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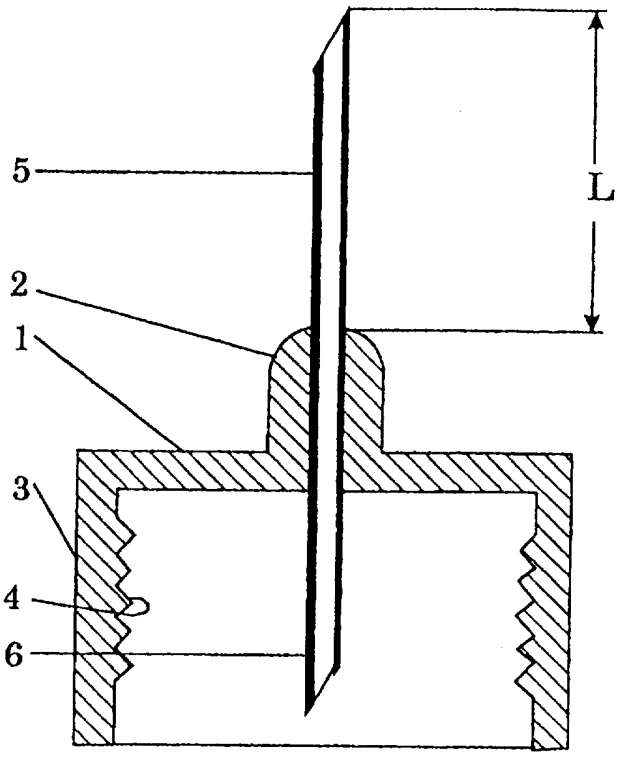
(54) Title: INJECTION NEEDLE

(57) Abstract

A needle mounted in a needle hub fitting onto an injection device from which preset doses of a medicine from a cartridge accommodated in the device is administered through the needle comprises a back needle penetrating a closure membrane of the cartridge and a free injection part shorter than 9 mm, the outer diameter of the needle and the diameter of its bore complying with one of the conditions: a) the outer diameter is smaller than 0,320 mm and the diameter of the bore is larger than 0,165 mm, or b) the outer diameter is smaller than 0,298 mm and the diameter of the bore is larger than 0,133 mm.



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Injection needle

The invention relates to injection needles especially needles mounted in a needle hub fitting onto an injection device of the kind from which preset doses of a medicine from a cartridge accommodated in the device may be administered through the needle mounted on the device and exposing a back needle penetrating a closure membrane of the cartridge and a free injection part.

Such an injection device, by which doses may be set individually and on which a needle may be mounted and changed after having been used for injection of a medicine from a cartridge in the device, is a common tool for people who have to inject themselves one or more times a day as it is the case by people who are treated with growth hormone or by diabetics who have to inject themselves frequently to keep their blood sugar on an acceptable level.

To reduce the malaise by frequent pricking of the skin the trend has lead towards use of still thinner needles as it have shown to cause less pain to be pricked with a fine needle than with a coarse one. With finer needles other problems occur one of them being that e.g. some kinds of insulin has coarse crystals which tends to clog at the inlet to the needle and in this way be sieved from the liquid in which the crystals are suspended. This way the concentration of the insulin injected may differ from what the user think it is which may cause injection of a wrong dose.

These problems has according to WO 93/00948 been overcome by using needles mounted in special needle hubs which fit only on devices about which it is known that they will only contain insulin which may flow freely through a thin needle defined as a G30 needle. This is obtained by making devices for which it is guaranteed that they will only contain insulin having a grain size less than 15μm and provide the devices

with needle receiving pieces onto which the hubs with the fine needles fits. It may be noticed that thicker needles of course may be provided with a corresponding hub as the insulin in the device of course without problems may pass a thicker needle having a larger bore.

Although the G30 needle cause less pain and allow even crystalline insulin to pass provided the crystals have no dimensions larger than 15 µm, the use of these needles are not without problems even by injection of solutions. One of the problems is that a relatively high pressure has to be established in the cartridge from which the medicine shall be pressed out which again means that a excessive force have to be exerted on a manually operated injection button. This may make it difficult to users with weak fingers to perform the injection sufficiently rapidly. With the high pressure in the cartridge, which is mainly of the kind wherein a piston closes one end of an cylinder ampoule whereas the other is closed by a rubber membrane which may be penetrated by a back needle of a double pointed needle to provide communication from the content of the ampoule through the hollow needle to the injection point of this needle, elasticity of the cartridge parts, especially the rubber membrane and the piston, may cause dripping from the needle when this needle is drawn out from the tissue into which it has been inserted during the injection. This means that not the whole set dose is actually injected.

It is the object of the invention to provide a thin needle by which the advantages of the G30 needle is enhanced and/or the drawbacks of this needle are overcome.

This may be obtained by an injection needle of the kind described in the opening of this specification which needle is according to the invention characterised in that the length of the injection part is shorter than 9 mm and that

the outer diameter and bore of the needle complies with one of the conditions:

a) the outer diameter is smaller than 0,320 mm and the diameter of the bore is larger than 0,165 mm,

or

b) the outer diameter is smaller than 0,298 mm and the diameter of the bore is larger than 0,133 mm.

As the standard ISO 9626 describes tolerances for injection needles defining that the length of a needle may be one millimetre longer or two millimetre shorter than the nominal length of the needle, and that for an ordinary G30 the outer diameter of the needle must be found within the range between 0,320 mm and 0,298 mm, and the diameter of the bore must be found within the range between 0,133 mm and 0,165 mm, the characterising clause may alternatively be worded as follows:

that the length of the injection part is nominally 8 mm or less, and

that one of the following two conditions is complied with:

a) the outer diameter corresponds to the outer diameter of a G30 needle and the bore diameter is larger than the bore diameter of an ordinary G30 needle,

or

b) the outer diameter is smaller than the outer diameter of a G30 needle and the diameter of the bore is larger than the minimum diameter of the bore in an ordinary G30 needle.

From WO 93/00948 it is known to use G30 needles for injection of insulin from a pen accommodating a cartridge with an insulin having a maximal crystal size of 15 µm. This will guarantee that the insulin stored in such injection devices will be able to run freely through needles having a bore with diameter larger than 0,133 mm which is the smallest bore occurring in a normal G30 needle. Other kinds of medicine not containing crystals at all will of course also be able to pass such a normal G30 needle.

The use of the smaller wall thickness by needles having outer diameters smaller than 0,320 mm will allow a larger bore in a G30 needle with a resulting better flow through the needle. Alternatively, if a bore diameter of 0,133 mm is accepted the use of thin walls may allow a needle which is still thinner than a G30 needle but which nevertheless guarantees free flow of even a crystalline insulin in the device.

Thin walled G30 needles are known , but as it has been the view that thin needles with thin walls should be handled by professionals due to the risk of breaking the needle, thin walled needles have not previously been manufactured for use with injection devices designed for self administration of medicine, e.g insulin. However, as described in WO 93/00948 needles as thin as a normal G30 has shown to be safe for use by self injection and as the bending strength of the needle tube is only reduced 6% when the wall thickness is reduced 50% a short thin walled needle will be safe too even in the hand of non professionals.

According to the invention the injection part of the needle is shorter than 9 mm and may appropriately be 4 - 8 mm. With a shorter needle the risk for breaking will be reduced, and further, short needles are to be preferred for subcutaneous injections as the use of short needles reduces the risk of inserting the needle deeper than subcutis. As further the needle is used with an injection device of the kind from which preset doses of a medicine are administrated from a cartridge, the needle part which has to penetrate the closure membrane is the short back needle which may be passed through the membrane without any risk for unallowable bending.

In the following the invention is explained in more details with reference to the drawing in which

Figure 1 shows schematically a sectional view of a needle hub with a needle according to the invention, and

Figure 2 shows a sectional view of a section of the needle tube.

In figure 1 a needle is mounted in a needle hub comprising a circular disc shaped element 1 which has along its periphery a circumferential depending sleeve which is on its inner wall provided with a thread 4 by which the needle hub may be screwed onto a needle receiving part of a syringe which needle receiving part is provided with an outer thread. At its centre the element 1 is provided with a protrusion 2 projecting from the disc in the opposite direction of the sleeve. Centrally through the protrusion 2 and the disc element 1 a double pointed needle is mounted so that one pointed end part 5 forming an injection part for piercing the skin of a user protrudes from the protrusion 2 and a so-called back needle 6 protrudes from the opposite side of the circular disc so that it is concentrically surrounded by the sleeve 3. The back needle 6 is shorter than the sleeve 3 so that this sleeve to some extent protect the pointed end of the back needle. The injection part 5 of the needle has a length L which is smaller than 9 mm which is according to ISO 7864:1993E the maximal length accepted for a needle denounced as an 8 mm needle. By limiting and reducing this length the bending moment exerted on the injection part 5 of the needle during insertion of this part through the skin is reduced. The back needle 6 which has to penetrate a closing membrane of an ampoule when the needle is mounted on a syringe is still shorter. This is advantageous as such a membrane is more difficult to penetrate than is the skin. The limited lengths of the unsupported needle makes a reduction of the wall thickness and the resulting reduction of the bending strength acceptable.

Figure 2 shows schematically a sectional view of a section of a needle tube presenting a wall 8 and a bore 7. The needle is characterised by its outer diameter D and the diameter d of the bore. A reduction of the wall thickness may be used for obtaining a larger bore diameter d in a needle as thin as G30 according to ISO 9626 or for obtaining a needle which has a bore diameter d at least corresponding to the minimum diameter of a G30 needle and an outer diameter D smaller than the minimum diameter of a G30 needle. This may be expressed by the conditions:

$d \geq 0{,}165$ mm and $D \leq 0{,}320$

or

$d \geq 0{,}133$ mm and $D \leq 0{,}298$ mm

taken with the following condition which must always be complied with: d + 2 x (wall thickness) = D.

The smallest wall thickness which may be accepted is defined by the demands set on the bending strength of the needle.

Claims

1. An injection needle mounted in a needle hub fitting onto an injection device of the kind from which preset doses of a medicine from a cartridge accommodated in the device may be administered through the needle being mounted on the device and exposing a back needle penetrating a closure membrane of the cartridge and a free injection part, characterized in that the length of the injection part is shorter than 9 mm and that the outer diameter and the diameter of the bore of the needle complies with one of the conditions:

a) the outer diameter is smaller than 0,320 mm and the diameter of the bore is larger than 0,165 mm, or

b) the outer diameter is smaller than 0,298 mm and the diameter of the bore is larger than 0,133 mm.

2. An injection needle according to claim 1, characterised in that the needle hub is designed to fit onto an injection system for insulin.

3. An incection needle according to claim 1, characterised in that the needle hub is designed to fit onto an injection system for insulin analogues.

4. Injection needle according to claim 2 or 3, characterised in that the injection system accommodates only cartridges with insulin types which are solutions or suspensions with a particles having a maximum diameter of 15 µm.

5. An injection needle according to claim 1, characterised in that the needle hub is designed to fit onto an injection system for growth hormones.

6. An injection needle according to anyone of the claims 1 - 5, characterised in that the free injection part of the needle has a length in the interval 4 - 8 mm.

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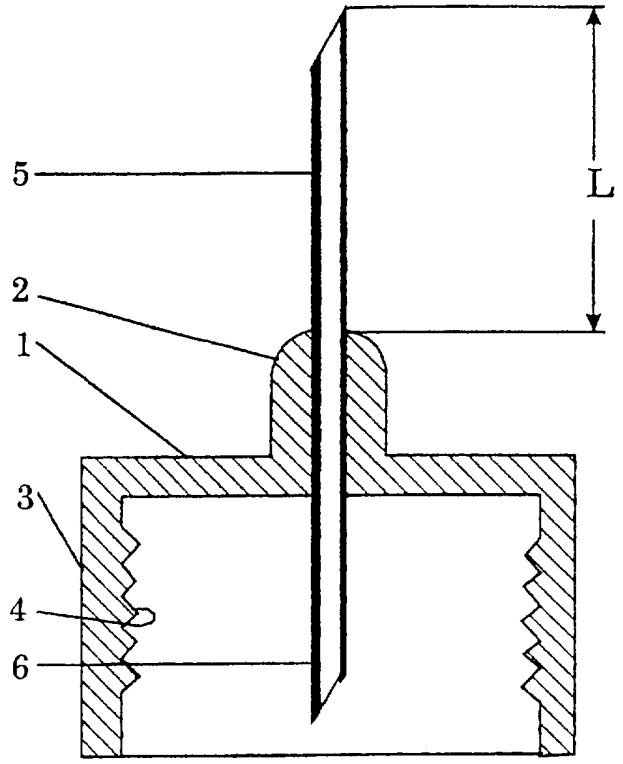

Fig. 1

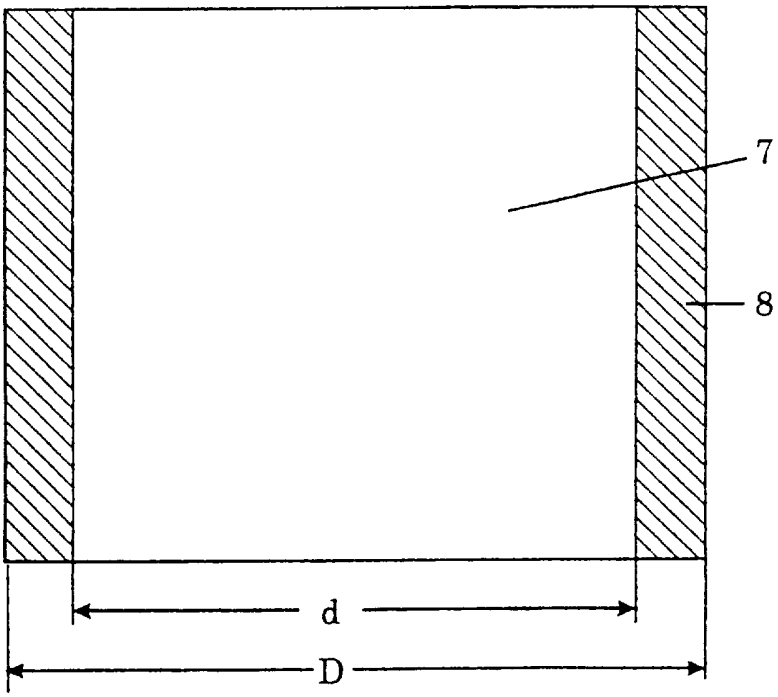

Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 97/00188

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/32
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)

IPC6: A61M

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9300948 A1 (NOVO NORDISK A/S), 21 January 1993 (21.01.93), abstract ---	1-6
A	WO 9007348 A1 (NEDERLANDSE ORGANISATIE VOOR TOEGEPAST-NATUURWETENSHAPPELIJK ONDERZOEK TNO), 12 July 1990 (12.07.90), page 3, line 27 - line 29 ---	1-6
A	EP 0279583 A2 (OWEN MUMFORD LTD.), 24 August 1988 (24.08.88), column 2, line 35 - line 44 --- --------	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Information on patent family members

01/07/97

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