be used. The drug cavities 4 in the cassette can be shaped for different filling volumes or types of formulation. The filling weigh can be from 500 ug

to 30 mg, preferably from 1 mg to 20 mg, and most preferably from 1 mg to 15 mg. The cassette 3 can have more than one drug cavity to accommodate several chemically incompatible drugs (see e.g. Fig. 3d) and the different formulations will be inhaled simultaneously to give a combinatory effect.

Each cassette can either be provided as a separate unit or be provided as a set of cassettes, the latter being illustrated in Fig. 4.

Fig. 4 illustrates the cassettes 3 placed in a row. The lidding material is folded in two layers (as illustrated in Figs. 3a-3d). A cassette 3 is torn off, suitably along a perforated line, from the row of cassettes. Next, as illustrated in Fig. 5a, the lidding material 5 in the shape of a strap on the cassette is folded back before the cassette is inserted into a delivery device which is then closed. The delivery device is then locked and cannot be opened. The strap extends out of the delivery device and can easily be pulled off. By pulling of the strap (Fig. 5b), the formulation is exposed and the device is ready for inhalation (Fig. 5c). During inhalation the air is forced through the drug cavity by a resilient member that bends down into the drug cavity after removing the foil. After inhaling, the complete system is disposed. All retained drug, if any, is contained inside the device and cannot be accessed by the user. Further, by disposing the system after use, the problem with repeated retention disturbing the system to give a correct dose is avoided. The system can be fitted with an auxiliary bellow to actively discharge the aerosol into a ventilator or spacer.

The use of two drug cavities illustrated in Fig. 3d is further illustrated in Figs. 6a and 6b, which show details of at least one embodiment of an inhalation unit as an alternative to the one illustrated in Figs. 2a and 2b. As can be seen in Figs. 6a and 6b, when the lidding material 5 is torn off, two resilient members 6 (here shown as formed in one piece) are enabled to protrude into their respective associated drug cavity 4, whereby both drugs may be inhaled simultaneously.

Fig. 7 schematically illustrates details of at least another embodiment of an inhalation unit. For clarity purposes, the inhalation unit is shown in a perspective view and partially in cross-section. While Figs. 6a and 6b illustrate the two cavities being serially arranged, Fig. 7 illustrates two cavities being arranged in parallel. A lidding material 5 in the form of a single strap may cover both cavities, or as illustrated in Fig. 7, two straps 5 may cover a

respective cavity, thereby allowing the user to uncover one or both cavities before inhalation. By uncovering one or both cavities, the user is thereby allowed to select how large dose to inhale (if the same drug is present in both cavities), or which drug or drugs to inhale (if different drugs are present in the two cavities). It should be noted that the schematic illustrations in Figs 2a and 2b may also represent a cross-sectional view of an inhalation unit according to Fig. 7.

The invention is not limited only to the embodiments described above and shown in the drawings. Thus, the system as well as the delivery device may be modified in all kinds of ways within the scope of the appended claims.

CLAIMS

1. An inhalation system for the administration of at least one drug in the form of dry powder by inhalation through an air flow path comprising:
-a delivery device (1), having a mouthpiece (2) through which the powder is inhaled,
- a dose cassette (3) comprising at least one drug cavity (4) for each dose, comprising a dose to be delivered, said cassette being sealed by at least one lid (5),
characterized in
that a resilient member (6) is introduced into the air flow path to guide/direct the air flow into the drug cavity (4) after the lid (5) is removed from the cassette.

2. The inhalation system according to claim 1, wherein said at least one drug cavity is at least partly embraced by moisture absorbent material.

3. The inhalation system according to claim 1 or 2, wherein the resilient member (6) protrudes into the drug cavity (4).

4. The inhalation system according to claim 3, wherein the resilient member (6) is adapted to create a turbulent air flow in the drug cavity (4) to efficiently retract the powder therefrom.

5. The inhalation system according to any one of the preceding claims, wherein said delivery device (1) is a single dose disposable delivery device.

6. The inhalation system according to any one of the preceding claims, wherein said resilient member (6) is provided with a triangular shaped end.

7. The inhalation system according to any one of the preceding claims, wherein said resilient member (6) is formed integrally with the inhalation device.

8. The inhalation system according to any one of the preceding claims, wherein said system is provided with at least a first and a second drug cavity, containing drug to be

inhaled simultaneously.

9. The inhalation system according to claim 8, wherein each of said drug cavities is at least partly embraced by moisture absorbent material.

10. The inhalation system according to claim 8 or 9, wherein said first and second drug cavities contain drug of the same type.

11. The inhalation system according to claim 8 or 9, wherein said first and second drug cavities contain drug of different type.

12. The inhalation system according to claim 11, wherein said drugs are being incompatible with each other.

13. The inhalation system according to any one of claims 8-12, wherein said first and second cavities are of the same size.

14. The inhalation system according to any one of claims 8-11, wherein said first and second drug cavities are of different size.

15. The inhalation system according to any one of claims 8-14, wherein said resilient member is a first resilient member which is introduced into the air flow path to guide/direct the air flow into the first drug cavity, the delivery device further comprising a second resilient member which is introduced into the air flow path to guide/direct the air flow into the second drug cavity after the at least one lid is removed from the cassette.

16. The inhalation system according to claim 15, wherein the first and second resilient members are introduced substantially simultaneously into the air flow path, whereby the drug in the first drug cavity and in the second drug cavity are inhalable substantially simultaneously.

17. A single dose disposable delivery device, having a mouthpiece through which at least one drug is inhaled from a single dose cassette comprising at least one drug cavity, comprising the dose to be inhaled, said cassette being sealed by at least one lid, **characterized** in that the device comprises a resilient member introduced into the air flow path to direct the air flow into the drug cavity after the at least one lid is removed from the cassette.

18. The delivery device according to claim 17, wherein it comprises a key, said key being adapted to fit a specific cassette being coupled to a specific delivery device.

19. The delivery device according to claim 17 or 18, wherein it comprises an auxiliary spacer.

20. The delivery device according to claim 19, wherein said spacer is a ventilator.

21. The delivery device according to claim 19, wherein said spacer is a holding chamber.

22. The delivery device according to any one of claims 19-21, wherein it comprises an auxiliary bellow arranged to discharge drug aerosol into the spacer.

23. The delivery device according to any one of claims 17-22, wherein said resilient member is a first resilient member which is introduced into the air flow path to guide/direct the air flow into a first drug cavity, the delivery device further comprising a second resilient member which is introduced into the air flow path to guide/direct the air flow into a second drug cavity after the at least one lid is removed from the cassette.

24. The delivery device according to claim 23, wherein the first and second resilient members are introduced substantially simultaneously into the air flow path, whereby the drug in the first drug cavity and in the second drug cavity are inhalable substantially simultaneously.

25. An inhalation system for the administration of at least one drug in the form of dry powder by inhalation through an air flow path comprising:
-a delivery device (1), having a mouthpiece (2) through which the powder is inhaled,
- a dose cassette (3) comprising for each dose at least at least a first and a second drug cavity (4) containing drug to be inhaled simultaneously, said cassette being sealed by at least one lid (5),
characterized in
that at least one directing member (6) is present in the air flow path to guide/direct the air flow into the drug cavities (4) after the at least one lid (5) is removed from the cassette.

26. A single dose disposable delivery device, having a mouthpiece through which at least one drug is inhaled from a single dose cassette comprising at least at least a first and a second drug cavity comprising the dose to be inhaled, said cassette being sealed by at least one lid,
characterized in that
the device comprises a directing member (6) introduced into the air flow path to direct the air flow into the drug cavities after the at least one lid is removed from the cassette.

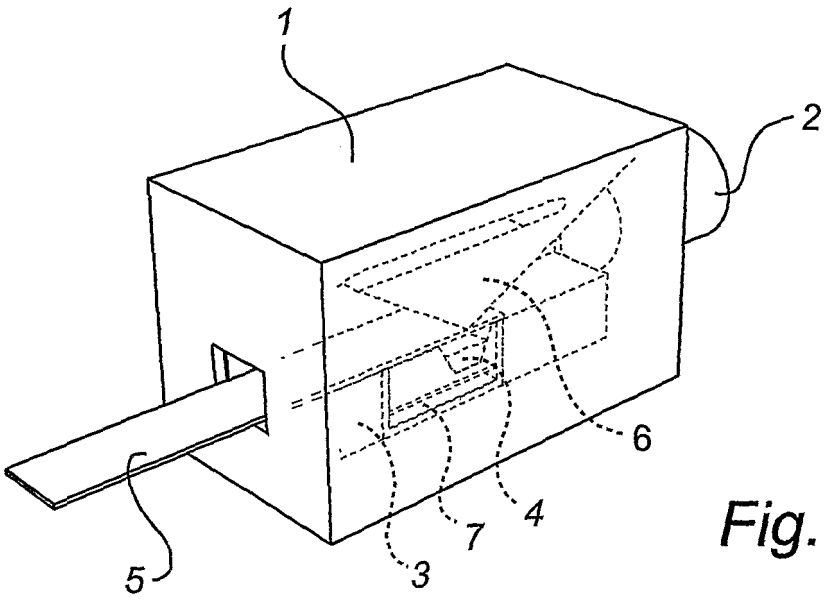


Fig. 1

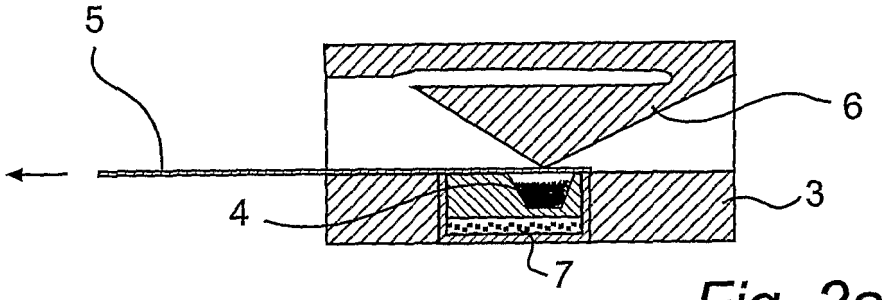


Fig. 2a

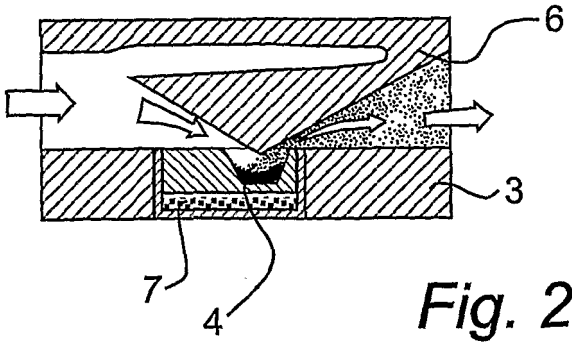


Fig. 2b

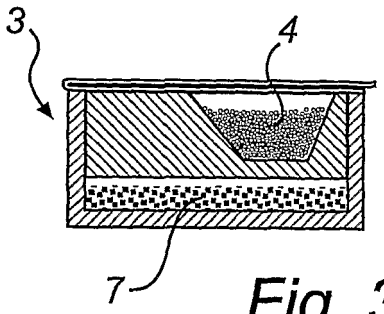


Fig. 3a

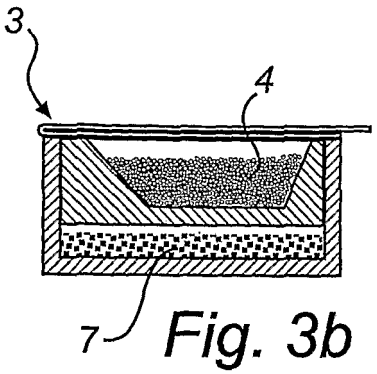


Fig. 3b

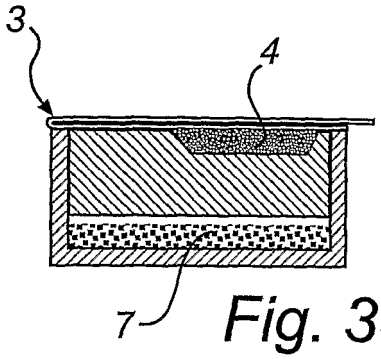


Fig. 3c

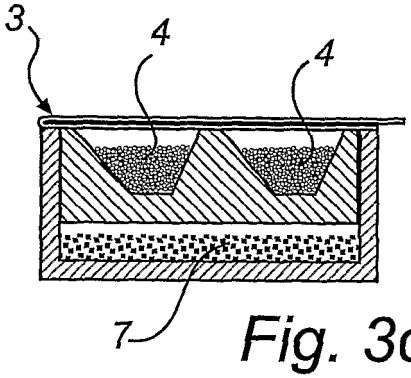


Fig. 3d

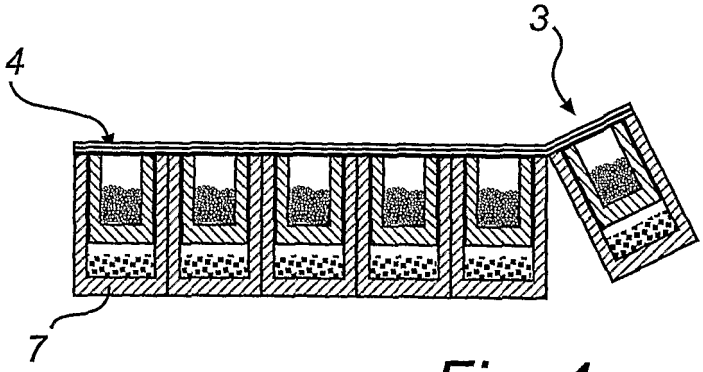


Fig. 4

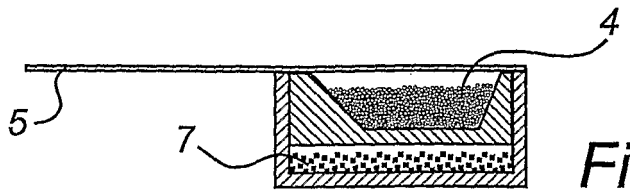


Fig. 5a

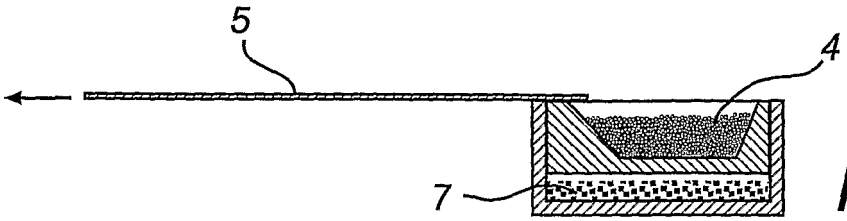


Fig. 5b

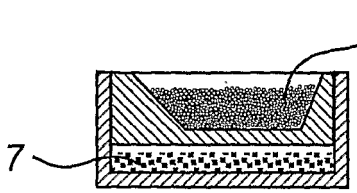


Fig. 5c

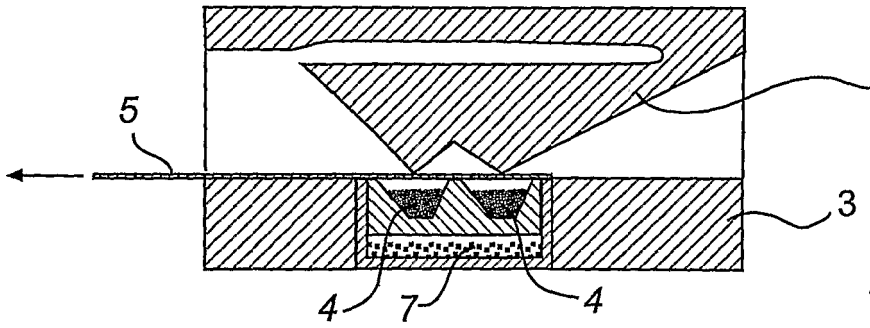


Fig. 6a

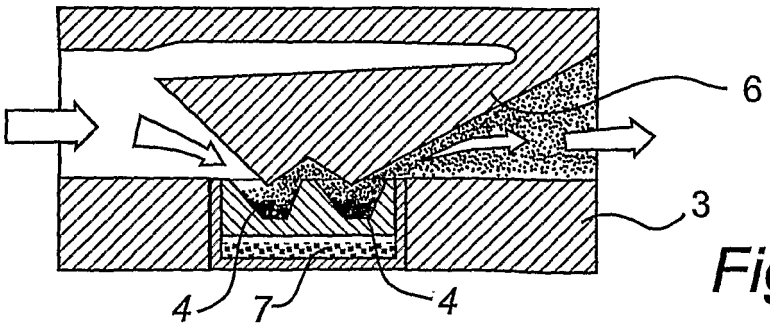


Fig. 6b

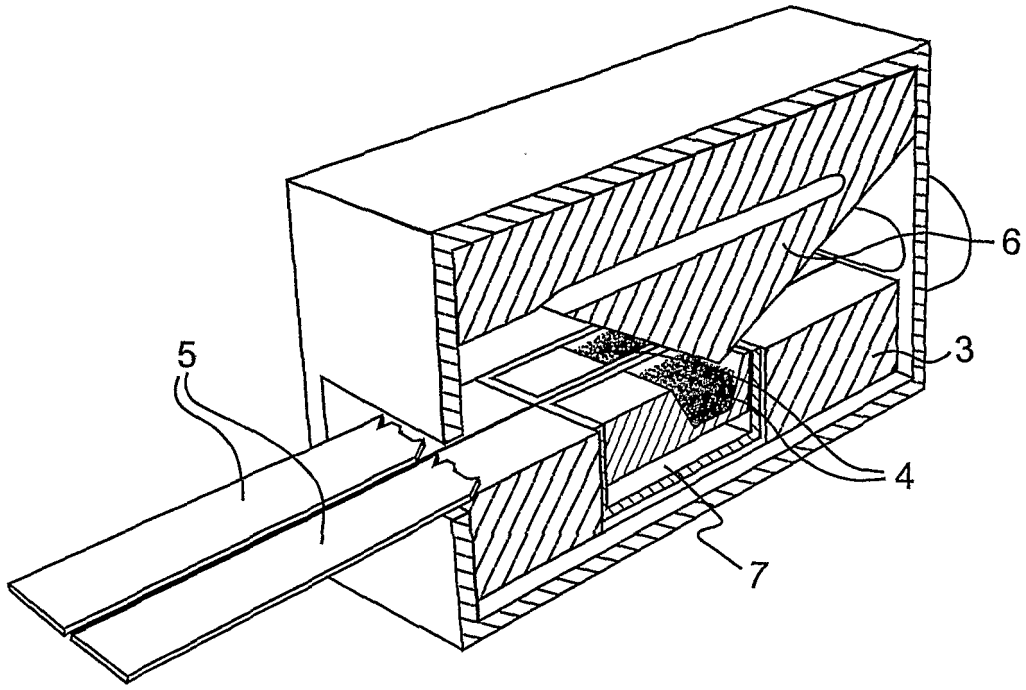


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/000682

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 0064779 A1 (GLAXO GROUP LIMITED), 2 November 2000 (02.11.2000), page 1, line 15 - line 21, figures 6a,6b --	1,2,5-7, 17-22
X	WO 0053248 A1 (GLAXO GROUP LIMITED), 14 Sept 2000 (14.09.2000), figures 1a,1b,5, abstract --	1,2,5-7, 17-22
A	US 20050048003 A1 (H. OHKI ET AL), 3 March 2005 (03.03.2005), figure 18, abstract --	8-16,23-26
A	WO 9204069 A1 (AKTIEBOLAGET ASTRA), 19 March 1992 (19.03.1992), figures 6,7, abstract --	1-26

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2007	16 -10- 2007
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Tomas Lund / MRo Telephone No. +46 8 782 25 00

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International application No.
PCT/SE2007/000682

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9834661 A1 (ASTRA AKTIEBOLAG), 13 August 1998 (13.08.1998), figures 3a-3c, abstract -- --------	1-26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/000682

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A61M 15/00 (2006.01)

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INTERNATIONAL SEARCH REPORT
Information on patent family members

01/09/2007

International application No.
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