

PHILIPPINE PATENT (19)

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[54] Title: DOSAGE

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[56] Reference(s) Cited and/or Considered:

U.S. Pat. Nos.	166,638	81875	Sears
	2587215	2-26-52	Priestly

[57] ABSTRACT see attached sheet

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S P E C I F I C A T I O N

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN THAT I, KJELL INGVAR LEOPOLD WETTERLIN, a citizen of Sweden, and residing at Västervång 19, S-240 17 S. Sandby, Sweden, have invented an improvement in "DOSAGE DEVICE" of which the following is a specification.

DOSAGE DEVICE

The present invention relates to a new dosage device intended to be used for dosing of micronized or granulated substances or microcapsules (hereinafter referred to collectively as particulate material) and containing pharmacologically active substances.

5 Several preparations of drugs are nowadays administered in micronized or granulated form or in the form of microcapsules. These substances are filled into capsules of hard gelatine, which are intended for oral administration and are swallowed whole by the patient. Children and adults who have difficulties in swallowing a whole capsule are
10 recommended to open the capsule and spread the contents on a suitable piece of food and to swallow. It is, however, difficult to open the capsule and pour out the contents without any loss of the substance. Capsules of hard gelatine are an expensive, but effective, way to administer pharmacologically active substances to patients, who
15 are able to swallow the capsules unbroken. It is, however, not sensible to use this expensive way of dispensing into capsules of hard gelatine, when the patient later on, with some difficulty, opens the capsule and pours out the contents.

20 It has previously been proposed to provide dosage devices to enable the particulate material to be dispensed accurately. For example DE-A-2 052 051 describes a dosage device comprising an operating unit and a storage chamber. The operating unit is fitted relatively loosely to the casing of the device. Substances having small particles
25 thus easily fall on the sliding surfaces between the two relatively movable units, so that substance being fed jams. With such a dosage device, which does not have a feeding under force it is difficult to dose small amounts of micronized or granulated substances with an accuracy which is sufficient for the dispensing of drugs.

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According to the present invention there is provided a dosage device for dosing with high accuracy a particulate material containing a pharmacologically active substance, said device comprising a storage

chamber, a rotatable dosing unit adjacent said storage chamber,
an operating unit to cause relative rotation between said dosing
unit and said storage chamber, a plurality of upwardly opening recesses
in said dosing unit, at least one of which opens into said storage
5 chamber, to receive particulate material therefrom, a scraping unit
with scrapers positioned to pack and level the particulate material
into the recesses and level it off with the upper surface of the
dosing unit as the dosing unit rotates relative to the storage chamber,
operating means on said operating unit for causing indexing of the
10 dosing unit between discrete rotational positions, and a generally
upwardly extending dispensing channel positioned at one of said
discrete positions to communicate with one of said recesses, so
that said one recess may be emptied by turning said device upside
down.

15 With the construction according to the present invention, the substance
is prevented from getting into contact with the sliding surfaces
in the two relatively movable parts of the dosage device and in
this way feeding of each dose can be achieved without any problems.

20 In the dosage device according to the invention, the scrapers make
it possible to fill the recesses in the dosing unit in a accurately
reproducible way. A high dosage accuracy can thus be obtained by
the rotation of the dosing unit.

25 In order that the invention may more readily be understood, the
following description is given, merely by way of example, reference
being made to the accompanying drawing, in which:

Figure 1 is an axial cross-section of one embodiment of dosage device
30 according to the invention; and

Figure 2 is a cross-section taken along the line II-II of Figure 1;

Figure 3 is an exploded, perspective view thereof.

35 The dosage device of the present invention, is preferably produced
in plastic and can be considered to comprise four separate units
as follows:

an operating unit 1 at the bottom of the dosage device;
a spring loaded dosage dispensing dosing unit 2;
a scraping unit 3; and
a storage chamber 4 provided with a dispensing channel 5
for the dose to be dispensed.

A further separate part is shown in the drawings and is preferred,
but is not essential, this being in the form of a plastic or metal
hood 6 which can be retained by a peripheral rib (not shown) at
the upper part of the operating unit 1. This rib enables the hood
to be removably retained. An alternative way of sealing the device
is to provide a plug in the top of the dispensing channel 5

At the lower mid part of the storage chamber 4, the scraping unit
3 is fixed to the inner wall of the storage chamber so that it
cannot rotate relative thereto. The scraping unit in fact includes
the lower part of the dispensing channel 5 which is formed in-
tegrally with the storage chamber 4. From Figure 2, it will be
seen more clearly that the scraping unit 3 includes 5 radially
extending arms 3A and outlet openings 3B, each arm of which
carries a resilient scraper 8 in sliding contact with the
upper surface of the dispensing unit 2 which, in turn, is
provided with six circumferentially spaced slightly frusto-
conical recesses 7 positioned immediately under the scrapers 8.
In order to guide for rotation of the dispensing unit 2, the
scraping unit has an outer peripheral skirt engaging the cylin-
drical outer surface of the dispensing unit 2 and a short
inner annulus engaging the upper surface of the dosing unit
inwardly of the recesses 7 in order to prevent jamming at
feeding. The dispensing unit 2 is loaded by a spring 9 in
order to press the dosing unit against the scraping unit.
Between the dosing unit, which has a toothed ring 13, and the
spring there is situated a disc 14 which is keyed to the
storage chamber. The operating unit 1, against which the
other end of the spring 9 abuts, carries a resilient arm 12
which is engageable with the toothed ring 13. Thus, the
disc 14, in effect, controls the angular movement of the
operating unit 1 and the dispensing unit 2 so that one of the
recesses 7 will always stop in the correct position that is
immediately below the dispensing channel 5 as shown in
Figure 1. Furthermore, the disc 14 reduces the friction
between the spring and the dosing unit.

In the operating unit 1 there is provided a space 10, as illustrated closed by a porous pad and into the space 10 can be inserted a drying agent such as silica gel in order to protect the contents of the device from the humidity of the air. The ingress of humidity will also be reduced by the provision of the hood 6.

The particulate pharmaceutically active substance is stored inside the storage chamber 4 and the actual dosing operation is carried out with the dosing device in the upright position shown in Figure 1, by rotating the operating unit at first clockwise and then counter-clockwise. The ratchet mechanism formed by the toothed ring 13 and the resilient arm 12 will thus index the dosing unit so that first one and then another recess appear immediately under the dispensing channel. All of the recesses passes successively the storage chamber and can be filled with the particulate material therein. Thus, a predetermined amount of particulate pharmaceutically active substance can be dosed by the correct choice of the size of the recess 7. The effect of the scrapers 8 on the scraping unit 3 is firstly to force and pack the particulate material into the recesses and secondly accurately to level off the particulate material at the top of the recesses. This means that when a recess 7 arrives immediately below the dispensing channel 5 it will be completely and accurately filled.

All that is then necessary is to turn the dosage device upside down and the particulate material will flow down the dispensing channel 5. By choosing the size of the recess for which ever substance is to be dispensed, one can thus choose the size of a dose which may for example be varied within wide limits, say from 1 to 5 mg or 5 to 200 mg. The number of recesses in the dispensing unit may vary depending on different factors, such as the amount of active substance which should be administered in each dose, the physical properties of the active substances and so on. In a preferred embodiment, the dosing unit has six recesses and these recesses are preferably cylindrical or preferably frustoconical as shown and should preferably hold 1 dose of active substance.

The size of the storage chamber may be chosen to suit the requirements expected for a particular active substance. In the dosage device the chamber may, for example, contain sufficient active substance for about 100 doses. The dosage device has an opening for filling or refilling of active substance in the upper part of the storage chamber. The opening is preferably sealed by a plastic plug 11.

In an alternative embodiment the dosage device has a resilient key which makes it possible to feed the device with one hand. Each push on the key causes indexing of the dosing device so that a recess filled with the active substance is placed in communication with the dispensing channel.

The dosage device may be used as container and aid in dispensing of a great number of active substances such as enprophylline, theophylline and terbutaline.

The best mode of carrying out the invention known at present is illustrated in Figure 1.

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Example

In order to demonstrate the dosage accuracy of the dosage device according to the present invention the following tests have been carried out with different dosing units with different sizes of the recesses A-G. The container was filled with Theo-Dur Sprinkle substance (which is a slow release microencapsulated preparation of theophylline) mixed with 1 and 2% of talcum respectively. When the dosage accuracy of 500 doses was established a maximum deviation of 3.5% was obtained. Cf. the table below.

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Test with seven different dosage units containing
Theo-Dur Sprinkle substance mixed with talcum

The figures below are the average values of 500 doses from each
 5 dosage device.

10	Dosage unit	Talcum					
		1%			2%		
		mg/dose	^s rel	%	mg/dose	^s rel	%
15	A	104.1	2.15	2.1	104.2	2.45	2.4
	B	94.0	2.36	2.5	94.0	2.66	2.8
	C	85.4	2.29	2.7	84.8	2.30	2.7
	D	73.2	2.45	3.3	75.1	1.73	2.3
	E	64.7	1.68	2.6	64.5	2.02	3.1
	F	54.3	1.33	2.5	53.4	1.87	3.5
	G	45.8	1.34	2.9	45.9	1.30	2.8

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As a comparison reference is made to Pharm. Nord, which specifies
 that 90% of the capsules shall have a weight which does not deviate
 more than 10% from the stipulated weight. The rest shall not deviate
 25 more than 20%. With the new dosage device according to the invention
 these requirements are thus met with an ample margin.

I CLAIM:

1. In a device for releasing a dosage of a particular medication that includes:

a dosage dispensing unit having a face with a plurality of recesses therein adapted to receive and meter a reproducible amount of said medication.

a storage chamber adapted to contain the medication with the lower end portion thereof bounded by a scraping unit having outlet openings on a face thereon and dispensing outlet, said scraping unit being mounted in slidable, abutting relation to the face of said dispensing unit, and

a dispensing channel integrally provided on said storage chamber, having a first open end through which medication can be discharged and a second open end in communication with said dispensing outlet, ^{the improvement} wherein:

(1) said dispensing unit is mounted for rotation around an axis, and said recesses, the outlet openings of said storage chamber and the dispensing outlet of said scraping unit are all disposed in relation to said

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axis, such that, upon rotation of said dispensing unit, said recesses are rotated successively between operative engagement with the outlet openings of said scraping unit for reception of medication and operative engagement with the dispensing outlet for discharge of medication.

(2) there is a plurality of resilient scrapers located in the outlet openings in sliding, resilient contact with the face of said dispensing unit and configured and disposed relative to the axis of rotation such that it first pushes medication into the recess and then removes excess medication from above said recesses during rotation of said dispensing unit and insure that each recess contains a reproducible amount of medication.

(3) said dispensing unit has ratchet means thereon arranged around the axis on which said unit rotates.

5 (4) said device has ratchet engaging means mounted for rotation around the axis on which said dispensing unit rotates, said ratchet engaging means being in slidable spring-loaded contact with said ratchet means.

10 (5) said ratchet means and ratchet engaging means are adapted to cooperate with each other such that rotation of said engaging means in one rotational direction will cause said dispensing unit to rotate in the same direction to a plurality of stations wherein at each station, the recesses in said dispensing unit are in mating relation to the corresponding outlet openings and one of the recesses

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is in mating relation to the dispensing outlet such that said engaging means will release from said ratchet means as the ratchet engaging means is rotated in the opposite rotational direction, and

5 (6) the device has stop means coacting between the ratchet engaging means and the storage chamber for stopping the dispensing unit at each station and preventing it from advancing to the next station until the ratchet means has been released, the ratchet engaging means has been rotated in
10 said opposite rotational direction, and the ratchet means corresponding to the next station has been engaged.

15 2. A device according to claim 1 wherein spring means are included to maintain said dosage dispensing unit in slidable abutting relationship to the outlet openings and said dispensing outlet.

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Inventor

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Abstract

2/ A dosage device for dosing with high accuracy a particulate material containing a pharmacologically active substance, including a storage chamber (4), a rotatable dosing unit (2) adjacent the storage chamber, an operating unit (1) to cause relative rotation between the dosing unit and the storage chamber, the dosing unit (2) being provided with a plurality of upwardly opening recesses (7) opening into said storage chamber (4), to receive particulate material therefrom. Scrapers (8) are positioned immediately above these recesses to pack and level the particulate material into the recesses (7) and level the material off with the upper surface of the dosing unit as the dosing unit rotates relative to the storage chamber (4). The operating unit (1) causes an indexing of the dosing unit (2) between discrete rotational positions in one of which one of the recesses (7) is in direct communication with a generally upwardly extending dispensing channel (5) so that when the unit is turned upside down that recess will discharge through the channel (5).

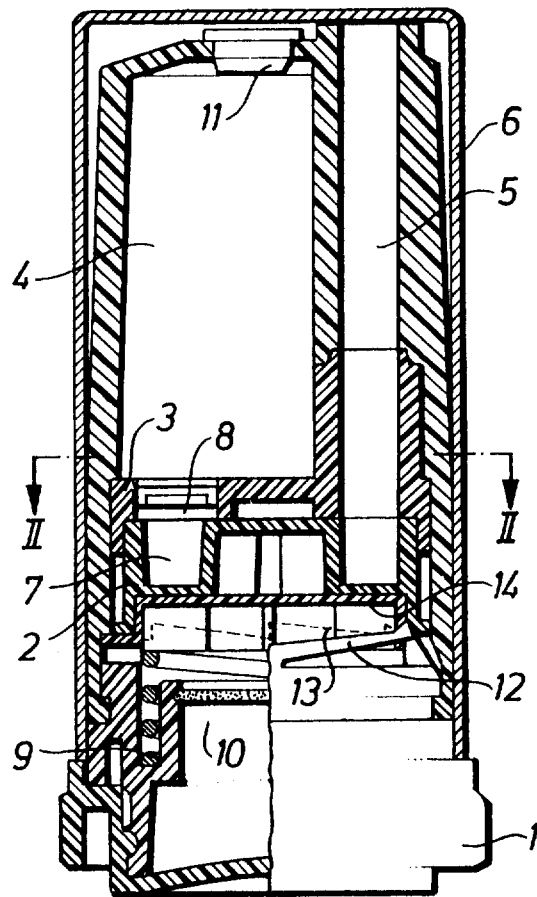
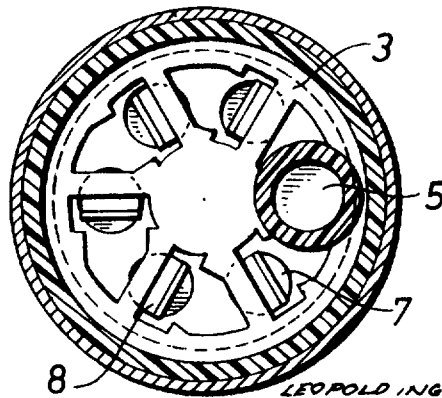


FIG. 1

FIG. 2



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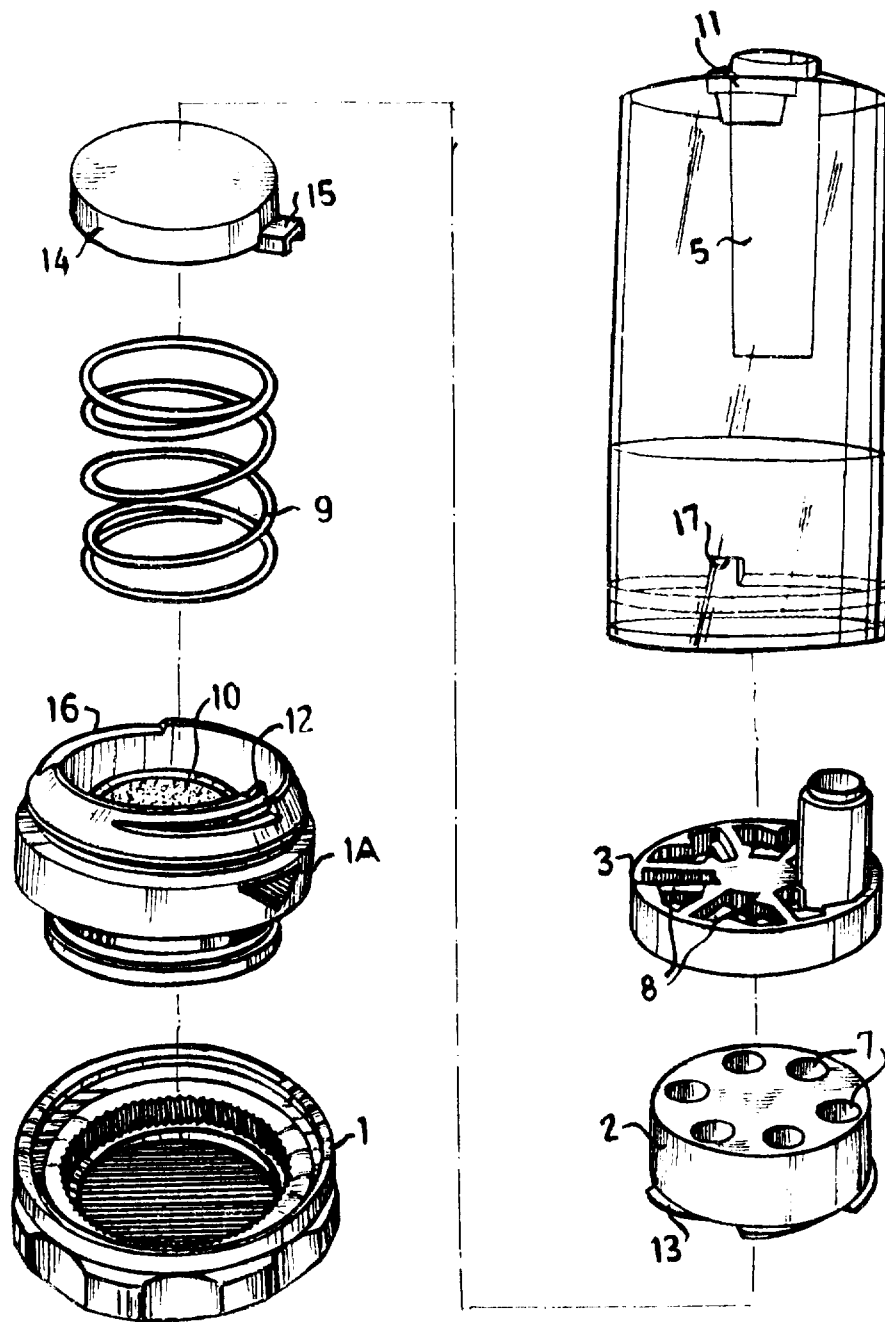


FIG. 3

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