

Deformable pre-packaged device for injecting a liquid

[001] The present invention relates to a deformable pre-packaged device for injecting a liquid.

Background art

[002] Currently, sterile powdered raw materials are mainly packaged by active ingredient manufacturers in aluminum containers, or in plastic bags, generally based on polyethylene.

[003] In order to market them, the producers have shown that each of the raw materials, in addition to maintaining sterility, remains stable inside the containers or bags used for a certain period of time; in other words, such powders do not degrade, for a predefined number of years, if stored in such containers or bags.

[004] The sterile raw materials are sold to the producers of the finished pharmaceutical product, who see to the fractionation using known technologies, placing the finished sterile powder product contained in a bottle on the market. The bottle is accompanied by solvent.

[005] The use of valuable materials for the vial (glass), of compatible materials for the sterile powder, the use of disposable syringes, make this system globally very expensive.

[006] It is known in the field to use syringes provided with a compartment for receiving a deformable cartridge, made of flexible material, containing

pharmaceutical substances kept separate in respective containment chambers until the moment of use by a special yielding partition. An example of such known devices is described in patent document US2001/0047162. A further example of such known devices is described in patent document W02017137854 A1.

[007] However, it has been observed that in the deformable cartridges of the prior art it is particularly difficult to maintain a high degree of isolation between the various containment chambers. This is particularly problematic if the containment chambers of the deformable cartridge are filled with mutually different substances, for example a solid substance and a liquid substance or for example two substances which, if accidentally mixed together earlier than expected, cause a stability loss of the active ingredients thereof.

[008] Patent document WO 2020/070576 to the Applicant, shown in Fig. 1, provides a solution by means of the deformable cartridge P1 which has a cartridge body P10, P20 comprising (Fig. 1(a)):

- at least a first containment chamber P11 of a first component of the injectable solution, in which the first containment chamber P11 comprises at least a first wall deformable by compression;
- at least a second containment chamber P21 of a second component of the injectable solution, in which the second containment chamber P21 comprises at least a second wall deformable by compression so as to allow the transfer of the second component from the second containment chamber P21 to the first containment chamber

P11, thus achieving the mixing of the first component and the second component; and

- a needle P5 connected to the first containment chamber P11.

[0009] As shown in Fig. 1(b), such a device P1 is to be used with a specific tool P200 to deform the chambers so as to mix the components and the simultaneous injection. This involves the production of a specific element and therefore a considerable investment in molds and materials, as well as a certain difficulty of use by the operator who performs the injection.

[0010] In particular, with regard to the difficulty of use, it is not only a question of the use of the specific tool for crushing the chambers, but also the fact that the operator or nurse will have a reduced sensitivity in pointing and inserting the needle with respect to what is obtainable by means of traditional syringes in which the mixture to be injected is sucked and the syringe held with only one hand.

[0011] Document WO 2019/246435 concerns a bellows device for ejecting a liquid substance, comprising two chambers, which are not separately crushable and therefore which are not adapted to separately store and reconstitute a substance starting from two components.

Purpose and object of the invention

[0012] It is the object of the present invention to provide a deformable pre-packaged device for injecting a liquid which at least partially solves the problems and overcomes the disadvantages of the prior art.

[0013] The present invention relates to a device and a corresponding kit according to the appended claims.

Detailed description of embodiments of the invention

List of drawings

[0014] The invention will now be described by way of non-limiting example, with particular reference to the figures of the accompanying drawings, in which:

- figure 1 shows a reconstitution and injection device according to the prior art;
- figure 2 shows a vertical sectional view of an embodiment of the invention;
- figure 3 shows the device in Fig. 2 in successive steps of use (a)-(d);
- figure 4 shows the same device in the same steps as in Fig. 3, but not in section.

[0015] It is worth noting that hereinafter elements of different embodiments may be combined together to provide further embodiments without restrictions respecting the technical concept of the invention, as those skilled in the art will effortlessly understand from the description.

[0016] The present description also refers to the prior art for the implementation thereof, with regard to the detail features which are not described, such as elements of minor importance usually used in the prior art in solutions of the same type.

[0017] When an element is introduced, it is always understood that there may be "at least one" or "one or more".

[0018] When a list of elements or features is given in this description, it is understood that the finding according to the invention "comprises" or alternatively "consists of" such elements.

[0019] When "upper" and "lower" are mentioned, reference is made to the next location along an axis, which will be specified. In particular, "lower" means a location farther away from the outlet of a fluid from a containment element and "upper" means a location closer to the outlet of a fluid from a containment element.

Embodiments

[0020] With reference to Figure 2, in an embodiment, the injection device 100 of the invention comprises:

- a first containment chamber 40 for a first component of a liquid mixture to be injected;
- a second containment chamber 30 for a second component (for example in powder form, in the drawings rendered with the dotted line) of the liquid mixture to be injected;

which are fluidly connected by (rigid or semi-rigid) mechanical and fluidic connection means 33, 43.

[0021] In greater detail, such (first) mechanical and fluidic connection means can consist of a rigid or semi-rigid tubular outlet element (or "neck") 43 connected to (or formed in one piece with) the first containment chamber 40, and a tubular inlet element 33 connected to

(or formed in one piece with) the second containment chamber 30.

[0022] A one-way valve can optionally be added to one of the elements 33 or 43 so as to allow the passage of the liquid from the chamber 40 and the retention thereof in the chamber 30.

[0023] The tubular outlet element 43 and the tubular inlet element 33 are provided with appropriate mutual mechanical coupling means (not shown), preferably watertight (without fluid leaks). The tubular elements 33 and 43 can have any section, as long as the fluidic connection can be made in a watertight manner. When the first containment chamber and the second containment chamber are provided, separated, in an injection kit (optionally also comprising the needle, it being possible to provide other means of administration or discharge of the mixture such as tubes), such tubular elements can comprise breakable or openable or removable watertight closing elements, such as peelable partitions.

[0024] The second containment chamber also comprises a tubular outlet element 20 (also referred to as "second mechanical and fluidic connection means") configured so that an injection needle 10 can be fixed thereto (in a watertight manner, i.e., without fluidic communication with the outside). When the second containment chamber is provided in the above kit, the tubular element (or the second mechanical and fluidic connection means) is provided with a removable watertight closing element, such as a peelable partition.

[0025] As mentioned, the first 40 and the second 30 containment chambers are configured so that they can be stored separately, therefore with the tubular elements 33 and 43 detached, and joined when the injection is to be made (see Figures 3 (a) and 4 (a)). The combination of the elements 33 and 43 can occur in any known manner, for example by means of threading and/or breakable membranes.

[0026] One or both of the tubular elements 33 and 43 can comprise a filter and/or a valve, for example a valve adapted to allow a one-way flow of said first component of the liquid mixture.

[0027] The first mechanical and fluidic connection means 43,33 comprise an outlet neck of said first containment chamber 40 and an inlet neck of said second containment chamber 30 connected to form a single fluidic connection duct; and

[0028] Said single fluidic connection duct is such as to keep said first lower surface 42 and said second lower surface 32 at a distance configured to be larger than the section of a finger. The section of a finger can be standardized to a size such as to comprise all human fingers or most of them.

[0029] The first containment chamber 40 preferably has, in vertical section (plane x-y of the sheet), a diamond shape or cone section or truncated cone section. For example, in the first containment chamber 40, the angle β between the upper 41 and lower 42 sides (on one side as well as on the other side of the diamond in the direction x) has a predetermined (non-zero) value before

the use of the device. The same applies to the lower tip angle (vertex of the cone 45) γ between two sides 42 (on one side as well as on the other side of the diamond in the direction x), with the pre-determined (non-zero) value thereof before the use of the syringe 100. The upper tip angle (in the direction y) may not exist in this case, because the tubular outlet element 43 is fixed in the position of such vertices. In reality, the lower tip 45 may not exist as well, as a flat or other shaped part may be formed, on which the thumb will push, as explained below.

[0030] The second containment chamber 30 also has a diamond shape, and in this case the angle α between the upper 31 and lower 32 sides (on one side as well as on the other side of the diamond in the direction x) has a predetermined value thereof before the use of the device. The lower or upper tip angle may not exist in this case, because the tubular inlet 33 and outlet 20 elements are fixed in the position of such vertices.

[0031] In the above, it is understood that the shape of the containment chamber has, in the volume device, a circular extension along an axis of symmetry S (in the direction y) of the syringe 100, i.e., the section is rotated by 180° to obtain the volume of the containment chambers (or each corresponding upper and lower side is rotated by 360°), to obtain an overall shape which corresponds to the combination of two cones with opposite vertices (or truncated cones or the like) along a common base 44 or 34.

[0032] Furthermore, the surfaces obtained from the above rotation do not necessarily have a perfectly conical shape, but can be more or less rounded, because this does not much change the functionality thereof.

[0033] In fact, the double cone shape (diamond or the like in section) has a very specific function, namely that of allowing the containment chambers to be crushed with the fingers according to determined steps illustrated without limitation in Figures 3 and 4.

[0034] Specifically, according to an embodiment of the present invention, after the mechanical and fluidic joining of the first and second containment chambers 40 and 30 (Figures 3(b) and 4(b)), the operator (or nurse) who must perform the parenteral (or other) administration places the index and middle fingers (or two fingers other than the thumb) of a hand above the diamond 40 (on the sides 41) while pressing the lower surface of the diamond with the thumb (sides 42, see also the arrows in the figure) until the latter are crushed against the former, making the angle γ an angle approximately equal to $180^\circ - \gamma$, and thus allowing the liquid component of the first containment chamber to enter the second containment chamber. Since the material of the diamond 40 is inelastically deformable (deformable by compression), such crushing will remain even after loosening the thrust between the index and middle fingers on one side and thumb on the other. This will allow (Fig. 3/4(d)) to reposition the index and middle fingers (or the other two fingers other than the thumb) again on the upper surface of the containment

chamber 30, i.e., on the sides 31 in section, while the thumb will be able to continue pushing in the same position as before. Similarly to the previous step, the lower surface of the containment chamber 30 (walls 32 in section) will be pressed (see the arrows in the figure) against the corresponding upper surface (walls 31 in section). Here, as well, the material used will allow inelastic deformation, so as to ensure the safety of the injection.

[0035] According to an aspect of the invention, said first lower surface 42 and said second lower surface 32 in the device 100 are made of an inelastically deformable material. In particular, the inelastically deformable material is such as to allow a total crushing of said first lower surface 42 and said second lower surface 32 against said first upper surface 41 and second upper surface 31, respectively in the various steps of reconstituting and ejecting the mixture. The deformability is separately ensured for each chamber 40 and 30.

[0036] The needle 10 of the syringe 100 can be conveniently introduced into the body to receive the administration after step (c) in the figures, or after the two components in the two containment chambers have been reconstituted in the first containment chamber. Obviously, the corresponding initial filling of the two containment chambers (and therefore the sizing thereof) will be such as to perform the whole operation.

[0037] According to an aspect of the invention, a method for reconstituting a reconstitutable liquid

mixture and ejecting it from an injection needle is provided, comprising the following successive steps:

- providing the device according to the invention;
- positioning two fingers on said first upper surface 41 and the thumb against said first lower surface 42;
- crushing said lower surface 42 against said first upper surface 41 bringing the thumb closer to said two fingers;
- positioning two fingers on said second upper surface 31 and the thumb against said first lower surface 42; and
- crushing said second upper surface 31 against said second lower surface 32 bringing the thumb closer to said two fingers.

Advantages of the invention

[0038] By virtue of the solution of the invention, it is possible to store two components of a mixture to be injected, in two separate connectable devices, and to reconstitute the syringe and the mixture at the time of injection.

[0039] This is done, by virtue of the invention, without having to use any device other than the syringe itself, since the means for crushing the containment chambers of the two components are integrated in the syringe itself.

[0040] Such a solution allows to save the costs of the molds and the production of the separate crushing and reconstitution means, as well as simplify the

reconstitution and injection operations. In particular, with the device according to the invention the operator or nurse will have a needle pointing and insertion sensitivity which is similar to or better than that obtainable by means of traditional syringes into which the mixture to be injected is sucked.

[0041] The preferred embodiments and possible variants of the present invention have been outlined above, but it is to be understood that those skilled in the art may make modifications and changes without thereby departing from the scope of protection thereof, as defined in the appended claims.

CLAIMS

1. A device (100) for injecting a reconstitutable liquid mixture, comprising:

- a first containment chamber (40) for a first component of the liquid mixture;
- at least a second containment chamber (30) for a second component of the liquid mixture,
- first mechanical and fluidic connection means (43,33) between said first (40) and said second (30) containment chambers;
- second mechanical and fluidic connection means (20) between said second containment chamber (30) and an injection needle (10);

the device (100) being characterized in that:

- said first containment chamber (40) comprises, along a mixture injection direction (y), a first upper surface (41) and a first lower surface (42), in the shape of a cone or truncated cone, substantially having the same axis of symmetry (S) and a common base circumference (44);
- said first upper surface (41) and said first lower surface (42) have extensions in opposite directions along said axis of symmetry (S) and form a non-zero angle β therebetween at the common base (44);
- said second containment chamber (30) comprises, along said mixture injection direction (y), a second upper surface (31) and a second lower surface (32), in the shape of a cone or truncated cone,

both substantially having said axis of symmetry (S) and a common base circumference (34),

- said second upper surface (31) and said second lower surface (32) have extensions in opposite directions along said axis of symmetry (S) and form a non-zero angle α therebetween at the common base (34);
- said first lower surface (42) and said second lower surface (32) are separately deformable by compression;

and in that:

- said first mechanical and fluidic connection means (43,33) comprise an outlet neck of said first containment chamber (40) and an inlet neck of said second containment chamber (30) connected to form a single fluidic connection duct; and
- said single fluidic connection duct is such as to keep said first lower surface (42) and said second lower surface (32) at a distance configured to be larger than the section of a finger.

2. A device (100) according to claim 1, wherein said first mechanical and fluidic connection means (43,33) comprise a filter and/or a valve.

3. A device (100) according to claim 2, wherein said first mechanical and fluidic connection means (43,33) comprise a valve adapted to allow a one-way flow of said first component of the liquid mixture.

4. A device (100) according to one or more of claims 1 to 3, wherein said first upper surface (41) and said first lower surface (42) are formed in one piece.

5. A device (100) according to one or more of claims 1 to 4, wherein said second upper surface (31) and said second lower surface (32) are formed in one piece.

6. A device (100) according to one or more of claims 1 to 5, wherein said first lower surface (42) and said second lower surface (32) are made of an inelastically deformable material.

7. A device (100) according to claim 7, wherein said inelastically deformable material is such as to allow a total crushing of said first lower surface (42) and said second lower surface (32) against said first upper surface (41) and second upper surface (31), respectively.

8. An injection kit for injecting a reconstitutable liquid mixture, comprising:

- a first containment chamber (40) and a second separate containment chamber (30), as individually defined in one of claims 1 to 5;
- first mechanical and fluidic connection means (43,33) between the first containment chamber (40) and the second containment chamber (30) according to claim 1, wherein said outlet neck of said first containment chamber (40) and an inlet neck of said second

containment chamber (30) are configured to connect and form a single fluidic connection duct;

- second mechanical and fluidic connection means (20) between said second containment chamber (30) and an injection needle (10);
- said injection needle (10) which is connectable to said second containment chamber (30) by said second mechanical and fluidic connection means (20).

9. An injection kit according to claim 8, wherein said outlet neck of said first containment chamber (40) and an inlet neck of said second containment chamber (30) each comprise a removable or breakable or openable watertight closing element.

10. An injection kit according to claim 9, wherein the removable watertight closing element is a peelable partition.

11. An injection kit according to one or more of claims 8 to 10, wherein said second mechanical and fluidic connection means (20) comprise a removable watertight closing element.

12. A method for reconstituting a reconstitutible liquid mixture and ejecting it from an injection needle, comprising the following successive steps:

- providing the device according to one or more of claims 1 to 7;

- positioning two fingers on said first upper surface (41) and the thumb against said first lower surface (42);
- crushing said lower surface (42) against said first upper surface (41) bringing the thumb closer to said two fingers;
- positioning two fingers on said second upper surface (31) and the thumb against said first lower surface (42); and
- crushing said second upper surface (31) against said second lower surface (32) bringing the thumb closer to said two fingers.