INHALER

The present invention relates to an inhalation device for inhalation of medicaments, and to a holder for such medicaments.

Dry powder inhalation (DPI) devices are generally used for inhalation of powdered medicament from capsules. The DPI devices may either single dose or multidose. In the single dose or multiple unit dose DPI formulations, the drug is pre-packaged in capsules or blisters. The reservoir DPI formulations involve a device containing at least a reservoir and a metering chamber to administer an accurate dose of the drug.

Medicament holders, particularly for inhalation devices known in the art are used for receiving and holding a medicament in granular form or powder form, or volatile form or in a capsule containing powdered or volatile medicament. The configuration of the holder is such that the medicament or the capsule located inside the chamber is rotated or moved up and down by air flowing through the chamber in order to disperse the powdered drug medicament into air being sucked.

The medicament holders, for example capsule chambers, known in the art are generally tubular or cylindrical in shape with an air inlet and air outlet arranged coaxially at the bottom and top ends respectively. The air inlet is generally smaller and outlet opening generally larger than the diameter of the capsule. A mouthpiece is arranged axially to the air outlet. Generally, a piercing mechanism is provided to pierce the capsule to enable the medicament present in the capsule to be inhaled. During inhalation, air passes from the air inlet and causes movement of the capsule, and due to this, the medicament present in the capsule is carried by the air to the air outlet opening and mouthpiece and reaches the patient's lungs.

Single dose DPI devices working with capsules, usually possess a system to pierce the capsule. After piercing, the patient inhales the powder contained in the capsule through the device without swallowing the capsule. The capsule remains in the device which is discarded from the device prior to the next use of the device.

WO 91/06333 describes a device for dispensing single doses of a powdered medicament from a container having a plurality of apertures, each of which holds a respective one of said doses, and is sealed by two opposed seals. The device comprises a housing for holding the container, the housing having an outlet and an

airway, which communicates with the outlet and being configured to allow the container to move relative thereto to bring each aperture in succession into registry with the airway. The device includes a piercing member movable from a retracted position in which it is positioned clear from the container into an extended position in which it extends into the aperture, said movement causing rupture of the seals, while expelling substantially no medicament from the aperture.

US Patent No 5,685,294 discloses an inhaler for inhalation of powdered medicament, more particularly a microionised drug preparation, from capsules, the housing of the inhaler comprising tubular chambers for receiving and holding medicament-containing capsules in a revolver magazine with an air inlet at the bottom and an air outlet at the opposite end of the chamber opening into a mouth piece, a cutting device with two blades which are movable into the interior of the chamber in order to open the capsules near the top and bottom ends thereof.

US Patent No 3,807,400 discloses an inhaler comprising an upper member comprising a whirling chamber; a lower member comprising a capsule-receiving chamber and a series of cams and recesses on the inner wall of the lower member; and piercing members resiliently biased away from a capsule received in the capsule-receiving chamber by the action of a spring. In use, rotation of upper and lower members relative to each other causes reciprocations of the piercing members against the cams and recesses provided on the inner wall of the lower member, so as to effect a number of diametrically opposed piercing operations on the capsule.

US Patent No 3,795,244 discloses an inhaler comprising a housing; a rotary member located within the housing and having at one end engagement means adapted to receive a medicament-containing capsule; and a piercing assembly comprising opposed arms with piercing pins mounted thereon and a tubular member slidable relative to the housing and having cam projections from the inner wall. In use, and prior to inhalation, the user inserts a capsule into the engagement means and is then required to manually slide the tubular member towards the mouthpiece, so that the cams provided on the inner wall of the tubular member push opposed piercing arms towards the capsule, resulting in perforation of the capsule at its free end. The user is then required to manually return the tubular member to its original position, allowing the piercing arms to return to the non-piercing position.

US Patent No 4,069,819 discloses a dry powder inhaler device comprising a nebulising chamber adapted to receive a medicament-containing capsule. A capsule received in the chamber is freely moveable within it. In use, air flow through the nebulising chamber and around the capsule contained therein causes the entire capsule to move within the nebulisation chamber.

US Patent No 3,635,219 discloses a dry powder inhaler device comprising a propeller-like member rotatably mounted in a housing and having mounting means adapted to receive a medicament-containing capsule. In use, flow of inhaled air through the device causes rotation and vibration of the propeller-like member and a capsule mounted thereon, so dispensing medicament into the air stream. The device further comprises spring-loaded piercing members mounted in the housing so as to be normally urged into an inoperative position but which may be manually pushed inwards to perforate a medicament containing-capsule received in the device by the action of pushbuttons or sliding cams.

US Patent No 3,906,950 describes a dry powder inhalation device comprising a swirl compartment and, separately, a capsule-receiving cavity comprising two components, said cavity slidably attached to a pair of relatively moveable elements which hold piercing needles and which telescopically slide inside capsule holder components against the action of a pair of return springs.

US Patent No 5,947,118 relates to a capsule holder for receiving two part capsules, which holder comprises a recess adapted to receive a capsule, wherein the sidewalls of the recess have three or more ribs arranged parallel to the central axis of the recess between which capsules can be clamped by both upper and lower parts with some deformation of the capsule walls. The relative dimensions of the cylinder defined by the ribs and the capsule is such that in use, a capsule received by the ribs is clamped and held firmly in place within the holder.

US Patent No 4,889,114 discloses a dry powder inhaler device comprising a capsule-receiving chamber comprising an air inlet and an air outlet located at opposed ends of the chamber. In use, air flow through the chamber on inhalation causes movement of a capsule received therein, between the air inlet end and the air outlet end of the capsule-receiving chamber. The capsule is freely moveable within the confines of the chamber.

All the known inhalation devices require the user of the device to open the device, insert a medicament-containing capsule, close the device, and pierce the capsule manually by a pushing or rotating action prior to inhalation of the medicament. The user has to perform numerous actions before actual inhalation of the medicament.

We have found that the known medicament holders also have the disadvantage of requiring the user of the inhaler to inhale very deeply in order to try to inhale the full dose of the medicament.

Having appreciated these drawbacks, we have now devised an improved inhaler device and holder.

In its broadest aspect, the present invention provides an inhaler device for inhalation of a medicament from a pierceable capsule, which inhaler comprises a housing for receiving a medicament capsule; closure means for closing the housing, said closure means being moveable relative to the housing; piercing means suitable for piercing a medicament capsule; wherein movement of the closure means relative to the housing causes movement of the piercing means.

In another aspect of the present invention, there is provided an inhaler device for inhalation of a medicament from a pierceable capsule, which inhaler comprises a housing for receiving a medicament capsule; closure means for closing the housing, said closure means being moveable relative to the housing; piercing means suitable for piercing a medicament capsule; and linking means connected to both the closure means and the piercing means, wherein movement of the closure means causes movement of the linking means so as to move the piercing means.

Thus, in use, piercing or perforation of a capsule received in the housing occurs as a consequence of merely closing the housing subsequent to having placed a medicament-containing capsule therein. The user is not required to perform any additional actions prior to inhalation of medicament from the inhaler device, other than inserting a capsule and closing the device.

Preferably, the medicament contained within the capsule is a dry powder medicament. The term capsule is intended to be understood broadly and includes any suitable receptacle for medicament. The capsule may be formed from any suitable material, including gelatin, HPMC, or plastic.

The device may be made from any suitable material. Preferably the device is made of plastic, for example ABS (acrylonitrile butadiene styrene), PC (polycarbonate),

PA (polyacetal) or PS (polystyrene). or mixtures thereof, or of an antistatic material such as delrin.

The closure means can be moveable relative to the housing in any suitable way. The closure means is typically connected to the housing, although they may, if desired be separate parts. Suitably, the closure means is adapted to, or comprises suitable means for, producing movement of the piercing means so as to cause piercing of a capsule. Preferably, the closure means is rotatable relative to the housing. For example, the closure means may be pivotally connected to the housing. Preferably, movement of the closure means causes movement or rotation of a linking means. In one embodiment, rotation of the closure means drives linear displacement of the piercing means. However, the movement of the piercing means is not limited and the piercing means may move in any way, so long as the object of piercing a capsule is achieved. For example, we envisage rotary motion of the piercing means as a possibility.

The movement of the closure means preferably moves the piercing means so as to pierce a capsule positioned within the inhaler housing. Suitably, movement of the closure means from a fully open or fully closed position drives movement of the piercing means from a fully retracted position. The piercing means preferably moves from a fully retracted position to a fully extended piercing position and back to a fully retracted position in response to movement of said closure means between the fully open and fully closed piercing positions.

The housing preferably comprises means to hold a medicament capsule, said holding means preferably comprising a chamber having one or more air inlets and air outlet(s). The or each air inlet and outlet are preferably provided at opposing ends of the chamber. In a preferred embodiment, the or each air inlet is positioned in, or near to, the base of the medicament holder. They may, for example, be provided on the walls of the chamber, for example on the lower walls. The flow of air via the or each inlet may be at a tangent to, or at an angle offset from, the longitudinal axis of the chamber. In one embodiment, a single air inlet may be used. Alternatively, two or more inlets may be used. For example, two air inlets may be provided at or near the bottom of the holder. Preferably, they are provided in the lower vertical walls of the chamber. For example, two inlets may be provided substantially opposite to one another in the

lower walls. These inlets may, if desired, be offset from one another; for example in a tangential arrangement.

The interior of the chamber may be of any suitable shape and dimension. It may, for example, define a single cavity of uniform dimensions Alternatively, the interior of the chamber may comprise one or more steps such that the internal cavity is non-uniform. One additional step in the interior of the chamber is preferred. The or each step is preferably substantially perpendicular with the respect to the longitudinal axis of the chamber, although any suitable angle may be employed.

The closure means preferably comprises a mouthpiece. That is to say, the closure means is preferably such that it includes means by or via which medicament may be inhaled from the device by the user. In what follows, the invention is described with reference to a device wherein the closure means comprises a mouthpiece, it being understood that the invention includes embodiments wherein the closure means may not necessarily comprise or include a mouthpiece. For example, the closure means and mouthpiece could be separate. Thus, in what follows, it is to be understood that references to a mouthpiece may be substituted with references to closure means. The inhaler mouthpiece is preferably pivotably attached to the housing.

The air outlet is suitably positioned so as to connect or coincide with the mouthpiece in its fully closed position. For example, the mouthpiece may suitably comprise means to receive air from an outlet of the medicament chamber, such that when the mouthpiece is closed the means for receiving air is connected with, or cooperates with, the outlet. Any suitable means may be used, for example a tube, which may for example be cylindrical. Conical means may be used. The means may be formed as an integral part of the mouthpiece or may be a separate part. Suitably, the means (e.g. a cylindrical tube) comprises one end which connects with the outlet of the medicament chamber, and another end which comprises an outlet for the medicament, from which outlet medicament is inhaled by the user.

The portion or means of the mouthpiece adapted to receive air (for example the tube described above) from the medicament chamber is preferably of an optimised length. Preferably, the length is between about 25 and 35mm. We have found a length of 31.6 mm +/- 10 % to give very good performance.

The mouthpiece is preferably provided with a mesh which is positioned in proximity to the chamber outlet when the mouthpiece is in a fully closed position.

Preferably, the mesh is provided on a means for receiving air from the outlet of the chamber. Preferably, the mesh is on, or near to, the end of the said means (for example, a tube), such that the mesh is brought into proximity with the outlet of the medicament chamber when the mouthpiece is in the closed position. The mesh may be provided as a separate part or as an integral part of the device. A mesh may if desired also, or alternately, be provided on or close to the outlet of the medicament chamber. Again, the mesh may be an integral or a separate part. The primary function of the mesh is to prevent the capsule or fragments thereof from being inhaled by the user.

The device preferably further comprises locking means. The locking means suitably locks the closure means, for example the mouthpiece, in a predetermined position relative to the housing. Preferably, the locking means is operable to retain said closure means in the fully closed position. The locking means may provide a rigid pivot for the opening and closing of the device. Alternatively, the locking means may comprise a lip or suitable projection on a portion of the capsule holder adapted to be received by a portion of the closure means, for example to provide a snap-fit. Preferably, the arrangement is such as to secure or lock the mouthpiece in the closed position.

The piercing means may be any suitable means but preferably comprises one or more piercing pins and/or one or more blades, although piercing pins are most preferred. The piercing means (suitably pins) may be of any suitable material, and are preferably metallic. For example, stainless steel may be used.

The device preferably further comprises guide means to guide the movement of the piercing means. For example, the guide means may comprise one or more tubes extending from an external part of the medicament chamber. One or more suitable holes may be provided in the chamber, the arrangement being such that the guiding means serve to guide the piercing means through the said holes so as pierce a capsule.

The mouthpiece (3) preferably coincides with the outlet (12) of the capsule holder (2) so as to receive the medicament during inhalation. Preferably, a link actuator (4) adapts the link (5) to the mouthpiece (3) in such a manner that the link actuator (4) rotates on rotation of the mouthpiece enabling the piercing pins (7) move laterally.

In another embodiment of the present invention, a link actuator may be replaced or substituted by a link member or a horse-shoe shape member, or any suitable alternate embodiment which serves to move the piercing pin(s) on opening/closing of the mouthpiece.

Another embodiment of the present invention provides a method for piercing a capsule or similar suitable medicament receptacle in an inhaler device according to the present invention.

In the following description the terms housing and lower body are used interchangeably.

In one aspect, the present invention provides an inhalation device comprising a lower body (1) having a medicament or capsule holder (2) to hold the capsule or similar suitable medicament receptacle; a mouthpiece (3) laterally pivoted to the lower body (1) to rotate about an axis; a link actuator (4) adapted to rotate on rotation of the mouthpiece (3) and being held in the lower body (1); one or more piercing pins (7) for piercing capsules or similar suitable medicament receptacle and being adapted to a link (5); characterized in that the mouthpiece rotates the link actuator (4) that moves the piercing pin(s) linearly to pierce the capsule or similar suitable medicament receptacle in a partial open/closed position of the mouthpiece.

An inhalation device according to the present invention (as shown for example in Figures 1, 2, and 3) generally comprises a lower body (1) having a capsule holder (2) for holding capsules or similar suitable medicament receptacle (10); said capsule holder (2) having an air inlet (11) and an outlet (12); a mouthpiece (3) pivoted laterally to the lower body (1) so as to rotate about an axis and thereby open and close the outlet (12) of the capsule holder (2). The capsule holder (2) is preferably adapted to receive one or more piercing pins (7) that are held in retracted position in a piercing pin holder (6). The piercing pins (7) are operated by a link (5) that enables the linear movement of the piercing pin (7) to pierce the capsule or similar suitable medicament receptacle (10) and retract back.

According to another embodiment of the present invention, the mouthpiece (3) is opened to place the capsule or similar suitable medicament receptacle (10) in the capsule holder (2). On opening the mouthpiece (3) to full open position as shown in Figure 1, the link actuator (4) rotates the link (5) thereby the piercing pins (7) are retracted. On closing the mouthpiece (3) for inhalation, in a partially open/closed

position, the piercing pin(s) (7) pierces the capsule or similar suitable medicament receptacle (10) in the capsule holder (2) as shown in Figure 2. On fully closing the mouthpiece (3), the link actuator (4) rotates and retracts the piercing pin from the medicament holder (2).

According to another embodiment of the present invention, a cover member (8) (for example illustrated in Figures 1-3 and Figure 19) may be attached to the housing or may be moveable relative to the housing. The cover member may be rotatable relative to the housing. For example, it may pivot about the same point as the closure means and housing pivot with respect to each other. The cover member preferably comprises locking means enabling it to lock with the housing. The cover member serves to cover the piercing pin holder, pins, and the link/link actuating mechanism. Preferably the cover member comprises means for locking with the holder when the device is in the assembled state.

In another aspect of the invention, there is provided a holder for a medicament, suitably a dry powder medicament capsule, which holder comprises a chamber suitable for receiving a medicament capsule; and means for generating turbulence in a fluid flow through the chamber such that, in use, the turbulent fluid flow causes vibration of a capsule received by the chamber so as to assist in releasing medicament contained within the capsule.

The present medicament holder maximizes the turbulence in the chamber thereby enhancing drug dispersion and delivery.

The means for generating turbulence preferably also holds, or partially holds, a medicament capsule within the holder. Preferably, the means for generating turbulence holds one end of a medicament capsule. Preferably the capsule is held loosely (either completely, partially or at one end). Suitably, this means that any significant movement of the capsule is prevented but the capsule is still enabled to make small vibratory movements within the chamber. The means for generating turbulence may be any suitable means but preferably comprises one or more projections or flow barriers extending from the inner walls of the chamber. The or each projection may, for example, comprise a flat or polygonal facet, or one or more grooves, ridges, helices, rings, or spheres. The means may, for example, comprise one or more transverse, or substantially transverse, projections (relative to the longitudinal axis of the chamber). By polygonal we mean that the projection or barrier presents several faces to the inside

of the chamber. For example, in cross section, the means for generating turbulence may be substantially triangular or square, or pentagonal, or hexagonal and so on.

The holder is preferably such that the diameter of the space defined by the means for generating turbulence relative to the diameter of a medicament capsule placed in the holder is such that the capsule is held loosely by the means for generating turbulence. The chamber may be any suitable shape, for example cylindrical or conical. Preferably, it is substantially conical.

Preferably the length of the chamber is optimised. Chamber lengths of between about 15 to 30mm may for example be used. We have found particularly good performance with a chamber length of 22 mm +/- 10%.

The holder suitably comprises one or more openings in the sidewalls of the chamber. Preferably, one or more of the openings is provided with guide means for receiving the piercing means, for example one or more piercing pin. Preferably, the guide means protrudes to the exterior of the holder.

The holder preferably comprises a chamber provided with an air inlet and an air outlet. Preferably, the air inlet and air outlet are arranged at opposing ends of the chamber.

The holder may comprise a mesh, and suitably the mesh is provided in the vicinity of the air outlet, the mesh preventing the medicament capsule contained within the chamber to be moved through the air outlet by inhalation during use of the holder. The mesh may be provided as an integral or non-integral component of the holder. For example, the mesh may be manufactured as a separate part and attached to the lower body by a hinge at the pivot point between the mouthpiece and lower body. Alternatively, or in addition, the mesh may be provided within the mouthpiece as described above.

The invention also provides an inhaler device comprising a holder according to the invention, as described herein.

The inhaler device and medicament holder according to the present invention can be manufactured by standard methods well known in the art, as will be apparent to the skilled reader.

The capsule holder (2) according to the present invention, an embodiment of which is shown in Figures 11 to 17, is preferably substantially conically shaped and preferably comprises an air inlet (11) at one end and an air outlet (12) at the opposition

end. The diameter of the air inlet (11) is preferably substantially less than, and the air outlet (12) preferably larger than the capsule diameter. The capsule holder (2) encloses a medicament cavity or chamber (14) for retaining medicament or a capsule containing medicament. The inner wall (12a) of the capsule holder (2) comprises means for generating turbulence (16) in a fluid flow through the chamber. The means for generating turbulence (16) according to the present invention restricts the free flow of air through the chamber (14) thereby causing maximum turbulence in the chamber (14). This turbulence enhances the vibration of the medicament or capsule containing the medicament in the chamber (14) thereby increasing the drug delivery. The means for generating turbulence (16) enables maximum turbulence to be produced with less volume of air during inhalation thereby enabling the user to inhale a substantially full dose of medicament with less effort. Preferably, the means for generating turbulence (16) holds or partially holds the, or part of the, capsule containing the medicament.

According to one embodiment of the present invention, the internal geometry of the capsule holder is different from the outer shape of the capsule holder. Preferably, the capsule holder has a smooth outer wall.

According to another embodiment of the present invention, the means for generating turbulence (16) is a projection (16) as shown in Figure 11. For example, four projections as can be appreciated from Figure 12 may be provided on the inner wall (12a) of the capsule holder (2) that traverse along the holder from the bottom of the holder to above the center of the holder. The number and shape of the projections used can vary widely, but should be such as to produce turbulence within the holder.

In a preferred aspect of the present invention, the facet of the or each projection (16) is flat. Other facet shapes may be used, including polygonal projections. The shape of the projections may also includes grooves, helices, slanting, ridges, spheres, rings and the like so as to provide turbulence in air flowing through the holder.

The capsule holder (2) according to the present invention may be used in inhaler devices with or without a piercing mechanism. According to an embodiment of the invention, the holder is provided with one or more openings (18) on the sidewalls to enable the piercing means that pierce the capsules to pass through the chamber.

To illustrate the invention, a preferred embodiment thereof will now be described with reference to the accompanying drawings (which in no way restrict the scope of the invention and are for the purpose of illustration only) in which:

Figure 1 is a cross-sectional view of the inhalation device, with piercing means in a fully retracted position and the inhaler mouthpiece in a fully opened position.

Figure 2 is a cross-sectional view of the inhalation device, with piercing means in a fully extended piercing position and the inhaler mouthpiece in a partially open/partially closed position.

Figure 3 is a cross-sectional view of the inhalation device, with piercing means in a fully retracted position and the inhaler mouthpiece in a fully closed position.

Figure 4 is a perspective view of the exterior of the inhalation device with the mouthpiece in the fully closed position.

Figure 5 is a plan view of a side of the inhalation device with the mouthpiece in the fully closed position.

Figure 6 is a plan view of the other side (with respect to Figure 5) of the inhalation device with the mouthpiece in the fully closed position.

Figure 7 is a plan view of the rear of the inhalation device with the mouthpiece in the fully closed position.

Figure 8 is a plan view of the front of the inhalation device with the mouthpiece in the fully closed position.

Figure 9 is a top end view of the inhalation device with the mouthpiece in the fully closed position, viewed from the mouthpiece end.

Figure 10 is a bottom end view of the inhalation device with the mouthpiece in the fully closed position, viewed from the lower body end.

Figure 11 is a perspective view of a holder for a dry powder medicament capsule.

Figure 12 is an end view of the medicament capsule holder, viewed from the air outlet end.

Figure 13 is an end view of the medicament capsule holder viewed from the air inlet end.

Figure 14 is a front view of the medicament capsule holder.

Figure 15 is a side view of the medicament capsule holder.

Figure 16 is a rear view of the medicament capsule holder.

Figure 17 is a side view of the medicament capsule holder.

Figure 18 shows a perspective view of a mouthpiece.

Figure 19 shows a perspective view of a cover member.

Figure 20 shows a perspective view of a housing.

Figure 21 shows a perspective view of a linking means.

Figure 22 shows a perspective view of a link actuator.

Figure 23 shows a perspective view of a pin holder.

Figure 24 shows a perspective view of a pin.

A preferred embodiment of the inhalation device is shown in Figures 1 to 10 of the accompanying drawings. A preferred embodiment of the capsule holder is shown in Figures 11 to 17.

The inhalation device comprises a lower body (1) and a mouthpiece (3) attached to the lower body by a pivot (30) about which the mouthpiece (3) is rotatable. The pivot also serves to secure the mouthpiece (3), lower body (1), link actuator (4) and body cover (8) together. The lower body comprises a capsule holder (2) comprising a chamber (14) adapted to receive a medicament-containing capsule, such as a dry powder medicament containing capsule. In use, a capsule is placed into the chamber (14).

The inhalation device comprises piercing pins (7), located within the lower body (1) and connected to the mouthpiece (3) via a link (5) and link actuator (4). The piercing pins (7) are moveable between a retracted position, shown in Figures 1 and 3, and an extended piercing position, shown in Figure 2. In the fully extended position, the piercing pins (7) are extended into the chamber (14) of the capsule holder (2) through openings (18) in a side wall of the capsule holder (2). In the fully extended position, the piercing pins will pierce a capsule (10) positioned within the chamber (14).

In one embodiment, guide means (20) extend from the openings (18) in a side wall of the chamber. The guide means (20) are positioned so as to guide the movement of the piercing pins (7) between fully extended and fully retracted positions. The guide means (20) can be best appreciated from Figures 11 to 17.

Referring to particularly Figures 1 to 3, during use of the inhaler, the mouthpiece (3) is rotated to a fully open position in order to insert a capsule into the housing, and then rotated to the closed position to close the housing and position the mouthpiece correctly for inhalation of medicament from the inhaler device. Rotation of the mouthpiece (3) causes rotation of the linking actuator (4), which rotation in turn drives movement of an assembly comprising link (5), piercing pin holder (6) and piercing pins (7). When the mouthpiece (3) is in either the substantially fully closed or substantially

fully open position the piercing pins (7) are in a fully retracted, non-piercing position; when the mouthpiece (3) is partially open/partially closed, preferably in a position midway between fully closed and fully open positions, the piercing pins (7) are in a fully extended piercing position. Movement of the mouthpiece (3) from a fully open to a fully closed position causes movement of the piercing pins (7) from a fully retracted position (when the mouthpiece (3) is in the fully open position) to a fully extended piercing position (when the mouthpiece (3) is in a position substantially midway between fully closed and fully open) and returns the piercing pins (7) to a fully retracted position when the mouthpiece (3) is in the fully closed position. Similarly, movement of the mouthpiece (3) from a substantially fully closed to a substantially fully open position causes movement of the piercing pins (7) from a fully retracted position to a fully extended piercing position (when the mouthpiece (3) is in a partially open/partially closed position) and returns the piercing means (7) from a fully extended piercing position to a fully retracted position. Although in a preferred embodiment the pins are fully extended when the mouthpiece (3) is about midway between open and closed, it will be understood that the fully extended position of the pins may be achieved when the mouthpiece (3) (or the closure means) is at any position between the open and closed positions, depending on the precise design of the device.

A mesh (9) is positioned in the mouthpiece (3) so as to align with the outlet (12) of the capsule holder (2) when the mouthpiece (3) is in the fully closed position. When the mouthpiece (3) is closed and the mesh (9) is positioned over the outlet (12), the mesh (9) retains a capsule (10) received in the chamber (14) of the capsule holder (2), preventing the capsule (10) from falling out of the inhaler, or being sucked into the outlet/mouthpiece on inhalation by the user. The mesh size can be any suitable size but is preferably of the order of 0.5mm X 0.5mm square to 2mm X 2mm square. More preferably, the mesh size is 1mm X 1mm square +/- 10%. The capsule holder (2) is also provided with locking means. The locking means may be used to lock the mouthpiece (3) in a predetermined position relative to the housing, for example in the fully closed position, and may be located at any suitable place on the device The locking means may comprise a lip or suitable projection (32) adapted to be received by a portion (34) of the mouthpiece (3), which together cooperate so as to provide a snap-fit when the mouthpiece (3) is closed. The mouthpiece (3) can thus be secured in the fully closed position.

A preferred embodiment of the capsule holder (2) is shown in Figures 11 to 17. The capsule holder (2) comprises a chamber (14) to receive a capsule and has an air inlet (11) and air outlet (12). Preferably, the chamber (14) is cylindrical or substantially conical and the air inlet (11) and air outlet (12) are located at opposing ends of the chamber (14). A wall of the chamber (14) is provided with openings (18). When the capsule holder (2) is used in combination with the inhalation device of the invention, these openings are positioned so as to receive the piercing pins (7). Guide means (20) extend from the openings (18) to the exterior of the chamber (14), so as to guide the back and forth movement of the piercing pins (7) into and out of the chamber (14) in response to rotation of the mouthpiece (3).

The holder (2) comprises turbulence generating means, for example projections (16), on the interior wall (12a) of the chamber (14). The projections (16) have a dual function: they both hold a capsule (10) received within the chamber (14), and generate turbulence in fluid flow through the chamber (14) and around a capsule (10) received therein.

When a capsule (10) is received in the chamber (14), the projections (16) loosely hold the capsule (10) within the chamber (14). During use of the inhaler, as air is inhaled by the user from the chamber (14) through the outlet (12) and mouthpiece (3), the projections (16) generate turbulence in the air flow through the chamber (14). Turbulence in the air flowing around the capsule (10) causes vibration of the capsule (10) within the chamber (14), and this vibration enhances the dispersion of medicament contained within the capsule (10). Accordingly, less forceful inhalation by the user is required to liberate a full dose of medicament from the capsule (10).

The projections (16) may be of various shapes, such as grooves, ridges, helixes, rings or spheres, or any other shape suitable for generating turbulence in a fluid flow.

The capsule holder (2) is provided with holes (28) which enable the holder (2) to be secured via projections (61) of lower body (1) (see Figure 20) within an inhalation device. Cooperating means (31) may be provided if desired to enable cooperation with the piercing pin holder (6); this may further assist with alignment of the piercing means.

Figures 18 to 24 show various components of a preferred embodiment. Fig 18 shows a closure means or mouthpiece (3) comprising connecting means (40) which enable the mouthpiece to connect to cylindrical portion (58) of link actuator (4) (see Fig 22). Mouthpiece (3) also comprises opening (57) via which medicament is inhaled by

the user. Means to receive air (for example a tube) from an outlet of the housing, extends downwards from opening (57) within the mouthpiece (not shown in the Figure).

Figure 19 shows a cover member (8) comprising eyes (41) and notch (48). An equivalent notch is provided on the corresponding side of the cover. In use notches (48) insert in corresponding recesses (49) on lower body (1) (see Figure 20), so as to lock the cover member and housing together. The cover member also comprises a further notch (not shown) on the underside of the left hand edge: in use this inserts in a corresponding recess (29) (see Figure 11) so as lock the cover member relative to capsule holder (2). Eyes (41) enable positioning of the cover around a (preferably two-piece) pivot (30) (refer to Figure 3) which passes through eyes (41), eyes (42) of the lower body (1) (see Figure 20), connecting means (40) of the mouthpiece (3), and opening (45) in link actuator (4) (see Figure 22) when the device is assembled. In use, the cover (8) is positioned inside mouthpiece (3).

Figure 20 shows lower body (1) comprising eyes (42) for receiving a pivot (30), and recesses (49) to receive notches (48) in cover (8) as described above. (An equivalent recess (49) (not shown) to that illustrated in Fig 20, is provided on the corresponding side of the housing (1).) The sides (50) of lower body (1) are suitably adapted to receive capsule holder (2).

Figure 21 shows link (5) comprising two arms comprising eyes (43) and end portion (44) supporting notches (51) (only one notch is shown) on either side. The eyes (43) cooperate with corresponding notches (55) on pin holder (6) (see Figure 23) and thus enable movement of the piercing means (7) when the link (5) is driven by link actuator (4). Notches (51) are received by eyes (46) on link actuator (4), and are rotatable relative to the said eyes (46).

Figure 22 shows link actuator (4) comprising substantially cylindrical body (58) which is extended via arms (47) which terminate in eyes (46). The actuator (4) also comprises square hole (45) which receives a corresponding sized square pivot (not shown). Correspondingly square holes (60) in connecting means (40) of mouthpiece (3) enable the link actuator (4) and mouthpiece (3) to be rigidly connected (that is, not rotate with respect to each other). In this way, movement of the mouthpiece (3) relative to the housing (1) enables movement of piercing means (7) via driving of link (5).

Figure 23 shows piercing pin holder (6) comprising notches (55), as described above, and cylindrical tubes (54) which are adapted to receive attachment means (31)

which project from capsule holder (2) (refer to Fig 11). The cylindrical attachment means (31) are slideable within the tubes (54). In use, pins (7) are mounted in holes (53) (one is obscured in Fig 23). The pins (not shown in Fig 23) project beyond tubes (54) and are slideably received within guide means (20) of capsule holder (2).

Figure 24 shows a preferred piercing means which is a cylindrical pin (7). Preferably, the piercing end of pin (7) comprises a face (56) formed by an oblique cut through the shaft of the pin. Further modification of the piercing end may also be made to achieve the desired shaped point.

The pins may be any suitable size. They may be in a range between 1 mm to 2 mm in diameter, although we prefer to use pins with a diameter of about 1.5mm +/- 10%.

The capsule or medicament holder described is not limited to the embodiments described, and includes various means and forms that may be provided for maximising the turbulence by providing suitable means for generating turbulence in the medicament holder.

CLAIMS:

1. An inhaler device for inhalation of a medicament from a pierceable capsule, which inhaler comprises a housing for receiving a medicament capsule; closure means for closing the housing, said closure means being moveable relative to the housing; piercing means suitable for piercing a medicament capsule; wherein movement of the closure means from an open position to a closed position or from a closed position to an open position drives movement of the piercing means from a retracted non-piercing position to an extended piercing position and back to a retracted position.

2. An inhaler device according to any claim 1, wherein movement of the closure means moves the piercing means so as to pierce a capsule positioned within the inhaler housing.

3. An inhaler device according to any preceding claim further comprising linking means connected to both the closure means and the piercing means; wherein movement of the closure means causes movement of the linking means so as to move the piercing means.

4. An inhaler device according to any preceding claim, wherein the closure means is rotatable relative to the housing.

5. An inhaler device according to claim 3 or 4, wherein movement of the closure means causes rotation of the linking means.

6. An inhaler device according to any preceding claim, wherein movement of the closure means drives linear displacement of the piercing means.

7. An inhaler device according to any preceding claim, wherein the housing comprises means to hold a medicament capsule, said holding means comprising a chamber having an air inlet and an air outlet.

8. An inhaler device according to claim 7, wherein the air inlet and outlet are provided at opposing ends of the chamber.

9. An inhaler device according to any preceding claim, wherein the closure means is pivotably attached to the housing.

10. An inhaler device according to any preceding claim, wherein the closure means comprises a mouthpiece.

11. An inhaler device according to claim 10, wherein the mouthpiece comprises means to receive air from an outlet of the housing, said means being connected to said outlet when the mouthpiece is in its closed position.

12. An inhaler device according to claim 11 wherein the means to receive air from an outlet of the housing comprises a tube.

13. An inhaler device according to claim 11 or 12, wherein the means to receive air comprises a mesh which is positioned in proximity to the chamber outlet when the mouthpiece is in a closed position.

14. An inhaler device according to claim 11, 12 or 13 wherein the length of the means to receive air is from about 25 to 35 mm.

15. An inhaler device according to claim 14 wherein the length of the means to receive air is 31.6 +/- 10%.

16. An inhaler device according to claim 13, 14 or 15 wherein the mesh size is from about 0.5mm X 0.5mm sq to about 2mm X 2mm sq.

17. An inhaler according to claim 16 wherein the mesh size is about 1 mm X 1 mm sq +/- 10%.

18. An inhaler device according to any preceding claim which device further comprises locking means to lock the closure means relative to the housing.

19. An inhaler device according to any preceding claim, wherein the piercing means comprises one or more piercing pins.

20. An inhaler device according to claim 19 wherein the one or more pins have a diameter of from about 1mm to about 2mm.

21. An inhaler device according to claim 20 wherein the one or more pins have a diameter of about 1.5mm +/- 10%.

22. An inhaler device according to any preceding claim, further comprising guide means to guide the movement of the piercing means.

23. An inhaler device according to any preceding claim comprising a holder for a medicament capsule which holder comprises a chamber suitable for receiving a medicament capsule; and means for generating turbulence in a fluid flow through the chamber such that, in use, the turbulent fluid flow causes vibration of a capsule received by the chamber so as to assist in releasing medicament contained within the capsule.

24. A device according to claim 23, wherein the means for generating turbulence comprises one or more projections extending from one or more inner walls of the chamber.

25. A device according to claim 23 or 24, wherein the or each projection comprises independently one or more grooves, ridges, helixes, rings, or spheres.

26. A device according to claim 24 or 25, wherein the or each projection comprises a flat facet.

27. A device according to claim 24 or 25 wherein the or each projection presents two or more sides or faces to the interior of the chamber.

28. A device according to any one of claims 23 to 27, wherein the means for generating turbulence also holds or partially holds a medicament capsule within the holder.

29. A device according to claim 28 wherein the means for generating turbulence holds one end of the capsule.

30. A device according to any one of claims 23 to 29, wherein the means for generating turbulence loosely holds a medicament capsule.

31. A device according to any one of claims 23 to 30, wherein the diameter of the space defined by the means for generating turbulence relative to the diameter of a medicament capsule placed in the holder is such that the capsule is held loosely by the means for generating turbulence.

32. A device according to any of claims 23 to 31, further comprising one or more openings in one or more walls of the chamber.

33. A device according to claim 32, wherein one or more of the openings is provided with guide means for receiving piercing means.

34. A device according to any one of claims 23 to 33, wherein the chamber is provided with an air inlet and an air outlet.

35. A device according to claim 34, wherein the air inlet and air outlet are arranged at opposing ends of the chamber.

36. A device according to claim 34 or 35, wherein a mesh is provided in the vicinity of the air outlet, said mesh preventing a medicament capsule within the chamber to be moved through the air outlet by inhalation during use of the holder.

37. A device according to claim 36 wherein the mesh size is from about 0.5mm X 0.5mm square to 2mm X 2mm square.

38. A device according to claim 37 wherein the mesh size is about 1mm X 1mm square +/- 10%.

39. A device according to any one of claims 23 to 38 wherein the chamber comprises one or more steps.

40. A device according to any one of claims 23 to 39 wherein the length of the capsule chamber is from about 15mm to about 30mm.

41. A device according to claim 40 wherein the length of the capsule chamber is 22 mm +/- 10%.

42. An inhaler device according to any one of claims 1 to 22 comprising a holder as described in any one of claims 23 to 41.