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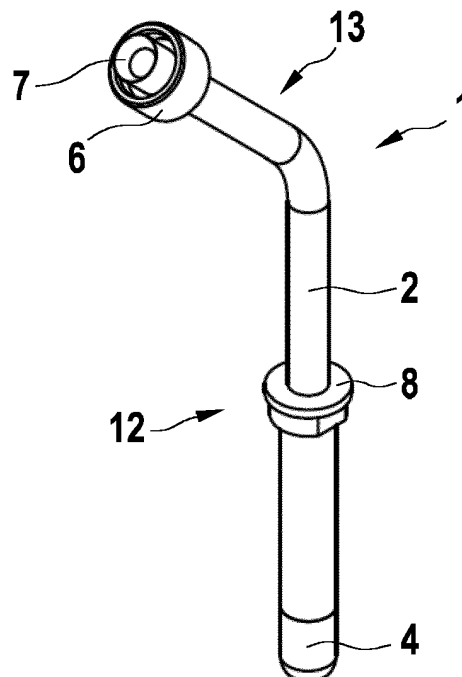
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(54) **FILLING NEEDLE FOR DISPENSING LIQUID COMPOSITIONS INTO CONTAINERS**

(57) The invention discloses a filling needle (1) for dispensing liquid compositions into a container, comprising a connector (6) for connecting a feeding line (22), a needle pipe (2) leading from the connector (6) to an outlet

(10) of the filling needle (1), wherein the needle pipe (2) is curved at an inclination angle (β) and/or the outlet (10) comprises at least two grid-elements (3).

Fig. 1



Description

[0001] The present invention relates to a filling needle that is preferably used for filling medicinal liquids having low viscosity and/or low surface tension and/or low density into containers. The filling needle according to the invention is preferably used for filling medicinal pharmaceutical and veterinary liquid compositions that are used in small volumes.

[0002] Filling needles are used for dispensing or dosing medicinal liquids into containers such as vials, ampules, pipettes, bottles. There are several different types of filling needles known in the art that aim to fulfil a number of critical requirements in filling liquid compositions, such as: accurate and reproducible dose volumes; no drip formation, cavitation, or bubble formation during filling; accurate dosing for different surface tensions, densities, and viscosities; precise bottom-up, high-speed filling; a range of needle diameters for small and large volumes; compatibility with existing filling machines; robust and rigid construction; suitability for use according to pharmaceutical good manufacturing practice (GMP) regulations; and compliance with appropriate pharmacopoeia tests

[0003] Known filling needles - e.g. disclosed in WO 2008/103484 A2 - use several different approaches to deal with above-mentioned requirements. The blunt, straight-end tip, needles are the "standard" needle type provided by most manufacturers. The blunt needle dispenses liquid directly into the bottom of a container. Problems that are likely to occur with blunt tip needles can include dripping, foaming, and wicking - particularly with hydrophobic and low surface tension products.

[0004] Liquids having low viscosity and low surface tension are found more challenging for filling in accurate and reproducible dose volumes, without dripping and air bubbles formation. By using the needle tip geometry used in the art it was not possible to achieve satisfactory results regarding dripping, inconsistent filling volumes and air bubble formation.

[0005] The basket tip type needles are used in applications where foaming and dripping occur, usually because a blunt tip needle can't support the fluid column (even when the tubing is properly occluded). A basket tip needle has a larger combined surface area for fluid to exit, reducing the flow rate, but better supporting the fluid column. The basket design directs fluid towards the sides of the container, causing spraying and wetting of the whole wall of the container that result in incomplete sealing of the containers and leaking of the seals.

[0006] The showerhead type needles are constructed to help to prevent foaming and dripping but they are especially helpful with larger fill volumes and usually not feasible with smaller needles. Showerhead needles work by directing product flow in as many as six individual streams. In high volume fills, this greatly reduces the fill times of foamy or soapy products, allowing operators to run pumps with product at full speed without issues.

[0007] Product characteristics such as density, polarity, and surface tension all greatly affect the ease of filling a product. There still exist a problem of developing the needle geometry and needle tip geometry that would overcome the above mentioned problems and enable quick and accurate filling of low viscosity, low surface tensions liquid compositions in small volumes. By using the needles known from the prior art several problems arises when filling liquids of low viscosities, low surface tension and low densities. It was not possible to fill the accurate and reproducible dose volumes, dripping and air bubble formation occurred during filling, spraying the wall of the container caused troubles with seal integrity of the containers, such as pipettes.

[0008] The object of the invention is to provide a filling needle, that allows to fill containers both accurately and quickly - especially the filling of liquids having low viscosity, low density and low surface tension. The product loss should be minimized, therefore foaming of product in the container or dripping through the needle should be minimized.

[0009] The solution of this object is achieved by the features of the independent claims. The dependent claims provide advantages embodiments of the invention.

[0010] The present invention discloses a filling needle having optimized design that solves above-mentioned drawbacks and provides for quick and accurate filling of liquid compositions, without formation of air bubbles, without dripping and leakage of the seals.

[0011] The following description and the claims disclose different features of the invention which can be combined. To certain configurations value ranges with upper and lower limits are disclosed. For an open range of values, only one limit, for example only one upper limit or one lower limit, can be used to restrict the invention. Alternatively, any upper and lower limits can be combined to define a closed value range.

[0012] The invention discloses a filling needle for dispensing liquid compositions into a container; preferably for filling liquids of low viscosities and/or low surface tension and/or low densities. The container is preferably a vial, ampule, pipette, or bottle. The filling needle comprising a connector for connecting a feeding line and a needle pipe leading from the connector to an outlet of the filling needle. The liquid to be filled runs through the feeding line and through the connector into the needle pipe. The center line of the needle pipe defines a flow direction of the liquid from the connector to the outlet of the filling needle.

[0013] In order to at least reduce the disadvantage of dripping, there are two design measures for the filling needle, which can be used alternatively or in combination:

(i) The needle pipe is curved at an inclination angle β - other than 180° or 0° . This allows the length of the needle, and thus the liquid column in the needle, to be relatively long. At the same time, the gravity relevant height of the liquid column can be kept as small as possible due to the curved portion - thus reducing the influence of the weight force on the liquid in the filling needle, thereby preventing dropping. Further, the angle of the curved filling needle is advantageous for keeping the flow of the liquid laminar in order to avoid any problems in the production.

(ii) In addition or alternatively, the outlet of the filling needle comprises at least two grid-elements arranged one behind the other in the flow direction. This improves the dripping behavior and reduces foam formation at the same time

[0014] Low viscosity liquids are preferably characterized by having viscosity of less than 6 mPa·s at 20°C .

[0015] Liquids with low surface tension are preferably characterized by having surface tension of less than 35 mN/m, preferably less than 30 mN/m, more preferably less than 25 mN/m.

[0016] Low density liquids are preferably characterized by having density at 20°C of less than 0.95 g/ml, preferably less than 0.9 g/ml.

[0017] All problems mentioned above have been solved by the filling needle of the present invention.

[0018] Preferably, each of the grid-elements have plurality of apertures, each with a micrometer size aperture width w .

[0019] Preferably, the aperture width w is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 10 micrometers, preferably 20 micrometers, further preferably 100 micrometers; the upper limit is 900 micrometers, preferably 750 micrometers, further preferably 650 micrometers, further preferably 500 micrometers.

[0020] Preferably, at least one of the grid-elements is a mesh, preferably a woven mesh, and/or a perforated plate. Both grid-elements can be a mesh or both grid-elements can be a perforated plate or one grid-element can be a mesh and the other one a perforated plate.

[0021] The aperture width w of the mesh is the mesh size; which is preferably measured perpendicular to the warp or weft wire. The aperture width w of the perforated plate is the diameter of the holes in the plate.

[0022] Preferably, at least one of the grid-elements is made of steel, preferably stainless-steel, or copper, or galvanized wire, or brass, or aluminum, or phosphor bronze, or synthetic monofilaments.

[0023] Preferably, the inclination angle β is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 100° , preferably 110° , further preferably 120° , further preferably 130° ; the upper limit is 170° , preferably 160° , further preferably 150° , further preferably 140° . Most preferably, the inclination angle β is 135° .

[0024] A first section of the filling needle having a first length and a second section of the filling needle having a second length, wherein the first section starting with the outlet and merging with the inclination angle β into the second section; the second section ending with the connector. Preferably the ratio of the second length to first length is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 1:4, preferably 1:3; the upper limit is 1:1, preferably 1:2.

[0025] Preferably, an entire length of the filling needle, preferably of the needle pipe plus connector, is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 100 mm, preferably 150 mm, further preferably 170 mm; the upper limit is 300 mm, preferably 270 mm, further preferably 250 mm.

[0026] Preferably, an inner diameter of the filling needle, preferably of the needle pipe, is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 4 mm, preferably 6 mm, further preferably 7 mm; the upper limit is 10 mm, preferably 9 mm, further preferably 8 mm.

[0027] Preferably, the at least two grid-elements form a plane flow-through layer perpendicular to the flow direction and therefore perpendicular to the center axis of the needle pipe.

[0028] Preferably, the filling needle ends at the outlet side with a blunt end.

[0029] Preferably, the grid-elements, at least the inner grid-element, contacts against a blunt front end of needle pipe. Preferably, the grid-elements are jammed between the front end of the needle pipe and a holding sleeve; the holding sleeve is preferably plugged onto the needle pipe.

[0030] Preferably, the needle pipe over its entire lengths from the connector to the outlet is made in one piece or is made of firmly assembled parts that cannot be detached non-destructively.

[0031] Preferably, the needle pipe is made of metal, further preferably steel, more preferably stainless steel.

[0032] Preferably the filling needle comprises the connector as only "connection". Preferably the filling needle comprises no other connections and/or no other couplings and/or no branches.

[0033] Preferably the curved portion (also: kink or bended portion) with the inclination angle β is between the connector and the outlet.

[0034] The invention further discloses a filling device comprising the filling needle and a feeding line connected to the connector. The other end of the feeding line is preferably connected to a pump.

[0035] Preferably, the inner surface of the needle pipe, preferably also of the connector, is made of a first material

and the inner surface of the feeding line is made of a second material different from the first material.

[0036] Preferably, the first material is metal, preferably steel, further preferably stainless-steel, and/or the second material is plastic, preferably polytetrafluoroethylene.

[0037] The invention further discloses the use of the filling needle or of the filling device for filling liquid compositions - preferably medical liquid compositions - into containers. Thereby the used liquid composition

(i) having surface tension of less than 35 mN/m, preferably less than 30 mN/m, further preferably less than 25 mN/m;

(iii) and/or having a density at 20 °C of less than 0.95 g/ml, preferably less than 0.9 g/ml;

(iii) and/or having a viscosity at 20 °C of less than 6 mPa·s.

[0038] Another problem, which is solved by the present invention, are the low fill volumes that are in the ranges from 0.2 to 5 ml, preferably from 0.25 to 4.5 ml. Specifically fill volumes such as 0.25 ml, 0.50 ml, 0.67 ml, 0.75 ml, 1.0, 1.34 ml, 2.0 ml, 2.5 ml, 2.68 ml, 3.0 ml, 4.0 ml are required. So, preferably, each container is filled with a fill volume greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein the lower limit is 0.2 ml, preferably 0.25 ml; the upper limit is 5 ml, preferably 4.5 ml.

[0039] Any fluctuations in the volume can have great impact on efficacy and in case of over fillings also on toxicity of the product. Therefore, the filling needle was developed which enables accurate and reproducible fill volumes.

[0040] In the industrial production, the important factor is the speed of the filling. The filling needle or of the filling device is preferably used to fill at least 60 containers per minute, preferably at least 75 containers per minute.

[0041] The enclosed figures and following description disclose further details of the invention.

Fig. 1 shows a perspective view of a filling needle according to an embodiment of present invention,

Fig. 2 shows a planar view of the filling needle according to the embodiment of present invention,

Fig. 3 shows a detail of the filling needle according to the embodiment of present invention,

Fig. 4 shows a connector of the filling needle according to the embodiment of present invention,

Fig. 5 shows a mesh as a grid-element of the filling needle according to the embodiment of present invention,

Fig. 6 shows a perforated plate as a grid-element of the filling needle according to the embodiment of present invention,

Fig. 7 shows a filling device according to present invention with the filling needle according to the embodiment of present invention, and

Fig. 8 shows a filling device with a filling needle according to prior art.

[0042] Figures 1 to 6 disclose a filling needle 1 according to present invention and details thereof. The filling needle 1 is used in a filling device 20 shown in Figure 7 for liquids as defined above. Within the filling device, a feeding line 20 connects the filling needle 1 to a pump 21.

[0043] The filling needle 1 comprising a connector 6 for connecting a feeding line 22. Further the filling needle 1 comprising a needle pipe 2 leading from the connector 6 to an outlet 10 of the filling needle 1, wherein the needle pipe 2 is curved at an inclination angle β of 135°.

[0044] A first section 12 of the filling needle 1 having a first length $a+b$ (see Fig. 7) and a second section 13 of the filling needle 1 having a second length c . The first section 12 starting with the outlet 10 and merging with the inclination angle β into the second section 13; the second section 13 ending with the connector 6.

[0045] The first section 12 can be partially covered by an attachment 8.

[0046] The outlet 10 comprises two grid-elements 3 arranged one behind the other in the flow direction. According to Fig. 5 and 6 the grid-elements 3 each have plurality of apertures 11, each with a micrometer size aperture width w .

[0047] Fig. 5 shows a woven mesh as the grid-element 3. The aperture width w of the mesh is the mesh size; which is preferably the distance between two adjacent warp or weft wires, measured in the projected plane at the mid positions. The mesh preferably consists of longitudinal wires (warp) and transverse wires (weft), which are intertwined to form apertures 11 of rectangular shape and allow a stable connection. Preferably a mesh with one of the following types of weaving is used: canvas, keper, twill, blind weaving in the shape of canvas, and/or blind weaving in the shape of twill.

[0048] Fig. 6 shows a perforated plate as the grid-element. The aperture width w of the perforated plate is the diameter

of the holes/apertures 11 in the plate.

[0049] According to the embodiment, the two grid-elements 3 form a plane flow-through layer perpendicular to the flow direction and therefore perpendicular to the center axis of the needle pipe 2. The filling needle 1 ends at the outlet side with a blunt end.

[0050] The grid-elements 3, at least the inner grid-element 3, contacts against the blunt front end of needle pipe 2. The grid-elements 3 are jammed between the front end of the needle pipe 2 and a tapered portion 5 of a holding sleeve 4.

[0051] The holding sleeve 4 is plugged onto the needle pipe 2 - and preferably welded onto the needle pipe 2 as shown in Fig. 3.

[0052] The connector 6 shown in Fig. 4 comprises a fitting 7 for connecting the feeding line 22 to the filling needle 1. According to the fitting 7, an inner diameter 23 of the feeding line 20 is greater than an inner diameter 9 of the filling needle 1.

[0053] By using the curved filling needle 1, the gravity of the liquid in the filling needle 1 is reduced - compared to a not curved needle - which results in avoiding dripping and air bubble formation.

[0054] The filling needle 1 is preferably made of stainless steel but the pipe (feeding line 22) that connects the filling needle 1 and the pump 21 is made of preferably polytetrafluoroethylene (Teflon). Liquid having low viscosity has in the section of the Teflon pipe (feeding line 22) also low surface tension, but in the section of the filling needle 1 the surface tension is higher than in the section of the Teflon pipe (feeding line 22). Therefore, the length (a+b+c) of the filling needle 1 should be in the range from 170 to 200 mm in order to prevent liquid to tear down from the outlet 10. The required height (h1) for keeping laminar flow in a straight filling needle (see Fig. 8) is higher than the required height (h2) in the curved filling needle 1 as shown in Fig. 7.

[0055] Fig. 3 shows schematically by horizontal arrows the surface tension of the liquid on the wall of the needle 1 which contribute to prevent dropping of the liquid which is caused by gravity force of the liquid.

[0056] The gravity force of the liquid is further reduced by "closing" the needle tip (outlet 10) by at least two mesh of micron size - the grid-elements 3. When flow of fluid comes into contact with the mesh the gravity force is reduced. The effect is schematically shown by the vertical arrows in Fig. 3.

[0057] Surface tension and reducing the gravity force results in preventing dripping and splashing of the fluid on the wall of containers, especially pipettes.

[0058] Fig. 7 and 8 show the comparison of the influence of the height (sum of the length of the needle 1 and height of the feeding line 22) on the gravity force for the straight needle (Fig. 8) and the curved needle 1 (Fig. 7).

[0059] In Fig. 8, the height influencing the gravity force of the liquid, h1, can be calculated as follows:

$$h1 = a + b + c + R1$$

[0060] Wherein dimension a is part of the needle from the lower edge to the upper part of the needle attachment, dimension b is part of the needle from the upper part of the attachment to a distance equal to the distance of the curved part of the needle, dimension c is part of the needle from the curved part of the needle to the end of the needle where the Teflon pipe is attached and dimension R1 is the radius or half the distance between the needle and the filling pump. The values for this dimensions are known so the height h1 can be calculated.

[0061] In the invention according to Fig. 7 dimension a is part of the filling needle 1 from the lower edge to the upper part of the attachment 8, dimension b is part of the filling needle 1 from the upper part of the attachment 8 to the curved part of the filling needle 1, dimension c is part of the filling needle 1 from the curved part of the filling needle 1 to the end of the filling needle 1 where the feeding line 22 is attached, dimension R1 is the radius or half the distance between the filling needle 1 and the filling pump 21, dimension R2 is the radius from end of curved filling needle 1 to the position of filling pump 21. Dimension R2 is different than dimension R1. Angle α is the difference in angles between the angle of the curved filling needle 1 and 90 degrees ($\alpha = \beta - 90^\circ$) and angle α_1 is the difference in angles between 90 degrees and α ($\alpha_1 = 90^\circ - \alpha$).

[0062] The values x, x1, y and y1 can be calculated using angle functions:

$$y = c * \sin \alpha$$

$$x = c * \cos \alpha$$

$$y1 = R2 * \sin \alpha_1$$

$$x_1 = R_2 * \cos \alpha_1$$

$$2 * R_1 = x + x_1 + R_2$$

$$2 * R_1 = c * \cos \alpha + R_2 * \cos \alpha_1 + R_2$$

$$2 * R_1 - c * \cos \alpha = R_2 * (\cos \alpha_1 + 1)$$

$$\frac{(2 * R_1 - c * \cos \alpha)}{(\cos \alpha_1 + 1)} = R_2$$

[0063] The height influencing the gravity force of the liquid, h_2 , can be calculated as follows:

$$h_2 = a + b + y - y_1 + R_2$$

$$h_2 = a + b + c * \sin \alpha - R_2 * \sin \alpha_1 + R_2$$

$$h_2 = a + b + c * \sin \alpha + R_2 - R_2 * \sin \alpha_1$$

$$h_2 = a + b + c * \sin \alpha + R_2 * (1 - \sin \alpha_1)$$

$$h_2 = a + b + c * \sin \alpha + \frac{(2 * R_1 - c * \cos \alpha)}{(\cos \alpha_1 + 1)} * (1 - \sin \alpha_1)$$

[0064] Values a , b , c , R_1 are known so the height h_2 can be calculated.

[0065] It is evident from the calculation that the height influencing the gravity force of the liquid is much lower in the case of the curved filling needle 1 than in the case of the straight needle of Fig. 8. In case the filling needle 1 is curved under an inclination angle β of 135° (angle α is 45°) the height is lower for 66% in comparison to the straight needle, thereby also the gravity force is lower. The influence on the gravity force can be calculated from the following equations.

$$F_g = \rho * g * h * S$$

$$F_{g1} = \rho * g * h_1 * S$$

$$F_{g2} = \rho * g * h_2 * S$$

$$\frac{F_{g2}}{F_{g1}} = \frac{\rho * g * h_2 * S}{\rho * g * h_1 * S} = \frac{h_2}{h_1}$$

$$F_{g2} = \frac{h_2}{h_1} * F_{g1}$$

[0066] The influence of gravity force is lowered for around 66% in the curved needle 1 compared with straight needle

when the needle 1 is curved under angle of 135° .

List of reference signs

5 [0067]

- 1 filling needle
- 2 needle pipe
- 3 grid-elements
- 10 4 holding sleeve
- 5 tapered portion
- 6 connector
- 7 fitting
- 8 attachment
- 15 9 inner diameter of filling needle
- 10 outlet
- 11 apertures
- 12 1st section
- 13 2nd section
- 20 20 filling device
- 21 pump
- 22 feeding line
- 23 inner diameter of feeding line
- w aperture width

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Claims

1. A filling needle (1) for dispensing liquid compositions into a container, comprising
 - a connector (6) for connecting a feeding line (22),
 - a needle pipe (2) leading from the connector (6) to an outlet (10) of the filling needle (1),
 - wherein the needle pipe (2) is curved at an inclination angle (β) and/or the outlet (10) comprises at least two grid-elements (3).
2. The filling needle of claim 1, wherein the grid-elements (3) each have plurality of apertures (11), each with a micrometer size aperture width (w).
3. The filling needle of claim 2, wherein the aperture width (w) is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein
 - the lower limit is 10 micrometers, preferably 20 micrometers, further preferably 100 micrometers,
 - the upper limit is 900 micrometers, preferably 750 micrometers, further preferably 650 micrometers, further preferably 500 micrometers.
4. The filling needle of any of the preceding claims, wherein at least one of the grid-elements (3) is a woven mesh and/or at least one of the grid-elements (3) is a perforated plate.
5. The filling needle of any of the preceding claims, wherein at least one of the grid-elements (3) is made of steel, preferably stainless-steel, or copper, or galvanized wire, or brass, or aluminum, or phosphor bronze, or synthetic monofilaments.
6. The filling needle of any of the preceding claims, wherein the inclination angle (β) is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein
 - the lower limit is 100° , preferably 110° , further preferably 120° , further preferably 130° ,
 - the upper limit is 170° , preferably 160° , further preferably 150° , further preferably 140° .

7. The filling needle of any of the preceding claims, wherein a first section (12) of the filling needle (1) having a first length (a+b) and a second section (13) of the filling needle (1) having a second length (c), wherein the first section (12) starting with the outlet (10) and merging with the inclination angle (β) into the second section (13), the second section (13) ending with the connector (6),

- wherein the ratio of the second length (c) to first length (a+b) is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein
- the lower limit is 1:4, preferably 1:3,
- the upper limit is 1:1, preferably 1:2.

8. The filling needle of any of the preceding claims, wherein an entire length (a+b+c) of the filling needle (1) is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein

- the lower limit is 100 mm, preferably 150 mm, further preferably 170 mm,
- the upper limit is 300 mm, preferably 270 mm, further preferably 250 mm.

9. The filling needle of any of the preceding claims, wherein an inner diameter (9) of the filling needle (1) is greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein

- the lower limit is 4 mm, preferably 6 mm, further preferably 7 mm,
- the upper limit is 10 mm, preferably 9 mm, further preferably 8 mm.

10. A filling device (20) comprising a filling needle (1) of any of the preceding claims and a feeding line (22) connected to the connector (6).

11. The filling device of claim 10, wherein the inner surface of the needle pipe (2) is made of a first material and the inner surface of the feeding line (22) is made of a second material different from the first material.

12. The filling device of claim 11, wherein the first material is a metal, preferably steel, further preferably stainless-steel, and/or the second material is plastic, preferably polytetrafluoroethylene.

13. Use of the filling needle (1) of any of the claims 1 to 9 or of the filling device (20) of any of the claims 10 to 12, for filling liquid compositions into containers, the liquid composition

- having surface tension of less than 35 mN/m, preferably less than 30 mN/m, further preferably less than 25 mN/m,
- and/or having a density at 20 °C of less than 0.95 g/ml, preferably less than 0.9 g/m
- and/or having a viscosity at 20 °C of less than 6 mPa·s.

14. Use according to claim 13, wherein each container is filled with a fill volume greater than or equal to a lower limit and/or less than or equal to an upper limit, wherein

- the lower limit is 0.2 ml, preferably 0.25 ml,
- the upper limit is 5 ml, preferably 4.5 ml.

Fig. 1

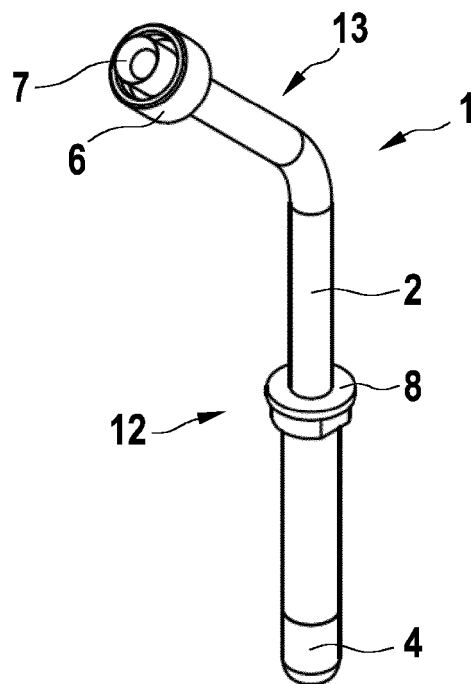


Fig. 2

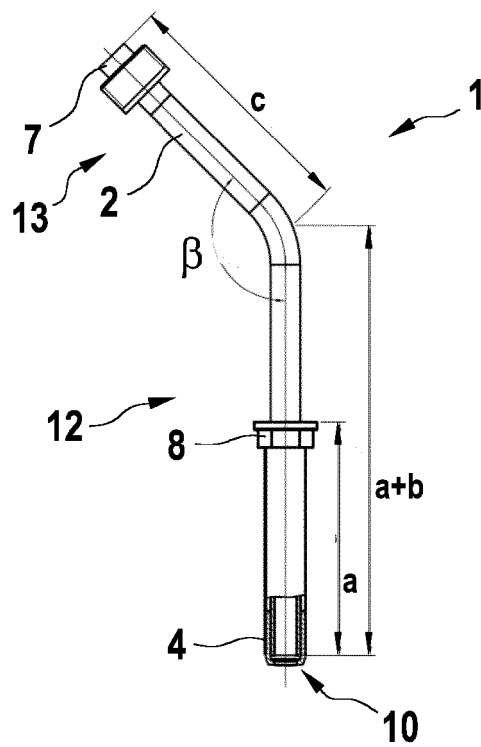


Fig. 3

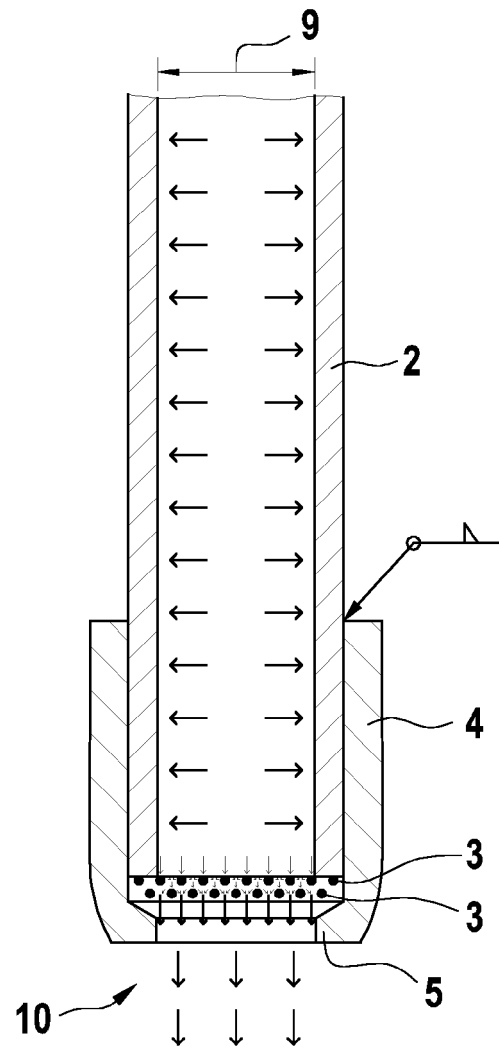


Fig. 4

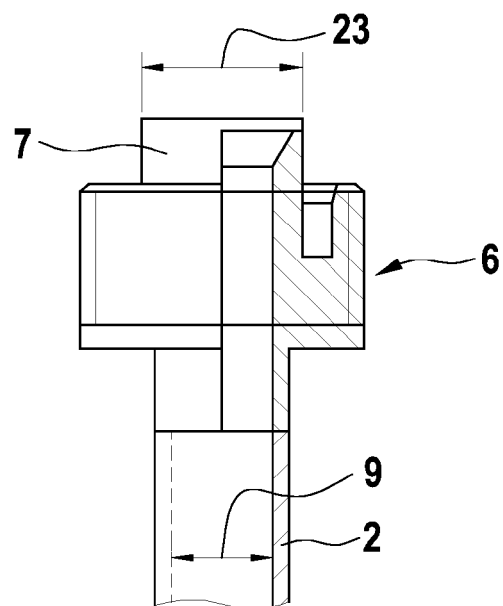


Fig. 5

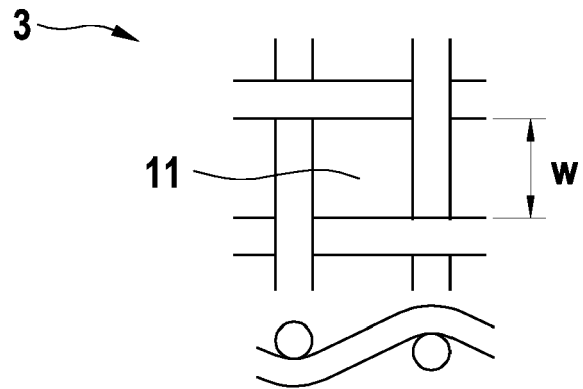


Fig. 6

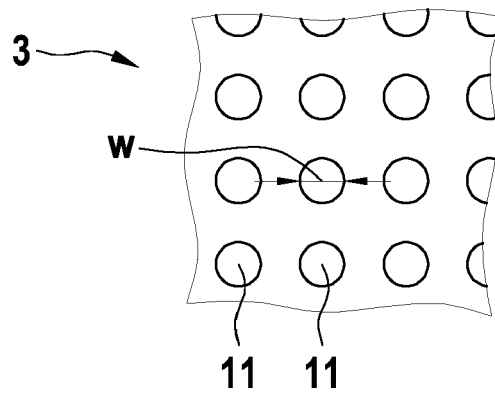


Fig. 7

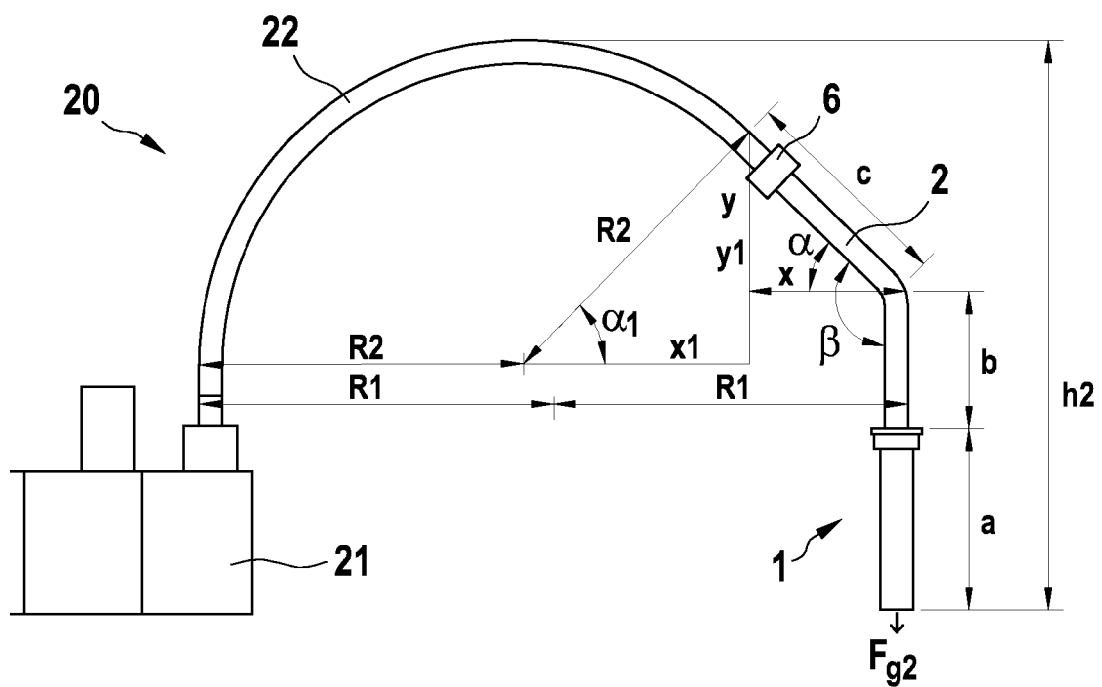
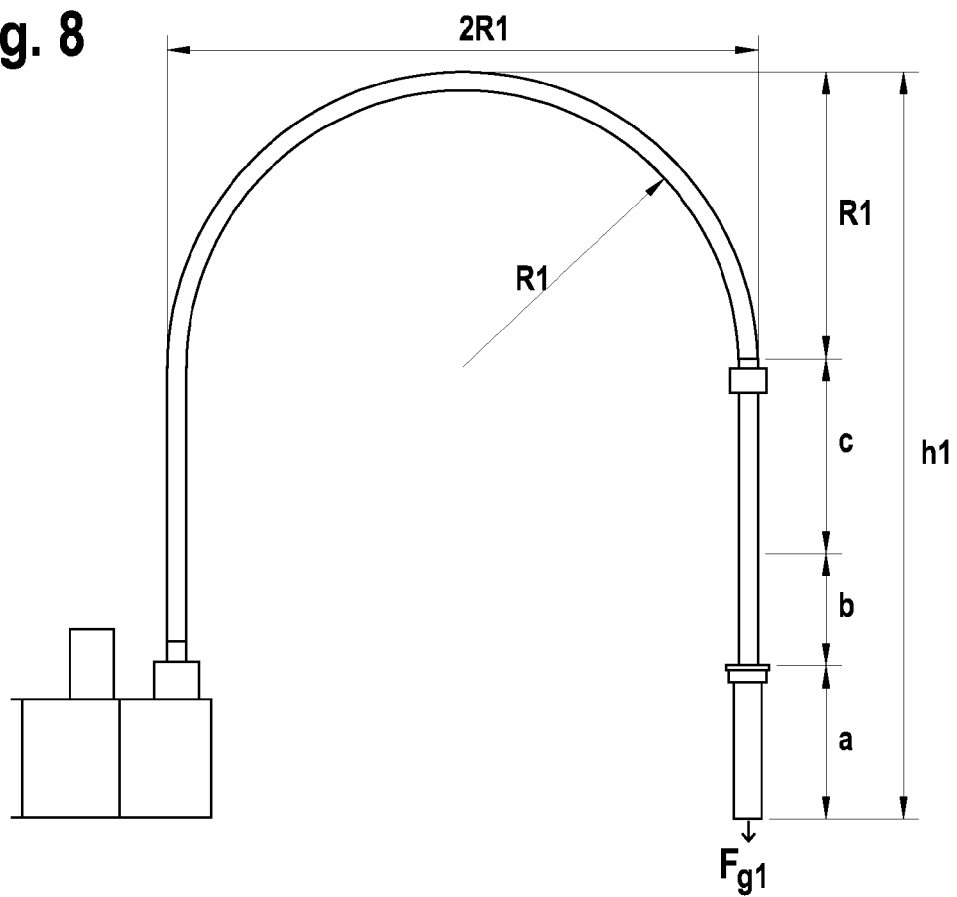


Fig. 8





EUROPEAN SEARCH REPORT

Application Number
EP 20 21 4143

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DOCUMENTS CONSIDERED TO BE RELEVANT			
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