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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Inhalation Device

We, FISONS PHARMACEUTICALS LIMITED, a British Company, of 12 Derby Road, Loughborough, Leicestershire, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention is concerned with improvements in or relating to a device for the application of medicaments in finely divided form by oral inhalation.

The application of medicaments by oral inhalation, inhalation therapy, is of considerable value in the alleviation of ailments of the bronchial tract and of the lungs and this route also proves of value in the systemic application of medicaments.

In order to obtain the maximum beneficial effect, the medicament should be carried to the area to be treated in the form of fine particles suspended in the inhaled air. This may be achieved, for example, by applying the medicament with a nebuliser or, more recently, by applying the medicament from a solution or suspension in a pressurised pack. Both these methods are, however, rather costly and, in the case of the pressurised pack, the apparatus is not re-usable.

It is an object of the present invention to provide an improved simple device for the application of a medicament in finely divided form by oral inhalation. More particularly it is an object of this invention to provide a device for the application of a finely divided solid medicament by oral inhalation which device depends only upon the inspiration of inhaled air to ensure dispersion of the powder in the air.

It has new been found that a finely divided powder may be well dispersed in a stream of air by mounting a perforated container containing the powder on the upstream side of a propeller rotatably mounted on a shaft so that the stream of air imparts rotational and vibrational movement to the propeller.

According to the invention, therefore, there is provided a device for the oral inhalation of medicaments in finely divided form which comprises a hollow elongate housing, preferably a tubular housing, having at both ends thereof one or more passageways to permit the passage of air and having one end thereof adapted for insertion into the mouth; and a propeller-like device rotatably mounted in the said housing on a rigid shaft mounted in said housing and co-axial with the longitudinal axis of the housing, said propeller-like device having, on the part thereof furthest from the end of the housing adapted for insertion in the mouth, mounting means adapted to receive a container for the finely divided medicament and said propeller-like device being so mounted on said shaft that the passage of a stream of air through the device causes not only rotational movement of the propeller-like device, but also vibrational movement of the propeller-like device.

By the term "propeller-like device" as used herein is meant a device having two or more blades or vanes symmetrically disposed about a central axis or hub, such that impingement of an air stream on the said vanes or blades tends to cause rotation of the device about said axis or hub.

It is essential that the propeller-like device be so mounted upon the shaft that the passage of an air stream causes not only rotational movement of the propeller-like device but also a vibrational component of motion. This vibrational component of the motion has been found essential for release

[Price 4s. 6d.]

Price 25p

of the powdered medicament from the capsule, and to obtain constant and reproducible results from the inhalation device.

In order that the propeller-like device should be capable of undergoing vibrational movement, it has been found desirable that the bearing in the propeller-like device in which the shaft engages should have certain dimensional characteristics. Thus the bearing takes the form of an elongate cavity of circular cross-section and the shaft is, of course, also of circular cross-section.

The internal diameter of the bearing at its inner end, i.e. the end housing the free end of the shaft, is desirably from 1.5 to 6% preferably 2.5 to 5%, e.g. 3.75% greater than the diameter of the shaft and the internal diameter of the bearing at its outer end equal to the diameter of the shaft plus from 1.3 to 3.5% e.g. about 2.5% of the total length of the bearing. The actual length of the bearing is not critical but may be, for example, from 4 to 10 times the diameter of the shaft.

The inner end wall of the bearing is preferably flat and the end of the shaft which engages with it is suitably of frusto conical shape, preferably terminating in a hemispherical portion e.g. of a radius of about half that of the shaft.

The shaft itself should be rigidly mounted since we have found that undue flexibility of the shaft and mounting causes malfunctioning of the device.

Preferably the capsule for use with the device, e.g. a gelatine capsule, is provided with at least two holes, suitably of about 0.6-0.65 mm in diameter, symmetrically arranged around the walls of the capsule, desirably in the part of the capsule furthest from the propeller-like device and advantageously in the shoulders of the capsule.

The device may be fitted with a non-return valve so that air may only be inhaled and not blown through the device.

In order that the invention may be well understood, two embodiments thereof will now be described with reference to Figures 1 and 3 of the drawings accompanying the provisional specification of Application No. 11697/65 and Figure 2 of the drawings accompanying the provisional specification of Application No. 43563/65, in which:—

Figure 1 represents a longitudinal section of a simple device according to the invention;

Figure 2 represents a longitudinal section through a preferred form of device according to the invention; and

Figure 3 represents a longitudinal section through a cap suitable for use with the device shown in Figure 2.

Referring now to Figure 1 of the accompanying drawings an inhalation device comprises a tubular housing 1, one end of which, B, is adapted to be inserted in the mouth. Mounted co-axially with housing 1 is a shaft 2 having loosely rotatably mounted thereon a propeller-like device 3 having blades 4, the propeller-like device 3 having cup-like means adapted to engage and hold a perforated capsule containing finely divided medicament 5.

When end B of housing 1 is inserted in the mouth and air is inhaled through the mouth the resulting air stream causes the propeller-like device 3 to rotate about shaft 2 and also to vibrate with the result that the finely powdered medicament in capsule 5 is expelled therefrom and passes with the air stream past blades 4 out of end B of housing 1 and into the mouth and bronchial tract.

Referring now to Figure 2 of the accompanying drawings an inhalation device comprises a housing of approximately circular cross-section having a diameter of about 1.9 cm. and a length of about 5 cm. and comprising two engaging members 6 and 7, housing member 7 being adapted for insertion into the mouth and having passageways 8 therein to permit the passage of air. Mounted rigidly in and co-axially with housing member 7 is shaft 2 upon which is loosely and rotatably mounted propeller-like device 3 having blades 4.

Propeller-like device 3 has a cup shaped member adapted to receive and hold a capsule or container of finely powdered medicament.

Shaft 2 engages in bearing 17 in propeller 3. The internal diameter at the inner end of bearing 17 is about 3.75% greater than the diameter of shaft 2 and the internal diameter at the outer end of bearing 17 is equal to the diameter of shaft 2 plus about 2.5% of the total length of the bearing, which is about 7 times the diameter of shaft 2.

The tip 18 of shaft 2 is conical in shape, having a cone angle of about 30°, and terminates in a substantially hemispherical portion having a diameter of about half the diameter of shaft 2.

Housing member 6 has in its end wall air passages 9 to permit the passage of air and constricting member 10 which serve to constrict the air stream through the device and thus increase its velocity past the capsule.

Through the end wall of housing member 6 extends locking member 11 which is attached at its outer end to base piece 12. Between base piece 12 and housing member 6 is a spring 13 which urges locking member 11 in a normally open position. Base piece 12 has a screw thread 14 which engages in a similar screw thread 16 in cap 15 to hold locking member 12 in a closed position

and to engage and hold capsule 5 mounted in the cup shaped member of propeller 3. When cap 15 is in position no air may be inhaled through the device and capsule 5 is firmly held in position. When cap 15 is removed from the device spring 13 urges locking member 11 into its normally open position and air may be inhaled through the device with consequent rotation of propeller-like member 3 and dispersal of the finely powdered medicament in capsule 5. Capsule 5 may for example be in a gelatine capsule which may be readily perforated with two or more holes, e.g. with a pin, at the shoulder on the end thereof furthest from propeller-like device 3.

Around locking member 11 is disc 19 which serves as a non-return valve for the device. Thus if air is blown through the device disc 19 is urged against the end wall of housing 6 and closes air inlets 9 and thus prevents any further air from passing in that direction. If air is sucked through the device, disc 19 is urged away from the end wall of housing 6; freeing inlets 9 and thus allowing air to pass through the device.

The whole device may be constructed of any suitable material, preferably of a synthetic thermoplastic resin such as nylon in which case it may be made by an injection moulding technique.

The propeller and propeller blades should be designed so that adequate medicament is delivered with the volume of air that can be inhaled by the patient. We have found it desirable that the device should operate with the inhalation of about 500 millilitres of air over a period of about 0.5 secs. and this can easily be achieved by the majority of adult patients.

The inhalation device according to the invention does not require skill or co-ordinated effort on the part of the user since inspiration through the device automatically delivers the powder in an amount proportional to the rate of inhalation and total volume of inhaled air. Thus the device automatically regulates the quantity of powder released in accordance with the depth of inspiration.

The consistently effective administration of a powdered material by the device has been confirmed by experimental trials carried out using a bronchodilator as medicament. The efficient inhalation of a bronchodilator in powder form (particle size 80% between 2-6 microns) causes rapid bronchodilation and the degree of bronchodilation at a minimal dose is a measure of the effectiveness of the administration of the dose to the lung.

The device according to the invention was used to administer over 1000 doses of bronchodilator to some 30 persons and the response determined spirometrically. Inadequate response in any single case was found to be due to lack of response to the medicament itself as confirmed by administration by alternative routes. In all other cases the administration was found to be fully effective.

WHAT WE CLAIM IS:—

1. A device for the inhalation of medicaments in finely divided form which comprises a hollow elongate housing having at both ends thereof one or more passageways to permit the passage of air through the housing and having one end thereof adapted for insertion into the mouth; and a propeller-like device rotatably mounted in said housing on a rigid shaft mounted in said housing and co-axial with the longitudinal axis of the housing, said propeller-like device having, on the part thereof furthest from the end of the housing adapted for insertion in the mouth, mounting means adapted to receive a container for the finely divided medicament and said propeller-like device being so mounted on said shaft that the passage of a stream of air through the device causes not only rotational movement of the propeller-like device but also a vibrational movement of the propeller-like device.

2. An inhalation device as claimed in claim 1 in which the hollow elongate housing is a tubular housing.

3. An inhalation device as claimed in claim 1 or claim 2 in which the bearing in the propeller-like device in which the shaft engages has an internal diameter at its inner end from 1.5 to 6% greater than the diameter of the shaft and an internal diameter at its outer end equal to the diameter of the shaft plus from 1.3 to 3.5% of the total length of the bearing.

4. An inhalation device as claimed in claim 3 in which the internal diameter of the bearing at its inner end is from 2.5 to 5% greater than the diameter of the shaft.

5. An inhalation device as claimed in claim 3 or claim 4 in which the internal diameter of the bearing at its inner end is substantially 3.75% greater than the diameter of the shaft and the internal diameter of the bearing at its outer end is equal to the diameter of the shaft plus substantially 2.5% of the total length of the bearing.

6. An inhalation device as claimed in any of the preceding claims in which the length of the bearing of the propeller-like device is from 4 to 10 times the diameter of the shaft.

7. An inhalation device as claimed in any of the preceding claims in which the inner end wall of the bearing in the propeller-like device is flat and the end of the shaft which engages with it is of frusto-conical shape.

8. An inhalation device as claimed in

and to engage and hold capsule 5 mounted in the cup shaped member of propeller 3. When cap 15 is in position no air may be inhaled through the device and capsule 5 is firmly held in position. When cap 15 is removed from the device spring 13 urges locking member 11 into its normally open position and air may be inhaled through the device with consequent rotation of propeller-like member 3 and dispersal of the finely powdered medicament in capsule 5. Capsule 5 may for example be in a gelatine capsule which may be readily perforated with two or more holes, e.g. with a pin, at the shoulder on the end thereof furthest from propeller-like device 3.

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2. An inhalation device as claimed in claim 1 in which the hollow elongate housing is a tubular housing.

3. An inhalation device as claimed in claim 1 or claim 2 in which the bearing in the propeller-like device in which the shaft engages has an internal diameter at its inner end from 1.5 to 6% greater than the diameter of the shaft and an internal diameter at its outer end equal to the diameter of the shaft plus from 1.3 to 3.5% of the total length of the bearing.

4. An inhalation device as claimed in claim 3 in which the internal diameter of the bearing at its inner end is from 2.5 to 5% greater than the diameter of the shaft.

5. An inhalation device as claimed in claim 3 or claim 4 in which the internal diameter of the bearing at its inner end is substantially 3.75% greater than the diameter of the shaft and the internal diameter of the bearing at its outer end is equal to the diameter of the shaft plus substantially 2.5% of the total length of the bearing.

6. An inhalation device as claimed in any of the preceding claims in which the length of the bearing of the propeller-like device is from 4 to 10 times the diameter of the shaft.

7. An inhalation device as claimed in any of the preceding claims in which the inner end wall of the bearing in the propeller-like device is flat and the end of the shaft which engages with it is of frusto-conical shape.

8. An inhalation device as claimed in

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claim 7 in which the end of the shaft terminates in a hemispherical portion.

9. An inhalation device as claimed in any of the preceding claims provided with a non-return valve so that air may only be inhaled through the device.

10. An inhalation device as claimed in any of the preceding claims in which the mounting means for a container of medicament on the propeller-like device is cup-shaped.

11. An inhalation device as claimed in claim 1 substantially as herein described.

12. An inhalation device as claimed in claim 1 substantially as herein described with reference to the accompanying drawings.

13. An inhalation device as claimed in any of the preceding claims having a capsule of finely divided medicament mounted therein, said capsule being provided with at least two holes symmetrically arranged around the walls of the capsule.

14. An inhalation device as claimed in claim 13 in which the holes in the capsule have a diameter of about 0.6-0.65 mm. and are located in the shoulders of the capsule furthest from the propeller-like device.

15. An inhalation device as claimed in claim 13 substantially as herein described.

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