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Dated this 17th day of September 2019

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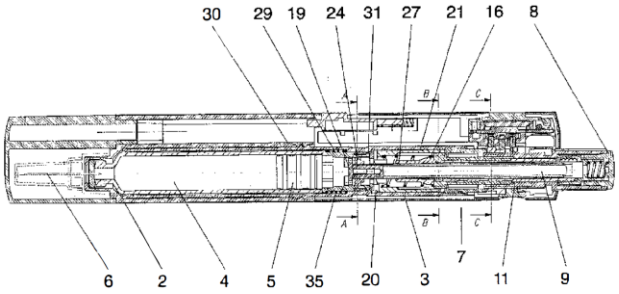
(54) Title: **Injection device**

(57) Abstract The invention relates to an injection device for injecting respectively selected liquid quantities from an ampule, preferably insulin. The manual actuator comprises an axially mobile operating head, only mobile in a (rear) resting position, a tubular drive element connected to the operating head in a torque-proof fashion, an axially fixed and torque-proof guide element, and an axially mobile driven member, held torque-proof in the device, which propels the piston of the ampule. A rotary catch is provided between the rotary mobile and the torque-proof parts of the injection device, which upon turning of the actuator knob generate acoustic noises, for example a clicking noise, matching the dosage. According to the invention the rotary catch is designed such that the actuator knob is mobile in its (rear) resting position in both directions of motion. An accidentally selected excessive dosage, caused by rotating the actuator knob too far in the rotary direction, can easily be reduced again according to the invention by a reverse rotation of the actuator knob in the opposite rotary direction, with once more during the reverse rotation audible acoustic noise being generated, based on which the patient can determined audibly the dosage adjusted.



Description

[0001] The present invention relates to an injection device according to the preamble of claim 1.

[0002] An injection device according to the preamble of claim 1 is known from EP 0 581 924 B1 of the applicant. The injection device of prior art serves for the injection of respectively selected liquid quantities of a product from a product container, particularly an ampule equipped with a piston, which preferably contains a medicinal or therapeutically effective agent. The device comprises a manually driven, tubular actuator, which includes: an actuator knob, which is mobile in the axial and rotational direction, a drive element connected to the actuator knob in a torque-proof fashion, which follows the motions of the actuator knob, a drive element, which is torque-proof in reference to a housing of the device, as well as a guide element for the driven element.

[0003] In the device of prior art a drive element, at which the dispensing element is supported in a mobile fashion, is axial, i.e. the propulsion element of the piston can be moved from a resting position over a distance, predetermined by a mechanic element, to a frontal end position. By distorting the operating head the product dosage to be dispensed is adjusted.

[0004] A rotary catch is provided between the torque-proof and the rotational parts of the injection device of prior art, which comprises two disk-shaped catch elements, which are opposite each other and respectively show a plurality of catch projections and preferably corresponding catch recesses, which cooperate with each other.

[0005] In order to adjust the dosage to be injected by distorting the actuator knob the catch projections glide over the catch recesses. Here, a sound is generated, which clearly reflects the rotary motion of the actuator knob. In EP 0 581 924 B1, here a clicking noise is generated, when the catch projections snap into the correspondingly embodied catch recesses. Based on the noise generated, particularly based on the number of clicking noises, the patient can adjust by way of counting the amount of the new injection dosage, purely by sound, i.e. even without looking at the device. Such an adjustment of the dosage to be injected by sound has proven particularly advantageous, particularly for patients with sickness-related vision impairment, as is frequently the case in diabetes patients, for example.

[0006] In prior art the rotary catch comprises two disk-shaped catch elements, on which in the circumferential direction in regular intervals saw-tooth shaped catch projections and recesses, respectively, are arranged. The two catch elements are pressed towards each other via a spring acting as the return element, so that the rotary catch and/or the actuator knob can only be rotated in one rotary direction, but is/are blocked in the other rotary direction. This is disadvantageous in that on the one hand, upon rotating the actuator knob, the dosage adjusted by rotation in the first rotary direction can only be further increased, namely by a further distortion of the actuator knob in said first direction, however it cannot be reduced by a reverse rotation of the actuator knob in the opposite rotary direction. If the patient has here accidentally selected an excessive dosage, for example because the number of clicking sounds were not correctly recognized, the wrongly set dosage must first be removed by advancing the drive member into the frontal end position, and the drive member must be returned back into the resting position before in another attempt can be made to set a new dosage. This procedure is cumbersome, prone to errors, and unnecessarily wastes some of the product.

Objective

[0007] The objective of the present invention is to further improve the generic injection device such that the dosage to be administered can be reliably predetermined in a simple fashion, and also allows to reduce the selected dosage at any time.

[0008] This objective is attained in an injection device comprising the features of claim 1. Advantageous variants are disclosed in the dependent claims.

[0009] An injection device according to the invention is characterized in that the rotary catch is designed such that the actuator knob in its resting position, i.e. when the drive member is distanced from the piston, can be moved in both rotary directions. Since the device according to the invention still shows a rotary catch, which generates acoustic sounds when twisted, preferably clicking noises, the patient is still able to set the dosage based on hearing, particularly based on the number of clicking noises, for example. This ensures a simple and reliable dosing. Due to the fact that according to the invention the rotary catch is mobile in both directions in the default position, even without any unnecessary discharge of products as explained above, the dosage can be easily reduced even after it was selected.

[0010] Preferably the rotary catch generates the above-mentioned acoustic noise not only when the actuator knob is rotated in the first direction of rotation, for example clockwise, but also when the actuator knob is rotated in the opposite direction of rotation, i.e. counter-clockwise, for example. This way, based on the acoustic noise generated, the patient can reversely rotate the actuator knob and/or the rotary catch and draw conclusions regarding the respectively set dosage.

[0011] The injection device according to the invention can therefore be operated reliably and easily even without reading it.

[0012] According to a preferred embodiment the actuator knob and jointly with it the driven member are adjustable only axially out of the resting position in to the frontal end position when the rotary catch has engaged, when the catch protrusions essentially cooperate completely with the correspondingly embodied catch recesses. In this simple fashion it can be ensured that only one dosage can be administered, which is adjusted by distorting the actuator knob by an integral multiple of the circumferential angular distances of the catch projections.

[0013] In the above-mentioned embodiment, preferably at the outer perimeter of the actuator knob or at an element arranged thereat in a torque-proof fashion, for example at the housing of the injection device, a plurality of catch bodies are arranged, for example recesses extending in the axial direction and corresponding thereto protrusions extending in the axial direction, with

the number of catch bodies preferably being equivalent to the number of catch projections which are formed on the facial sides of the catch elements of the rotary catch. Only when the catch bodies allow an axial advance of the actuator knob and the driven member coupled thereto can the adjusted dosage actually be administered.

[0014] Preferably the above-mentioned catch bodies generate an acoustic noise, particularly a clicking noise, which is particularly preferred synchronized with the acoustic noises, particularly clicking noises, generated by the rotary catch so that the angular position of the catch bodies are in particular essentially equivalent to the angular positions of the catch projections and/or catch recesses of the rotary catch.

[0015] According to a preferred embodiment a second return element is provided which pushes an ampule holder, which forms for example a first catch element, e.g. a lower disk of the rotary catch or is coupled thereto, axially in the direction of the actuator knob such that the rotary catch engages, with in the engaged position of the rotary catch the catching projections essentially cooperating with the catch recesses embodied correspondingly, for example engaging them almost completely. The second return means can be located for example between the rear part of the injection device, where the manually driven actuator is located, and the ampule holder.

[0016] It is particularly preferred when the return force of the second return element is lower than the one of the first return element so that the rotary catch is not supported stiffly but rather in an elastic fashion, so that the catch elements of the rotary catch, brought into mutual contacting by the return elements, snap back in an elastic fashion when the catching projections glide along the catch recesses, which allows to better hear the acoustic noise generated.

[0017] The present invention is applicable in general for the device described in EP 0 581 924 B1, although the present invention is generally not limited to the specific embodiment described there. In such an embodiment a drive element, at which the driven element is supported in an articulate fashion, can be guided axially, i.e. in the direction of advance of the piston, from a resting position over a distance defined by the mechanics to a frontal end position. Over a portion of the predefined distance the driven member is not in contact with the piston of the product container. Over the remaining part of the predetermined distance the driven member is in contact with the piston plug, so that the piston is axially moved during the further advance of the driven member by the remaining part of the predefined distance such that a product, particularly a liquid, is dispensed from the product container. After the product has been dispensed the driven member is returned into the resting position with the help of a return means. During the renewed axial movement of the driven member by the distance adjusted for the previous injection, since the driven member cannot contact the piston, no additional product can be dispensed from the product container.

[0018] The dosing occurs in this embodiment as follows: In the resting position the actuator knob is rotatable. When rotating the actuator knob in the resting position, for example clockwise, the driven member which is not in contact with the piston is axially advanced in a controlled fashion, which shortens the distance between the driven member and the piston. The distance by which the space between the driven member and the piston is shortened when the operating knob is rotated, is equivalent to the distance during which the driven member comes into contact with the piston when advanced to the frontal end position, in order to dispense another product dosage from the product container. The rotary angle by which the actuator knob is rotated in the first direction, for example clockwise, therefore unambiguously defines the product dosage to be dispensed.

[0019] In the following, preferred exemplary embodiments are described based on the attached drawings, in which:

[0020] **Fig.** 1 shows a longitudinal section through an injection device of prior art;

[0021] **Fig.** 2 shows in a longitudinal section schematically a rotary catch according to a first embodiment of the invention;

[0022] **Fig.** 3 shows in a layout schematically a second embodiment of the rotary catch according to the invention;

[0023] **Fig.** 4 shows the cross-section A-A of the injection device according to **Fig.** 1;

[0024] **Fig.** 5 shows the cross-section B-B of the injection device according to **Fig.** 1;

[0025] **Fig.** 6 shows the cross-section C-C of the injection device according to **Fig.** 1;

[0026] **Fig.** 7 shows in an enlarged illustration the detail D of the layout according to **Fig.** 3; and

[0027] **Fig.** 8 shows the layout according to **Fig.** 3 in three different angular positions of the actuator knob of the injection device according to the invention.

[0028] In the figures, identical reference characters mark identical elements or elements or functional groups with essentially the same function.

[0029] In order to better illustrate an injection device according to the invention, in the following first the injection device is described as shown in **Fig.** 1 in a longitudinal section, which is known from **Fig.** 2 of EP 0 581 924 B1 of the applicant. However, the present invention is not limited to this particular embodiment. The injection device comprises in a front part **2**an exchangeable ampule **4,** in which a piston **5** is located in an axially displaceable fashion, which dispenses the substance stored in the ampule, which preferably comprises a medicinal or therapeutic effective agent, via an injection syringe **6**. In the rear part **3** the device comprises a manually operated, tubular actuator **7.**It houses an actuator knob **8,**a driven member, embodied essentially as a rod **9** with a flange **19,** a guide element **24** and a drive element **11.**

[0030] As shown in the cross-sections according to **Figs.** 4 to 6, the rod **9** shows at both sides planar surfaces and comprises for the rest a circular cross-section, which carries a thread. This thread rests in a mother thread **27** of the drive element **11,** which rests in the injection device in a torque-proof fashion. The drive element **11** can be transferred together with the entire actuator **7** via an axial operation of the actuator knob **8** and transfer of this movement via the guide element **24** against the force

of a spring **16** serving as a first return means from a (rear) resting position to a (frontal) end position. The rod **9** also performs this axial advance motion. Here, finally the flange **19** located at the rod **9** pushes against the piston **5** of the ampule **4,**pushes it forward, and this way triggers the injections.

[0031] The rod **9** is mounted torque-proof but axially mobile in the guide element **24,** which in turn is connected torque-proof to the actuator knob **8**. As shown in the cross-section according to **Fig. 4,**the guide element **24**comprises an interior contour, which (except for some potential tolerances) is adjusted to the exterior contour of the rod **9**, The actuator knob **8,** the guide element **24,** and the rod **9** allow only a rotation in the (rear) resting position of the actuator **7**. Here, the rod **9** rotates in the mother thread **27** of the drive element **11** arranged torque-proof in the injection device and this way moves forward, when the actuator knob **8** is rotated in a first rotary direction, for example clockwise. As shown in the following, in the status shown in **Fig.** 1 the actuator knob of prior art cannot be turned back in the opposite rotary direction, i.e. in the above-mentioned case in the counter-clockwise fashion.

[0032] As described above, the injection of the substance is caused by axially advancing the actuator knob **8** and the flange **19** serving as a driven member, to the frontal end position. The actuator knob and thus the flange **19** can here only be advanced by a uniform, predetermined distance, for example limited by stops in the direction of motion**7** and by the maximum stroke of the actuator knob **8**. When the actuator knob **8** is returned after an injection into the (rear) resting position, in another axial advance of the actuator knob **8** and the flange **19** no additional substance is dispensed from the ampule**4**. In order to dispense another dosage the flange **19** must be advanced by rotating the actuator knob **8** in the first rotary direction over a distance appropriate for the dosage to be administered so that the distance between the flange **19** serving as the driven member and the piston **5** is shortened by this predeterminable distance. This way, in case of another advance of the actuator knob **8** and the flange **19,** serving as the driven member, the flange **19** at the end of its axial forward motion contacts the piston **5** and displaces it by the rotary motion of the actuator knob **8** over the adjusted distance axially forward such that a new dosage is dispensed from the ampule **4**, which is clearly defined by the rotation of the actuator knob **8**.

[0033] The tubular drive element **11** is connected to the actuator knob **8** in a torque-proof fashion. The axially mobile actuator knob **8** is rotational only in its (rear) resting position, namely according to EP 0 581 924 B1 only in a rotary direction, in order to trigger an axial advance of the flange **19**, serving as the driven member. Inside the drive element **11** the rod **9** is held, with its threaded parts engaging at the circular areas **13, 13'** the mother thread **27** of the drive element **11**. The rod **9** engages through the drive element **11** and the guide element **24**.The latter is connected fixed to the rear part **3**of the injection device and can perform neither an axial motion nor a rotary motion. The opening in the guide element **24** adjusted to the rod **9** causes that the rod **9** can perform only axial movements, but no rotary motions.

[0034] When the actuator knob **8** is manually advanced in the axial direction, it moves the drive element **11** up to its (frontal) end position, which is defined by a stop **31,**for example the drive element **11** at the guide element **24**. This axial motion is transferred to the rod **9** resting on the mother thread **27** of the drive element **11**, which can perform only axial motions but no rotary movements.

[0035] The axial movement is performed against the spring **16** serving as the first return element, which rests in a recess between the drive element **11** performing the axial motion and a sheath part **21** of the rotary catch **20** described in the following. The spring **18** returns the actuator device **7** back to the resting position.

[0036] Since the rod **9** is supported in the guide element **24** in a torque-proof fashion, the rotary motion performed for adjusting the next injection dosage at the actuator knob **8** cannot be transferred to the rod **9**. Rather, by the rotating mother thread **27** of the guide element **11** the rod **9** is driven via the threaded parts at the circular areas **13, 13'** (compare **Fig.** 4) in a torque-proof fashion axially to the front and this way the flange **19** is brought into the position which is equivalent to the next injection dosage to be administered. During the axial advance of the flange **19** the distance between the flange **19** and the piston **5** is reduced according to the distortion of the actuator knob **8**.

[0037] The stroke of the flange **19** from the (rear) resting position into the (frontal) end position of the actuator device **7** remains the same at all times and is equivalent to the constant distance by which the flange **19** is separated from the piston **5**before adjusting the injection dosage. By rotating the actuator knob **8** in the (rear) resting position this way the injection dosage to be administered can be adjusted in advance, i.e. prior to dispensing the product from the ampule**4**. By a controlled rotation of the actuator knob **8** in the first direction of rotation this way the injection dosage can be clearly defined.

[0038] In order to allow reliably adjusting the injection dosage even by ear based on acoustic sounds a two-part rotary catch is known from the generic EP 0 581 924 B1, which allows a distortion of the actuator knob **8** only in a first direction of rotation. Upon distorting the rotary catch the catch projections glide over catch recesses such that a defined acoustic sound, namely a clicking sound is generated for the unambiguous allocation to the rotary motion of the actuator knob **8**.

[0039] The rotary catch **20** rests generally between the torque-proof and the rotational parts of the injection device. The rotary catch **20** is schematically shown in a layout in **Fig.**7. According to EP 0 581 924 B1 the rotary catch **20** comprises two catch elements **21, 22** contacting each other in the resting position, which comprise a plurality of saw-tooth shaped catch projections and correspondingly embodied catch recesses arranged in regular angular distances, as shown in **Fig.** 7. The catch element **22** is equivalent to the ampule holder **29**or is mechanically coupled thereto. The catch element **21** is equivalent to a sheath part of the tubular drive element **11**, which is torque-proof with the actuator knob **8** and rotationally supported.

[0040] When rotating the two catch elements **21, 22** in reference to each other, the saw-tooth shaped catch projections glide over the correspondingly embodied

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