pawls of the coupling mechanism toward and inter engagement with the cylindrical extension of the syringe plunger.

As the advancing pawls initially enter the cavity of plunger extension, their forward ends are forced toward one another by the walls of the cavity, overcoming the outward bias of the springs. In order to eliminate an initial clearance between plunger and drive ram, the pawls have to fully enter the cavity to grip the knurled wall of the cavity. Henceforward, the syringe plunger and drive ram will move in a cooperated motion.

These known solutions feature the common drawback, that for elimination of axial clearance between piston rod and piston, the piston rod has to be axially shifted. Axial clearance- and backslash elimination implies to bring the piston rod in direct abutment position with a cartridge's piston. Such axial displacement of the piston rod for the purpose of clearance elimination is regarded as disadvantageous, because it typically involves a respective actuation of dose setting or dose dispensing means by the user.

Object of the Invention

Embodiments~~It is therefore an object~~ of the present invention seek to provide a drive mechanism for a drug delivery device featuring improved and facilitated clearance and manufacturing tolerance elimination. An embodiment~~It is a further object~~ of the invention provides to redundantize a priming procedure to be conducted by the end user. The invention further focuses on improvements related to patient safety and intends to simplify the general device handling. It is a further object of the invention, to provide a drive mechanism for a drug delivery device with clearance eliminating means being inexpensive to produce and being easy to assemble. Finally, a further embodiment~~it is an object~~ of the invention ~~to~~ provides a method of eliminating clearance in a drive mechanism of a drug delivery device.

Summary of the Invention

In a first aspect, ~~the invention provides a drive mechanism for~~ a drug delivery device for dispensing of a dose of a medicinal product, typically a medicinal fluid, such as a fluid drug is provided. The drug delivery device comprises a housing, a cartridge comprising the medicinal product, and a drive mechanism.

The drive mechanism comprises a holder for the~~a~~ product-containing cartridge comprising the medicinal product, wherein the cartridge has a piston being slidably arranged therein in an axial direction. The drive mechanism further comprises a piston rod to be operably engaged with the cartridge's piston for dispensing of a well-defined dose of the medicinal product. With a distal outlet, the container may be engaged with a needle, a cannula, an infusion tube or similar delivery devices in a fluid-transferring way. The cartridge itself may be designed as replaceable or disposable ampoule, carpule or syringe. Its piston is displaceable in distal direction for purging or expelling a pre-defined dose of medicinal product from the container in an accurate way.

The drive mechanism further comprises at least one adjusting member being axially displaceable or being slidably arranged in axial direction relative to the piston and/or relative to the piston rod and/or a proximal end. The adjusting member serves to eliminate axial clearance between the piston and the piston rod, that might be due to manufacturing or assembly tolerances of the drive mechanism, the drug delivery device and their various components. The adjusting member is attached to a proximal end of the piston or is pre-assembled to a distal portion of the piston rod and further comprises a receptacle to receive a distal portion of the piston rod.

The drive mechanism is further provided with an interlock means adapted to interact with the adjusting member for mutually locking in position ~~the piston and~~ the piston rod's distal portion in place at an arbitrary position inside the adjusting member's receptacle to establish a mechanical coupling rigid in compression of piston rod and piston, irrespective of the relative distance between piston and piston rod. In this way, interaction of adjusting member and interlock means effectively provides a clearance- or backslash-elimination, wherein the piston rod itself may remain stationary, e.g. with respect to the cartridge or with respect to a housing component of the drug delivery device.

In a further aspect, the interlock means is accordingly adapted to lock the piston rod's distal portion in place at an arbitrary position inside the adjusting member's receptacle to establish a mechanical coupling rigid in compression of piston rod and piston irrespective of a relative distance between piston and piston rod. Therefore, the interlock means may be designed as positive, frictional or adhesive lock, adapted to lock in position the adjusting member's receptacle and the piston rod irrespective of their mutual distance, as soon as piston and piston rod are axially offset within certain limits, governed by the size of the receptacle.

In a further embodiment, the adjusting member's receptacle and the distal portion of the piston rod are mutually bonded or welded, e.g. by means of an appropriate adhesive or by means of deposition of energy in a region, where receptacle and piston rod overlap in radial direction. Energy deposition for the purpose of mutually welding the adjusting member and the piston rod's distal portion can for instance be provided by electromagnetic radiation, e.g. by laser irradiation of the respective portions.

According to a further embodiment, a deformable adhesive disposed in the adjusting member's receptacle is adapted to provide a clearance-eliminating axial displacement of piston rod and adjusting member, especially during assembly and manufacture of the drive mechanism and/or the drug delivery device. The interlocking of the adjusting member and the piston rod is then achieved in a second step by curing of said adhesive. The curing of said adhesive and hence the immobilization and mutual interlocking of adjusting member and piston rod can be supported or triggered by energy deposition, e.g. by means of irradiation with electromagnetic radiation or by application of thermal energy.

Typically, in this embodiment, the receptacle is only partially filled with the plastically deformable adhesive, such that the piston rod's distal portion is at least partially insertable into said receptacle. Furthermore, it is of advantage, when the piston rod's cross-sectional area is substantially smaller than the corresponding cross-sectional area of the receptacle. Preferably, upon insertion of the piston rod's distal end into said receptacle, at least one circumferential gap between an

adjustment step, the adjustment sleeve may still be subject to the spring-induced rotational movement. As a consequence, the adjusting sleeve may rotate and axially shift with respect to both receptacles of piston rod and adjusting member until a predefined spring deflection is depleted.

Due to the self-locking property of the threaded engagement of adjustment sleeve and receptacles of adjusting member and piston rod, an additional axial interlock becomes superfluous. The inventive interlock means is then provided by the self-locking threaded interaction of adjusting member, adjustment sleeve and piston rod.

In another aspect, the invention provides a drug delivery device for dispensing of a dose of a medicinal product comprising a housing, a cartridge filed with the medicinal product to be dispensed, e.g. insulin, and further comprising the drive mechanism according to the present invention.

In a further aspect, the housing of the drug delivery device comprise a through opening or at least a transparent window for delivery of an adhesive or for the delivery of energy adapted for curing of adhesive disposed between the adjusting member's receptacle and the piston rod's distal portion. In case the housing comprises a transparent window, especially for the deposition of electromagnetic radiation, said window is preferably substantially transparent for the electromagnetic radiation to be used. Said radiation is intended for e.g. curing of an adhesive or for directly welding and/or interlocking of piston rod and adjusting member.

In another aspect, there is provided a method of eliminating clearance between a piston and a piston rod in a drive mechanism in accordance with any of the above-mentioned aspects.

Additionally or alternatively, the through opening of the housing may be adapted to provide access to an interlock mechanism by means of an applicable tool to be inserted into said through opening for engagement and actuation of the interlock mechanism.

Claims

1. A drug delivery device for dispensing of a dose of a medicinal product, comprising:

- a housing ~~(12, 14; 42; 72, 74)~~,

- a cartridge ~~(16)~~ comprising the medicinal product, the cartridge ~~(16)~~ further comprising a piston ~~(18)~~ slidably arranged therein in an axial direction,

- a drive mechanism for a drug delivery device for dispensing of a dose of a medicinal product, the drive mechanism comprising:

- a holder ~~(14)~~ for the cartridge ~~(16)~~,

- a piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ to be operably engaged with the cartridge's piston ~~(18)~~ for dispensing of a dose of the medicinal product, characterized by:

- at least one adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ displaceably arranged in axial direction relative to the piston ~~(18)~~ and/or relative to the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ for eliminating axial clearance ~~(34)~~ between the piston ~~(18)~~ and the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~, wherein the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ is attached to a proximal end of the piston ~~(18)~~ or is pre-assembled to a distal portion of the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ and further comprises a receptacle to receive a distal portion ~~(22; 49; 55; 68, 69; 84)~~ of the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~,

- an interlock means ~~(24; 58; 66; 80; 100)~~ adapted to interact with the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ for locking the piston rod's ~~(26; 48; 52; 62; 76; 92; 116)~~ distal portion ~~(22; 49; 55; 68, 69; 84)~~ in place at an arbitrary position inside the adjusting member's ~~(20; 46; 54; 64; 78; 90; 112)~~ receptacle to establish a mechanical coupling rigid in compression of piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ and piston ~~(18)~~ irrespective of a relative distance between piston ~~(18)~~ and piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~.

2. The drug delivery device according to claim 1, wherein the interlock means ~~(24; 58; 66; 80; 100)~~ is adapted to provide a retention force substantially larger than an axial force required to displace the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ and/or the piston ~~(18)~~.

3. The drug delivery device according to any one of the preceding claims, wherein the interlock means ~~(24; 58; 66; 80; 100)~~ is designed as positive, frictional or adhesive lock.

4. The drug delivery device according to any one of the preceding claims, wherein the adjusting member's ~~(46; 54)~~ receptacle and a distal portion ~~(49; 55)~~ of the piston rod ~~(48; 52)~~ are bonded or welded.

5. The drug delivery device according to any one of the preceding claims, wherein a deformable adhesive ~~(58)~~ disposed in the adjusting member's ~~(54)~~ receptacle is adapted to provide a clearance-eliminating axial displacement of piston rod ~~(52)~~ and adjusting member ~~(54)~~, and wherein the adjusting member ~~(54)~~ and the piston rod ~~(52)~~ are to be mutually interlocked by curing of said adhesive ~~(58)~~.

6. The drug delivery device according to claim 4 or 5, wherein in a pre-assembly configuration, the adjusting member ~~(54)~~ is pre-assembled to the distal portion ~~(55)~~ of the piston rod ~~(52)~~ by means of the deformable nun-cured adhesive ~~(58)~~.

7. The drug delivery device according to claim 5, wherein in a pre-assembly configuration, the adjusting member ~~(54)~~ comprises a first adhesive component and the piston rod ~~(52)~~ at its distal portion ~~(55)~~ comprises a second adhesive component of a two-component adhesive ~~(58)~~.

8. The drug delivery device according to any one of the preceding claims, wherein the interlock means ~~(24; 66; 80)~~ is adapted to radially clamp the adjusting member's ~~(20; 46; 64; 78)~~ receptacle and the piston rod's ~~(26; 48; 62; 76)~~ distal portion ~~(22; 49; 84)~~.

9. The drug delivery device according to any one of the preceding claims, wherein piston rod ~~(26)~~ at its distal portion comprises at least one radially

movable jaw ~~(22)~~ to interact with the adjusting member's receptacle ~~(20)~~, wherein the jaw ~~(22)~~ has a slanted inner surface to engage with a correspondingly slanted surface ~~(28)~~ of an axially movable lock rod ~~(24)~~.

10. The drug delivery device according to any one of the preceding claims 1 to 8, wherein the interlock means comprises an eccentrically supported clamping member ~~(66)~~ to mutually clamp the adjusting member ~~(64)~~ and the piston rod ~~(62)~~.

11. The drug delivery device according to any one of the preceding claims 1 to 8, wherein the interlock means comprises a blocking ring ~~(80)~~ arranged on the outer circumference of the piston rod's ~~(76)~~ distal portion ~~(84)~~ to radially prop against an inside facing wall of the adjusting member's receptacle ~~(78)~~, wherein the blocking ring ~~(80)~~ is further adapted to impede an axial movement of piston rod ~~(76)~~ and adjusting member ~~(78)~~ towards each other.

12. The drug delivery device according to any one of the preceding claims, wherein the piston rod ~~(26; 48; 62; 76)~~ comprises a hollow shaft adapted for axial insertion of a lock rod ~~(24; 82)~~ for activating a locked mode or for eliminating axial clearance.

13. The drug delivery device according to any one of the preceding claims, wherein the adjusting member ~~(90; 112)~~ and the piston rod ~~(92; 116)~~ are threadedly engaged and rotatably biased by a spring member ~~(98; 126)~~.

14. The drug delivery device according to claim 13, wherein an interlock member ~~(100)~~ movably arranged in radial direction at the piston rod ~~(92)~~ radially engages with a corresponding recess at an inner surface of the adjusting member ~~(90)~~ for selectively releasing and/or interlocking of a clearance-eliminating relative rotation between piston rod ~~(92)~~ and adjusting member.

~~(90).~~

15. The drug delivery device according to claim 13, wherein the adjusting member ~~(112)~~ and the distal portion of the piston rod ~~(116)~~ comprise threaded receptacles ~~(128, 130)~~ facing towards each other, wherein the receptacles ~~(128, 130)~~ are threadedly engaged by means of a threaded adjustment sleeve ~~(114)~~, rotatably biased by the spring member ~~(126)~~ relative to the piston rod ~~(116)~~ or relative to the adjusting member ~~(112)~~.

16. The drug delivery device according to any one of the preceding claims 13 to 15, wherein the threaded engagement of adjusting member ~~(90; 112)~~, adjusting sleeve ~~(114)~~ and/or piston rod ~~(92; 116)~~ is of self-locking type.

17. The drug delivery device according to any one of the preceding claims, wherein the housing ~~(42)~~ comprises a through opening ~~(44)~~ or a transparent window to deliver an adhesive or an electromagnetic radiation for locking in position of piston ~~(18)~~ and piston rod ~~(48)~~.

18. A method of eliminating clearance ~~(34)~~ between a piston ~~(18)~~ and a piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ in a drive mechanism of a drug delivery device ~~(10; 40; 60; 70)~~, wherein the drive mechanism comprises a holder ~~(14, 74)~~ for a product-containing cartridge ~~(16)~~ having a piston ~~(18)~~ slidably arranged therein in an axial direction, wherein the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ is to be operably engaged with the cartridge's piston ~~(18)~~ for dispensing of a dose of the medicinal product, further comprising an adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ attached to a proximal end

of the piston ~~(18)~~ or being pre-assembled to a distal portion of the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~, wherein the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ comprises a receptacle to receive a distal portion ~~(22; 49; 55; 68, 69; 84)~~ of the piston rod ~~(26; 48; 52; 62; 76)~~, the method of eliminating said clearance ~~(34)~~ during or after assembly of the drive mechanism is characterized by the steps of:

- axially moving of the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ relative to the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ and/or axially moving the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ relative to the piston ~~(18)~~ for eliminating axial clearance ~~(34)~~ between the piston ~~(18)~~ and the piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~,

- locking the piston rod's ~~(26; 48; 52; 62; 76; 92; 116)~~ distal portion ~~(22; 49; 55; 68, 69; 84)~~ in place at an arbitrary position inside the adjusting member's ~~(220; 46; 54; 64; 78; 90; 112)~~ receptacle by an interlock means ~~(24; 58; 66; 80; 100)~~ adapted to interact with the adjusting member ~~(20; 46; 54; 64; 78; 90; 112)~~ and

- establishing a mechanical coupling rigid in compression of piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ and piston ~~(18)~~ irrespective of a relative distance between piston ~~(18)~~ and piston rod ~~(26; 48; 52; 62; 76; 92; 116)~~ by means of the interlock means ~~(24; 58; 66; 80; 100)~~.