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The invention relates to a propellant-free inhalation device, comprising a storage space for a powdery medicinal substance to be inhaled, a manually operable metering device associated with said storage space for receiving a specified dosage of the medicinal substance for each inhalation process in at least one metering chamber, and comprising a lateral mouthpiece for active inhalation which has an air channel for distributing each dose of medicinal substance into the air stream.

An inhalation device of this kind is known from DE 35 35 561 A1.

In this known inhalation device, underneath the storage container and in parallel to the mouthpiece, there is a rotating lock which has recesses (metering chambers) for measuring the medicinal substance. When the recesses face the storage container, they are filled automatically. If the filled recess faces the air chamber of the mouthpiece as a result of a rotation of the rotating lock by 180°C, the powdery dose drops by gravitational force, aided by a shaking mechanism, from the recess into a hollow space of the air channel from where it reaches the lungs of the patient by active inhalation. Here, the air channel has a throttle region which is intended to facilitate the mixing of air with the medicinal substance through turbulence i.e. through the formation of an aerosol.

The aerosol, therefore, is produced in this device by active inhalation in such a way that the air inhaled by the user is passed over the powder which is then carried along.

The known inhalation device has two crucial disadvantages.

On the one hand, the dose to be inhaled is not reproducible to a sufficient extent. On the other hand, the air stream generated by active inhalation is not

able to completely remove the dose from the device, despite the supportive action of the throttle point in the air channel, and to disperse the medicinal substance in the air stream. Here, it must be remembered, that the powder is only allowed to have a typical particle size of about 5 µm, depending on the kind to be inhaled, in order to reach the site of action in the bronchial tubes. Powders with such a fineness of grain, however, tend to agglomerate during storage so that when the powder is used and the disagglomeration is not very intense as is the case during normal inhalation, at least a part of the powder is inhaled in the form of agglomerates which have a larger diameter than that of the primary grain. These agglomerates do not reach the site of action in the bronchial tubes resulting in a highly incorrect dosage which is not permissible when highly active pharmaceuticals are used.

The invention has the object of providing a propellant-free inhalation device based on the one mentioned above, so that the available dosage may be reproduced to a large extent, and that a large amount of this dosage leaves the inhalation device and a reproducible dispersion of the medicinal substance is achieved.

According to the invention, this object is achieved by the features of the characterising part of the claim.

The inhalation device, according to the invention, operates with a metered extraneous air current which is triggered automatically and in synchrony with the breath. The pressure air blast blows the entire specified dosage of the medicinal substance to be inhaled from the metering chamber into the air channel. The dosage in the individual inhalation processes, therefore, is largely equal. In so doing, it is dispersed very finely by the air pressure blast which considerably increases the inhalation effect. Any powder agglomerates present are disagglomerated as a result of the extraneous air impulse.

In order to avoid the disadvantage of insufficient disagglomeration, devices are known in which the powder agglomerates are disagglomerated by means of an extraneous air impulse. Such a device is, for example, disclosed by WO-A-9007351. In order to generate this extraneous air impulse, an air volume compressed by means of a piston or a bellows is quickly released. The air impulse pulls the powder along with it and as result of the turbulences and shearing forces produced, the agglomerates are again disagglomerated to form a primary grain. Because of the regained fineness of grain, the disagglomerated product may now enter deeply into the bronchial tubes, without any great losses of the substance in the oral or pharyngeal region.

When producing aerosols in the above manner, however, it is necessary to trigger the extraneous air impulse precisely at the time when the respiratory air current is greatest during inhalation. If no impulse is produced at this time, faulty operation and faulty metering occurs. This triggering of the extraneous air impulse in synchrony with inspiration is achieved by the mechanical switching device which responds to reduced pressure during breathing.

Generating an extraneous air current in inhalation devices is known *per se* in US-PS 3 921 637. In the known inhalation device, a manually operable bellows pump is provided which only produces air at an increased pressure while pressure is manually exerted onto the pump bellows. In the known device, between the pump and a chamber into which a dosage to be inhaled is supplied in the form of capsules, there is a valve arrangement operated by a switching device which responds to the respiratory air current during inhalation. Thus, in contrast to the invention, this switching device does not operate the trigger mechanism of a pretensioned pump but opens a valve. This switching device consists of a flap balanced by means of springs, which opens a valve via levers.

According to an advantageous further development of the invention, a dispersing nozzle is connected downstream of the metering chamber, through which the extraneous air current is guided. This nozzle ensures a particularly satisfactory dispersion and, if necessary, disagglomeration of the medicinal substance in the respiratory air current.

In one embodiment of the invention, the element for the manual operation of the metering device is mechanically coupled with the activation of the pretensioning device. When constructed in this way, the device, according to the invention, may be initiated, with regard to the metering and triggering of respiratory air, by means of a single tensioning movement.

A further embodiment of the invention, is characterised in that a pump arrangement has a pump chamber with an air outlet nozzle and a pump piston which may be pretensioned against the force of a spring because of the manual operation and may be detachably interlocked on the side of the pump space facing the outlet nozzle. Such a tensionable piston pump is a particularly simple but highly effective construction of a triggerable pump arrangement for the device, according to the invention. Tensionable piston pumps are also known *per se* in medical devices (DE - 27 26 934 A1). They cannot, however, be triggered automatically and in synchrony with inspiration.

Further constructional features and advantages of the invention are apparent from the specification of the embodiments shown in the drawings.

Shown are:

Fig. 1: an embodiment of the propellant-free inhalation device, according to the invention, in its normal state, shown in section,

Fig. 2: the construction of the metering chamber, shown in Figure 1, in two different views and

to an elevated scale,

Fig. 3: a cross-sectional view of the suspension of the nozzle, shown in Figure 1, in the air channel of the mouthpiece,

Fig. 4: the embodiment as shown in Figure 1, when ready for inhalation,

Fig. 5: the embodiment as shown in Figure 1, immediately after inhalation of the dosage blown out,

Fig. 6: a particular arrangement for metering the active substance to be inhaled (tape tension metering), shown in an exploded view,

Fig. 7: the metering arrangement as shown in Figure 6, when mounted in a position enabling the filling of the storage container,

Fig. 8: the metering arrangement as shown in Figure 6, in a position in which the metering chamber is filled by rotating the metering plunger,

Fig. 9: the metering arrangement as shown in Figure 6, in a position in which the medicinal substance stored in the metering chamber is discharged, and;

Fig. 10: a diagrammatic representation of an alternative embodiment of the metering arrangement shown in Figure 6.

Figs. 11 - 13: a further embodiment of a tape tension metering in three different views

Fig. 14: a further embodiment of the propellant-free inhalation device, according to the invention, when in the normal state, in a sectioned diagrammatic view.

Fig. 15: an embodiment as shown in Figure 14, when ready for inhalation.

The propellant-free inhalation device, shown in Figure 1, has a housing 3 with a side opening 3a. A push button 1 is mounted at the top of the device so as to be displaceable against the force of a spring 2 which is supported on the housing. The push button 1 has toothed or corrugated edges 4 on the inside and also has a lever 17 formed on the push button for the interlocking with a counter part provided on the housing 3, on which the spring 2 is also supported. Furthermore, the inhalation device has a funnel-shaped storage container 6 as a storage space for the powdery medicinal substance to be inhaled. This storage container may be closed by a cover 5 and has a window 24 to indicate the amount used. A metering plunger 8 is associated with the storage container, which plunger has a metering chamber 7 for receiving the dose of medicinal substance to be inhaled in the respective inhalation process. This metering chamber is shown in more detail in different views in Figures 2a and 2b. Figure 2a, a view parallel to a horizontal axis, shows that the metering chamber has a substantially triangular cross-section. As is apparent, in particular, from the cross-sectional view in Figure 2b, Figure 2a has an undercut on which a meshed bottom 7a is provided which delimits the metering chamber inwardly.

The metering plunger 8 passes through the cover 5 and the cone-end of the storage container 6 and is mounted therein so as to be displaceable against the force of a spring 10 which is supported on the other side in a receiving part 1a of the push button 1. On

the side of a metering chamber, the metering plunger has a bore 8a for the supply of air to the metering chamber 7 and is correspondingly formed at this end for the positive connection to a nozzle 12a of a pump housing 12 which is explained in greater detail below.

The cover 5 of the storage chamber has a rounded edge along which the corregated edge 4 is guided so as to brush against it, when the push button 1 is depressed, whereupon the storage container 6 is shaken. This ensures the uniform filling of the metering chamber 7 on the metering plunger 8.

Furthermore, the inhalation device has a mouthpiece 11 for the active inhalation, which is attached to the side and has an air channel 9. A nozzle 23 is mounted in this air channel, via cross-pieces 23a (see Figure 3). The mouthpiece 11 is fixedly connected with the storage container 6 and the nozzle 12a of the pump housing and forms a movable unit with the latter. The left end of the mouthpiece is closed by a cover 21 which has a ventilation bore 21a. At the end near the cover, the mouthpiece 11 also has ventilation bores 11a whose function is explained below.

The inhalation device has, moreover, a pump arrangement for generating a pressure air blast (extraneous air current) during the inhalation process. This pump arrangement has the above-mentioned pump housing 12 with the nozzle 12a from which the air is expelled. The pump housing is closed by a base 20 having a ventilation bore 20a; a release tongue 13 is mounted in this ventilation base so as to be radially movable. The pump arrangement also has a pump piston 19 which is mounted in the pump base so as to be displaceable against the force of a spring 22. The pump piston 19 has a circumferential groove 19a in which the release tongue 13 engages when the spring 22 is tensioned with the release tongue holding the pump piston in a tensioned state. The pump piston 19 is also mounted in a housing member 24a which receives a spring

18 which is supported at the other end of the pump housing base 20.

In order to start the pump movement, a trigger mechanism is provided which automatically responds to active inhalation in the embodiment shown. This trigger mechanism has a trigger piston 15 which is mounted in the mouthpiece 11 against the initial stress of a relatively weak spring. Here, in the extension of the trigger piston there are ventilation bores 15a. Another element of the trigger mechanics is the release lever 14 which is rotatably mounted on an extension 11b of the mouthpiece 11. This release lever 14 is movably guided in the piston rod of the trigger piston 15 and has, near the top, a release element 14a for the push button ratchet lever 17. On the other side, the ratchet lever is movably guided in the release tongue 13 which also forms part of the trigger mechanism.

Figure 1 shows the inhalation device in its normal operational state i.e. before use. The spring 22 of the pump piston 19 is tensioned; the other springs 2, 10, 16 and 18 are in the released state.

In order to adjust the device so that it is ready for inhalation, the following measures are necessary:

The push button 1 is manually depressed against the force of the spring 2. In so doing, the toothed or corregated edge 4 is brushingly guided past the container cover 5 whereupon the powder storage container 6 is shaken and the metering chamber 7 is filled. Upon further depression of the push button 1 against the force of the spring 10, the metering plunger 8 is pushed down until it is positioned on the pump nozzle 12a. In so doing, the spring 10 is tensioned. When the push button 1 is then completely depressed, the entire movable unit, comprising powder storage container 6, mouthpiece 11, pump housing 12, trigger mechanics 13, 14, 15, 16, are placed into the lowermost position whilst the pushbutton with its attached lever 17 is arrested on the housing. Upon complete depression, the

spring 18 is tensioned and the pump piston 19 is also moved downwards, together with the release tongue 13 arranged in the pump housing base 20.

The inhalation device is now in the stand-by state, i.e. ready for inhalation. This operational state is shown in Figure 4. The metering chamber 7 is now directly positioned at the height of nozzle 23. All the springs are tensioned, with the exception of the return spring 16 associated with the trigger piston 15. As a result of the active inspiration, a reduced pressure is produced during inhalation, in the mouthpiece 11 in front of the trigger piston 15. The trigger piston 15 is moved forward against the weak spring 16 and releases the pump piston 19, via the release lever 14 and the release tongue 13. The ventilation bore 21a in the mouthpiece cover 21 ensures that no vacuum is formed at the rear of the trigger piston.

The released pump piston 19 is suddenly pushed upwards by the spring 22. The air volume conveyed by the pump piston is now thrust through the meshed base of the metering chamber 7. The powder on the mesh is blown out through the nozzle 23 by the air blast and dispersed. During further active inhalation, extraneous air may flow in via bore 11a provided in the wall of the mouthpiece and bore 15a provided in the trigger piston 15, the bores coinciding with one another during suction, so that the dispersed powder is mixed with the main respiratory air current in the mouthpiece. This operational state immediately after using the inhalation device is shown in Figure 5.

When the inhalation process has ended, the trigger piston 15 automatically returns to its starting position by relaxation of the return spring 16. Here, the pushbutton 1 is released by the lever 14, via the ratchet lever 17, and returns to its initial position as shown in Figure 1, as a result of the tensioning of the springs 2, 10 and 18 and while tensioning spring 22.

The elements of the inhalation device, shown in

Figures 1 to 5, are embodiments of the invention which, however, is not limited to these constructions. In a possible variant to the trigger mechanics shown in these Figures, the trigger piston 15 may be replaced by a flap and the lever mechanism 14 by a toggle lever construction.

In a further variant, the pump unit comprising parts 12, 18, 19, 22, may also be arranged above the mouthpiece 11. It is also possible to use an extensile bellows as pump unit.

In principle, the construction of the inhalation device may be such that the pump piston 19, i.e. the spring 22, is only tensioned when the pushbutton 1 is activated.

The construction shown in Figure 1 is such that the pump is automatically released during the breathing of the patient. This trigger means may in principle also be replaced by a release button which is operated manually.

A replenishment of the device is possible. For this, the component comprising the powder storage container 6, the metering plunger 8 and the spring 10, may be replaced. This is achieved by either dismantling the pushbutton 1 or by a construction which allows the unscrewing of the upper part of the device. Alternatively, the cover 5 of the powder storage container 6 may be constructed in such a way that it can be filled with powder from a refill cartridge. It may, for example, be provided with a stopper.

Another possible variant is to fill the metering chamber 7 at the end of a funnel-shaped storage container. A further preferred variant is now described in greater detail with reference to Figures 6 to 10.

The metering of powders which do not flow easily (for example fine-grained glucose) by filling a dosage volume is not possible without active support measures, such as shaking the storage container. The metering method mentioned below, hereinafter called "tape tension

metering", makes it possible to achieve an improved degree of filling the metering chamber with powders which do not flow easily, thus enabling a better reproducibility of the prepared dose.

Though the tape tension metering may be used to advantage in the inhalation device, according to the invention, it may in principle also be used in other inhalation devices.

Figure 6 shows, in an exploded view, the main elements of the tape tension metering, namely a magazine 25 (which replaces, for example, the storage container 6 in Figure 1), a tape 26, the metering plunger 8 with the metering chamber 7 and an axial bore 8a which extends from the base of the metering plunger to the metering chamber 7. As shown in Figure 7, the metering plunger is received in the opening 25b of the magazine 25. At the narrow end face of the magazine 25, the tape 26 is looped in by means of its free ends which pass through the magazine and issue at the opposite end face. During operation, the powder dose 27 stored in the magazine 25 is enclosed at the rear and to the side by the tape loop and is given a push "f" along the longitudinal axis of the magazine, in the direction of the metering plunger 8 or the metering chamber 7. The tape consists of a sufficiently tension-proof and tear-resistant paper which is silicone- or teflon-coated on either side and has a defined surface roughness. This roughness is meant to decrease the adhesive forces of the powder on the tape and to minimise friction between the wall of the magazine, the paper and the metering plunger.

The magazine can be filled at the rear, when the tape is in the position as shown in Figure 7; the powder dose is then slightly compressed against the metering plunger by pulling at the tape loop.

The metering is carried out by means of a specially formed metering notch 7 arranged as a metering chamber in the metering plunger 8 which chamber is rotated past the slightly compressed powder dose 27 (Figure 8), in a

specified preferred direction (clockwise) according to notch geometry, and is filled. In a further embodiment, the metering plunger 8 carries out a lifting motion. In this embodiment, the metering notch is, preferably, at an angle of 45° with respect to the longitudinal axis of the metering plunger. Here, the metering notch is lined at the rear in the direction of the axial bore 8a by, for example, a fine stainless steel mesh 7a, similar to the arrangement as shown in Figure 2b. The mesh width is, preferably, about 5-300 µm, preferably about 50 µm.

There are several options for discharging the dosage from the metering notch 7. One option used in the embodiment of Figure 1 is shown in Figure 9. After the metering notch 7 has been filled by the above rotational or lifting movement, the metering plunger 8 is pushed down through the bores 25b of the magazine 25, analogously to the transition from the operational state, as shown in Figure 1, to that, as shown in Figure 4, until the metering notch 7 is positioned in a small, specially formed dispersing volume 28 not explained here in greater detail, in front of a specially formed nozzle 29 which is not described in greater detail either. As powder is scraped off when the metering plunger is pressed through the bores 25b of the magazine, further precision of the dosage is achieved.

In the position shown in Figure 9, a pressure air blast acts upon the base of the metering notch, and the meshed tissue 7a, via the bore 8a, in order to blow out the powder stored on the screen cloth in the notch. The pressure air blast may, for example, be produced by a pump arrangement as shown in Figure 1. Other embodiments, however, are also feasible.

The empty spaces of the magazine in front (narrow side) and at the back (broad side) may be filled with drying agents in order to protect the stored powder from humidity.

The active substance may also be mixed with a carrier substance in order to provide a more precise

metering thereof.

One of the main features of the tape tension metering is that during the filling of the metering notch, the wall of the slowly emptying magazine also moves in the delivery direction, together with the powder batch. The tape 26 may in principle also be replaced by a rigid wall, for example a U-shaped clamp 26a (Figure 10) which is subjected to the slight pressure of a spring 30 and follows the volume in store.

If the tape tension metering within the scope of an embodiment as shown in Figure 1 is used, the linear movement of the push button 1 with regard to the metering plunger 8 must be translated into a rotational movement.

Figures 11 to 13 show a further preferred embodiment of tape tension metering. This embodiment is constructionally more refined than those shown diagrammatically in Figures 7 to 9. It is an integral component of the further embodiment of the inhalation device, according to the invention, which is shown in the following Figures 14 and 15 and which is preferred over the embodiments shown in Figures 1 to 5.

In order to show clearly what the embodiments have basically in common, elements of the same functions are denoted by the same reference numeral, even if they do not conform constructionally with one another.

Figures 11 to 13 show a housing of the magazine 25 of the tensioning pin tension metering, which is in the form of two discs, the distance between the two discs corresponding to the width of the tape 26.

Figure 11 shows this magazine in a longitudinal section. Figure 12 shows a plan view of the magazine as shown in Figure 11, and Figure 13 shows a section along line I as shown in Figure 11.

The tape 26, looped into the magazine, holds the stored powder, the powder batch 27 (Figure 13) which is delimited on the right hand side by the metering plunger, a metering pin 8. The metering pin 8 rotatably

passes through the magazine 25 and has two metering notches 7 in this embodiment. Constructions with more than two metering notches distributed over the metering circumference are also possible. Here, the metering notches are, advantageously, closed at the rear with the sintered plastics material, sintered glass, sintered metal, a mesh or a screen. The metering pin 8 also has a number of chambers 8a which correspond to the number of metering notches so that only the metering notch "to be blown empty" can be blown at through the associated chamber, more particularly by the dispersing pressure air blast from a triggerable pump. The two chambers, separated by walls 31, are shown diagrammatically in Figure 11, the opening 30 representing the inlet for the dispersing air. In the lower part of the metering pin 8, there is a coupling part 32, via which the metering pin may be connected with a rotary drive. This portion of the metering pin has a bore 32b for a reduced pressure channel and an elongated bore 32a for transferring the reduced pressure. The significance of the bores is explained below with reference to Figures 14 and 15.

The dispersion nozzle is in communication with the metering notch 7 to be blown empty or the associated chamber in the metering pin 8. The nozzle in the magazine is attached, advantageously, by a suitable means (not shown), for example a cam, so that the nozzle lifts slightly above the metering pin when the tape moves and thus when the metering pin rotates in the region of entry of the metering notch 7 into the nozzle region, so as to avoid powder being scraped off.

Of particular importance for the operability of the tape tension metering is the tape feed. The embodiment shown in Figures 11 to 13 is a correspondingly advantageous construction. It has a pin 33 to which one end of the tape is secured. The other end of the tape is secured to the tensioning pin 34 so as to be capable of being wound on to it. The tensioning pin 34, i.e.

the winding axis, is coupled with the metering pin 8 via a belt 35. Instead of the belt drive, it is also possible to use a gear drive or the like. By rotating the metering pin 8, the tensioning pin 34 is driven by the belt 35. In so doing, the tape 26 becomes tensioned and compresses the powder bulk 27 until a certain tape tension is obtained. Upon reaching this tension, the belt slips like a slipping clutch on the tensioning pin 34. During this process the metering notch is filled.

It is important here that the force, by means of which the tape loop presses the slightly compressed powder bulk 27 against the metering pin 8, is limited, and that the powder is only acted upon by pressure when the metering takes place. This prevents the powder bulk 27 or the relevant part of the tape loop from becoming "wedged" in the magazine 25.

The size of the tape loop on the metering pin 8 is also a special constructional feature. The tape wound around the metering pin is advantageously such that it extends beyond the (vertical) diameter of the metering pin (Figure 13) i.e. that the loop angle is greater than 180°. This is achieved by the measure X, which is the inner free distance between the pins 33 and 34, being smaller than the outer diameter of the metering pin 8. This measure largely prevents a clogging-up of the plunger and enables a clean filling of the metering notch.

A significant advantage of the tape tension metering is that the positioning is of no relevance.

Figures 14 and 15 show a further embodiment of the inhalation device, according to the invention, in which a tape tension metering is provided as shown in Figures 11 and 13.

This inhalation device has a two-part housing, i.e. the top part 36 which is closed at the top by a cover 38, and the pump part 37 which simultaneously forms the cylinder for the piston 19 of the pump arrangement. Preferably, both housing parts are made of plastics and

have conventional connecting members not shown, for example screws.

The tape tension metering is accommodated in the top part 36 of the housing, as shown in Figures 11 to 13 and thus need not be explained here in greater detail. In the top part, there is also the mouthpiece 11 which is positioned opposite the dispersion nozzle 29 of the tape tension metering. The mouthpiece 11 has an air channel which is in the form of an inhalation nozzle 39, and respiratory air bores 40 for the external air flowing in during inhalation. The mouthpiece 11 also has a reduced pressure channel 41 which is in communication with the bore 32b provided on the metering pin 8 (Figure 11) and therefore with the elongated bore 32a. Because of the acceleration of air in the nozzle during active inhalation, a reduced pressure is produced in the nozzle and thus in the channel 41, which continues in the elongated bore 32a. The reduced pressure channel, therefore, is suitably at a point in the nozzle at which there is the greatest speed.

The two-part construction of the inhalation device makes it possible for the top part to be replaced quickly when the medicinal substance stored is used up or to be exchanged against other top parts of the housing filled with medicinal substances in the tape tension metering means in question.

The pump housing 37 has a rotary button 42 which is connected with a cocking shaft 44 and closed at its end face by a cover 43 provided with bores. The cocking shaft 44 like the metering pin 8, with which the cocking shaft 44 may be connected via the coupling 32 so as to be accurately positioned and interlocked by torsional force, also has the axial bore 32a.

The piston pump which may be tensioned and triggered is accommodated in the front part of the pump housing 37. The pump has the pump piston 19 which has a pin 19b guided in a spiral groove 19d of the cocking shaft 44. In a kinematic reversal of this principle of

converting a rotational movement into a translatory one, cams or the like may be provided on the cocking shaft which are received in a spiral groove provided in the piston bore.

Figure 14 shows the piston in the upward position after triggering and expelling air, whereas Figure 15 shows the tensioned piston. The latter shows particularly clearly the pump cylinder area above the piston 19 in which the air is compressed by the upwardly moving piston. The air outlet opening, and the pressure channel 12a which opens into the bore 30 provided on the metering pin 8 for supplying the dispersing pressured air to the respective chamber 8a or metering notch 7 are arranged in the pump cylinder area (see also Figure 11).

At the lower end of the piston, there is a radially symmetrical ratchet element 19c which is a retaining clamp by means of which the piston may be tensioned against the force of the spring 22, whilst engaging with a locking clamp which is also radially symmetrical and has resiliently yielding segments.

The parts of the retaining and locking clamp positioned on top of one another are slightly inclined so that the retaining clamp 19c tends, under the action of the force of the spring 22, to move the segments of the locking clamp inwardly and thereby effect the disengagement. The inclined surface, therefore, is of advantage to the disengagement which is additionally aided by the individual tension of the segments of the locking clamp. The ratchet and release mechanism also has a reset knob 45 which turns as the cocking shaft 44 turns, and a release knob 46 with a locking shoulder which is axially displaceable in the longitudinal direction. When tensioning the piston, the release knob 46 is pressed into the locking/release clamp 13, via the reset knob 45 positioned above the locking shoulder of the release knob, so that the release edge of the release clamp 13 is positioned above the locking shoulder of the release knob 46. In so doing, the

locking and release clamp engages in the ratchet element or retaining clamp 19c of the piston (Figure 15).

The edges of the reset and release knob 45 and 46, which are provided with a sliding block and slide on top of one another, are in the form of slopes. In the tensioned state (Figure 15), the highest point of the slope has already been surpassed so that the area behind the break-off point of the slope is available for the necessary axial movement of the release knob during the release operation.

The engagement shown is a comparatively simple installational solution which may also be achieved easily by machine.

For the automatic release of the pump during active inhalation, a particularly advantageous mechanism is provided which has a membrane 47 as a central element which responds to the reduced pressure which is produced during inhalation in the reduced pressure channel 41 and, in continuation, in the axial bore 32a. The membrane 47 delimits the end face of a membrane chamber 48 which accommodates a membrane cup 49 on which the release pins 50 abut, the release pins being guided in the rotary button 42. The other end of these release pins abuts on the release knob 46. This membrane triggering may in principle also be used in other inhalation devices or for the mechanical triggering of other technical processes.

In order to convert the device from the untensioned rest state, as shown in Figure 14, into the tensioned state ready for inhalation, as shown in Figure 15, the following measures are necessary:

The knob 42 is rotated manually through a certain angle. When the knob is turned, the cocking shaft 44, the reset knob 45 and the metering pin 8 (via the coupling 32) are also rotated. In the embodiment, the pitch angle of the spiral groove 19d is chosen such that a rotation of 180° is necessary in order to reach the tensioned state.

When the knob 42 is rotated, the metering notch 7 is, firstly, filled with the powder to be inhaled by the rotation of the metering pin 8 provided in the tape tension metering means in the top part 36 of the housing, as already explained in detail with reference to Figures 11 to 13. Furthermore, when the cocking shaft 44 is rotated, the pin 19b of the piston 19, guided in the spiral groove 19d of the cocking shaft is moved downwardly. In so doing, the piston 19 tensions the spring 22. After an angle of rotation of about 135°, the piston is in the starting position. When the knob 42 is rotated by 45°, the release knob 46 is pressed with its locking shoulder into the release clamp 13, by the reset knob 45. In so doing, said clamp engages in the ratchet element 19c of the piston, so as to be tensionally connected.

The piston is now tensioned and is retained in its position by the above locking. The inclined surfaces on the locking clamp 13 and the ratchet element 19c are such that under the effect of spring force, the ratchet element tends to move the locking clamp inwardly thereby releasing it. This, however, is prevented by the release knob 46 whose thicker upper part presses against the cams of the locking clamp and keeps them spread out. This produces a particularly advantageous safeguard against accidental faulty starting of the device.

The inhalation device is now in the working position, ready for inhalation, as shown in Figure 15.

During inhalation, when breathing in, air is supplied through the mouthpiece 11 via the extraneous air opening 40. The surrounding air flowing past the bore 41 and the nozzle 39 produces a reduced pressure in said bore 31, which continues into the membrane chamber 48, by the axial bore 32a. As a result of atmospheric pressure acting through the bores in the cover 43, the membrane 47 is pressed inwardly onto the membrane cup 49. The membrane cup presses against the release pins 50 which, themselves, abut the release knob 46 and start

to release when a certain reduced pressure is reached by moving the locking shoulder of the release knob 46, as a result of an axial movement of said knob, above the release edge (cam) of the release clamp 13. In so doing, the cams of the locking clamp 13, reach the region of the thinner shaft of the release knob and can no longer be supported thereon. Under the effect of the individual tension of the locking clamp segments which tends to bend the spring segments inwardly, and under the effect of the inwardly directed force produced on the inclined surfaces of the locking clamp and the ratchet element 19c, the segments of the locking clamp bend inwardly and the tensional connection between the clamp and the ratchet element 19c is suspended.

These unlocking forces with a two-fold action ensure a particularly reliable and advantageous release.

Through the force of the spring 22, the piston 19 is moved upwardly. The resultant air pressure blast is transmitted through the pressure channel 12a and reaches the right-hand chamber 8a in the tensioning pin metering, via bore 30. The powder in the right-hand notch 7 is dispersed through nozzle 29 and added to the respiratory air current, i.e. converted into an aerosol. The device is then again in the starting position as shown in Figure 14.

The components and constructional elements used in Figures 14 and 15 are embodiments but the invention is not limited to these. Other constructional elements may, for example, also be used for transferring a rotational motion into a longitudinal displacement of the piston 19 or other locking and release mechanisms which will still be within the scope of the invention.

A further advantage of the device, according to the invention, is apparent from Figures 14 and 15. The above known inhalation device, which is released in synchrony with inspiration, comprises a great number of high-precision parts which must be assembled and adjusted in a costly assembly operation. In the

interest of economy, however, such devices should be constructed in a very simple manner. If a series production of such devices is intended, the mounting thereof by machine, in a quick operation, is particularly essential.

A serious disadvantage in the known device (US-PS 3921637) is, moreover, the fact that the respiratory air passes through the device and over the mechanical parts. This results over a period of time in an unavoidable dust and dirt accumulation on the high-precision bearing parts. This may, in particular, also be due to the fact that devices of this kind are carried around in one's pockets. Any soiling of the sensitive mechanical parts, however, may impair the operability of such devices which may have serious consequences, for example in the event of an asthma attack.

Devices of this kind are only allowed to produce a slight resistance to the respiratory air during inhalation. This means that only small forces are available for initiating the extraneous air impulse. All the mechanical parts, therefore, must be of extremely easy action.

The disadvantages of known inhalation devices are avoided in the device, according to the invention, and the objectives sought are achieved. The respiratory air or extraneous air reaches the mouthpiece along a very short path. The extraneous air only passes previously through the metering pin and the metering chamber. Accumulation of dust and dirt, therefore, is avoided and the parts remain easy of action. If an aerosol application becomes urgently necessary, for example in an acute asthma attack, an extremely simple and quick use of the device is possible.

Furthermore, the assembly of the constructional parts is comparatively easy and simple so that the device may be manufactured in large numbers, in a cost-effective manner.

Claims

1. A propellant-free inhalation device, comprising a storage space (6) for a powdery medicinal substance to be inhaled, a manually operable metering device (8) being associated with said storage space for receiving a specified dosage of the medicinal substance for each inhalation process in at least one metering chamber (7), and comprising a lateral mouthpiece (11) for active inhalation which has an air channel (9) for distributing each dose of medicinal substance into the air stream, characterised in that a triggerable pump arrangement (12, 12a, 19, 20, 22), associated with the metering chamber, is provided, which has a manually operable pretensioning device (13, 19a; 19c) and a mechanical switching device (14 - 16; 47 - 50) that is in operative connection with the pretensioning device and the air channel (9) in the mouthpiece (11) such that the switching device responds to the reduced pressure produced upon inhalation and releases the pretensioning device, producing an extraneous air current which blows empty the filled metering chamber (7) and disperses the substance.

2. An inhalation device according to claim 1, characterised in that a dispersing nozzle (23; 29) is connected downstream of the metering chamber (7) through which the extraneous air current is guided.

3. An inhalation device according to claim 1 or 2, having a mechanical member (1, 42) for manual operation, characterised in that the member (1, 42) for manual operation of the metering device (8) is mechanically coupled with the actuating means of the pretensioning device (13, 19a; 19c).

4. An inhalation device according to claim 1, 2 or 3, characterised in that the mechanical switching device

has a trigger piston (15) in the air channel (9) which is pretensioned by a spring and connected with one lever arm of a release lever (14), the other lever arm of which is connected with the release mechanism (13, 19a) provided on the pretensioning device of the pump arrangement.

5. An inhalation device according to any one of claims 1 to 3, characterised in that the mechanical switching device has a flexible membrane (47), one side of which is in communication with the mouthpiece (11), via a reduced pressure channel (41, 32a), and the other side of which is in communication with the surrounding air, mechanical release members (49, 50) being associated with the membrane, which are in an operative association with the release mechanism, (13, 19c, 46) provided on the pretensioning device of the pump arrangement.

6. An inhalation device according to claim 5, characterised in that the air channel (9) in the mouthpiece (11) is in the form of a nozzle (39), the region with the greatest velocity of flow being arranged in the region of the inlet of the reduced pressure channel (41).

7. An inhalation device according to claim 5 or 6, characterised in that a membrane chamber (48) is provided, one side of which is delimited by the membrane (47) and which accommodates a membrane cap (49) with which release pins (50) are associated which may be brought into an operative connection with the release mechanism (13, 19c, 46) provided on the pretensioning device of the pump arrangement, when the membrane and therefore the membrane cap respond to reduced pressure.

8. An inhalation device according to any one of claims 1 to 7, characterised in that the metering device has a metering piston (8) which is arranged in the

longitudinal direction of the inhalation device at right angles to the axis of the mouthpiece, and which has a metering chamber (7) which is formed by a notch-shaped incision having an inner perforated bottom (7a) connected with an air inlet (8a), and that the top of the metering piston (8) is received by a push button (1) displaceably mounted in the longitudinal direction in the housing (3) of the inhalation device, so that firstly, upon manual actuation of the push button (1), the metering chamber (7) is filled, then placed in the air channel (9) with its open side in front of the nozzle (23) and connected, by means of its air inlet (8a), with the air outlet (12a) of the pump arrangement (12, 12a, 19, 20, 22).

9. An inhalation device according to any one of claims 1 to 8, characterised by a metering device (8), in which at least a part of the wall (26, 26a) of the storage space (6) for the powdery substance (27) is yieldingly constructed in such a way that emptying of the storage space ensues from the metering chamber (7) being filled.

10. An inhalation device according to claim 9, characterised in that the wall of the storage space (6), which moves as the powder (27) is filled, is formed by a flexible tape (26) looped into a container (25) which delimits the storage space (6) by means of the width of the tape, and that the loop opening is closed by means of a metering pin (8) which has at least one metering notch (7) as a metering chamber around which pin (8) the loop ends are wound.

11. An inhalation device according to claim 10, characterised in that the tape (26) is made of a flexible material with a specified tensile strength and surface roughness.

12. An inhalation device according to claim 10 or 11,

characterised in that the tape (26) is secured at one end of the loop on a first shaft (pin 33) and may be wound onto a second shaft (tape tensioning pin 34) which is mechanically coupled to the metering pin (8).

13. An inhalation device according to claim 12, characterised in that the coupling between the metering pin (8) and the tape tensioning pin (34) is in the form of a slipping clutch so that it slips when a limiting torque is applied, thus limiting the force by means of which the tape loop presses the slightly compressed powder bulk (27) against the metering pin (8).

14. An inhalation device according to claim 13, characterised in that the metering pin (8) is coupled with the tape tensioning pin (34) via a belt (35).

15. An inhalation device according to any one of claims 10 to 14, characterised in that the loop ends of the tape (26) are guided with respect to the metering pin (8), while winding around it, so that their mutual spacing in the pulling direction behind the metering pin is smaller than the diameter of the pin (looping angle greater than 180°C).

16. An inhalation device according to claim 2 and any one of claims 10 to 15, characterised in that the dispersion nozzle (29) in the container (25) is constructionally associated with the metering pin (8), for example via a cam, so that the nozzle slightly lifts above the metering pin when the metering pin is rotated in the region of the entry of the metering notch (7), in the nozzle region.

17. An inhalation device according to any one of claims 10 to 16, characterised in that the container (25) has two plates as housing-end walls arranged at a spacing produced by the tape, in which the metering pin (8) is

arranged centrally, the pin rotatably passing through the walls, and between which the dispersion nozzle (29) is fixedly arranged, and between which the locking and tape tensioning pins (33, 34) are received in the nozzle portion, so that their mutual inner circumferential spacing (X) is smaller than the diameter of the metering pin (8).