

Container consisting of plastic material, and method for producing a container of this type

The invention relates to a container consisting of plastic material, which is produced using the blow, fill and seal method, and the filling of which, enclosed by a container wall, can be autoclaved. The invention further relates to a method for producing a container of this type.

A high packing density is required when packaging bulky drugs and medicinal products such as infusion or flushing solutions, as unnecessarily large and heavy packages lead to high costs in terms of material use, transport, and storage. For this reason, the glass bottles frequently used in the past for infusion solutions have largely been replaced with plastic containers. In a particularly rational manner, containers of this type are produced by the known blow, fill and seal (BFS) method, which is also known in the professional world under the designation (DE 103 47 908 AI, DE 10 2013 012 809 A1) "bottelpack®-system". A substantial advantage of such containers for medical and/or pharmaceutical applications is that the contents only come in contact with the polymer forming the container material, hence containers produced and filled using this BFS method ensure that the contents remain germ-free/sterile for prolonged periods.

In order to permit easy and safe handling of such containers, users prefer relatively rigid and stable bottles. For example, medications are injected into infusion solutions or emulsions or suspensions for infusion such as isotonic saline solution, mannitol or glucose solutions, for example. For cannulas, this can be accomplished much more easily using more rigid containers than using mechanically highly unstable, thin pouches.

However, as a consequence of this user requirement, rigid containers cannot be emptied completely without allowing a pressure equalization (aeration). In the case of glass containers, this is typically accomplished using suitable aerated infusion devices (see Figure 1 in DIN EN ISO 8536-4:2011- 01). However, for medical reasons aeration is not desired because of the associated risk of microbial contamination; hence preference is given to non-aerated infusion devices (see Figure 2 in DIN EN ISO 8536-4:2011-01). On the other hand, for medical reasons it is necessary for infusion solutions in the sealed container to be terminally sterilized, which according to European specifications is achieved by autoclaving at temperatures of 121°C for a period of at least 20 minutes. This means that

polymers having a suitably high heat distortion temperature must be used for the container production. This precludes the use of soft polyethylene (LDPE) because of the excessively low heat distortion temperature and necessitates the use of substantially more rigid polypropylene. However, the autoclaving in a high temperature range and the convenient handling of relatively rigid polypropylene containers thus made possible negatively impact the discharge behavior of polypropylene containers during infusion processes without aeration if said containers are nearly completely filled and therefore contain only a small relative air volume. Whereas soft bottles and pouches collapse at small pressure differences, the rigidity of the container prevents such a pressure equalization.

In emergencies, infusions are frequently administered as pneumatic pressure infusions using pressure infusion apparatuses (ISO 8536-8). To this end, the infusion container is placed in an inflatable cuff, which exerts an increased pressure on the bottle from the outside and the contents of the bottle. Here again, a low restoring force of the container is a key criterion for ensuring that the infusion is as administered as quickly and as uniformly as possible.

To address these problems, the invention is based on the object of providing an autoclavable plastic container produced using the BFS method that, when almost completely filled, empties completely during the infusion process even without aeration.

In accordance with the invention, this object is achieved by a container having the features of claim 1 in its entirety.

In accordance with the characterizing part of claim 1, an essential feature of the invention is that at least one shaping means is provided in the container wall, which ensures, in spite of a high filling ratio, that the container wall collapses at least partially reducing the volume when the filler material is administered by infusion, without the container being aerated. The design resulting in the collapsing of the container wall and hence in the volume reduction of the inner volume of the container during the infusion process provides the advantageous opportunity of producing containers using the BFS method that, in spite of the use of more rigid materials, ensure a reliable discharge during infusion processes without aeration.

Plastic materials having high heat distortion temperatures such as polypropylene, which are sufficiently heat resistant to autoclaving, can thus be used with particular advantage as container

materials well-suited for the BFS method.

In advantageous exemplary embodiments, the container wall is integrally formed with a hermetically sealed head part, which is arranged on one of its end faces and serves as an opening for extracting the container filler material. The containers can be easily produced in this form by means of molding tools of simple design.

In advantageous exemplary embodiments, the container is rectangularly shaped in terms of its basic design and has projecting wall parts on two opposite container wall sides as a shaping means, which are conically inclined, in pairs, toward one another and mutually form a cone angle (ifa) of 110° or less.

With particular advantage, the projecting wall part as the one shaping means can in each case form a shoulder surface in the form of a virtually isosceles triangle.

For a largely rectangular shape of the container, if one of its end faces is viewed from above, the width (Q) of a given container wall side in proportion (irsv) to the width (B) of an adjacent container wall side is preferably in the range of 0.7 to 1.2, wherein particular preference is given to the range of 0.8 to 1.1.

In a particularly advantageous manner, the arrangement can be such that starting from its two end faces and the allocatable container wall side, the shoulder surface slopes down, as a further shaping means in the form of a wall triangle, toward the projecting wall parts delimiting the cone angle (ifa), preferably at an angle of 30° to 60° , particularly preferably of 45° .

For facilitating the demolding process when blow molding and as a further shaping means, a gradually sloping recess can be formed on the opposite container wall sides, which recess extends in a center line along the longitudinal axis, ends at a distance from the bottom, and splits from there toward the adjacent front face into two end lines, which mutually form a 90° angle at the point of the transition to the center line.

In containers formed from rigid polypropylene material, the average thickness of the container wall is preferably 0.3 mm to 0.5 mm.

A hanging tab can advantageously be disposed on the front face forming a container bottom, which opposes and faces away from the front face with the head part. If the hanging tab is downfoldable, a recess can be formed on the container bottom, in which the downfolded hanging tab can be received
5 in such a way that a level base remains on the container bottom.

In accordance with claim 11, a method for producing a container in accordance with any one of claims 1 through 10 is also the subject matter of the invention.

10 The invention is explained in detail in the following, with reference to the appended drawing, wherein:

Fig. 1 shows a side view of an exemplary embodiment of the container in accordance with the invention, drawn 1.3 times larger than normal size and designed for a filling capacity of
15 approx. 100ml;

Figs. 2 and 3 show a frontal view and a top view of the head end, respectively, of the container of Fig. 1;

20 Fig. 4 shows a perspective, oblique view of the exemplary embodiment of the container;

Fig. 5. shows a highly simplified longitudinal section of a blow mold used for producing a container in accordance with the invention, which enables a pre-collapsing of the container; and
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Fig. 6 and 7 are illustrations corresponding to Fig. 5, in which work steps of the filled container are depicted during the pre-collapsing and sealing, respectively.

Figs. 1 through 4 show an exemplary embodiment of a finished container in accordance with the
30 invention, which is designated in its entirety by 1 and is designed for a filling capacity of ca. 100 ml. The container 1 in these figures is drawn ca. 1.3 times its natural size. The container 1 is formed from polypropylene having an average wall thickness of 0.4 mm, filled, and sealed using the BFS method, wherein a membrane 5 is formed as a top closure element on the head part 3. During use, this

membrane serves as an area that can be pierced by a cannula, an injection needle, or an infusion device. The mold separation line 7 extending over the membrane 5, which is formed during the process of removing the container 1 produced by the BFS method from the blow mold, reinforces the membrane 5 against inversion during the piercing.

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The round head part 3 transitions via a radially projecting flat collar 10 and a neck 9 into the shoulder 11 forming the top end face of the container 1, which end face is rectangular in outline. In each case a container main wall 15 that extends to the bottom 17 adjoins the two opposing side edges 13 of the sides of the rectangular outline of the shoulder 11. At the other two side edges of the shoulder 11, in each case a recessed, optional shoulder notch 19 is formed, adjoined by the side shoulders 21, which, together with other wall parts, form container wall sides 20 projecting from the rectangular basic shape. These side shoulders 21 have, adjacent to the associated optional shoulder notch 19, a side shoulder surface 23 having an approximately triangular outline, which surfaces are delimited on the outside by shoulder folds 25. These folds 25 mutually form a cone angle ifa of 110° . As can be discerned in the figures and most clearly in Fig. 2, the planes of the triangular side shoulder surfaces 23 slope downward from the optional shoulder notch 19, wherein the angle of inclination is about 45° . In analogous fashion to the side shoulder surfaces 23 facing the viewer in Figs. 3 and 4, starting from the bottom container end face, lower triangular side shoulder surfaces 27 are formed between the shoulder folds 25. A side fold 29 extending between the cone tips of the top side shoulder surface 23 and the bottom side shoulder surface 27 forms the end edge of the projecting container wall side 20. Longer side folds 33, each running parallel to the shorter side folds 29, are located between the relevant projecting container wall side 20 and each of the other container wall sides 31 adjoining the sides thereof, which form the container main walls 15.

In Fig. 3, the dimensions of two opposing sides of the rectangular basic shape, more precisely the width of the container wall side 31, are designated with Q, and the dimension of the other sides of the rectangular basic shape, in other words the width of the projecting container wall side 20, is designated with B. In the case of the invention, this inner rectangle side ratio $irsv = Q/B$ is in the range of 0.7 to 1.2, preferably in the range of 0.8 to 1.2. In the exemplary embodiment depicted in the drawing, the value of $irsv$ is approximately 1.1. As can be discerned most clearly in Fig. 4, the container wall sides 31 forming the non-projecting main walls 15 have a slight recess, which starting from the longer side folds 33 slopes down to a center line 35 that extends along the longitudinal axis

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of the top side edge 13 concerned to an end point 37, at which the center line 35 splits into end lines 39 that mutually form an angle A_{wi} of 90° and extend to the bottom part 17. An optional hanging tab 43 is formed thereon.

5 The shaping means in accordance with the invention, which effect the collapsing of the container 1 during infusion processes performed without aeration in spite of a more rigid container material such as polypropylene, make it possible to provide the container 1 in accordance with the invention with a very high filling ratio. In the production of the container 1 using the BFS method, in accordance with the invention it is thus also possible to proceed in a supporting manner such that after the filling and
10 prior to the sealing of the container 1, a pre-collapsing is performed that results in a reduction of the air volume remaining in the container 1. In the form of a schematic diagram, Figs. 5 through 7 show the corresponding process steps during the manufacturing process. As shown, the pre-collapsing takes places in such a way that at least one, preferably two movable dies 47 arranged in the blow mold 45, only one of which is shown in the simplified illustration, are moved into the mold and press on at least
15 one of the deformable walls 15, 20, 31 and/or the side folds 29 of the container 1. During this movement, as indicated by the arrow 49 in Fig. 6, the fill ratio 51 rises while air escapes via the remaining, still open hose attachment 55, with the head jaws 53 still open. Fig. 7 shows the finished state after the closure of the head jaws 53 and the container 1 thus sealed, which can be removed from the mold 45 after retraction of the dies 47 (see arrow 57), wherein the previously inward-pressed
20 container wall elastically springs back partially reverts to its initial shape.

As known *per se* for plastic containers from document DE 103 47 908 A1, the container in accordance with the invention can also consist of several layers of different polymers. Instead of the shown single access with the membrane on the circular cylindrical head part 3, the container can also
25 be equipped with several accesses, preferably on the bottom and in the head area. Furthermore, a pierceable elastomer element can be inserted prior to sealing the container 1, which can be a single- or multi-component element. In addition, the head part 3 can be equipped with a welded-on infusion cap, as known *per se* from DE 10 2013 012 809 A1, for example.

30 As described in the following, discharge tests were performed in order to compare the discharge behavior of the container 1 in accordance with the invention to the discharge behavior of typical standard containers without the shaping means in accordance with the invention:

A bp 364 Bottel-Pack® system (rommelag, Waiblingen, Germany) was used to manufacture water-filled and sealed single-piece infusion containers in accordance with the invention and standard containers having three different rated volumes (100ml, 250ml, 500ml) and with an average wall thickness of 0.35-0.52 mm from different polypropylene materials (LyondellBasell RP 270G;

- 5 Borealis SB 815 MO, Flint Hills Rexene 23M2A) using the blow, fill and seal method. Before sealing, some of the containers were pre-collapsed by an 8 mm travel distance of the die (47) and an infusion cap in accordance with ISO 15759 was then welded on as described above. The containers were subsequently sterilized by autoclaving at 121°C for 20min, and then the discharge behavior was measured and the maximum filling ratio was determined.

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For measuring the discharge behavior, the containers were pierced using a non-aerated infusion device in accordance with DIN EN ISO 8536-4:2011-01, and the mass of the outflowing fluid was monitored over time on an analytical balance. The discharge took place via an 0.6mm x 30mm injection cannula in accordance with ISO 13097. The measurements were taken at an ambient temperature of 21°C. The

- 15 height of the fluid column (discharge height) was 775mm.

In order to compare bottles of different volume classes to each other, the maximum filling ratio of the container, in other words the ratio of the experimentally determined total volume to the maximum filling volume, at which the container still drains, was chosen as a quality criterion for the evaluation.

- 20 Unavoidably remaining quantities of fluid, for example quantities located in the head space below the opening of the puncturing mandrel of the infusion device, were not considered.

An increase of the maximum filling ratio means that a considerably smaller volume of air is needed in comparison to the standard containers, which has very advantageous consequences in terms of

- 25 reduced pack sizes, packaging and transport costs, storage and disposal costs, etc.

The three materials used, as well as their moduli of elasticity (tensile modulus at 50 mm/min in accordance with ISO 527 and optionally bending modulus at 50 mm/min in accordance with ISO 178) and their densities in accordance with ISO 1183 at 23°C, are listed in the following table.

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Make/Material	Tensile modulus of elasticity MPa	Bending modulus of elasticity MPa	Density g/cm ³
Borealis SB815MO	475	425	0.900

Lyondell Basel I RP270C	950	850	0.900
Flint Hills Rexene 23M2A	1100	1000	0.902

The results for standard containers (tests 1 and 2) and for the containers in accordance with the invention (tests 3-14) are summarized in the following table.

Test no.	Bottle type	Material	Pre-collapsing	irsv	ifa angle Degrees	Total volume in ml	Max. filling volume in ml	Min. air volume in ml	Max filling ratio %
1	Standard	RP270G	no			205	139	66	68%
2	Standard	SB815MO	no			220	161	59	73%
3	EE-200-sb	SB815MO	no	1	110	220	180	40	82%
4	EE-200-sb	SB815MO	yes	1	110	215	181	34	84%
5	EE-201-sb	SB815MO	no	0.8	120	226	176	50	78%
6	EE-201-sb	SB815MO	yes	0.8	120	215	176	39	82%
7	EE-201 -rex	Rexene 23M2A	no	0.8	120	211	158	53	75%
8	EE-201-rex	Rexene 23M2A	yes	0.8	120	200	156	44	78%
9	EE-S00-sb	SB815MO	no	1.1	115	640	563	77	88%
10	EE-500-rex	Rexene 23M2A	no	1.1	115	590	478	112	81%
11	EE-500-sb	SB815MO	yes	1.1	115	630	573	57	91%
12	EE-501-rp	RP270G	no	0.9	105	585	474	in	81%
13	EE-100-sb	SB815MO	no	0.9	110	135	101	34	75%
14	EE-101-rp	RP270G	no	0.9	105	125	86	39	69%

As can be discerned from the table of test results, in comparison to the standard containers a substantially higher maximum filling ratio is achievable with the invention, wherein it can also be discerned that particularly high filling ratios of up to 91% are achievable if pre-collapsing is performed (see test no. 11).

Claims

1. A container consisting of plastic material that is produced using the blow, fill and seal method and the filling of which, enclosed by a container wall (15, 20), can be autoclaved, **characterized in that** at least one shaping means (19, 21, 23, 25, 29, 33) is provided in the container wall (15, 20), which ensures, despite a high filling ratio, the container (1) collapsing and reducing the volume upon administration of the filling by infusion, without aeration of the container (1).
2. The container according to claim 1, characterized in that said container consists of plastic materials having a high heat distortion temperature, such as polypropylene, which are able to withstand the heat of autoclaving.
3. The container according to claim 1 or 2, characterized in that the container wall (15, 20) is integrally formed having a hermetically sealed head part (3), which is arranged on one of its end faces (11) and serves as an extraction opening for the container filler material.
4. The container according to any one of the preceding claims, characterized in that said container is rectangularly configured in its basic design and has, as a shaping means, projecting wall parts (21-, 23) on two opposing container wall sides (20), which are conically inclined toward each other in pairs and mutually form a cone angle (α) of less than 120° or preferably 110° or less.
5. The container according to any one of the preceding claims, characterized in that as the one shaping means, the projecting wall parts (20) each form a lateral shoulder surface (23) in the shape of a virtually isosceles triangle.
6. The container according to any one of the preceding claims, characterized in that, when of one of its end faces (11) is viewed from above, in each case the width (Q) of a container wall side (15, 31) in proportion ($\frac{Q}{B}$) to the width (B) of the adjacent container wall side is in the range of 0.7 to 1.2, particularly preferably in the range of 0.8 to 1.2.
7. The container according to any one of the preceding claims, characterized in that, starting from its two end faces (11) and each allocatable container wall side (20), the lateral shoulder surface (23), as another shaping means in the form of a wall

triangle, slopes down diagonally, preferably at an angle of 30° to 60°, particularly preferably of 45°, towards the projecting wall parts (26) delimiting the cone angle (ifa).

- 5 8. The container according to any one of the preceding claims, characterized in that, on its opposing container wall sides (31), a gradually sloping recess is formed as another shaping means, which extends in a center line (35) along the longitudinal axis, ends at a distance from the bottom (17), and splits from there into two end lines (39) towards the neighboring end faces (11), which lines, at the point of the transition (37) to the center line (35), mutually form an angle of incidence (Awi) of 60°-130°, preferably of 60° to 100°, particularly preferably of 90°.
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9. The container according to any one of the preceding claims, characterized in that the mean thickness of the container wall consisting of rigid polypropylene material is 0.3mm to 0.7mm, preferably 0.4mm to 0.5mm.
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10. The container according to any one of the preceding claims, characterized in that a hanging tab (43) is disposed on the side forming a container bottom (17), which side opposes and faces away from the front face (11) having the head part (3).
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11. A method for producing a container (1) according to any one of the preceding claims, characterized in that said container is produced using the respective shaping means (19, 21, 23, 25, 29, 33) for better collapsibility of the container wall (15, 20, 31) in a molding tool (45, 53) using the blow mold method, filled by means of a filling process and pre-collapsed in the molding tool (45, 53) before sealing in order to reduce the air volume, sealed inside the molding tool (45, 53) by means of a sealing technique, and autoclaved outside the molding tool (45, 53).
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12. The method according to claim 11, characterized in that autoclaving is performed at at least 121°C for a period of at least 20 minutes.
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