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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.

More particularly the invention is concerned with a device for the oral inhalation of medicaments in finely divided form which comprises a hollow elongate housing, suitably 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 member rotably 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 member 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 such as a gelatine or like capsule. (By the term 'propeller-like member' is meant a member having two or more blades or vanes 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 member about said axis or hub).

In order to dispense its contents the container of the finely powdered medicament must be perforated and it has been found very convenient to perforate the container *in situ* in the dispensing device.

According to the invention, therefore, there is provided a dispensing device of the type described provided with means for perforating the container of the finely powdered medicament *in situ* in the device.

The device according to the invention is particularly convenient since it may be carried by the user with the closed container already in place in the device and is simply used by actuating the container perforating means and then inhaling the contents of the container by inspiration through the device. Since the container is closed or sealed until it is desired to use the device there is no risk of contamination of the contents of the container and, in the case of medicament powders showing hygroscopic tendencies, there is no risk of caking of the medicament prior to use.

Suitably the container used in the device is a capsule, for example a gelatine or plastic capsule, and conveniently the capsule perforating means is so arranged to provide two or more holes, suitably of about 0.6—0.65 mm. in diameter, desirably in the part of the capsule furthest from the propeller-like member, advantageously in the shoulders of the capsule. Where the perforating means is so arranged as to provide two or more holes in the container, these are conveniently positioned symmetrically around the container.

Suitably, the container perforating means may take the form of one or more spring-loaded piercing members mounted in the housing so that they are normally urged, by the springs, away from the container but which may be pressed inwards to perforate the container by the action of push buttons located on the exterior of the housing.

In a preferred embodiment of the invention the piercing means comprises a pair of opposed sharpened piercing members connected by a bent resilient bridging mem-

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ber and means for urging the piercing members together to pierce a capsule located between them. In this preferred form of the device, the piercing members will generally be formed in one piece with the bridging member of a resilient material such as spring steel, carbon steel or stainless steel. If the piercing members are formed of a corrodible material, such as spring steel or carbon steel, they may be plated, e.g. with nickel or chromium, to inhibit corrosion. In order to facilitate the piercing operation the piercing members are advantageously provided with stops which prevent the too deep penetration of one member into the capsule before the other member comes into operation, hence ensuring equal penetration by both members. The resilient bridging member may take the form of a simply bent strip or rod of material or may be provided with one or more turns to give better resistance to fatigue. The piercing members may be urged together by push buttons or, preferably, by sliding cams.

It has been found that, in order to obtain optimum perforation of a gelatine capsule, the perforating ends of the piercing members should not be sharpened to a conventional conical point but should be sharpened with a plane face at an acute angle. Further, the acute angled plane face should desirably face away from the propeller-like member.

We have found that, in the form of dispensing device to which the present invention relates, dispensing of powder from a powder container mounted therein may be facilitated if the container is subjected to vibration during rotation thereof. The rotation of the container is achieved by means of the passage of air past the vanes on the propeller-like member of the device and the vibration is achieved by means of the form of mounting of the propeller-like member on the shaft.

In order that the propeller-like member should be capable of undergoing vibrational movement, it has been found desirable that the bearing in the propeller-like member in which the shaft engages should have certain dimensional characteristics. Thus the bearing takes the form of a tube having an internal bore of circular cross-section in which the shaft is journalled. The shaft is 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 diameter of the bearing at its outer end is 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 frustro 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.

The device according to the invention is suitable for the administration of medicaments for the alleviation of ailments of the bronchial tract and of the lungs.

The device may also be used for the administration of medicaments having systemic action, for example it may be used for the administration of antidotes to poisonous substances such as nerve gases as it provides a very simple method of carrying medicaments which have to be used rapidly or in emergency.

In order that the invention may be well understood, two embodiments thereof will now be described with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal section through one device according to the invention;

Figure 2 is a longitudinal section through another device according to the invention, showing the piercing means in the non-piercing position;

Figure 3 is a longitudinal section through the device shown in Figure 2, showing the piercing means in the piercing position;

Figure 4 is a cross-section view at the line A—A in Figure 2;

Figure 5 is a cross-section view at the line B—B in Figure 2; and

Figure 6 is a cross-section view at the line C—C in Figure 2.

Referring now to Figure 1 of the drawings an inhalation device comprises a housing of approximately circular cross-section comprising two engaging housing 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 by means of bearing 17 propeller-like member 3 having blades 4.

Propeller-like member 3 has a cup shaped member adapted to receive and hold a capsule or container 5 of finely powdered medicament.

Shaft 2 engages in bearing 17 on propeller-like member 3. The diameter at the inner end of bearing 17 is about 3.75% greater than the diameter of shaft 2 and the diameter of the outer end of bearing

12 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 end 18 of shaft 2 is conical in shape, having a cone angle of about 30°, and terminates in a substantially hemispherical tip 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 serves to constrict the air stream through the device and thus increase its velocity past the capsule.

Mounted on the outside of housing member 6 are two hollow projections 20 and 20a having slidably engaged therein push buttons 21 and 21a. Push buttons 21 and 21a are retained in projections 20 and 20a by means of pins 22 and 22a engaging in slots in the push buttons, and are urged outwardly from housing member 6 by means of springs 23 and 23a. Attached to push buttons 21 and 21a are piercing pins 24 and 24a. For purposes of illustration, one assembly is shown in the non-piercing position whereas the other assembly is shown with the tip of pin 24a having pierced capsule 5, push button 21a having been depressed against the action of spring 22a.

In operation, housing members 6 and 7 are separated and capsule 5 is loaded into propeller-like member 3. Housing members 6 and 7 are then fitted together again and the device is ready for use. In use, the user first depresses buttons 21 and 21a to cause pins 24 and 24a to pierce capsule 5. The user then releases buttons 21 and 21a to remove pins 24 and 24a from the capsule and subsequently inhales through the device. The passage of air through the device causes propeller-like member 3 to rotate. Due to the dimensions of the bearing tube 17 in which shaft 2 engages, the rotation of the propeller-like member is given a vibrational component of motion which assists in the dispensing of the powder from the capsule mounted on propeller-like member 3. The powder issues from the holes pierced in the capsule wall and is entrained in the air stream inhaled by the user through the device.

Referring now to figures 2, 3, 4, 5 and 6 of the drawings, an inhalation device comprises a hollow body member 1 of generally circular cross-section provided at one end with an end piece 6 which is perforated by air passages 9, and at the other end with a mouthpiece 7 provided by air passages 8. End piece 6 is firmly attached to body member 1, for example it may be glued thereto, and mouthpiece 7 is removably attached to body member 1 by means of co-operating screw threads 34 in body member 1 and mouthpiece 7.

End piece 6 has a central projection 25 in a slot in which is mounted resilient piercing member 26. Piercing member 26 is retained in the slot in projection 25 by means of retaining block 27 which is, in turn, held in position in the slot by means of pin 28. The arms of resilient piercing member 26 are located in slots in the walls of body member 1 and in guideways formed by guide members 29 extending inwardly from the inner surface of body member 1.

Mounted in mouthpiece 7 and extending into body member 1, is shaft 2 on which is mounted propeller-like member 3 having blades 4 and a cup-like depression for receiving gelatine capsule 5.

Slidably mounted on body member 1 is tubular member 30 having cam-like projections 31 extending inwardly through the slots in body member 1. When member 30 is slid from the position shown in Figure 2 to that shown in Figure 3 cam-like projections 31 engage with the arms of resilient piercing member 26 to force them inwards and thus to force piercing projections 32 into contact with the surface of capsule 5 and finally to pierce capsule 5 as shown in Figure 3, the depth of piercing being limited by stops 33. When the member 30 is slid back from the position shown in Figure 3 to that shown in Figure 2 the resilience of member 26 causes the arms to spring apart and to resume the position shown in Figure 2.

In operation, the device is first loaded with capsule 5 by unscrewing mouthpiece 7 from body member 1 and placing capsule 5 in the cup-like depression in propeller-like device 3. Mouthpiece 7 is then screwed back into body member 1 and the device is ready for use.

In use, the user first pierces capsule 5 by sliding member 30 from the position shown in Figure 2 to that shown in Figure 3 and then back to the position shown in Figure 2.

The user then places mouthpiece 7 in the mouth and inhales through the device causing rotation and vibration of the propeller-like member 3, thus administering powdered medicament contained in capsule 5.

WHAT WE CLAIM IS:—

1. A device for the oral 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 and having one end thereof adapted for insertion into the mouth; and a propeller-like member 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 member hav-

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 end 18 of shaft 2 is conical in shape, having a cone angle of about 30°, and terminates in a substantially hemispherical tip 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 serves to constrict the air stream through the device and thus increase its velocity past the capsule.

Mounted on the outside of housing member 6 are two hollow projections 20 and 20a having slidably engaged therein push buttons 21 and 21a. Push buttons 21 and 21a are retained in projections 20 and 20a by means of pins 22 and 22a engaging in slots in the push buttons, and are urged outwardly from housing member 6 by means of springs 23 and 23a. Attached to push buttons 21 and 21a are piercing pins 24 and 24a. For purposes of illustration, one assembly is shown in the non-piercing position whereas the other assembly is shown with the tip of pin 24a having pierced capsule 5, push button 21a having been depressed against the action of spring 22a.

In operation, housing members 6 and 7 are separated and capsule 5 is loaded into propeller-like member 3. Housing members 6 and 7 are then fitted together again and the device is ready for use. In use, the user first depresses buttons 21 and 21a to cause pins 24 and 24a to pierce capsule 5. The user then releases buttons 21 and 21a to remove pins 24 and 24a from the capsule and subsequently inhales through the device. The passage of air through the device causes propeller-like member 3 to rotate. Due to the dimensions of the bearing tube 17 in which shaft 2 engages, the rotation of the propeller-like member is given a vibrational component of motion which assists in the dispensing of the powder from the capsule mounted on propeller-like member 3. The powder issues from the holes pierced in the capsule wall and is entrained in the air stream inhaled by the user through the device.

Referring now to figures 2, 3, 4, 5 and 6 of the drawings, an inhalation device comprises a hollow body member 1 of generally circular cross-section provided at one end with an end piece 6 which is perforated by air passages 9, and at the other end with a mouthpiece 7 provided by air passages 8. End piece 6 is firmly attached to body member 1, for example it may be glued thereto, and mouthpiece 7 is removably attached to body member 1 by means of co-operating screw threads 34 in body member 1 and mouthpiece 7.

End piece 6 has a central projection 25 in a slot in which is mounted resilient piercing member 26. Piercing member 26 is retained in the slot in projection 25 by means of retaining block 27 which is, in turn, held in position in the slot by means of pin 28. The arms of resilient piercing member 26 are located in slots in the walls of body member 1 and in guideways formed by guide members 29 extending inwardly from the inner surface of body member 1.

Mounted in mouthpiece 7 and extending into body member 1, is shaft 2 on which is mounted propeller-like member 3 having blades 4 and a cup-like depression for receiving gelatine capsule 5.

Slidably mounted on body member 1 is tubular member 30 having cam-like projections 31 extending inwardly through the slots in body member 1. When member 30 is slid from the position shown in Figure 2 to that shown in Figure 3 cam-like projections 31 engage with the arms of resilient piercing member 26 to force them inwards and thus to force piercing projections 32 into contact with the surface of capsule 5 and finally to pierce capsule 5 as shown in Figure 3, the depth of piercing being limited by stops 33. When the member 30 is slid back from the position shown in Figure 3 to that shown in Figure 2 the resilience of member 26 causes the arms to spring apart and to resume the position shown in Figure 2.

In operation, the device is first loaded with capsule 5 by unscrewing mouthpiece 7 from body member 1 and placing capsule 5 in the cup-like depression in propeller-like device 3. Mouthpiece 7 is then screwed back into body member 1 and the device is ready for use.

In use, the user first pierces capsule 5 by sliding member 30 from the position shown in Figure 2 to that shown in Figure 3 and then back to the position shown in Figure 2.

The user then places mouthpiece 7 in the mouth and inhales through the device causing rotation and vibration of the propeller-like member 3, thus administering powdered medicament contained in capsule 5.

WHAT WE CLAIM IS:—

1. A device for the oral 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 and having one end thereof adapted for insertion into the mouth; and a propeller-like member 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 member hav-

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ing, on the end 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; which device is provided with means for perforating the container of medicament *in situ* in the device.

2. An inhalation device as claimed in claim 1 in which the perforating means is so arranged as to provide two or more holes 0.6—0.65 mm. in diameter in the container.

3. An inhalation device as claimed in claim 1 or claim 2 in which the perforating means is arranged to provide the said holes in the part of the container furthest from the propeller-like member.

4. An inhalation device as claimed in any of the preceding claims in which, where the perforating means is adapted to produce two or more holes, these are symmetrically located around the circumference of the container.

5. An inhalation device as claimed in any of the preceding claims in which the container perforating means takes the form of one or more spring loaded piercing members mounted in the housing and provided with push-buttons so that they may be pressed inwards to perforate the container.

6. An inhalation device as claimed in claim 5 in which the piercing members are provided with piercing points taking the form of a plane face at an acute angle to the axis of the member.

7. An inhalation device as claimed in any of claims 1—4 in which the container perforating means takes the form of opposed sharpened piercing members connected by a resilient bridging member and having means for urging the piercing members together to pierce a capsule located between them.

8. An inhalation device as claimed in claim 7 in which the piercing members are provided with stops to limit the depth of penetration of the piercing member into a capsule.

9. An inhalation device as claimed in claim 7 or claim 8 in which the piercing members are provided with piercing points taking the form of a plane face at an acute angle to the axis of the member.

10. An inhalation device as claimed in any of claims 7—9 in which the piercing members are urged together by means of sliding cams.

11. An inhalation device as claimed in any of the preceding claims in which the hollow elongate housing is a tubular housing.

12. An inhalation device as claimed in any of the preceding claims in which the bearing in the propeller-like member 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.

13. An inhalation device as claimed in claim 12 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.

14. An inhalation device as claimed in claim 12 or claim 13 in which the internal diameter of the bearing at its inner end is about 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 about 2.5% of the length of the bearing.

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

16. 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 a frusto-conical shape.

17. An inhalation device as claimed in claim 16 in which the end of the shaft terminates in a hemispherical portion.

18. An inhalation device as claimed in claim 5 substantially as herein described with reference to Figure 1 of the accompanying drawings.

19. An inhalation device as claimed in claim 7 substantially as herein described with reference to Figures 2, 3, 4, 5 and 6 of the accompanying drawings.

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