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(54) **Title**: STOPPER FOR SEALING A COMPARTMENT OF A MEDICAMENT CONTAINER

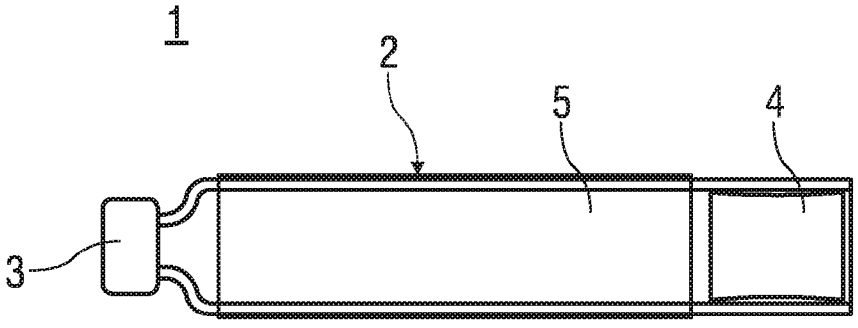

FIG 1

(57) **Abstract**: The invention refers to a stopper (4) for sealing a compartment (5) of a medicament container (1), wherein a microchip (6) comprising at least one sensor is embedded into the stopper (4), wherein the microchip (6) is arranged for storing data comprising measurement data acquired by the sensor and wherein the microchip (6) comprises wireless communication means for allowing the stored data to be retrieved by an external wireless unit. The invention also refers to a stopper (4) for sealing a compartment (5) of a medicament container (1), wherein at least one surface (7.1, 7.2, 7.3) of the stopper (4) is coated with a sensitive material which changes its visual appearance upon a change of an ambient condition or a condition inside the compartment (5).

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Description

Stopper for sealing a compartment of a medicament container

The invention refers to a stopper for sealing a compartment of a medicament container.

Medicament containers such as syringes or ampoules usually comprise a hollow cylinder made of a pharmaceutical glass which is inert and chemically resistant against the drug stored inside, e.g. insulin. The container is sealed by a stopper or bung at one end of the cylinder which can be moved along the longitudinal axis of the cylinder in order to displace the drug and force it out of an outlet end which may be sealed by a pierceable membrane. The stopper and the pierceable membrane are conventionally made of an elastomere ensuring mechanical tightness under defined pressure conditions and long term germ impermeability. Other important parameters affecting the dimensioning and choice of materials of the stopper and the pierceable membrane are the maximum force expected at the stopper and the number of allowable piercings of the pierceable membrane.

Before filling in the drug and sealing the container, the quality of the inner surface of the cylinder is improved by siliconization, so static and dynamic friction of the stopper are reduced.

DE 102 26 643 A1 discloses a stopper for an injection arrangement, the stopper comprising a stopper body, a stopper body support attached to a drive member of the injection arrangement and a sealing member for sealing a product container of the injection arrangement against the stopper body, wherein a membrane body is arranged in a cap-like manner at a proximal end of the stopper body wherein the sealing member is part of the membrane body. A sensor is provided for measuring a pressure exerted by the product on the proximal end of the membrane body. The sensor may be a pressure sensor.

US 2003/0125670 A1 discloses a medicament cartridge comprising a cylinder and a displaceable plunger. The cartridge is provided with an electrical element having specified electrical properties located on an external face of the plunger. The electrical element can take the form of a conductive disk or two conductive rings joined by a

resistive pad. The device may be equipped with electrical contacts for contacting the electrical element.

WO 01/56635 discloses a container for a substance, which container comprises a coupling element for coupling the container with an administration unit for the substance, and a recognition element associated with the substance. The recognition element may be a bar code printed on a package, a chip card enclosed in the package or a magnetic card.

It is an object of the invention to provide an improved stopper for sealing a compartment of a medicament container.

The object is achieved by a stopper with the features of the independent claim 1 or 11.

Advantageous embodiments are given in the dependent claims.

According to one embodiment of the invention a microchip is embedded into a stopper for sealing a compartment of a medicament container. The microchip is arranged for storing data. The microchip comprises wireless communication means for allowing the stored data to be retrieved by an external wireless unit.

This allows for providing the medicament container with an ID upon manufacturing in order to make it tamper proof. For example an injector or pen, which the medicament container may be replaceably received in may be equipped with the external wireless unit in order to check the ID of the medicament container. Thus, medicament containers, authorized for usage may be distinguished from fake ones in order to avoid injecting poor quality medicaments, wrong medicaments or dangerous substances. The injector may be able to block movement of a plunger for advancing the stopper once an error such as a fake ID has been detected.

The data may be stored into the microchip upon production via the wireless communication. The data may comprise time stamps for each manufacturing step in order to be able to retrace the production chain or the whole life cycle. The injector may thus detect whether the use-by date of the medicament is expired or not and prevent an expired medicament from being delivered to a patient.

The data may also comprise a country or regional or language information. This allows for automatically setting a display and menu language of a user interface of the injector depending on a destination market, the medicament container is intended for. However, the user may be given an option to overwrite the language setting.

The data may also comprise an information about the type of medicament stored in the medicament container thus allowing to use the injector for a variety of medicaments.

The microchip may also store information on when and how often the medicament container has been used for an injection in order retrace and/or control drug compliance. For example the injector may reject an injection once the daily dose has been injected already. Furthermore, the microchip may store information on a fill level of the medicament container and/or a number of doses already injected.

Preferably, at least one sensor connected to the microchip may be embedded in the stopper, wherein the microchip is arranged for storing data comprising measurement data acquired by the sensor. The data may be acquired continuously or time-discrete.

The sensor may preferably include the function of a light-sensitive sensor. According to other embodiments, the sensor may include the function of a temperature sensor or a pressure sensor. Combinations of said functions included in one sensor are also possible.

The stored data may comprise manufacturing data and data related to ambient and stocking conditions such as a manufacturing date and time, temperature data acquired by a temperature sensor, an ambient pressure acquired by a pressure sensor, light exposure data or data related to a haze of a medicament inside the compartment acquired by a light-sensitive sensor or a dose volume of the medicament container which is sealed by the stopper. Thus the whole life cycle of the medicament container comprising production, filling, storage and injection may be retraced. By means of a temperature sensor it may be retraced whether the cold chain was interrupted or not.

The temperature and/or pressure may be the temperature and/or pressure inside the compartment or an ambient temperature and/or pressure.

The stored data may also comprise a pH-value acquired by a pH sensor. The pH sensor may be a potentiometry or ISFET sensor or a hydrogel based sensor.

The stored data may also comprise a chemical composition of the substance held in the compartment acquired by a chemical composition sensor.

In general, the sensor may use physical or chemical measurement methods.

Preferably the wireless communication means is an RFID means.

In case that the sensor includes the function of a light-sensitive sensor, it is preferred that the sensor is adapted and arranged to receive only ambient light while light stemming from inside the stopper may have no or only a negligible effect on the sensor. Provided that the medicament is affected mainly through ambient conditions and not through internal conditions within the stopper, this may enhance the desired sensitivity of the sensor.

According to another embodiment, the stopper is free of any kind of light source which allows for omitting specific measures to suppress internal light, for example an opaque material or surface of the stopper, and helps to save electric power.

Furthermore, additional features may be included in the function of the light sensitive sensor.

For example, an optoelectronic sensor may be included which is adapted to measure the incident light which may be in the visible, in the infrared or in the ultraviolet range in order to establish a profile according to the storing conditions and in order to identify the deterioration of the medicament.

In addition, an optoelectronic sensor for conversion of light into electric energy may be included as a power supply for the microchip present in the stopper.

In addition, an optoelectronic sensor for receiving information from other devices, for example other drug delivery devices or blood glucose meters may be included.

In addition, an optoelectronic sensor for receiving information according to the bottling of the ampoule for storing process-related data may be included.

In addition, an optoelectronic sensor may be included for the identification of the location and the position, respectively of the stopper within the ampoule or relative to other components of the injection device, for example of a piston rod.

The sensor may be integrated in or connected to the microchip. A microchip is a cheap and tiny component which may be unremarkably embedded into the stopper. The microchip may comprise an antenna, an analogue circuit for transmitting and receiving, a digital circuit for processing data and a permanent memory. An energy source, e.g. a button cell for powering the microchip may be embedded into the stopper. The energy may also be provided by a coil, embedded into the stopper, which may be excited by an external exciting field.

According to another embodiment of the invention the stopper for sealing a compartment of a medicament container has at least one surface coated with a sensitive material which changes its visual appearance upon a change of an ambient condition or a condition inside the compartment. The change of the visual appearance may be a change of colour.

In particular, the compartment contains a medicament that is sensitive to a change of an ambient condition or a condition inside the compartment which means that the change is changing the medical properties of the medicament. The material of the coating is chosen such that it is also sensitive to the change. The sensitivity of the material is represented as a change of its visual appearance upon the change of condition once the change of condition occurs. A user may recognize the change of visual appearance and thus conclude that the medicament has been affected in view of its medical properties. On the other hand, the sensitivity of the medicament and possibly of the container is not represented as a change of its visual appearance, which means that the change leaves the visual appearance of both the medicament and the container unchanged. The user thus cannot conclude any affect to the medication when watching the medicament or the container alone.

For example, the medicament container may be exposed to a temperature of above 40 °C and below 60 °C. In this case, the temperature may be high enough to start the medicament to decompose although the decomposition is too weak to represent as a visible change of the medicament which would however be the case if the temperature would rise above 60 °C. By means of the sensitive material which changes its appearance already at 40 °C the user recognizes the affection of the medicament.

Preferably, in order to enhance the handling comfort for the user, the sensitive material is arranged on the stopper in such a way that it is permanently visible.

The condition, upon which the visual appearance changes, may be a temperature, a pressure, a light exposure, e.g. a cumulative light exposure, a haze of a substance, e.g. medicament stored in the compartment or an exposure to a chemical composition or pH value of the medicament.

Both embodiments allow for monitoring and retracing manufacturing and stocking conditions of the medicament container. This may help a patient or healthcare professional to determine whether the shelf life of the medicament container has been expired or not.

Furthermore, the change of visual appearance of the coating could be triggered by a chemical reaction between the coating and some sort of humidity or oxygen from the ambient air in order to recognize leakage or in order to indicate the storage time of the ampoule. For example a stopper in a freshly filled container may appear in green colour while the same stopper may appear in red colour when the medicament is subsided due to humidity or oxygen impact.

Furthermore, the coating may be sensitive to electromagnetic fields.

Generally, the effect of thermochromism may be used for the coating. Thermochromism is the ability of certain substances to change colour due to a change in temperature. This process is reversible, i.e. after cooling down the substance reverts to its initial colour. As an example, temperature indicating films may be used. These films may comprise self-adhesive laminas which are coated with a temperature-sensitive layer, whose colour changes from bright to dark when a certain temperature has been reached. The colour change is reversible. The relevant error range of such an indicator may lie between ±1 to ±2 % of the imprinted value. Such films can be used for a measuring range of between 40 to 250 °C.

For example, the indicator bromothymol blue being is embedded in a pH-dependent polymer matrix, can have thermochromic properties under certain conditions. The matrix changes the pH-value with a change in temperature, thus effecting a color change of the indicator. The polymer matrix, which contains lithium chloride, is green within a temperature range of between -5 to +33 °C and changes its colour to yellow when the maximum of the given temperature range is exceeded.

There are also thermochromic colours, whose colour change is irreversible. In these materials, exceeding a certain temperature results in a chemical change, e.g. oxidation prompted by oxygen, or a change in structure, e.g. melting.

Furthermore, temperature measuring colors may be used. These colours are also known as thermochromatic colors or thermochromic colors and show a change in temperature by a change in colour or a change in the colour tone.

The pigments of those colours are complex salt compounds. A change in temperature results for example in a colour change from white to green or from black to turquoise.

Furthermore, photochromic colours may be used. Such colours show a reversible change in the colour tone when they are exposed to ultraviolet light, e.g. sun light or black light. The ultraviolet light changes the chemical structure of the colours and thus

their absorption properties. In contrast to ordinary pigments, which reflect part of the light, photochromic colors absorb part of the light and allow the rest of the light to pass through. The remaining light is reflected from the background, in particular a bright, preferably white, background, and the material appears coloured.

The basic materials for the production of photochromic colours are available in the form of powder, microcapsules, and nurdles. There are four basic colours available, which change their colour from white to purple, blue, yellow, or red.

The stopper according to either embodiment can comprise the same materials as conventional stoppers, such as elastomeres. The primary packaging, i.e. the glass cylinder of the medicament container may remain unchanged. Design modifications of the ampoule or the injection device are not required.

The features of the embodiments may be combined with each other, i.e. the plunger may comprise both the microchip and the sensitive coating.

E.g. the stopper may be applied in an insulin pen injector, both for faster or slower reacting drugs. Preferably, the use of the stopper is restricted to the purpose of testing the injector or the injection device.

The injector may be a mechanical injector equipped with display means for allowing a user to check information encoded in the stored data. Preferably the injector is an electromechanical injector which may process the data and take appropriate action such as blocking an injection or restricting a dose depending on the data.

The term “medicament“ and the term “drug”, as used herein, preferably means 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, 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.

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.

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-(ω-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

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.

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(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)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(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Trp(O2)25, IsoAsp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)25, Asp28] Exendin-4(1-39),
des Pro36 [Met(O)14 Trp(O2)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(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Trp(O2)25] Exendin-4(1-39)-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,

H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)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(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)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(O2)25, Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)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.

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.

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.

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.

Pharmaceutically acceptable solvates are for example hydrates.

Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

Figure 1 is a conventional art medicament container with a glass cylinder sealed by a pierceable membrane and a stopper,

Figure 2 is a stopper with a microchip and sensor according to one embodiment of the invention, and

Figure 3 is a stopper coated with sensitive materials according to another embodiment of the invention.

Figure 1 is a conventional art medicament container 1 with a hollow cylinder 2 sealed by a pierceable membrane 3 and a stopper 4. The pierceable membrane 3 and the stopper 4 define a compartment 5 between for holding a substance, e.g. a medicament. The cylinder 2 may consist of glass. The stopper 4 can be moved along a longitudinal axis of the cylinder 2 in order to displace the medicament and force it out of an outlet provided

the pierceable membrane 3 is pierced. The stopper 4 and the pierceable membrane 3 may be made of an elastomere. The medicament container may have a label indicating its content, e.g. insulin.

Figure 2 is a stopper 4 with an embedded microchip 6 according to one embodiment of the invention. The microchip 6 comprises at least one sensor (not shown). The microchip 6 is arranged for storing data comprising measurement data acquired by the sensor. The data may be acquired continuously or time-discrete. The microchip 6 further comprises wireless communication means (not shown) for allowing the stored data to be retrieved by an external wireless unit (not shown). The external wireless unit may be arranged in an injection device where the medicament container 1 may be received as a replaceable cartridge.

The stored data may comprise manufacturing data and data related to ambient and stocking conditions such as a manufacturing date and time, temperature data acquired by a temperature sensor, an ambient pressure acquired by a pressure sensor, light exposure data or data related to a haze of a medicament inside the compartment acquired by a light-sensitive sensor or a dose volume of the medicament container 1 which is sealed by the stopper 4.

The temperature and/or pressure may be the temperature and/or pressure inside the compartment 5 or an ambient temperature and/or pressure.

The stored data may also comprise a pH-value acquired by a pH sensor. The pH sensor may be a potentiometry or ISFET sensor or a hydrogel based sensor.

The stored data may also comprise a chemical composition of the substance held in the compartment 5 acquired by a chemical composition sensor.

In general, the sensor may use physical or chemical measurement methods.

Preferably the wireless communication means is an RFID means.

The stopper 4 may have an embedded microchip 6 without a sensor just for storing data. The data may comprise an ID and/or time stamps for different production or life cycle steps.

The data may also comprise a country or regional or language information.

Furthermore the data may comprise information about the type of medicament stored in the medicament container 1.

An energy source, e.g. a button cell for powering the microchip 6 may be embedded into the stopper 4. The energy may also be provided by a coil embedded into the stopper 4, which may be excited by an external exciting field.

The microchip 6 may also store information on when and how often the medicament container 1 has been used for an injection. Furthermore, the microchip 6 may store information on a fill level of the medicament container 1 and/or a number of doses already injected.

Figure 3 shows a stopper 4, whose surfaces 7.1, 7.2, 7.3 are coated with sensitive materials according to another embodiment of the invention. The sensitive material changes its visual appearance upon a change of an ambient condition or a condition inside the compartment 5. The change of the visual appearance may be a change of colour.

The condition, upon which the visual appearance changes, may be a temperature, a pressure, a light exposure, e.g. a cumulative light exposure, a haze of a substance, e.g. medicament stored in the compartment 5 or an exposure to a chemical composition or pH value of the medicament.

The stopper 4 may be applied in an insulin pen injector or in another injection device, e.g. for injecting one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine and complex carbohydrates.

There may be more than one compartment 5 and more than one stopper 4 in a medicament container 1, e.g. in an injector where two or more substances have to be stored separately but mixed prior to use.

The features of the embodiments of figures 2 and 3 may be combined with each other, i.e. the stopper 4 may comprise both the microchip 6 and the sensitive coating.

Reference numerals

1	Medicament container
2	Cylinder
3	Pierceable membrane
4	Stopper
5	Compartment
6	Microchip
7.1, 7.2, 7.3	surface

Claims

1. Stopper (4) for sealing a compartment (5) of a medicament container (1), wherein a microchip (6) is embedded in the stopper (4), wherein the microchip (6) is arranged for storing data, wherein the microchip (6) comprises wireless communication means for allowing the stored data to be retrieved by an external wireless unit, wherein at least one sensor connected to the microchip (6) is embedded in the stopper (4), the sensor including the function of a light-sensitive sensor, wherein the data comprise measurement data acquired by the sensor.

2. Stopper (4) according to claim 1, wherein the data comprise light exposure data or data related to a haze of contents stored in the compartment (5).

3. Stopper (4) according to one of the claims 1 or 2, characterized in that the stored data comprise a manufacturing date and time.

4. Stopper (4) according to one of the claims 1 to 3, characterized in that the sensor includes the function of a temperature sensor and the stored data comprise temperature data.

5. Stopper (4) according to one of the claims 1 to 4, characterized in that the sensor includes the function of a pressure sensor and the stored data comprise an ambient pressure or a pressure inside the compartment (5).

6. Stopper (4) according to one of the preceding claims, characterized in that the stored data comprise a dose volume of the sealed medicament container (1).

7. Stopper (4) according to one of the preceding claims, characterized in that the stored data comprise a pH-value acquired by a pH sensor.

8. Stopper (4) according to one of the preceding claims, characterized in that the stored data comprise a chemical composition of a substance held in the compartment (5) acquired by a chemical composition sensor.

9. Stopper (4) according to one of the preceding claims, characterized in that the wireless communication means is an RFID means.

10. Stopper (4) according to one of the preceding claims, the stopper sealing a compartment (5) of a medicament container (1), the compartment (5) containing a medicament, wherein at least one surface (7.1, 7.2, 7.3) of the stopper (4) is coated with a material that is sensitive to a change of an ambient condition or to a condition inside the compartment (5), wherein the material changes its visual appearance upon the change, wherein the change is changing the medical properties of the medicament and wherein the change leaves the visual appearance of both the medicament and the container (1) unchanged.

11. Stopper (4) sealing a compartment (5) of a medicament container (1), the compartment (5) containing a medicament, wherein at least one surface (7.1, 7.2, 7.3) of the stopper (4) is coated with material that is sensitive to a change of an ambient condition or to a condition inside the compartment (5), wherein the material changes its visual appearance upon the change, wherein the change is changing the medical properties of the medicament and wherein the change leaves the visual appearance of both the medicament and the container (1) unchanged.

12. Stopper (4) according to one of the claims 10 or 11, characterized in that the sensitive material changes its colour.

13. Stopper (4) according to one of the claims 10 to 12, characterized in that the condition is a temperature.

14. Stopper (4) according to one of the claims 10 to 13, characterized in that the condition is an ambient pressure or a pressure inside the compartment (5).

15. Stopper (4) according to one of the claims 10 to 14, characterized in that the condition is a light exposure or a haze of a substance held in the compartment (5).

16. Stopper (4) according to one of the claims 10 to 15, characterized in that the condition is an exposure to a chemical composition of a substance stored in the compartment (5).

17. Stopper (4) according to one of the claims 10 to 16, characterized in that the condition is a pH-value of a substance stored in the compartment (5).

18. Medicament container (1), comprising a cylinder (2) and a stopper (4) according to one of the preceding claims moveably arranged in the cylinder (2).

19. Use of a stopper (4) according to one of the claims 1 to 18 in a medicament container (1) for an insulin injector or another injection device, particularly for injecting heparin, wherein the use is restricted to the purpose of testing the injector or the injection device.

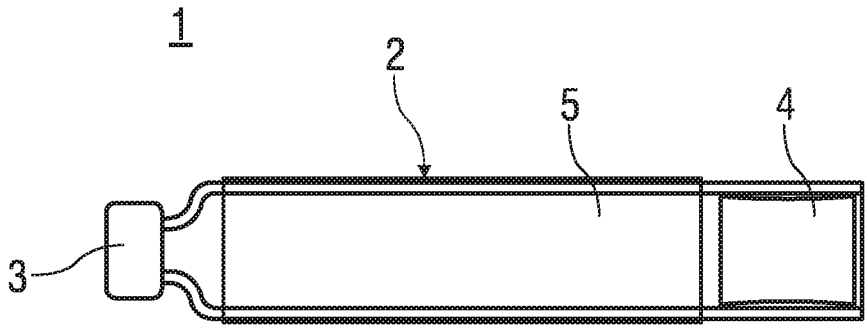

FIG 1

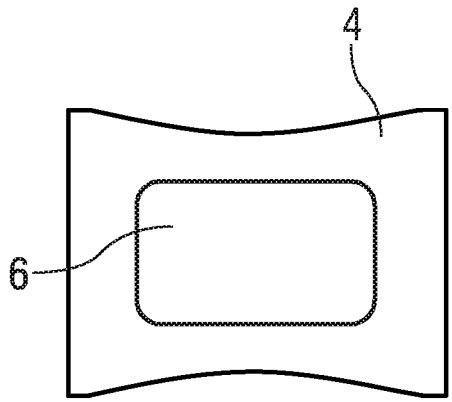

FIG 2

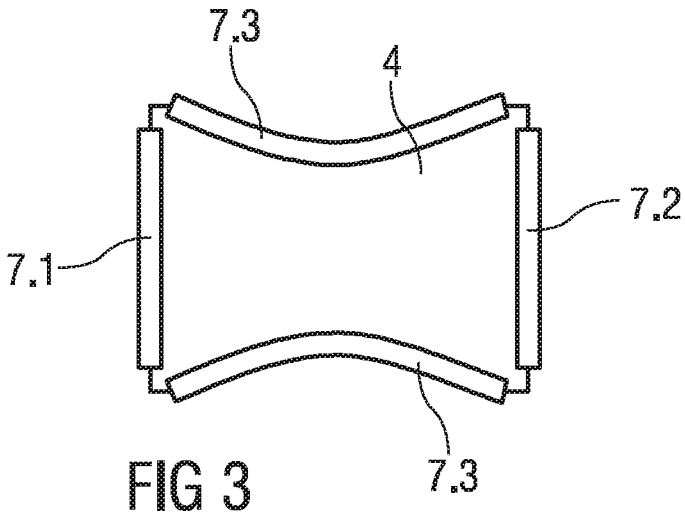

FIG 3

FIG 4a

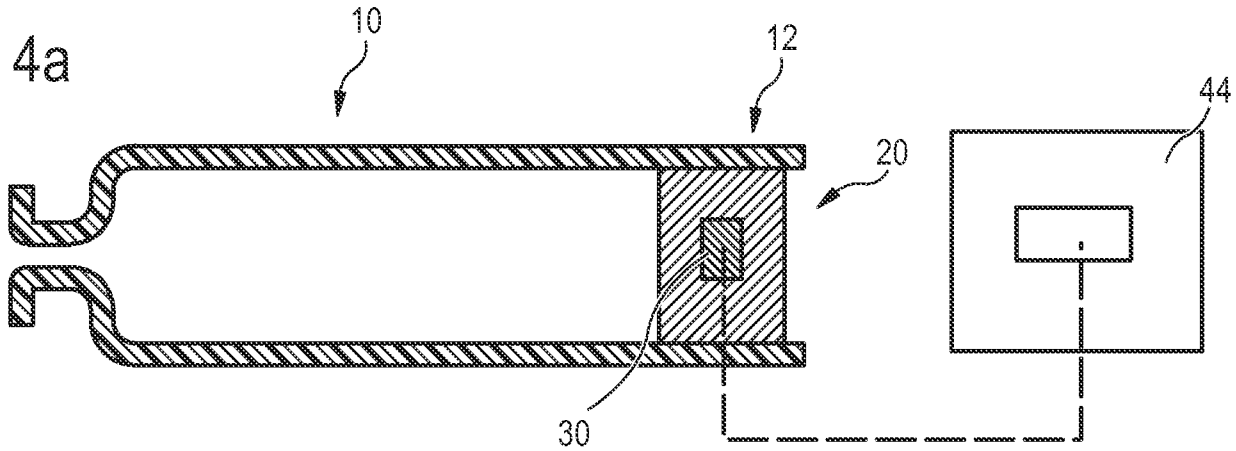

FIG 4b