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(73) Patenthaver: **Sanofi-Aventis Deutschland GmbH, Brüningstraße 50, 65929 Frankfurt am Main, Tyskland**

(72) Opfinder: **PLUMPTRE, David, 36 Shire Way, Droitwich Spa, Worcestershire WR9 7RQ, Storbritannien**

(74) Fuldmægtig i Danmark: **RWS Group, Europa House, Chiltern Park, Chiltern Hill, Chalfont St Peter, Bucks SL9 9FG, Storbritannien**

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DESCRIPTION

BACKGROUND

Field of the Present Patent Application

[0001] The present patent application is generally directed to drug delivery devices. More particularly, the present patent application is generally directed to drug delivery devices, such as pen type drug delivery devices. Such devices provide for self administration of medicinal product from a multi-dose cartridge and permit a user to set the delivery dose. The present application may find application in both resettable (i.e., reusable) and non-resettable (i.e., non-reusable) type drug delivery devices. However, aspects of the invention may be equally applicable in other scenarios as well.

Background

[0002] Pen type drug delivery devices have application where regular injection by persons without formal medical training occurs. This is increasingly common among patients having diabetes where self-treatment enables such patients to conduct effective management of their disease.

[0003] In certain types of medication delivery devices, such as pen type devices, cartridges of medication are used. These cartridges are housed in a cartridge holder or cartridge housing. Such cartridges include a bung or stopper at one end. At the other end of the cartridge, the cartridge comprises a pierceable seal. To dispense a dose of medication from such a cartridge, the medication delivery device has a dose setting mechanism that uses a spindle to move in a distal direction towards the cartridge and to press a distal end of the spindle against the bung. This expels a certain set dose of medication from the cartridge. It is therefore important that the distal end of the spindle does not press on the bung except during normal dose dispense, otherwise some loss of drug may be experienced and the subsequent dose would be below the set value. One perceived disadvantage of certain known medication delivery devices is that because of the various tolerance differences that may occur during manufacturing (e.g., tolerance differences that may arise during component molding) of the various parts making up the drug delivery device, the combination of these various tolerance differences result in that the cartridge may or may not be held rigidly within the cartridge holder. In other words, the cartridge (and hence cartridge bung) may move away relative to the distal end of the spindle. Therefore, there may be times where the cartridge is not held rigidly within the cartridge holder and can therefore move away from an inner front surface of the cartridge holder.

[0004] In addition, a needle assembly must frequently be attached to and removed from the cartridge holder. This allows a double ended needle of the needle assembly to pierce the seal of the cartridge. Frequently attaching and re-attaching needle assemblies may cause the cartridge to move within the cartridge holder.

[0005] One advantage of certain typical pen type drug delivery devices is that they are relatively compact. This allows a user to carry around the pen. However, if a user of such pen type delivery devices were to drop or mishandle the device, again movement of the cartridge away from the most distal portion of the cartridge holder could result.

[0006] There is, therefore, a general need to take these various perceived issues into consideration when designing either resettable or non-resettable pen type drug delivery devices. Such drug delivery devices would help to prevent unwanted movement of a cartridge contained within a cartridge holder. Specifically, such drug delivery devices would help prevent the cartridge from moving axially relative to the cartridge holder during use of the pen type delivery device: when a needle assembly is attached or removed, or when a user carries around (or drops the drug delivery device) during normal use. Preventing such unwanted movement of the cartridge within the cartridge holder would tend to help insure dispensing accuracy by the device by preventing the spindle distal end from pressing on the bung of the cartridge. Document US 2007/0021718 A1 discloses a housing and a container. Further, within the housing a spring bridging the space left free between the container and an insert is accommodated, wherein the spring biases the container against stop of the housing in the forward driving direction. The spring comprises a spring portion which is a coil having a single spring turn and operates as a compression spring. Further, the spring comprises positioning devices at the two terminal-face ends of the spring portion. The spring portion has two ends, which axially overlap with one another and a distance left free between the ends as measured in the circumferential direction is bridged by a connecting web having the same pitch as the spring turn. When a pressure is applied to the spring, the connecting web breaks

and the two tangential ends of the spring portion push past one another axially to an increasing degree. Further, a narrow axial slit remains free between the two ends.

[0007] Document EP 0 897 728 A1 shows a clutch detent spring which provides a predetermined slip torque action between an adjusting knob and its counter ring.

[0008] Document XP 000374732 discloses a wave spring which provides the same load/deflection characteristics in one-third space of round wire springs.

SUMMARY

[0009] It is an object of the present invention to provide an improved drug delivery device with regard to above explained needs.

[0010] This object is solved by a drug delivery device with the features of claim 1. The drug delivery device in particular comprises an element configured for biasing a cartridge in a cartridge housing of the drug delivery device, wherein at least one portion of said element is configured to be self retained by an internal surface of said drug delivery device.

[0011] In particular, the inventive drug delivery device comprises a non-plastic element for biasing a cartridge in a cartridge housing of a drug delivery device is provided. This non-plastic element does not comprise a coil spring. According to another exemplary arrangement, a self retained element for providing a spring bias to a cartridge in a cartridge holder of a drug delivery device comprises a first member having a shape that allows passage of a spindle of the drug delivery device. A portion of the first member is self retained by an internal surface of the drug delivery device. The self retained element biases the cartridge against an inner surface of the cartridge holder. In one arrangement, this cartridge is a removable cartridge. In another exemplary arrangement the element for biasing a cartridge comprises a first member and a second member folded over said first member. In a further exemplary arrangement said element comprises a first dimension associated with an uncompressed state when said element is not biasing said cartridge; and a second dimension associated with a compressed state when said element is biasing said cartridge, such that a difference between said first dimension and said second dimension is less than approximately 4 mm and preferably more than approximately 0.5 mm.

[0012] The element configured for biasing a cartridge described above and a drug delivery device form a system wherein said drug delivery device comprises a cartridge housing containing a cartridge. In an exemplary arrangement said drug delivery device comprises a cartridge housing with a removable cartridge. According to an exemplary arrangement the cartridge housing comprises a needle attaching portion, said needle attaching portion allowing for a mounting of a removable needle assembly.

[0013] Further, the object is solved by a method of biasing a cartridge in a drug delivery device cartridge holder providing the features of claim 12. The method in particular comprises the steps of defining an inner end face and a first inner surface of a cartridge holder housing and positioning a cartridge along the first inner surface of the cartridge housing. The method also includes the steps of positioning a self retained biasing element in a dose setting mechanism, preferably by flexibly engaging said self retained biasing element within the housing of said dose setting mechanism, and connecting the dose setting mechanism to the cartridge housing.

[0014] According to an exemplary arrangement the self retained biasing element is manufactured as a unitary element. According to another exemplary arrangement the self retained biasing element is compressed to a compressed height of less than approximately 4 mm and preferably more than approximately 0.5 mm.

[0015] These as well as other advantages of various aspects of the present invention will become apparent to those of ordinary skill in the art by reading the following detailed description, with appropriate reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Exemplary embodiments are described herein with reference to the drawings, in which:

Figure 1 illustrates an arrangement of the drug delivery device in accordance with the one aspect of the present invention;

Figure 2 illustrates the drug delivery device of Figure 1 with a cap removed and showing a cartridge holder containing a biased cartridge;

Figure 3 illustrates a perspective view of a biasing element that may be used to bias the cartridge contained in the cartridge holder of the drug delivery device illustrated in Figure 2;

Figure 4 illustrates one arrangement for mounting the biasing element illustrated in Figure 3 in a drug delivery device, such as the drug delivery device illustrated in Figures 1-2;

Figure 5 illustrates a flat profile of the biasing element illustrated in Figure 3;

Figure 6 illustrates a folded profile of the biasing element illustrated in Figure 5;

Figure 7 illustrates one perspective side view of a folded profile of the biasing element illustrated in Figure 3 in a no load state or an uncompressed state; and

Figure 8 illustrates one perspective side view of a folded profile of the biasing element illustrated in Figure 3 in a loaded (or a compressed state) and in a no load state (or in an uncompressed state).

DETAILED DESCRIPTION

[0017] The terms "drug" or "medicinal product" or "medicament", as used herein, mean a pharmaceutical formulation containing at least one pharmaceutically active compound,
wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a proteine, a polysaccharide, a vaccine, a DNA, a RNA, a antibody, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound,
wherein in a further embodiment the pharmaceutically active compound is useful for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis,
wherein in a further embodiment the pharmaceutically active compound comprises at least one peptide for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy,
wherein in a further embodiment the pharmaceutically active compound comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.

[0018] Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin; Lys(B3), Glu(B29) human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

[0019] Insulin derivates are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl- ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-Y-glutamyl)-des(B30) human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-(w-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

[0020] Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

[0021] Exendin-4 derivatives are for example selected from the following list of compounds:

H-(Lys)4-des Pro36, des Pro37 Exendin-4(1-39)-NH2,

H-(Lys)5-des Pro36, des Pro37 Exendin-4(1-39)-NH2,

des Pro36 [Asp28] Exendin-4(1-39),

des Pro36 [IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),

des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),

des Pro36 [Trp(02)25, Asp28] Exendin-4(1-39),

des Pro36 [Trp(02)25, IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(02)25, Asp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(02)25, IsoAsp28] Exendin-4(1-39); or

des Pro36 [Asp28] Exendin-4(1-39),

des Pro36 [IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),

des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),

des Pro36 [Trp(02)25, Asp28] Exendin-4(1-39),

des Pro36 [Trp(02)25, IsoAsp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(02)25, Asp28] Exendin-4(1-39),

des Pro36 [Met(O)14 Trp(02)25, IsoAsp28] Exendin-4(1-39),

wherein the group -Lys6-NH2 may be bound to the C-terminus of the Exendin-4 derivative;

or an Exendin-4 derivative of the sequence

H-(Lys)6-des Pro36 [Asp28] Exendin-4(1-39)-Lys6-NH2,

des Asp28 Pro36, Pro37, Pro38Exendin-4(1-39)-NH2,

H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH2,

des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36 [Trp(02)25, Asp28] Exendin-4(1-39)-Lys6-NH2,

H-des Asp28 Pro36, Pro37, Pro38 [Trp(02)25] Exendin-4(1-39)-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(02)25, Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(02)25, Asp28] Exendin-4(1-39)-NH2,

des Pro36, Pro37, Pro38 [Trp(02)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(02)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(02)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,

des Met(O)14 Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH2,

H-(Lys)6-desPro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,

des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-Asn-(Glu)5 des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-Lys6-des Pro36 [Met(O)14, Trp(02)25, Asp28] Exendin-4(1-39)-Lys6-NH2,

H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(02)25] Exendin-4(1-39)-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(02)25, Asp28] Exendin-4(1-39)-NH2,

des Pro36, Pro37, Pro38 [Met(O)14, Trp(02)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(02)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH2,

H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(02)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2;

or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

[0022] Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

[0023] A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

[0024] Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na+, or K+, or Ca2+, or an ammonium ion N+(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington's Pharmaceutical Sciences" 17. ed. Alfonso R. Gennaro (Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

[0025] Pharmaceutically acceptable solvates are for example hydrates.

[0026] Referring to Figure 1, there is shown a drug delivery device 1 in accordance with a first arrangement of the present invention. The drug delivery device 1 comprises a housing having a first cartridge retaining part 2, and dose setting mechanism 4. The drug delivery device may be a non-resettable drug delivery device (i.e., a non-reusable device) or alternatively a resettable drug delivery device (i.e., a reusable device). A first end of the cartridge retaining means 2 and a second end of the dose setting mechanism 4 are secured together by connecting features. For non-resettable devices, these connecting features would be permanent and for resettable devices, these connecting features would be releasable.

[0027] In this illustrated arrangement, the cartridge retaining means 2 is secured within the second end of the dose setting mechanism 4. A removable cap 3 is releasably retained over a second end or distal end of a cartridge retaining part or cartridge housing. The dose setting mechanism 4 comprises a dose dial grip 12 and a window or lens 14. A dose scale arrangement is viewable through the window or lens 14. To set a dose of medication contained within the drug delivery device 1, a user rotates the dose dial grip 12 such that a dialled dose will become viewable in the window or lens 14 by way of the dose scale arrangement.

[0028] Figure 2 illustrates the medical delivery device 1 of Figure 1 with the cover 3 removed from a distal end 20 of the medical delivery device 1. This exposes the cartridge housing 6 (cartridge holder). As illustrated, a cartridge 22 from which a number of doses of a medicinal product may be dispensed, is provided in the cartridge housing 6. Preferably, the cartridge 22 contains a type of medicament that must be administered relatively often, such as once or more times a day. One such medicament is either long acting or short acting insulin or an insulin analog. The cartridge 22 comprises a bung or stopper (not illustrated in Figure 2) that is retained near a second end or a proximal end 32 of the cartridge 22.

[0029] The cartridge housing 6 has a distal end 24 and a proximal end 26. Preferably, the distal end 24 of the cartridge housing 6 comprises a groove 8 for attaching a removable needle assembly however other needle assembly connection mechanisms could also be used. If the drug delivery device 1 comprises a resettable device, the cartridge housing proximal end 26 is removably connected to the dose setting mechanism 4. In one preferred embodiment, cartridge housing proximal end 26 is removably connected to the dose setting mechanism 4, preferably to an inner or an outer housing of the dose setting mechanism 4, via a bayonet connection. However, as those of ordinary skill in the art will recognize, other types of removable connection methods such as threads, partial threads, ramps and detents, snap locks, snap fits, and luer locks may also be used.

[0030] The cartridge housing 6 further comprises an inner end face 28 near the first end or distal end 24 of the cartridge housing 6. Preferably, in order to maintain dose accuracy, the cartridge 22 is pressed up against or abuts this inner end face 28. In order to achieve this abutment, as will be discussed in greater detail below, the drug delivery device 1 comprises a biasing member 40 (or biasing means, e.g., a non-coiled spring element) that biases the cartridge 22 against this inner end face 28. In one preferred arrangement, this biasing member 40 comprises a self retained spring like member that is releasably connected to an inner or outer housing of the dose setting mechanism 4. By self retained, it is meant that no other component part is required to retain the biasing member 40 to the drug delivery device.

[0031] As previously mentioned, the dose setting mechanism 4 of the drug delivery device illustrated in Figure 2 may be utilized as a reusable drug delivery device. (i.e., a drug delivery device that can be reset). Where the drug delivery device 1 comprises a reusable drug delivery device, the cartridge 22 is removable from the cartridge housing 6. The cartridge 22 may be removed from the device 1 without destroying the device 1 by merely having the user disconnect the dose setting mechanism 4 from the cartridge housing 6.

[0032] In use, once the removable cap 3 is removed, a user can attach a suitable needle assembly (not illustrated) to the groove 8 provided at the distal end 24 of the cartridge housing 6. Such needle assembly may be screwed onto a distal end 24 of the housing 6 or alternatively may be snapped onto this distal end 24. After usage, the replaceable cap 3 may be used to re-cover the cartridge housing 6. Preferably, the outer dimensions of the replaceable cap 3 are similar or identical to the outer dimensions of the dose setting mechanism 4 so as to provide an impression of a unitary whole when the replaceable cap 3 is in position covering the cartridge housing 6 when the device is not in use.

[0033] Figure 3 illustrates a perspective view of a biasing member 40 that is used to bias the cartridge 22 contained in the cartridge housing 6 of the drug delivery device 1 illustrated in Figures 1 and 2. In one preferred arrangement, the biasing member 40 is assembled between the cartridge 22 and the dose setting mechanism 4 of a drug delivery device 1. In this position, the biasing member 40 biases the cartridge 22 in an axial direction so that the distal end 21 of the cartridge 22 remains up against the inner end face 28 of the cartridge housing 6.

[0034] Using the biasing member 40 between the dose setting mechanism 4 and the cartridge 22 results in certain perceived advantages. First, the biasing member 40 will tend to prevent the cartridge 22 from moving axially relative to the cartridge housing 6 when a needle assembly is connected to or disconnected from the distal end 24 of the cartridge housing 6. Second, the biasing member 40 will also help prevent the cartridge 22 from moving axially relative to the cartridge housing 6 when a user handles the device or inadvertently drops the drug delivery device 1. Third, because of the flexible nature of the biasing member, the biasing member 40 will tend to hold the cartridge 22 adjacent the inner end face 28 of the cartridge housing 6 even where a range of manufacturing tolerances between the various component parts particularly in axial direction is experienced. This will therefore help to ensure dose setting and dose administration accuracy of the drug delivery device 1.

[0035] Returning to Figure 3, the biasing member 40 comprises a first connection side loop 42 and a second connection side loop 44. These connection side loops 42 and 44 are disposed at opposite ends of the biasing member 40. These side loops 42, 44 are flexible substantially in a direction radial to the longitudinal axis of the cartridge 22 or the cartridge housing 6 and allow the biasing member 40 to be assembled into a distal end of a dose setting mechanism 4, preferably in two side apertures of the inner or outer housing of the dose setting mechanism, and be self retained therein.

[0036] The biasing member 40 further comprises an upper wave spring 46 and a lower wave spring 48. Both wave springs 46, 48 have inner diameters and outer diameters that are essentially equal. The upper wave spring 46 and the lower wave spring 48 illustrated in Figure 3 are shown in an uncompressed or unbiased state. In this state, the upper wave spring 46 is flexing in a proximal direction and the lower wave spring 48 is flexing in a distal direction relative to the connection side loops.

[0037] Unlike certain conventional coil springs, when the biasing mechanism 40 is in a biased state or is in a compressed state, the biasing mechanism has a relatively small height H2 (see Figure 8), in the order of only approximately between 1.9 mm and 0.5

mm. The biasing member 40 has also been designed so that it is self retained in the dose setting mechanism 4 using two small side apertures into which side loops 42, 44 lock when assembled into the dose setting mechanism 4.

[0038] Figure 4 illustrates one arrangement for assembling the biasing member 40 in the drug delivery device 1 illustrated in Figures 1-2. As illustrated in Figure 4, the cartridge housing 6 is shown partially connected to the dose setting mechanism 4 and the biasing member 40 is in an uncompressed state. If the cartridge housing 6 were fully connected to the dose setting mechanism 4, the cartridge 22 would act on the upper wave spring 46 so as to result in both the upper and lower wave springs 46, 48 being in a compressed or biased state (see, e.g., Figure 8). However, for ease of explanation, Figure 4 merely illustrates the cartridge housing 6 and the dose setting mechanism in a partially connected position.

[0039] When the biasing member 40 is assembled within the dose setting mechanism 4, the first connecting side loop 42 flexes inwards towards an internal cavity 5 of the dose setting mechanism 4. The flexing nature of the first side loop 42 allows the loop 42 to engage a first aperture 49 in a first side wall 50 of the inner or outer housing of the dose setting mechanism 4. Similarly, the second connecting side loop 44 also flexes inwards towards the internal cavity 5 of the dose setting mechanism 4 internal cavity 5. This second connecting side loop 44 engages a second aperture 51 in a second side wall 52 of the inner or outer housing of the dose setting mechanism 4. Preferably, the first side wall 50 and the second side wall 52 may form the same side wall. In this uncompressed or unbiased state of biasing member 40, a difference in height between the upper wave spring 46 and the lower wave spring 48 has been designated in Figure 4 by H1.

[0040] The biasing mechanism 40 can be retained in the housing whose internal diameter is just slightly larger than the outer diameter of the cartridge 22. More preferably, the biasing member 40 can be assembled over a spindle whose maximum outer diameter is slightly less than an inner diameter of the cartridge 22. For example, in Figure 4, the dose setting mechanism 4 comprises a spindle 60 for acting on a proximal surface 30 of bung 23 of a cartridge 22 so that medicine can be expelled from the cartridge 22. The spindle 60 may comprise a spindle bearing 62 near a distal end of the spindle. The spindle bearing 62 comprises a spindle bearing surface 63 for acting on the proximal surface 30 of the bung 23. The biasing mechanism 40 has an inner diameter that is slightly larger than an outer diameter of the spindle bearing 62 or spindle 60 so that an assembled biasing mechanism 40 does not impede movement of this spindle 60 or the spindle bearing 62 during use of the drug delivery device. (i.e., during dose administration or during drug delivery device reset).

[0041] Figure 5 illustrates a flat profile 66 of the biasing mechanism 40 illustrated in Figure 3. As illustrated in Figure 5, the biasing member 40 comprises a self-contained part or a single unitary part. This self contained member comprises a first member and a second member that are flexibly coupled to one another. The first member comprises an upper wave spring 46 having an inner diameter designated in Figure 5 by D46 as well as a bar-like left side section 42a and bar-like right side section 44a. The second member comprises a lower wave spring 48 having an inner diameter designated in Figure 5 by D48 as well as a bar-like left side section 44a and a bar-like right side section 42b. The flexible nature of the first and second members, in particular of the side sections 42a, 42b, 44a, allow these members to be manipulated or bent or folded over one another to form the biasing mechanism 40 illustrated in Figure 3. In one preferred arrangement, the upper and lower wave springs 46, 48 comprise circular members however those of skill in the art will recognize other shapes may be utilized as well.

[0042] Preferably, once the biasing mechanism 40 is in a folded state, the side section 42a engages the side section 42b to form a first connection side loop 42. Therefore the front end part of side section 42b is bent forming a round section as a brace support for the front end part of the side section 42a which is accommodated behind the front end part of side section 42b (cf. Figure 3). The side section 44a is bent in the way that it forms a second connection side loop 44. In addition, the inner diameter D46 is generally equal to the inner diameter D48 of the second member. This may be seen from Figure 6.

[0043] Figure 6 illustrates a folded profile 72 of the biasing member 40 illustrated in Figure 3. As can be seen from this folded profile 72, when the first member 46 and second member 48 are folded over one another, the biasing member 40 will now have an inner diameter D46, D48 and an outer diameter Dout. Preferably, the inner diameter D46, D48 of the biasing member 40 will be sized to be larger in size or roughly the same size as the inside diameter of the cartridge 22. In addition, the outside diameter 56 identified as Dout of the biasing member 40 will be sized to be smaller or roughly the same size as the outside diameter of the cartridge 22.

[0044] Figure 7 illustrates a partial side view of the folded profile 72 of the biasing member 40 illustrated in Figure 3. In this partial side view, the biasing member 40 is illustrated in a no load state. That is, where the biasing member 40 is not biasing a cartridge similar to that illustrated in Figure 4. In this unbiased state, the upper wave spring 46 of the biasing member 40 will have a first dimension associated with an uncompressed state and the lower wave spring 48 will have a first dimension associated with this uncompressed state. The difference in height between these two dimensions is represented by the height H1.

[0045] Figure 8 illustrates a folded profile of the biasing member 40 illustrated in Figure 3 in a compressed state: where the biasing member 40 is biasing a cartridge, in comparison with the biasing member 40 in the uncompressed state. In this bent state, the upper wave spring 46 of the biasing mechanism will have a second or different dimension than in the uncompressed state. (Cf., Figure 7). Similarly, the lower wave spring 48 will have a second or different dimension than in the uncompressed state. (Cf., Figure 7). The difference in height between the upper wave spring 46 and the lower wave spring 48 in this compressed state is represented by the height H2.

[0046] In one preferred arrangement, the difference in height between the uncompressed state H1 and the compressed state H2 of the biasing member 40 will be greater than approximately 0.5 mm, and preferably less than approximately 4 mm. One advantage of this arrangement is that this low height H2 allows for having a shorter (and less obtrusive) drug delivery device, an advantage for certain users that must carry their pen type drug delivery devices with them throughout the day.

[0047] Exemplary embodiments of the present invention have been described. Those skilled in the art will understand, however, that changes and modifications may be made to these embodiments according to the claims.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US20070021718A1 [0006]
- EP0897728A1 [0007]

Non-patent literature cited in the description

- Rote Liste20080000 [0022]
- Remington's Pharmaceutical SciencesMark Publishing Company19850000 [0024]

Patentkrav

1. Lægemiddelfremføringsanordning med et element (40), der er konfigureret til at påvirke en patron (22), fortrinsvis en udtagelig patron, i et patronhus (6) mod dets indre overflade, hvor patronhuset (6) har en længdegående akse, og hvor mindst én del af elementet (40) er konfigureret til at være selvholdt af en indre overflade af lægemiddelfremføringsanordningen, hvor elementet (40) omfatter
en første forbindelsessidesløjfe (42) og
en anden forbindelsessidesløjfe (44), der er fleksibelt koblet til den første forbindelsessidesløjfe (42),
hvilken første og anden forbindelsessidesløjfe (42, 44) er disponeret på modsatte ender af elementet (40) og er fleksible i en retning radialt på den længdegående akse af patronhuset (6) og er kendetegnet ved, at de åbner mulighed for at gå i indgreb med en indre overflade af lægemiddelfremføringsanordningen til selvfastholdelse i lægemiddelfremføringsanordningen.

2. Lægemiddelfremføringsanordning ifølge krav 1 hvor elementet (40) omfatter en første del og
en anden del, der er foldet over den første del,
hvilken første del har en form, der åbner mulighed for passage af en tap (60) i lægemiddelfremføringsanordningen under dosisadministration af lægemiddelfremføringsanordningen.

3. Lægemiddelfremføringsanordning ifølge ét af ovennævnte krav, hvor elementet (40) omfatter
en første dimension (H1), der er forbundet med en ikke-sammenpresset tilstand, når elementet (40) ikke påvirker patronen (22); og
en anden dimension (H2), der er forbundet med en sammenpresset tilstand, når elementet (40) påvirker patronen (22),
således at forskellen mellem den første dimension (H1) og den anden dimension (H2) er mindre end ca. 4 mm og fortrinsvis mere end ca. 0,5 mm.

4. Lægemiddelfremføringsanordning ifølge ét af ovennævnte krav, hvor elementet omfatter
en øvre bølgefjeder (46) og
en nedre bølgefjeder (48), der er fleksibelt koblet til den øvre bølgefjeder.

5. Lægemiddelfremføringsanordning ifølge krav 4, hvor den øvre bølgefjeder (46) omfatter en ydre diameter (Dout), der er generelt mindre end en ydre diameter af patronen (22).

6. Lægemiddelfremføringsanordning ifølge krav 4, hvor den øvre bølgefjeder (46) omfatter en indre diameter (D46, D48), der er generelt større end en indre diameter af patronen (22).

7. Lægemiddelfremføringsanordning ifølge et hvilket som helst af ovennævnte krav, hvor patronen (22) er en patron, hvorfra der kan dispenseres et antal doser af et medicinsk præparat.

8. Lægemiddelfremføringsanordning ifølge krav 7, hvor patronhuset omfatter en kanylepåsætningsdel, hvilken kanylepåsætningsdel åbner mulighed for montereing af en aftagelig kanylesamling.

9. Lægemiddelfremføringsanordning ifølge krav 8, hvor det selvholdte element, forhindrer, at patronen (22) bevæger sig aksialt i forhold til patronhuset (6), når en bruger sætter kanylesamlingen på eller tager den af kanylepåsætningsdelen af patronhuset (6).

10. Lægemiddelfremføringsanordning ifølge krav 8 eller 9, hvor kanylepåsætningsdelen omfatter en spiralformet fure (8).

11. Lægemiddelfremføringsanordning ifølge et hvilket som helst af kravene 7 til 10, der omfatter patronen, hvorfra antallet af doser af et medicinsk præparat kan dispenseres, hvor det medicinske præparat omfatter en farmaceutisk formulering, der indeholder mindst én farmaceutisk aktiv

forbindelse, hvilken farmaceutisk aktive forbindelse omfatter mindst én human insulin eller en human insulinanalog eller et derivat deraf, glucagonlignende peptid (GLP-1) eller en analog eller et derivat deraf eller exedin-3 eller exedin-4 eller en analog eller et derivat af exedin-3 eller exedin-4.

12. Fremgangsmåde til påvirkning af en patron (22) i et patronhus i en lægemiddelfremføringsanordning (6), hvilken fremgangsmåde omfatter trinene:
definering af en indre endeflade og en første indre overflade af patronhuset (6);
placering af en patron (22) langs den første indre overflade af patronhuset (6);
placering af et selvholdt påvirkningselement (40) ifølge et af ovennævnte krav i en dosisindstillingsmekanisme (4), hvor elementet (40) omfatter en første sløjfe og (42) en anden sløjfe (44), der er fleksibelt koblet til den første sløjfe (42), hvilken første og anden sløjfe (42, 44) er i indgreb med en indre overflade af lægemiddelfremføringsanordningen til selvfastholdelse inde i lægemiddelfremføringsanordningen ved fleksibelt indgreb af det selvholdte påvirkningselement (40) inde i et hus i dosisindstillingsmekanismen (4); og
påsætning af dosisindstillingsmekanismen (4) på patronhuset (6),
hvor det selvholdte påvirkningselement (40) anvendes til at fastholde patronen (22) mod den indre endeflade (28) af patronhuset (6).

13. Fremgangsmåde ifølge krav 12, der yderligere omfatter trinet:
fremstilling af det selvholdte påvirkningselement (40) som et enhedselement.

14. Fremgangsmåde ifølge et af kravene 12 til 13, der yderligere omfatter trinet:
sammenpresning af det selvholdte fjederpåvirkningselement (40) til en sammenpresset højde (H2) på mindre end ca. 4 mm og fortrinsvis mere end ca. 0,5 mm.

DRAWINGS

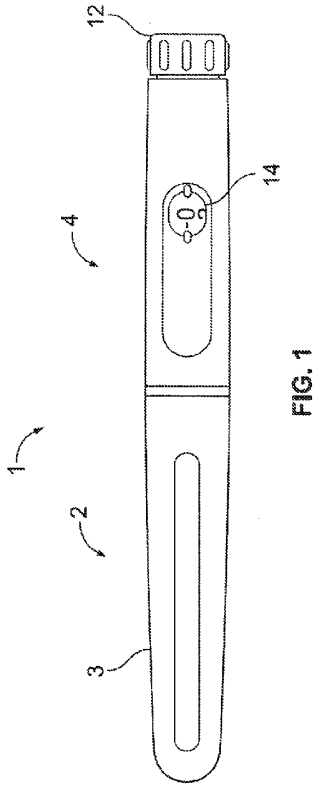

FIG. 1

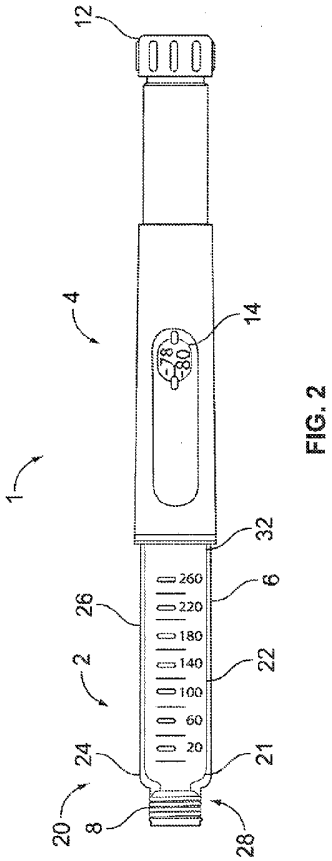

FIG. 2

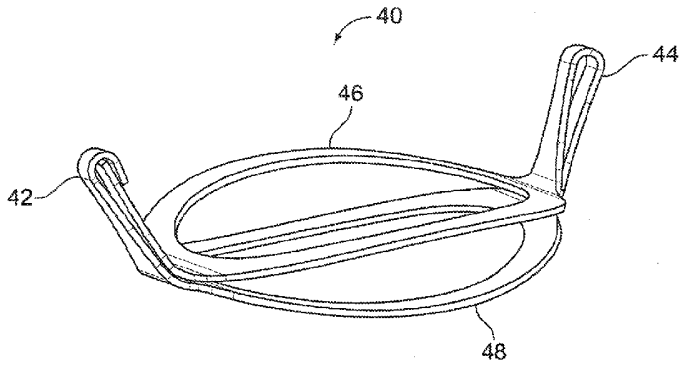

FIG. 3

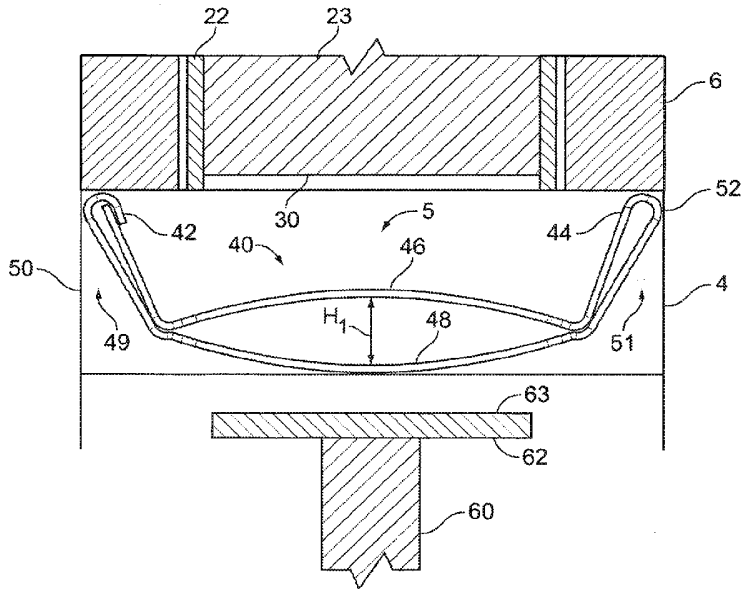

FIG. 4

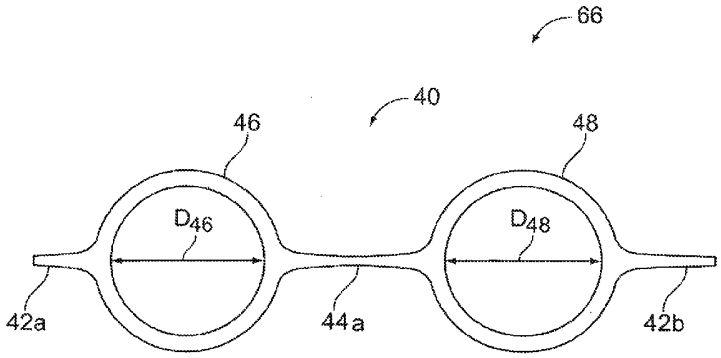

FIG. 5

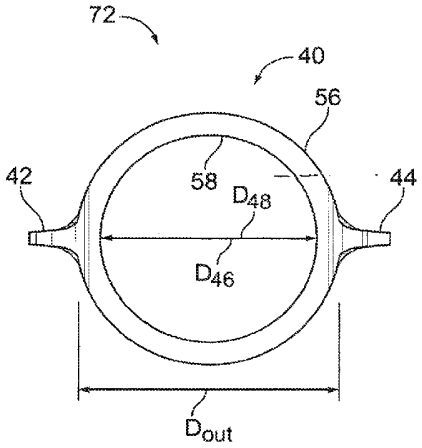

FIG. 6

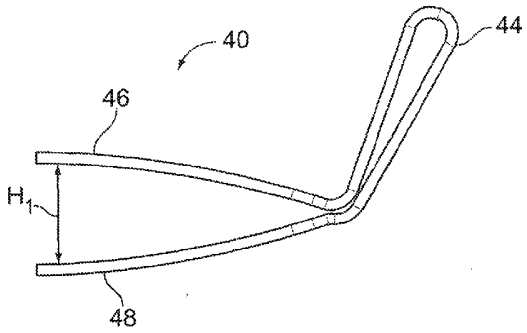

FIG. 7

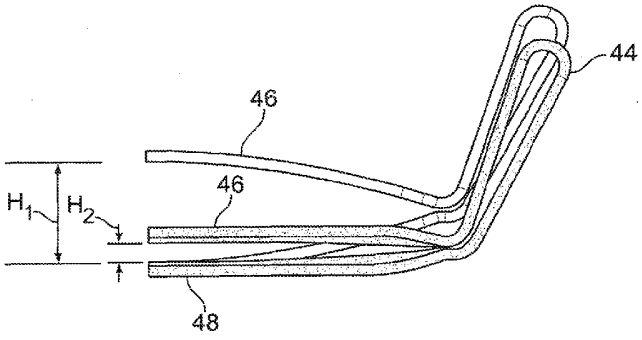

FIG. 8