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Method for producing a filled and closed container
and device for carrying out the method and
container produced thereby

The invention relates to a process for producing a filled and closed container, in particular in accordance with the blow molding, filling and closing process.

Such processes for blow molding, aseptic filling and hermetic sealing in a machine are used in particular in the field of pharmaceuticals, but also in soft drinks and chemical-technical products. In the process, patented by the company kocher-plastik and marketed worldwide by the company rommelag, which has become known under the brand name "bottelpack®", a tube is extruded in a first step analogous to traditional extrusion blow molding and taken over by the open blow mold. The main part of the blow mold closes and welds the bottom of the container shut. A specially shaped blow-mold-filling unit is set on the neck area, which unit seals the actual container area towards the not yet formed neck area. This blow mandrel is used to inflate the actual container using sterile air. Smaller containers, such as single-dose eye drop vials, are formed by vacuum, leaving the remaining outside part of the tube hot and plastically deformable during this process. During the next step, a filling mandrel is used to fill the product into the container. After the blow mold-filling unit has been lifted off, the head jaw of the mold tool closes and welds the container hermetically sealed. Simultaneously the desired head contour or closure contour is formed by means of a vacuum. When the blow mold is opened, the filled, finished

container leaves the blow mold and the next production cycle can be started. The whole process is preferably conducted under aseptic conditions (stainless steel, sterile blowing and purge air, etc.), ensuring that the international standards (e.g. cGMP, FDA) for aseptic packaging are fulfilled („Blasformen von Kunststoff-Hohlkörpern" [blow molding of hollow plastic bodies]; Michael Thielen, Klaus Hartwig und Peter Gust; Hanser-Verlag 2006).

A double-chamber vial produced using this process is known from EP 1 799 557 B1. The vial-like container consists of an elastically yielding plastic material having a metering chamber containing a single dispensing medium as a filled container part, one end of the metering chamber having a dispensing opening and the opposite end being connected via a connection point to a collapsible container head part, in which a gaseous expulsion medium, in particular in the form of air, is present, wherein upon compression of the container head part, the expulsion medium at least partially dispenses the dispensing medium from the metering chamber via the cleared dispensing opening to the outside for administration to a patient or the like. The mentioned connection point between the metering chamber as the one further container part and the container head part of the container is formed from a bottleneck, which is designed such that a capillary effect results, which prevents a transfer of the discharge medium from the metering chamber into the container head part holding the expulsion medium in any case, regardless of the spatial position of the container.

In addition, DE 44 20 594 C2 has already proposed inserting an end piece in the form of a separating piston in the metering chamber between the stored dispensing medium and the bottleneck, at the top of which the container head part holding the absorbed expulsion agent adjoins, which piston travels in the direction of cleared dispensing opening of the container and thereby helps facilitate the discharge of the container contents again in the form of a single dispensing medium from the container as soon as the air in the container head part is displaced through the bottleneck in the direction of the metering chamber by manually squeezing and thereby carries along the separating piston for the discharge process.

Based on this prior art, the invention addresses the problem of improving the known, technically proven solutions to the effect that an extended field of application for said BFS technology is created.

This problem is solved by a process having the features of claim 1 in its entirety and a device having the features of claim 10 and a container having the feature configuration of claim 12.

According to the inventive process provision is made that an initially open, blow-shaped by a blow mandrel and/or vacuum-shaped container part held in a mold tool is filled via its clear, upwardly aligned container part opening by means of metering units in succession with media of different types, in particular different viscosities, in such a way that the filled media are separated from each other in the container part, and then a container head part is formed by closing the head mold halves of the mold tool, and the container part is closed to form the container. In this way, at least two formulations different from each other can be introduced into only one container in the course of one filling process, the media, which are filled to different levels, remaining separated from one another even if the container is closed. It has proven to be particularly advantageous to use high-viscosity, slow-moving ointment-like products, including creams and gels, as media to be filled, and to fill these in layers one above the other into the container, the separation being maintained even when the container is closed.

If ointments having different viscosities are used as the medium to be filled in each case according to the inventive process, a compact filling of the ointment without air pockets within the container is desired, the subsequent extraction function of the container applicator produced in this way is not impaired due to the lack of air pockets. After the first layer or the first medium has been filled into the container part of the container, any mixing with the subsequent, overlying media layer has to be prevented, which is aided by the subsequently filled medium not being introduced in the container part of the container using a too strong filling jet. In such a way, a separating layer between the ointments can be produced as far as possible as a flat

surface and also without cratering, which otherwise might encourage the mixing of the media layers in the container.

More preferably, only two media are introduced into the container to be formed; however, it is also possible to store more than two media separated from each other in the container to be closed. Also, the application need not be limited to high viscosity media and products; rather, it is also possible to provide highly viscous media with low-viscosity media for separate container filling. Basically, all types of media that can be separated as such and in particular due to their viscosity are suitable for the filling process according to the invention. In principle, therefore, depending on the application, all types of fluids as well as pasty and powdery or particulate substances are possible. Thus, in the context of the process according to the invention, the container is able to hold a highly viscous ointment and a pasty drug powder permanently separated from each other by means of a separating layer.

In the device according to the invention for preferentially performing said process, an independent metering unit is provided for every medium, depending on the number of media to be introduced into the container. In particular, the device according to the invention has at least two metering units for every dispensing medium to be filled in a container part of the container via the clear opening, every metering unit being fixed on a displacement unit by means of at least one drive means, which moves the metering unit in question at least partially via a slanted guide from a starting position to a dispensing position over the container part opening and then back to the starting position.

The invention also relates to a container, which is produced in particular according to the process described above including a device also as described above, and which is characterized in that in its closed container part at least two media are held in a superimposed arrangement and separated from each other, wherein the pertinent media separation also is maintained once the composite media as a whole are, in turn in the same order as introduced into the container part, squeezed from the same for an application or otherwise removed.

Below, the solution according to the invention is explained in detail with reference to the drawing. In the schematic figures, which are not to scale,

5 Figs. 1 and 2 show the manufacturing device for performing the manufacturing process according to the invention in a basic starting position in side view and in plan view;

10 Figs. 3 to 5 show a representation corresponding to Figure 1 in different manufacturing positions; and

Fig. 6 shows a container product manufactured using the device of Figs. 1 to 5.

15 The manufacturing device shown in a side view in Fig. 1 is intended for the supply of two different media in the form of ointments, whose viscosities should differ from each other. In this case, one metering unit 10 is provided for supplying the one ointment and one metering unit 12 for the other ointment. The respective metering units 10, 12 have an identically designed filling mandrel 14 on their undersides. As the machine device for moving the metering unit 10 and the metering unit 12 are basically identically designed, the pertinent actuating device of the metering unit 10 is
20 the only one to be explained in more detail, Fig. 2 showing a plan view of the manufacturing device according to Fig. 1.

On a machine table 16 of a blow molding, filling and sealing machine not shown in any detail a base support 18 is arranged like a stand, which, as shown in Fig. 2, is formed of substantially U-shaped, mutually arranged wall parts shown in cross-section or in plan view.
25 In the parallel walls of the base support 18 opposite to each other, a sliding block guide 20 is introduced continuously, which, as is apparent from Fig. 1, has, initially in the upper part, an inclined guide 22, which in its lower part transitions into a vertically extending, rail-like guide piece 24. A fictitious extension of the inclined guide 22 forms an included angle having an inclination angle of approx. 65 ° with the top of the machine table 16. Furthermore, a drive

spindle 26, which can be driven via a gear 28, for example in the form of a belt drive, which in turn can be driven by an electric motor 30 is guided approximately centrally within the base support 18. In place of said belt drive, a gear transmission or the like can also represent the gear 28.

As is further apparent from Figs. 1 and 2, two guide rods 32 are arranged within the U-shaped base support 18 and also in a vertical arrangement running in parallel to the rod-shaped drive spindle 26, along which rods a console 34 is movably guided in the manner of a machine support, comprising the spindle drive 26 and its drive gears with a drive nut 36. If the electric motor 30 drives the console 34 via the drive spindle 26 in the manner of a support, it can be downwardly displaced from the uppermost position shown as seen in the viewing direction in Fig. 1. Viewed in the direction of Fig. 1, on the underside of the console 34 a displacement unit 38 is arranged, which is guided longitudinally movably in the horizontal direction via a horizontal guide 40 in the console 34 beneath the same. Furthermore, the displacement unit 38 has two rearwardly projecting guide webs 42, each carrying a guide roller 44 projecting in the direction of the base support 18, each engaging in the assignable sliding block guide 20. Furthermore, the metering unit 10 with its two guide webs extending above the intermediate displacement unit 38 is arranged on the underside of the console 34.

If the console 34 along with gear 28 and drive spindle 26 moves downwards viewed in the direction of Fig. 1 after actuation of the electric motor 30, it includes the displacement unit 38 in this movement, wherein these, due to the sliding block guide 20, with which the guide rollers 44 of the displacement unit 38 engage, simultaneously undergo a horizontal movement until the end of the inclined guide 22, where in turn the displacement unit 38 is moved only in the vertical direction along the two vertically extending guide pieces 24 of the sliding block guide 20. As shown in particular in the illustration of Fig. Figure 3, then the guide rollers 44 of the displacement unit 38 in their fully extended dispensing position or dispensing position come to a lower abutment with the end of each vertically extending guide piece 24 of the sliding block guide 20. In this position, the guide webs 42 of the displacement unit

38 within the horizontal guide 40 of the console 34 are in their fully extended position and the metering unit 10 is located as shown in Fig. Figure 3 above the mold tool 46 for a container as shown in Fig. 6.

5 The above-described moving mechanism is also implemented accordingly for the further metering unit 12 in this way. While Fig. 1 shows the initial state for both metering units 10, 12, Fig. 3 refers to the lowering and metering operation for a first ointment to be dispensed having a predeterminable viscosity, while the metering unit 12 with the other ointment is still in the starting position. In the illustration according to
10 Fig. 4, in turn, the metering unit 10 is in the raised start or home position and the metering unit 12 is in the lowered, dispensing position for metering the other ointment into the container.

The mold tool 46 shown in Figs. 3 to 5 consists of two mold halves 48, 50, which jointly delimit a mold cavity for the blow molding of a container part 52 made of
15 plastic material, which has an upwardly oriented slot 54. The respective filling mandrels 14 of the metering units 10, 12 can engage in the interior of the container part 52 through this opening 54 of the container part 52 for a delivery of media. Further, the mold tool 46 has on its upper side mutually corresponding head mold halves 56, 58 (cf. Fig. 3), which form the container head part 60 (cf. Fig. 6) of the
20 container in its collapsed state as soon as the clear opening cross-sections of the respective filling mandrels 14 have moved out of the overall mold 46, as shown in the illustration of Fig. 5. Preferably, however, provision is made that before closing the head mold halves 56, 58 a ball 64 is placed on the top of the layered ointment composite using a vacuum gripping device 62, the ball serving as an end piece for
25 the filled media and ointments respectively.

While at first the first ointment 74 was filled into the container part 52 using the metering unit 10, the second ointment 76 was subsequently introduced into the container part 52 in superposition via the metering unit 12, and then the ointment 76
30 introduced last by means of the metering unit 12 is provided with the ball 64 as an end

part. As soon as the vacuum gripper 62 for the ball 64 is again disengaged from the mold tool 46 and its mold halves 48, 50, 56 and 58, the head mold halves 56, 58 can travel towards each other, with the opening 54 tapering into a narrow gap 66 as a capillary opening. Furthermore, closing the head mold halves 56, 58 causes the container head part 60 to be formed and the container as a whole with the media and/or ointments it holds, is hermetically sealed from the environment.

Below, the container produced by the inventive device according to Figs. 1 to 5 is explained in more detail with reference to its illustration in Fig. 6, which refers to a finished container product. The container shown in Fig. 6 consists of a transparent, elastically yielding plastic material, which alone or together with other containers can be manufactured, filled and closed preferably sterile in the manner of a conventional card-like container composite (not shown) by means of the device shown and illustrated, according to the illustrations of Figs. 1 to 5. The container has a tubular, cylindrical metering chamber as a container part 52, which at its lower end in the drawing is closed by a toggle closure 68, which has a constricted predetermined breaking point 70, via which the toggle closure 68 can be turned off by hand, to clear the discharge port 72 at the lower end of the container part 52. Viewed in the direction of Fig. 6, at least one ointment 74 is arranged on the bottom of the container part 52, which is separated by a horizontal separating surface 75 from a topmost further ointment 76, the aforementioned ball 64 again resting as an end part on the top or surface. It is clear from the illustration according to Fig. 6 that upon clearing the dispensing opening 72 of the container, one after another first the ointment 74 and then the ointment 76 is discharged, while the ball 64 remains in the container part 52 of the container. Due to the downwardly conically tapered discharge opening 72, it can easily be introduced in body openings, such as in a nostril or the like.

The opposite end of the container part 52 is connected via the junction 66 to the compressible container head part 60, in which a particular gaseous expulsion medium, in the present case in the form of air, is present. When the container head part 60 is compressed by hand, the expulsion medium stored there displaces the

ointment to be dispensed from the container part 52 via the discharge opening 72 for an application process outwards into the environment, the ball 64 being carried along. The connection point 66 between the container part 52 and the container head part 60 is formed from a bottleneck such that a capillary effect results, which prevents the transfer of the respective delivery medium from the container part 52 into the container head part 60, regardless of the spatial position of the container. Likewise, the expulsion medium cannot unintentionally be moved in the direction of the container part 52 holding the ointments 74, 76 without squeezing the container head. Not shown and explained in detail, is the fact that the ball 64 may be punched out of the plate-shaped toggle fastener 68, to which end the toggle closure 68 originally has an approximately centrally arranged shaped ball part (not shown). The respective ball 64 can be removed from the toggle closure 68 for a subsequent process operation as soon as the pertinent container with the toggle closure 68 still containing the ball 64 has left the molding machine including the mold tool 64.

The process according to the invention will now be explained in more detail below with reference to the device shown, together with the container product. As already explained, the process for producing the filled and closed container relates to a blow molding, filling and closing process (BFS process), in which an initially open, container part 52 held in a mold tool 46 is filled in succession with media 74, 76, of preferably different viscosity, such that in the container part 52, the filled media 74, 76 are separated from each other, the container part 52 being subsequently closed to form the entire container. Basically, media for filling in the container part 52 having high-viscosity properties, such as ointment products are preferable.

Further, for the metered dispensing of the respective medium, in particular in the form of the ointment products 74, 76, a volumetric media or ointment metering is used, wherein a compact air-free filling, starting from the tube or filling mandrel 14 of the respective applicator in the form of metering units 10, 12, must be implemented. Such a volumetric media metering is shown by way of example in DE 10 2008 028 772 A1, which relates to a device for filling containers comprising a device for feeding product

to at least one metering device in the form of the metering units 10, 12, which forms a flow path in which a metering valve, which can be opened at least for the period of metering operations, is arranged to deliver metered quantities of the media or other product to the respective containers via at least one filling line. In this case, the known metering device for volumetric media metering in the flow path downstream of the metering valve has a device for selectively generating a suction effect in the flow path, wherein a control device is provided, which activates the element generating the suction effect for a metered dispensing action according to metering actions completed by closing the metering valve.

As shown in particular in the illustration according to Fig. 3, the filling mandrel 14 of the metering unit 10 must be positioned in the container part 52 at a sufficient distance from the eventually reached filling level and performs no product-specific movement during the filling, or only a small one if at all. The pressure range of the metering required for this purpose is determined product-specifically on the basis of the media product or ointment product.

Similar to the foregoing description and shown in Fig. 4 by way of example, the medium and/or the ointment 76, is subsequently filled by means of a volumetric ointment dosage, as presented above, via the metering unit 12 into the container part 52 of the ointment 74, for which both the metering rate and the volume flow can be controlled. To prevent unwanted cratering or mixing with the already filled ointment 74, the filling is performed at a lower pressure range than the filling of the ointment 74. By synchronizing the controlled metering and the movement of the filling mandrel 14 of the metering unit 12 during filling, again, a compact, preferably air bubble-free metering in the tube in the form of the container part 52 can be implemented. To implement the synchronization between the metering speed and the movement of the respective filling mandrel 14, the "piston stroke" of the metering unit 12 and the movement of the filling mandrel 14 itself are performed by means of the already described servo drives in the form of an electric motor 30, gear 28 and drive spindle 26 using a suitable control and regulating device (not shown).

Giving priority to the lowering stroke and filling process in the mold tool 46 described above, the metering units 10, 12 must be alternately moved horizontally into the central position via the opening 54 of the container part 52 in the mold tool 46. This in turn is achieved by a synchronized movement of the horizontal and vertical axes using the sliding block guide 20 along a predetermined defined path movement. Due to the oblique guide 22 of the sliding block guide 20 there is no need for an additional horizontal cross stroke, resulting in a reduction of the travel times between their respective basic and dispensing positions of the respective metering units 10, 12.

In principle, it would also be possible to use handling systems, such as robot arms, to move different metering units with different discharge media through the opening 54 of the container part 52. In this way, more media can be introduced in a sequential order into the container part 52 in a synchronized manner. There is also the option of arranging the metering units 10, 12 in a stationary manner and to then move the mold tool 46 with the container part 52 and its opening 54 to be kept clear, under the respective metering units 10, 12, always in chronological succession, which would also be possible within the framework of a so-called carousel arrangement. It would also be conceivable to introduce with the machine arrangement according to Figs. 1 to 5 by means of the metering unit 10 first an ointment 74, then using the metering unit 12 an ointment 76 having a different viscosity in addition to the pharmaceutical effect and then in turn with the metering unit 10 the ointment 74 is applied again onto the ointment 76 in a separated manner, etc.

Analogous to the previous construction in so-called Bottelpack manufacturing machines, the machine device presented in Figs. 1 to 5 can be arranged on an existing bridge of the machine above the closing unit, in particular in the form of the mold tool 46 with its mold halves 48, 50, 56, 58; in this way existing, delivered machine units can be retrofitted or converted in a simple and cost-effective manner.

Claims

1. Device for filling a container, at least two dosing units (10, 12) for respective discharge media (74, 76) to be poured into a container part (52) via the free opening (54) thereof being fixed on a displacement unit (38), **characterised in that** the at least two dosing units are each fixed on a displacement unit and in that the displacement unit (38) moves the respective dosing unit (10, 12) from a starting position into a discharge position over the container part opening (54) and back again by means of at least one drive means (26, 28, 30) via an oblique guide (22) of a sliding guide (20).
2. Device according to claim 1, characterised in that the respective oblique guide (22) extends as part of the sliding guide (20) in a base support (18), which comprises a spindle drive (26), which moves a support panel (34) in the vertical direction, the displacement unit (38) being arranged with the assigned dosing unit (10, 12) on said support panel such that it can be moved in the horizontal direction.
3. Method using a device according to claim 1 or 2 for producing a filled and closed container, in particular using the blow-fill seal method, in which an initially open container part (52) held in a moulding tool (46) and blow-moulded and/or vacuum-moulded by means of a blow pin is filled in succession via its free, upwards-pointing container part opening (54) by means of dosing units (10, 12) with media (74, 76) of varying types, in particular viscosity, such that the poured media (74, 76) are separated from one another in the container part (52), and a container top part (60) is then formed by closing the top halves (56, 58) of the moulding tool (46) and the container part (52) is sealed, forming the container.
4. Method according to claim 3, characterised in that at least one medium (74), which is poured into the container part (52), is a high-viscosity product such as an ointment, cream or gel.
5. Method according to claim 3 or 4, characterised in that at least one further medium (76) to be poured into the container part (52) is also selected from the high-viscosity products such as ointments, creams or gels.
6. Method according to any one of claims 3 to 5, characterised in that the respective media (74, 76) to be poured in are placed one on top of the other in the container part (52) such that there is no mixing between the adjacent, adjoining media (74, 76) in that the separating layer (75) arising between the adjoining media (74, 76) is produced in a crater-free manner during filling.
7. Method according to any one of claims 3 to 6, characterised in that the respective medium (74, 76) is preferably poured in pre-definable quantities into the container part (52) by means of a volumetric dosing unit (10, 12) such that it is substantially free of air inclusions.

8. Method according to any one of claims 3 to 7, characterised in that each medium (74, 76) to be poured into the container part (52) is supplied with its own dosing unit (10, 12) that can be assigned to said medium.
9. Method according to any one of claims 3 to 8, characterised in that the assignable dosing units (10, 12) are moved in succession over the free container part opening (54) in the sequence of filling with the respective medium (74, 76) such that the first dosing unit (10) is moved from a starting position over the free opening (54) of the container part (52) into a discharge position, the first medium (74) is discharged into the inside of the container part (52) via this free opening (54) and then moved back into its starting position, and in that a second (12) and any further dosing units are then moved in succession from their starting position to the free container part opening (54) into their discharge position for a medium discharge process and moved back into said starting position again.