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System for Preparing and Making Available
a Flowable Medium Formed by Mixing a
Dry Substance with a Fluid

The invention relates to a system for preparing and making available a flowable medium formed by mixing a dry substance with a fluid, in particular a medium for therapeutic purposes.

Fluid media which are intended, for example, for therapeutic purposes or also for other purposes must often be freshly prepared close to the time they are actually to be used, because only the components which form the medium are inherently stable and/or storable enough, but not the ultimately prepared medium. In practical applications therefore it is often necessary to store a dry substance and a fluid separately from one another until the use of the medium formed from a mixture of the dry substance and the fluid is imminent.

Generally the procedure followed here is such that the fluid, for example, a solvent, is taken up by means of a hypodermic needle and injected into a container which contains the dry substance. Afterwards the resulting solution is removed with a new syringe in order to be applied or administered in the desired manner; in therapeutic applications this can take place, for example, by injection, placement as an additive in an infusion container or the like.

Such application processes, in which injection needles are used, entail the risk that injuries can occur. This circumstance is extremely problematical when working in an environment in which the presence of HIV viruses can be expected.

In this respect, embodiments of the invention seek to provide a system for preparing and making available a flowable medium which is formed by mixing a dry substance with a fluid, which is characterized by improved handling safety.

According to an aspect of the invention, there is provided a system for preparing and making available a flowable medium formed by mixing a dry substance with a fluid, in particular a medium for therapeutic purposes, with the following system components: a) a first container which holds the fluid with a wall part which can be deformed against a restoring force to change the volume; b) a second container which holds the dry substance and c) a transfer device for producing a fluid connection between the first and second container; wherein the wall part of the first container which can be deformed against the restoring force is formed by a bellows which has an inherent restoring force against deformation; wherein the first container for its connection to the transfer device on one end of the bellows has a head part on which catch means are provided for forming a catch with the catch means which are present on an assigned connecting means of the transfer device; wherein the head part has a central, projecting connection piece whose end is normally closed by a removable closure part, preferably a twist-off toggle which is integral with the connection piece; and wherein the catch means of the head part are formed by arms which are integral with the head part and which extend along the outside of the connection piece with the formation of an intermediate space, on the free end regions of the arms catch bodies are molded which project in the direction to the connection piece and on which there are recessed catch notches.

Because, according to embodiments of the invention, there is a transfer device as the additional system component, the fluid exchange between the containers involved which is necessary for preparing and making available the medium takes place in a closed operating process, i.e., without separate handling of the individual containers themselves and drawing up a syringe from one container and injection of the withdrawn fluid into the other container having been necessary. Because the first container which holds the pertinent fluid has a wall part which can be deformed against a restoring force, the fluid from the first container can be forced by way of a transfer device into the second container which holds the dry substance so that in the latter container the dry substance is mixed with the fluid. When this has taken place, the deformable wall part of the first container is released, so that as a result of the restoring force acting on the first container its volume increases again and thus the prepared medium is intaken by way of the transfer device into the first container in which now the completely prepared medium is ready for use. The system according to embodiments of the invention, enables not only safe handling without the risk of injury, but moreover, as a result of the closed operating process also offers special protection against contamination.

Preferably the wall part which can be deformed against the restoring force is formed by a bellows which has an inherent restoring force against deformation. This container is preferably an

ampule-like plastic container which is produced using the known bottelpack® molding process and is filled with the pertinent fluid, and whose wall is provided with folds and is designed bellows-like such that it can be compressed in the axial direction in order to express the enclosed fluid. Such a bellows, which is formed from a suitable plastic material after the compressive force acting on it is removed, returns to its original shape in which the volume of the container is returned to its original size.

Preferably the first container for its connection to the transfer device on one end of the bellows can have a head part which is preferably molded onto the bellows in one piece, on the head part there being catch means for forming a catch with the catch means which are present on an assigned connecting means of the transfer device.

Preferably the arrangement can be such that the head part has a central, projecting connection piece whose end is normally closed by a removable closure part, preferably a twist-off toggle which is integral with the connection piece.

The catch means of the head part can be formed by arms which are integral with the head part and which extend along the outside of the connection piece with the formation of an intermediate space; on the free end regions of the arms catch bodies are molded which project in the direction to the connection piece and on which there are recessed catch notches.

In such a configuration of the head part and of the catch means of the first container, the connecting means of the transfer device assigned to this container can have a hollow connecting shank which, in order to form a plug connection with the connection piece of the first container, has an end-side widening as a seat for holding the connection piece which extends with its outside wall surface into the intermediate space between the arms which form the catch means of the head. In an especially simple manner, when the plug connection is formed by the holder of the connection piece

of the first container in the seat of the hollow connecting shank of the transfer device, a fluid-tight connection is formed with simultaneous mechanical connection by the interacting catch means.

As catch means which are provided on the connecting means of the transfer device there can be catch projections which are molded onto the outer wall surface of the connecting shank and which interact with the catch notches on the arms of the head part and thus ensure the plug connection which has been formed in this way.

In advantageous embodiments the transfer device in an extension of the connecting shank has a through channel whose end section as a component of the connecting means of the transfer device which is intended for the second container is formed by a projecting cannula, via which at the same time a fluid connection can be produced with the second container which contains the dry substance when the second container has a closure which can be penetrated by the cannula. Containers such as these, preferably in the form of small-volume glass bottles, are standard.

In especially advantageous embodiments, an additional system component can be a device which facilitates and simplifies joining the transfer device and the second container in the positional relationship which is provided for penetration of the closure by the cannula. For this purpose there can be a sleeve body which is open on one end and which on the other end has an end plate with a central through opening for the cannula of the transfer device, the sleeve body being designed such that it forms a guide for the second container which can be inserted into the sleeve body from the open end in the direction to the cannula. To implement the connection process, therefore the second container, for example, in the form of a small-volume glass bottle of the conventional type, need simply be pushed into the sleeve body after the transfer device has been inserted beforehand into the sleeve body through the central through opening of the end plate. This ensures that when the container is pushed into the sleeve body the cannula penetrates the central region, i.e., the region of the closure of the second container which can be penetrated.

In this configuration of the sleeve body, at the same time it forms a protective jacket of the inserted cannula. Although this cannula, in contrast to conventional injection needles, does not pose a significant injury risk, an additional improvement of handling safety is achieved by the jacketing.

The subject matter of the invention is also a container which is intended for use in the system according to embodiments of the invention and is characterized by the features specified in claim 8.

Another embodiment of this invention relates to the use of a system according to one of claims 1 to 7 and a container according to one of claims 8 to 11 for preparing and making available a flowable medium.

The invention will be detailed below using the drawings.

FIG. 1 shows a side view of a bellows ampule which is intended as the first container of the system, shown approximately in natural size,

FIG. 2 shows a detached view of only the region of the ampule from FIG. 1 adjacent to its head part, conversely turned 90° around the longitudinal axis of the ampule,

FIG. 3 shows a partial view solely of the region of the connecting piece provided with a Luer connection on the head part of the bellows ampule, which region is identified with arrow III in FIG. 1, and which view is shown detached and greatly enlarged relative to FIGS. 1 and 2;

FIG. 4 shows a representation of one embodiment of the system according to the invention drawn in a longitudinal section, the system components such as the bellows ampule from FIG. 1 being shown as a first container, a transfer device and a glass bottle as the second container being shown in positions pulled apart from one another;

- FIG. 5 shows a representation which corresponds to FIG. 4, but the system components being shown in the assembled position and in a state which corresponds to a first working step of the operating sequence;
- FIG. 6 shows a partial longitudinal section solely of the region designated as VI in FIG. 5, which is detached and greatly enlarged compared to FIG. 5;
- FIG. 7A, 7B and 7C show representations of the system which are similar to FIG. 5, the operating states which correspond to a second, third and fourth step of the operating sequence being shown;
- FIG. 8 shows a side view which is slightly enlarged relative to a practical embodiment, in which the second container, a sleeve body which is used as a connecting device, and only the end section of the transfer device which is adjacent to the second container are shown, and
- FIG. 9 shows a view corresponding to FIG. 8 in a representation which has been turned 90° relative thereto.

FIG. 1 shows a bellows ampule which is designated as a whole as 1 in the closed state which forms a component of the system according to the invention which is to be described here as the first container. The ampule 1 together with the bellows 3 which forms its actual receiving space, a head part 5 which adjoins it as a closure part, and with a twist-off toggle 7 which closes its outlet opening 9 (FIG. 3) is produced using the known bottelpack® process from plastic in one piece and is filled with a fluid. The plastic material used for production has a certain elastic property so that when the twist-off toggle 7 is removed, the bellows 3 can be compressed in the axial direction so that by a respective reduction of the volume the contained fluid can be expressed from the opening 9 (FIG. 3) on the connection piece 11. If the bellows 3 is released, due to the restoring force which is

dictated by its elasticity it returns to the original shape shown in FIG. 1, the interior of the bellows 3 again having the initial volume.

FIG. 3 shows the outside shape of the connection piece 11 of the head part 5, its being apparent that on the end region which is located on the opening 9 there is a Luer connection 13. As is likewise apparent from the figures, arms 15 are molded onto the head part 5 on both sides of the connection piece 11 and extend in the axial direction at a distance from the outside of the connection piece 11. In the vicinity of the end edges of these arms 14 there are recessed catch notches 17 which are intended for locking with a catch rib 19 which is located on a transfer device 21 which is used as another component of the system. Locking occurs when, proceeding from the operating state shown in FIG. 4, the twist-off toggle 7 of the bellows ampule 1 is removed and as the next step of the operating sequence a plug connection to the transfer device 21 is established, as is shown in FIG. 5. Details of the plug connection produced with the transfer device 21 are illustrated in FIG. 6 on a larger scale which shows the region identified with VI in FIG. 5. As is to be seen, the connection piece 11 in this instance is located on the head part 5 within a widened seat 23 in a hollow connection shank 25 of the transfer device 21, the connection piece 11 being suitably held in the seat 23, i.e., sealed. As is likewise apparent most clearly from FIG. 6, the catch rib 19 is located on the outside of the shank 25 in the vicinity of its free end. The arms 15 which have the catch notches 17 extend proceeding from the head part 5 over the outside of the shank 25 to above the catch rib 19 which snaps into the notches 17.

FIGS. 5, 7A, 7B, and 7C illustrate the continuing operating sequence in the use of the system according to the invention. As is apparent, the transfer device 21 in an extension of the seat 23 of the connecting shank 25 has an axial through channel 29 which extends through a thickened region 31 which forms a stop shoulder 32 (FIG. 4) and ends in an axially projecting cannula 33. A glass bottle 35 which acts as the second container of the system with a closure 37 which can be penetrated by a cannula 33 can be placed on the stop shoulder 32 so that the end of the cannula 33

extends into the interior of the bottle 35. When this is the case, and when a plug connection has been established between the bellows ampule 1 and the transfer device 21, by compressing the bellows 3 the fluid in the ampule 1 is expressed and forced into the bottle 35 by way of the transfer device 21. For preparing the medium to be produced, in the initial state which is shown in FIG. 4 the bottle contains, for example, a dry substance 39 to which the fluid, for example, a solvent 41, see FIG. 5, is added.

FIG. 7A shows as the next step the operating state in which after mixing the dry substance 39 with the solvent 41 the prepared medium 43 is in the bottle 35. In order to return the prepared medium from the bottle 35 by way of the transfer device 21 to the bellows ampule 1 so that the prepared medium is made available in it, as is shown in FIG. 7B, it is possible to proceed such that the system is turned around, whereupon, as is shown in FIG. 7C, the compressed bellows 3 is now released so that due to the increase of its volume the medium 43 is sucked back out of the bottle 35 into the bellows ampule 1, see FIG. 7C. After releasing the plug connection with the transfer device 21 the prepared medium is now made available in the ampule 1.

FIGS. 8 and 9 show a version of the system, there being a connection device in order to bring the bottle 35 which forms the second container easily and comfortably into defined alignment with the transfer device 21. One particular feature of the device is that at the same time it forms a protective jacket for the cannula 33 of the transfer device 35, as is apparent from FIGS. 8 and 9. These figures show that the bottle 35 with the cannula inserted is surrounded by the sleeve body 45 in the form of a hollow cylinder which is open on the end facing away from the transfer device 21, so that the bottle can be pushed into the sleeve body 45 in the axial direction from the open end and can be moved into a position in which the cannula 33 enters the bottle 35. The sleeve body 45 on the end which lies on the stop shoulder 32 of the transfer device 21 has an end plate 44 which surrounds the central through opening for the cannula 33.

As FIGS. 8 and 9 moreover show, in the wall of the sleeve body 45 notches 59 are cut out which extend elastically into the interior of the jacket 45. When the bottle 35 is pushed into the sleeve body 45, these wall parts on the bottle neck snap in behind the top part of the bottle 61 so that the bottle 35 which has been pushed into the sleeve body 45 is secured in position. The sleeve body 45 is preferably molded from a transparent plastic material so that when the system is being used the process of mixing of the fluid 41 and the dry substance can be visually observed.

C l a i m s

1. A system for preparing and making available a flowable medium formed by mixing a dry substance with a fluid, in particular a medium for therapeutic purposes, with the following system components:
 - a) a first container which holds the fluid with a wall part which can be deformed against a restoring force to change the volume;
 - b) a second container which holds the dry substance and
 - c) a transfer device for producing a fluid connection between the first and second container;wherein the wall part of the first container which can be deformed against the restoring force is formed by a bellows which has an inherent restoring force against deformation;

wherein the first container for its connection to the transfer device on one end of the bellows has a head part on which catch means are provided for forming a catch with the catch means which are present on an assigned connecting means of the transfer device;

wherein the head part has a central, projecting connection piece whose end is normally closed by a removable closure part, preferably a twist-off toggle which is integral with the connection piece; and

wherein the catch means of the head part are formed by arms which are integral with the head part and which extend along the outside of the connection piece with the formation of an intermediate space, on the free end regions of the arms catch bodies are molded which project in the direction to the connection piece and on which there are recessed catch notches.

2. The system according to claim 1, wherein the connecting means of the transfer device assigned to the first container has a hollow connecting shank which, in order to form a plug connection with the connection piece of the first container, has a end-side widening as a seat for holding the connection piece, the connection shank extending with its outside wall surface into the intermediate space between the arms which form the catch means of the head part.
3. The system according to claim 2, wherein on the outer wall surface of the connecting shank there is a catch rib as the catch means of the transfer device which interacts with the catch notches of the arms of the head part.
4. The system according to claim 2 or 3, wherein the transfer device in an extension of the connecting shank has a through channel whose end section as a component of the connecting means of the transfer device which is intended for the second container is formed by a projecting cannula.
5. The system according to claim 4, wherein the second container has a closure which can be penetrated by the cannula.

6. The system according to claim 5, characterized by a device for joining the transfer device and the second container in a positional relationship which is intended for penetration of the closure by the cannula.
7. The system according to claim 6, wherein the device has a sleeve body which is open on one end and on the other end has an end plate with a central through opening for the cannula of the transfer device and wherein the sleeve body forms a guide for the container which can be inserted into the sleeve body from the open end in the direction to the cannula.
8. A container for a system according to one of claims 1 to 7, wherein it has a wall part which can be deformed against the restoring force and which is formed by a bellows which has an inherent restoring force against deformation.
9. The container according to claim 8, wherein the container for its connection to the transfer device on one end of the bellows has a head part on which there are catch means for forming a catch with the catch means which are present on an assigned connecting means of the transfer device.
10. The container according to claim 9, wherein the head part has a central, projecting connection piece whose end is normally closed by a removable closure part, preferably a twist-off toggle which is integral with the connection piece.
11. The container according to claim 10, wherein the catch means of the head part are formed by arms which are integral with the head part and which extend along the outside of the connection piece with the formation of an intermediate space, on the free

end regions of the arms catch bodies are molded which project in the direction to the connection piece and on which there are recessed catch notches.