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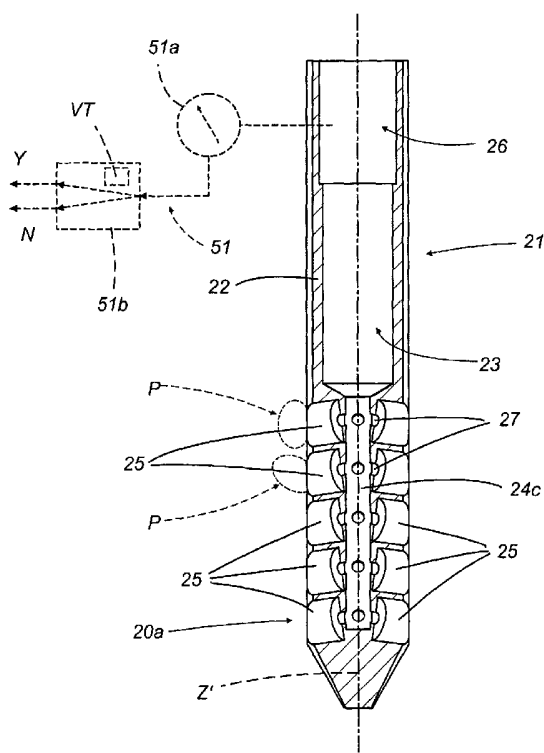
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- (74) Agent: **LANZONI, Luciano**; Bugnion S.p.A., Via Goito, 18, I-40126 Bologna (IT).
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- (71) Applicant (for all designated States except US): **I.M.A. INDUSTRIA MACCHINE AUTOMATICHE S.P.A.** [IT/IT]; Via Emilia Levante, 428-442, I-40064 Ozzano Emilia (IT).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **TREBBI, Roberto** [IT/IT]; Via Forno Rosso, 2/3, I-40055 Castenaso (IT). **ZERBINATI, Enrico** [IT/IT]; Via della Lamma, 5/15, I-40017 Monterenzio (IT).
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(54) Title: A CAPSULE FILLING MACHINE



(57) Abstract: A capsule filling machine (10) for the production of hard gelatin capsules (C) of the type with a capsule lid and a capsule body (13, 14) containing pharmaceutical micro-tablets (12) comprises a first rotary carousel (2) supporting a plurality of slide units (3) for picking up and handling capsules (C) in order to open then close the capsules (C) by separating then joining the capsule lids (13) and the capsule bodies (14); a second carousel (4), which rotates in such a way that it is synchronized with the first carousel (2), having a plurality of reciprocating doser means (21) moving between a first operating position in which the doser means (21) are designed to pick up particulate material (12) from a tank (11) containing the material which is attached to the machine (10) and a second operating position in which they release the material into the capsule (C) bodies (14). The doser means (21) each comprise a hollow nozzle (22) with a plurality of seats (25) on its edge for picking up and holding the particulate pharmaceutical material (12), each seat (25) communicating with pneumatic means (24, 24a, 24b), the pneumatic means (24, 24a, 24b) comprising pneumatic vacuum means (24a) which, in the first operating position, suck up and hold individual particles (12) of the material in respective seats (25) of the nozzle (22), and pressurised pneumatic means (24b) which generate a flow that discharges the particles (12) from the seats (25) in the second operating position to release the material into the capsule (C) bodies (14).



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DescriptionA capsule filling machineTechnical Field

The present invention relates to a capsule filling machine for the production of hard gelatin capsules containing pharmaceutical material.

5 In particular, the pharmaceutical material in the hard gelatin capsules of the type with a capsule lid and a capsule body to which the present invention advantageously refers is in the form of particles, that is to say, micro-tablets or pellets.

10 Background Art

Generally speaking, a capsule filling machine of the known type currently used basically comprises a central turret or carrousel rotating with discontinuous or stepping motion and equipped with a plurality of operating units located along the edge of the turret and driven by the turret by means of reciprocating drive parts.

15 Each operating unit on the turret comprises a slide supporting element for holding one or more capsules to be carried to a plurality of work stations in which successive operating steps take place, in accordance with a known method. For example, closed capsule feed and angled positioning, subsequent opening of each capsule, that is to say, separation of the capsule body from the capsule lid, feeding a quantity of pharmaceutical material into the capsule body, then closing each capsule body with the relative capsule lid and, finally, discharge of the closed filled capsule

20

25 obtained in this way.

In this process cycle, dosing units of known type, each comprising a hollow punch which forms a cylinder and houses a piston (normally pneumatically driven), pick up the pharmaceutical material by lowering the cylinder into a tank containing the material which

30 is attached to the turret, together with an upward movement of the

piston to allow dosing, that is to say, to allow the pharmaceutical material to be held in the cylinder previously immersed in the tank.

The cylinder is then lifted out of the tank and, after a scraping or brushing step to remove any excess micro-tablets, the piston downstroke is activated to push the product, dosed according to the volume of the cylindrical chamber, into the capsule body, aligned in succession with the corresponding cylinder.

At present, the above-mentioned dosing units are used for efficient, precision dosing of pharmaceutical material in powder form, whilst if capsules are to be filled with particulate material such as micro-tablets or pellets, dosing is not as precise.

Whilst the piston can pick up precise and constant volumes of powdered pharmaceutical material in the hollow cylinder, in the case of micro-tablets, the piston cannot exert sufficient pick up force on the micro-tablets to guarantee a given and constant number of micro-tablets which will then be released into each capsule body.

Disclosure of the Invention

The aim of the present invention is to produce a capsule filling machine which can overcome the above-mentioned disadvantage of the prior art.

In particular, the aim of the present invention is to produce a capsule filling machine which guarantees high precision dosing.

Another aim of the present invention is to propose a capsule filling machine which, together with the above-mentioned precision dosing, continues to guarantee the reliability, productivity and safety levels required of such machines, as well as the production speed typical of current capsule filling machine, in particular of high productivity continuous-motion capsule filling machines.

Accordingly, the present invention provides a capsule filling machine for the production of hard gelatin capsules of the type with a capsule lid and a capsule body containing particles of pharmaceutical material, in particular micro-tablets or pellets, the machine comprising a first rotary carrousel, which supports a plurality of slide units for picking up and handling the capsules in order to open then close the capsules by separating then joining the capsule lids and the capsule bodies; a second carrousel, which rotates in such a way that it is synchronised with the first

carousel, having a plurality of reciprocating doser means moving between a first operating position in which the doser means are designed to pick up pharmaceutical material from a tank containing the material which is attached to the machine and a second operating position in which they release the material into the capsule bodies. The machine is characterised in that the doser means each comprise a hollow nozzle with a plurality of seats on its edge for picking up and holding the particulate pharmaceutical material, each seat communicating with pneumatic means. The pneumatic means comprise pneumatic vacuum means which, in the first operating position, suck up and hold individual particles of the pharmaceutical material in respective seats of the nozzle, and pressurised pneumatic means which generate a flow that discharges the particles from the seats in the second operating position to allow the above-mentioned release of material into the capsule bodies.

Brief Description of the Drawings

The features and advantages of the invention are more clearly illustrated in the detailed description which follows, with reference to the accompanying drawings, which illustrate a preferred embodiment of the invention without limiting the scope of the inventive concept, and in which:

Figure 1 is a diagram illustrating the operating cycle of a capsule filling machine made according to the present invention;

Figures 2 and 3 are side views with some parts cut away and others in cross-section of a detail of the capsule filling machine made according to the present invention in two different operating configurations;

Figure 4 is a front view with some parts in cross-section of a detail of a particular component of the capsule filling machine illustrated in Figures 2 and 3;

Figure 5 is a cross-section of the component illustrated in Figure 4;

Figure 6 is a detail of a part of the capsule filling machine illustrated in Figure 1.

Detailed Description of the Preferred Embodiments of the Invention

With reference to Figure 1, the capsule filling machine disclosed, labelled 10 as a whole, is used for filling capsules C of the known type with a capsule lid and a capsule body, labelled 13 and 14 respectively, with given quantities of particles 12 of pharmaceutical material, specifically pharmaceutical micro-tablets 12 or pellets.

As illustrated in Figures 1, 2 and 3, the capsule filling machine 10 comprises a first carrousel 2 rotating about a vertical axis Z in the direction indicated by the arrow L and having radial arms 2a, 2b supporting a plurality of slide units 3 for picking up capsule bodies 14 of capsules C and moving them in a horizontal direction, and a tank 11 with a known, substantially toroidal shape, located at the base of the capsule filling machine 10 and designed to hold a mass of micro-tablets 12 supplied from a feed hopper 30.

The machine 10 also comprises a second carrousel 4 (Figure 2), also rotating about the vertical axis Z, again in the direction indicated by arrow L in Figure 1 and synchronised with the first rotary carrousel 2. The carrousel 4 is equipped with a plurality of micro-tablet 12 doser means 21.

As illustrated in Figures 2, 3 and 6, the doser means 21 are mobile in a vertical direction parallel with the axis Z alternatively between a first, pick up operating position (Figures 2 and 6), in which the means 21 are inside the tank 11 containing the micro-tablets 12 for picking up quantities consisting of a given number of individual micro-tablets 12 and, a second operating position for releasing the quantities of micro-tablets 12 into the capsule body 14 of a capsule C (Figure 3).

According to a known method, illustrated in Figures 1, 2 and 3, the first rotary carrousel 2 picks up the capsules C from an upper hopper (of the known type and not illustrated), containing the empty capsules C, then the capsules C are individually placed in the pick up means 3, each of the means comprising two bushings 15 and 17 for angling and guiding the capsules C. Each capsule C is handled in successive operating steps consisting of capsule C opening by separating the capsule lid 13 from the relative capsule body 14, filling the capsule body 14 with a quantity of micro-tablets 12 by means of the dosers 21, closing the capsule body 14 with the capsule

lid 13 and, finally, discharge of the finished capsule C from the capsule filling machine 10 at an outfeed and unloading zone S (Figure 1).

As is better illustrated in Figure 4, each of the doser means 5 21 comprises a cylindrical rod 20 with a free end 20a having a plurality of seats or openings 25 on the edge, for picking up and holding individual micro-tablets 12.

Each of the openings 25 on the edge is also controlled by pneumatic means 24 (Figure 2), specifically pneumatic means 24a for 10 generating a vacuum and pneumatic means 24b for generating a pressurised air jet. The means 24a are designed so that, in the first operating position, they pick up by suction a given number of micro-tablets 12 held in corresponding openings 25 on the edge, whilst the means 24b are designed so that, in the second operating 15 position, they discharge and release the micro-tablets 12 into a capsule body 14 thanks to a pneumatic thrust coming out of the openings 25.

More specifically, each opening 25 preferably has dimensions corresponding to the dimensions of the micro-tablets 12 contained in 20 the tank 11. In this way, positioning and holding the individual micro-tablet 12 at the opening 25 results in precision sealed closing of the opening 25.

Again as illustrated in Figure 4, each opening 25 is preferably circular in shape, so that it forms a cylindrical cavity 25 communicating with the pneumatic means 24 through pipes 27.

As is better illustrated in Figure 4 and Figure 5, the openings 25 on the edge are arranged in such a way that they are separated by angular spaces which are equal and relative to a longitudinal axis Z' of the cylindrical rod 20. They are arranged in two or more 30 adjacent horizontal planes.

The angular spaces separating the openings preferably have an angle α of around 120° between one opening 25 on the edge and the next.

The pneumatic means 24 also comprise a central channel 18, 35 inside the cylindrical rod 20, for the circulation of air, whether pressurised or forming a vacuum, to the openings 25 on the edge by means of the pipes 27.

The above-mentioned free pick up end 20a consists of a nozzle 22 with a tubular body whose central cylindrical cavity 23 has a constriction at the end, designed to form the central channel 18 for the passage of air forming a vacuum.

5 The top of the nozzle 22 with the tubular body is, in turn, attached to a vertical hollow rod, forming the cylindrical rod 20, by a connecting zone 26.

As illustrated in Figure 2, the hollow rod 20 is connected to selection valve means 50 controlling the pneumatic means 24.

10 The selection valve means 50 are preferably located on the second carrousel 4 and connect the suction means 24a to the openings 25 in the first, pick up operating position illustrated in Figure 2, that is to say, with the nozzle 22 immersed in the mass of micro-tablets 12 contained in the tank 11 and, alternatively, switch to
15 the connection between the openings 25 and the pressurised air means 24b, in the second operating position in which the micro-tablets 12 are released in to the capsule body 14 by pneumatic discharge of the micro-tablets 12.

In particular, to allow a correct release of the micro-tablets
20 12 into the capsule body 14, the arm 2a of the first carrousel 2 (Figures 2 and 3) has a chamber 19 which is substantially funnel-shaped, designed to engage with the nozzle 22 in the second, release operating position, allowing and facilitating micro-tablet 12 infeed into the capsule body 14.

25 Operation of the capsule filling machine 10 described so far can be easily inferred from the description above.

With micro-tablet 12 feed into the tank 11 guaranteed by suitably loading the turret 30, the capsule filling machine 10 automatically performs all of the guided capsule C filling
30 operations, according to the successive steps of opening, filling, closing and, finally, discharge from the machine 10.

In particular, the filling step is performed by means of an operation whereby a predetermined number of micro-tablets 12 is picked up from the tank 11.

35 This is done by lowering the hollow rod 20, equipped with the nozzle 22, into the mass of micro-tablets 12, then activating the suction means 24a designed to create a vacuum with a predetermined

value, so that the nozzle 22 attracts and holds micro-tablets 12 at the openings 25.

The rod 20 is then lifted in the known way to the position illustrated in Figure 3, and the bushing 17 with the capsule body 14
5 is moved horizontally to bring the capsule body precisely into position below the funnel-shaped chamber 19.

At this point, the selection valve means 50 switch the hollow rod 20 connection from the suction means 24a to the pressurised air means 24b.

10 This causes the release of each of the micro-tablets 12 held in the relative opening 25 into the funnel-shaped chamber 19 and, from here, into the capsule body 14 of the capsule C being filled.

At this point the bushing 17 supporting the capsule body 14 is again moved, to the position illustrated in Figure 2, continuing the
15 rotary path illustrated in the diagram in Figure 1 with the upper bushing 15.

Therefore, the machine described above achieves the preset aims thanks to a simple feed nozzle structure which allows precise dosing of the number of micro-tablets to be inserted in the capsules.
20 During testing, optimum dosing results were obtained with a number of openings 25 for each nozzle 22, and therefore, a number of micro-tablets 12, varying between thirteen and thirty.

Thanks to the construction of the pick up nozzle, the precise and constant number of micro-tablets 12 which fills the capsule body
25 14 of each capsule C is precisely determined by the number of openings 25 in the nozzle 22, since a single micro-tablet 12 is held by suction in each opening 25.

Obviously, varying the number of openings in the pick up means varies the number, and therefore the dosage, of the micro-tablets.

30 The dimensions of the openings may vary, as may the profile of the cavities formed by the openings in the nozzle body.

In addition to the total number of openings in each nozzle, the number of openings distributed in each plane and, therefore, their angular distribution, may also vary. There may be alternative
35 embodiments of the nozzle body, including the connecting zone and the lower channel.

The pneumatic means for suction and pressurised air connected to the hollow rod may be of various types and powers, depending on the applications.

5 The invention described can be subject to other practical - application modifications without thereby departing from the scope of the inventive concept as described in the claims.

Claims

1. A capsule filling machine (10) for the production of hard gelatin capsules (C) of the type with a capsule lid and a capsule body (13, 14) containing particles (12) of pharmaceutical material, in particular micro-tablets (12) or pellets, the machine (10) comprising a first rotary carrousel (2), which supports a plurality of slide units (3) for picking up and handling the capsules (C) in order to open then close the capsules (C) by separating then joining the capsule lids (13) and the capsule bodies (14); a second carrousel (4), which rotates in such a way that it is synchronised with the first carrousel (2), having a plurality of reciprocating doser means (21) moving between a first operating position in which the doser means (21) are designed to pick up particulate material (12) from a tank (11) containing the material which is attached to the machine (10) and a second operating position in which they release the material into the capsule (C) bodies (14); the machine being characterised in that the doser means (21) each comprise a hollow nozzle (22) with a plurality of seats (25) on its edge for picking up and holding the particulate pharmaceutical material (12), each seat (25) communicating with pneumatic means (24, 24a, 24b), the pneumatic means (24, 24a, 24b) comprising pneumatic vacuum means (24a) which, in the first operating position, suck up and hold individual particles (12) of the material in respective seats (25) of the nozzle (22), and pressurised pneumatic means (24b) which generate a flow that discharges the particles (12) from the seats (25) in the second operating position to allow the above-mentioned release into the capsule (C) bodies (14).

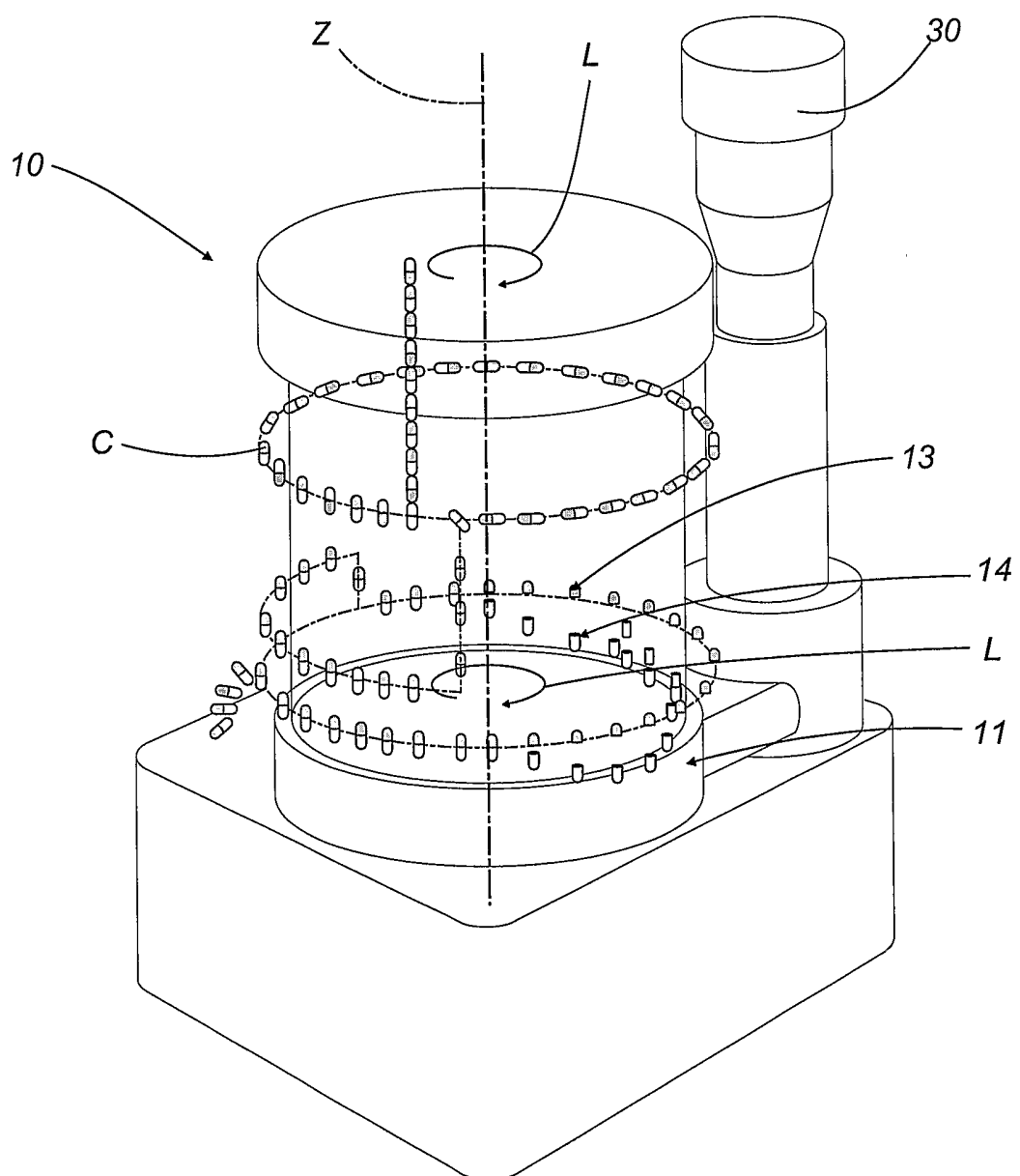
2. The capsule filling machine according to claim 1, characterised in that the seats (25) on the edge are arranged on the surface of the nozzle (22) separated by angular spaces that are equal and relative to a longitudinal axis (Z') of the nozzle (22).

3. The capsule filling machine according to claim 2, characterised in that the angular spaces have an angle (α) equal to 120° between adjacent seats (25).

4. The capsule filling machine according to any of the foregoing claims from 1 to 3, characterised in that the first carrousel (2) has a substantially funnel-shaped chamber (19) designed to engage
40 with the nozzle (22) in the second operating position, allowing and facilitating particle (12) infeed into the capsule (C) body (14).

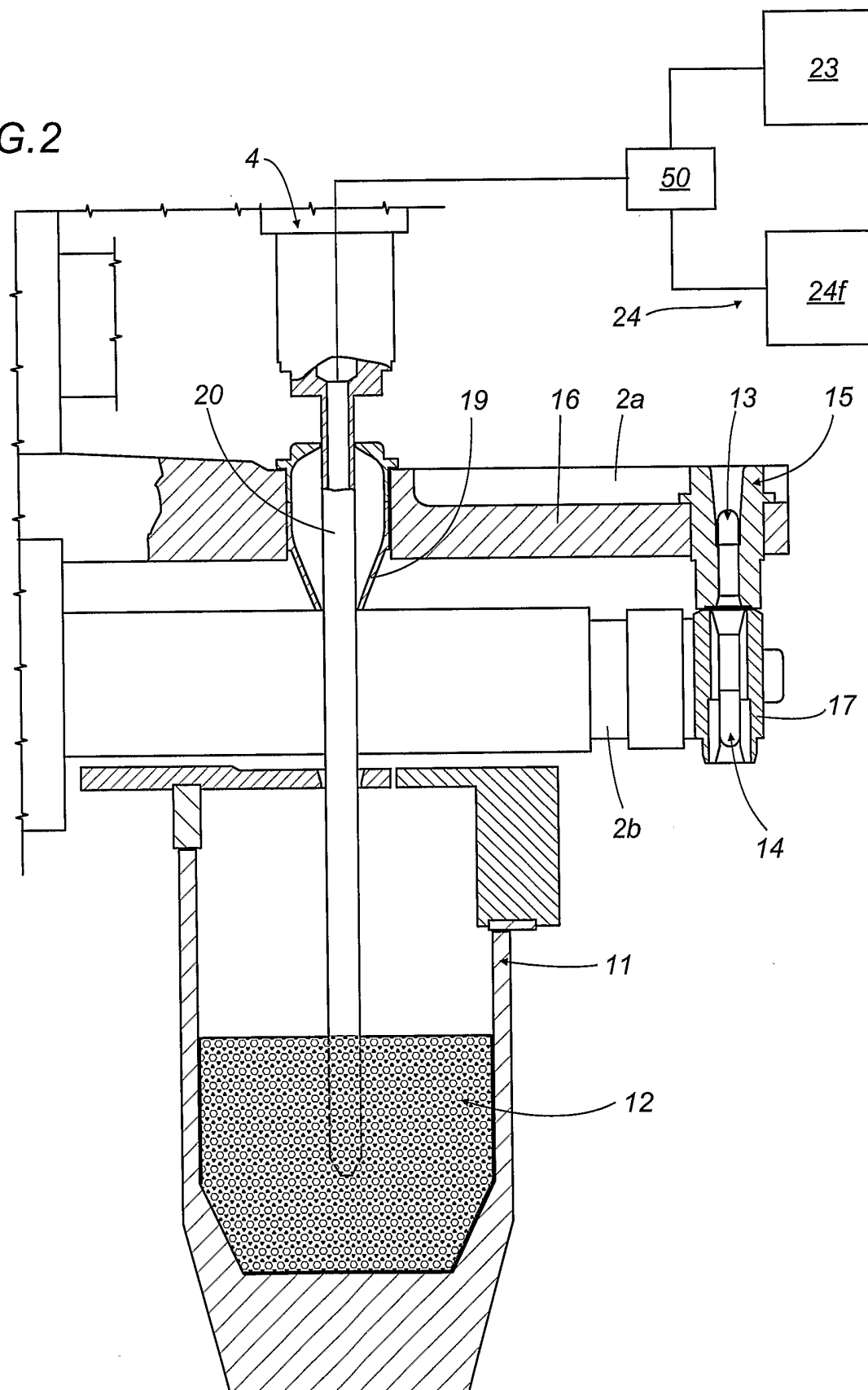
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FIG. 1



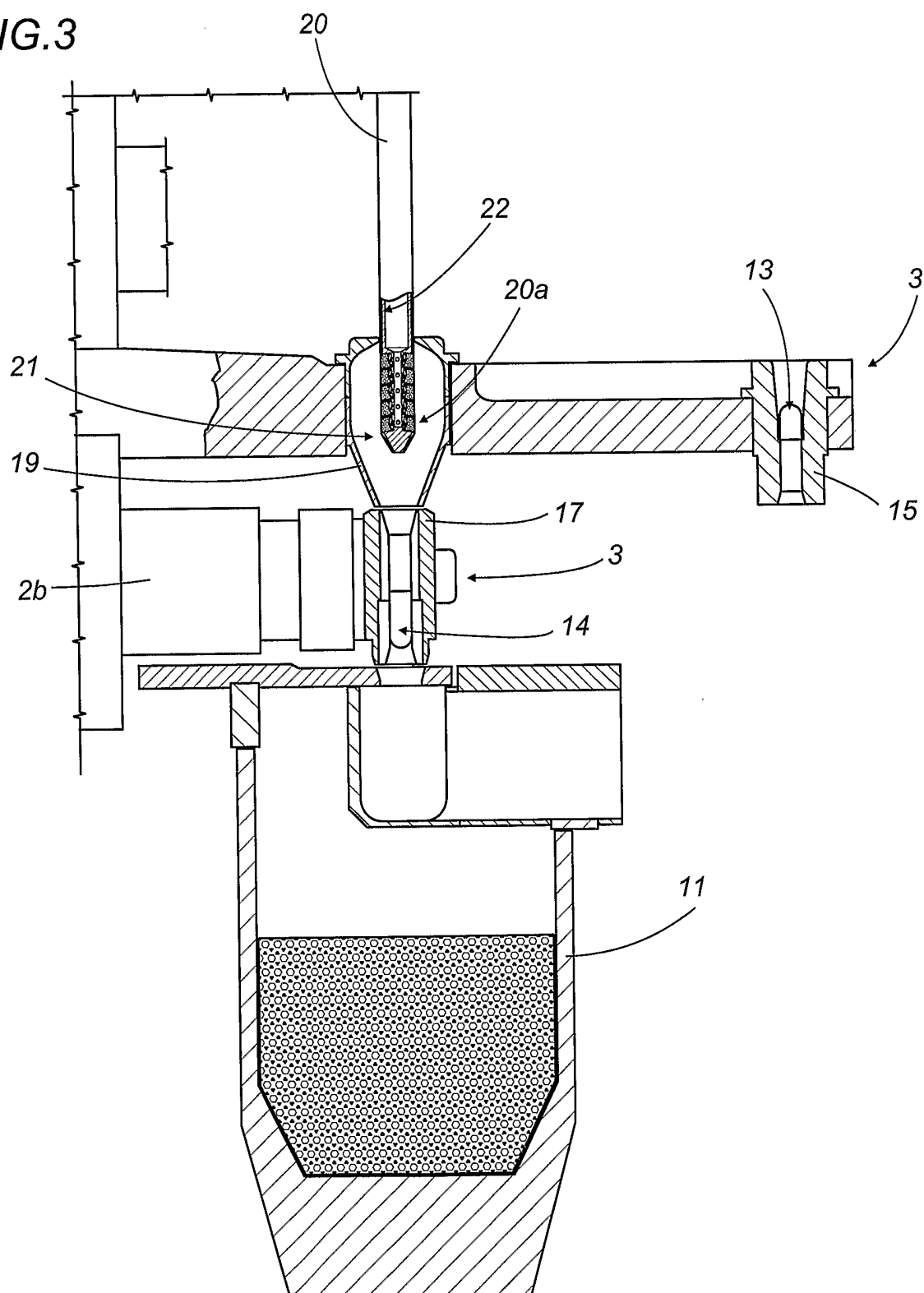
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FIG. 2



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FIG.3



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FIG.5

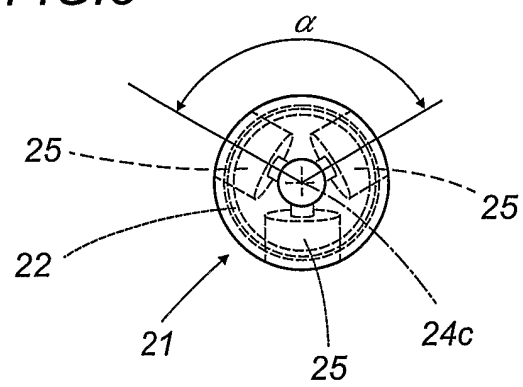
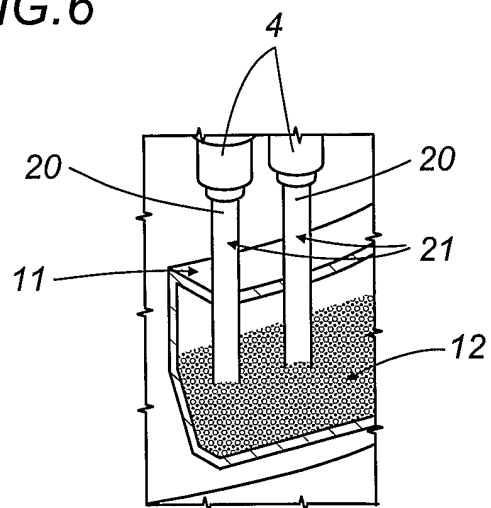


FIG.6



INTERNATIONAL SEARCH REPORT

PCT/IB 03/03566

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J3/07 B65B35/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J B65B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 70171 A (FACCHINI LIBERO ; B L MACCHINE AUTOMATICHE SPA (IT)) 27 September 2001 (2001-09-27) page 4, line 11 -page 4, line 21; figures 21-38 ---	1
A	US 6 363 801 B1 (CARNAHAN JAMES CLAUDE) 2 April 2002 (2002-04-02) abstract; figures 1-4 ---	1
A	US 2002/002809 A1 (KUHNLE MANFRED ET AL) 10 January 2002 (2002-01-10) abstract; figure 1 ---	1
A	DE 20 50 885 A (FRATELLI ZANASSI) 29 April 1971 (1971-04-29) page 9, line 6 -page 15, line 28; figures 1-3 -----	1

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Farizon, P

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0170171	A	27-09-2001	WO 0170171 A1	27-09-2001
			AU 3314800 A	03-10-2001
			EP 1265581 A1	18-12-2002
US 6363801	B1	02-04-2002	AU 3703201 A	07-11-2001
			WO 0180990 A1	01-11-2001
US 2002002809	A1	10-01-2002	DE 10027008 A1	06-12-2001
			CN 1325811 A	12-12-2001
			IT MI20011128 A1	29-11-2002
DE 2050885	A	29-04-1971	DE 2050885 A1	29-04-1971