Description

Technical Field

The present invention relates to a filled thermoplastic unit dose injection container of the kind described in the preamble to claim 1.

Background Art

Injection solution, for instance to obtain local anesthesia within surgery or veterinary medicine, is normally stored in a glass vial being permanently sealed with a thick latex membrane as a sterility cover. The vial generally contains injection solution for several doses. The injection solution is transferred to a syringe by means of a thick withdrawal needle which is fitted on to the inlet opening of the syringe which is often designed as a male Luer cone. Subsequently, the latex membrane is sterilized by means of ethanol or the like whereupon the membrane is penetrated by the withdrawal needle and air is introduced under pressure into the vial by means of the injection syringe. Finally the volume desired of the injection solution is drawn into the syringe, the withdrawal needle is removed and replaced by a thinner injection needle and the solution is injected into the patient.

Unit dose containers for injection solutions are known, the known unit dose containers, ampoules, are however intended to be inserted directly into an injection syringe of a special kind. They are made of glass and comprise both a penetratable membrane and a plunger. They are expensive to produce and are only suited for small volumes of injection liquid.

Thermoplastic unit dose containers sealed by means of a non-resealable cap are also known. These unit dose containers are however less adapted for injection solutions the sterility of which must be preserved also after the transfer into the injection syringe.

There have been some developments in this field. Thus DE-U-1 806 636 discloses a bottle for injection solutions of the general kind described above, which is covered by a removable, piercable membrane and provided with a conventional screw cap. The teachings of this document forms the basis for the preamble of the main claim. The opening of the container thus inter alia has a female, conical shape and the idea of utilizing the opening for for receiving differently shaped ("verschiedenartig") needle-holding parts of syringes after removing the piercable membrane for transferring the contents of the bottle to the syringe if the bottle is made of an elastic plastics material is discussed.

Some other prior art documents are:

DE-U-74 07 072, which discloses an infusion bag intended to be connected to a infusion tubing by means of a female connecting part which may be conically tapering, it being possible to cover the female part by an integral non-resealable cap which may be provided with a breaking line, and

FR-A-1 566 283, which discloses a collapsible container which may serve as a disposable syringe or as a conventional squeeze bottle for medicaments to be taken orally, the container being provided with a male cone part intended to cooperate with an injection needle when used as a syringe.

Description of the Invention

The object of the invention is to provide a unit dose container which ensures complete disposability, which may be produced and filled efficiently at a high speed under complete sterility, which is easy to handle and use, and whose contents can be transferred directly to a syringe in a safe and sterile way.

These and other objects are according to the invention achieved in a surprisingly simple way by means of a unit dose container having the features defined in the characterizing portion of the appended main claim. A unit dose container of this kind is easy to prepare and brings about many advantages as to for instance sterility, identification etc.

The invention will be further described below with reference to some embodiments shown on the accompanying drawing, wherein

Fig. 1 shows a front view of a unit dose container of the invention, partly in section, sealed by a non-resealable cap;

Fig. 2 shows the unit dose container of Fig. 1 with the cap removed from the outlet opening;

Fig. 3 shows the unit dose container of Fig. 2 with a syringe connected to the outlet opening;

Fig. 4 shows a view in perspective of a special embodiment of the unit dose container of Fig. 1 provided with a projection;

Fig. 5 shows a partial view in section of another embodiment of a unit dose container comprising a capillary constriction; and

Fig. 6 shows a partial view in section of another embodiment of a unit dose container the outlet opening of which comprises circular grooves with a syringe connected thereto.

In the embodiment of the invention shown in Fig. 1 a unit dose container 1 is provided with an outlet opening 2 in the form of an outwardly widening truncated cone. The outlet opening 2 is sealed by a non-resealable cap 3. The purpose of making the cap non-resealable is among other things to ensure a complete disposability and sterile handling. The cap comprises a breaking line 4 indicating where the cap will be broken to expose the

outlet opening of the container; see Fig 2. In order to facilitate this breaking, in this case by means of a rotary motion, the cap 3 is provided with a planar, transversal tab or wing 5 giving an enlarged torsional movement at the breaking. This tab can also be used to display identification marks. The breaking line 4 is designed as a slot arranged along the periphery of the cap. It is of course possible to arrange the breaking line in other ways, for instance according to any known way where a breaking line in a cap is broken by a breaking movement instead of a torsional movement.

The outlet opening 2 is designed to fulfil the specifications for a standardized female cone, preferably a standard Luer female cone having a conicity of 6:100 or a Record female cone having a conicity of 1:10. The female cone is intended to be connected to a standard male cone 8 of an injection syringe, as is shown in Fig. 3. This connection of conical fittings makes it possible to transfer injection solution directly into the syringe without any intermediate steps or means. The female cone preferably has a maximum opening diameter smaller than 1.0 cm, preferably from 0.2 to 0.8 cm.

In the embodiment shown in Fig. 4 the upper part of the unit dose container has been provided with an extra projection 6 to be used as a support in removing the cap by breaking the breaking line 4. Such a projection or support can alternatively be placed in the lower part of the unit dose container, provided that the wall of the unit dose containers is stiff enough.

The embodiment of the invention shown in Fig. 5 is provided with a capillary constriction 7 below the outlet opening in order to prevent the outflow of the content of an opened container being placed on the side or being kept upside down.

In Fig. 6 another preferred embodiment of the outlet opening 2 is shown in which the opening has been provided with peripherally arranged interior grooves across the outlet direction. Grooves of this kind apparently give an improved syringe tip 8 sealing, especially if the outlet opening is made of a very thin and flexible plastic material.

It is of advantage if the bottom part of the container is designed so that a filled container can be placed upright and remain standing with the outlet opening turned upwards. This might be attained even though the wall of the container is so thin and flexible that the container collapses in drawing out the injection solution with a syringe, for instance if the container in its entirety is shaped as a truncated cone, a tetrahedron or the like. Such a thin and flexible wall is of advantage as the drawing of the injection solution into the syringe is then facilitated. In this case it will also be possible to fill the syringe by squeezing the unit dose container.

The unit dose container of the invention has a total inside volume of preferably 1-100 ml. It is conveniently filled with a standardized volume of injection solution of 1-50 ml, for instance 5, 10, 20 or 50 ml solution, or preferably somewhat more than a standardized volume as it in certain cases might be difficult to draw all the contents into the syringe.

The filled unit dose container according to the invention might be enclosed into a moisture impermeable bag. By this an undesired increase of the concentration of the injection solution, generally a water solution, by diffusion of water vapour through the thermoplastic wall of the dose container can be prevented. An additional purpose of the bag is to preserve the sterility of the container. The moisture impermeable bag is preferably made of a laminate of metal and plastic, for instance an aluminum-plastic-laminate. The bag preferably also can comprise one or more longitudinal breaking lines or tearing notches to facilitate the opening thereof. The bag normally is airtight and light impermeable and can thus also be used to protect the injection solution against oxidation and ultraviolet radiation. In this case it might be adequate to introduce an inert or reducing gas into the bag before it being sealed about the unit dose container.

The design of the unit dose container of the invention is such that it may well be produced by the very efficient so called "bottle-pack"-system. This system is among others described in the German patent 14 11 469 (Rommelag AG). The unit dose container is then formed by vacuum moulding and blowing and is then filled with liquid and sealed by a cap formed at the same time, the container still being left in the moulding tool. The liquid, that is the injection solution, then rapidly cools the formed container which consequently can be produced at a high speed. Finally the container is separated from the moulding tool and optionally enclosed into a moisture impermeable bag. These process steps can be accomplished under complete sterility. In order to ensure sterility of the outside of the container too it is appropriate to sterilize the final container, preferably by autoclaving.

The unit dose container is made of a thermoplastic, such as polypropylene or polyethylene, preferably polypropylene.

The unit dose container of the invention can be filled with a solution of any drug which is suited for injection, but is particularly advantageous to use for aqueous solutions of autoclavable local anesthetics, such as lidocaine, prilocaine, mepivacaine, bupivacaine, etidocaine, or other drugs which are used under conditions where the demands for easy handling and sterility are especially high.

Claims

1. Filled injection solution container (1) of thermoplastic material formed by vacuum moulding and blowing and containing a unit dose of a sterile medication, said container having an outlet opening (2) having a conically shaped inner surface (2) for engaging the tip of a syringe for removably and tightly receiving the tip of the syringe, said syringe having a mating conically shaped outer surface (8), said outlet opening (2) being shaped for transferring the injection solution directly from the container (1) to a syringe and to thereby form a substantially leak proof seal between said container and said syringe, said outlet opening (2) being formed of said thermoplastic material by the moulding, the bottom of the container being designed so that the container can be placed upright and remain standing with the outlet opening (2) turned upwards, **characterized** in that said container has a non-resealable cap (3) provided with a breaking line (4) over the outlet opening (2), all moulded of said thermoplastic material, said outlet opening (2) fulfilling the specifications of a standardized female cone and said conically shaped outer surface (8) fulfilling the specifications of a corresponding standardized male cone of a syringe, the wall of the container being so thin and flexible that the container collapses when the injection solution is drawn out by a syringe, the container (1) further holding 1-50 ml.

2. Unit dose container (1) according to claim 1, characterized in that the outlet opening (2) of the container (1) fulfils the specifications for a standardized Luer female cone.

3. Unit dose container (1) according to claim 1, characterized in that the outlet opening (2) has a maximum opening diameter smaller than 1.0 cm.

4. Unit dose container (1) according to any of claims 1-3, characterized in that the cap (4) comprises a transversal projection (5) providing an increased torsional moment in breaking the seal.

5. Unit dose container (1) according to any of claims 1-4, characterized in that the container (1) comprises a projection (6) to be used as a support in breaking the seal.

6. Unit dose container (1) according to any of claims 1-5, characterized in that the container is enclosed in a moisture impermeable bag made of laminate of metal and plastic.

7. Unit dose container (1) according to any of claims 1-7 characterized in that a capillary constriction (7) is provided below the opening.

Revendications

1. Récipient à solution d'injection (1) en matière thermoplastique formé par moulage sous vide et soufflage et contenant une dose unitaire d'un médicament stérile, ledit récipient ayant une ouverture de sortie (2) ayant une surface interne de forme conique (2) pour venir en contact avec la pointe d'une seringue pour recevoir de façon amovible et hermétique le bout de la seringue, ladite seringue ayant une surface extérieure de forme conique correspondante (8), ledit orifice de sortie (2) étant conformé pour transférer la solution d'injection directement du récipient (1) à une seringue et pour former ainsi un joint étanche pratiquement résistant aux fuites entre ledit récipient et ladite seringue, ladite ouverture de sortie (2) étant formée de ladite matière thermoplastique par le moulage, le fond du récipient étant conçu de telle sorte que le récipient puisse être disposé verticalement et rester stationnaire avec l'ouverture de sortie (2) tournée vers le haut, caractérisé en ce que ledit récipient a un capuchon ne pouvant pas être refermé de façon étanche (3) muni d'une ligne de rupture (4) au-dessus de l'ouverture de sortie (2), le tout moulé à partir dans ladite matière thermoplastique, ladite ouverture de sortie (2) répondant aux caractéristiques d'un cône femelle normalisé et ladite surface extérieure en forme de cône (8) répondant aux caractéristiques d'un cone mâle normalisé correspondant d'une seringue, la paroi du récipient étant suffisament mince et souple pour que le récipient s'affaisse lorsque la solution d'injection est soutirée par une seringue, le récipient (1) contenant en outre 1 à 50 ml.

2. Récipient à dose unitaire (1) selon la revendication 1, caractérisé en ce que l'ouverture de sortie (2) du récipient (1) répond aux caractéristiques d'un cône femelle Luer normalisé.

3. Récipient à dose unitaire (1) selon la revendication 1, caractérisé en ce que l'ouverture de sortie (2) a un diamètre d'ouverture maximale inférieur à 1,0cm.

4. Récipient à dose unitaire (1) selon l'une quelconque des revendications 1 à 3, caractérisé en ce que le capuchon (4) comprend une

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saillie transversale (5) ménageant un moment de torsion accrue lors de la rupture du joint d'étanchéité.

5. Récipient à dose unitaire (1) selon l'une quelconque des revendications 1 à 4, caractérisé en ce que le récipient (1) comprend une saillie (6) à utiliser comme support lors de la rupture du joint d'étanchéité.

6. Récipient à dose unitaire (1) selon l'une quelconque des revendications 1 à 5, caractérisé en ce que le récipient est enfermé dans une poche imperméable à l'humidité réalisée en un stratifié de métal et de matière plastique.

7. Récipient à dose unitaire (1) selon l'une quelconque des revendications 1 à 7, caractérisé en ce que le resserement capillaire (7) est ménagé au-dessous de l'ouverture.

Patentansprüche

1. Gefüllter Injektionslösungsbehälter (1) aus thermoplastischem Material, der durch Vakuumformen und Blasen gebildet ist und eine Dosiseinheit eines sterilen Arzneimittels enthält, wobei der Behälter eine Auslaßöffnung (2) mit einer konisch geformten inneren Oberfläche (2) zum Eingreifen mit der Spitze einer Spritze zwecks entfernbarer und dichter Aufnahme der Spitze der Spritze hat, und die Spritze eine dazupassende konisch geformte äußere Oberfläche (8) aufweist, wobei die Auslaßöffnung (2) so geformt ist, daß die Injektionslösung direkt vom Behälter (1) in eine Spritze transferiert wird, um dadurch eine im wesentlichen auslaufsichere Abdichtung zwischen dem Behälter und der Spritze zu bilden, wobei die Auslauföffnung (2) durch die Formung aus dem thermoplastischen Material gebildet ist und der Boden des Behälters so gestaltet ist, daß der Behälter aufrecht aufgestellt werden kann und mit der Auslauföffnung (2) nach oben gewandt stehen bleibt, dadurch gekennzeichnet, daß der Behälter eine nichtwiederverschließbare Kappe (3) aufweist, die mit einer Bruchlinie (4) über die Auslaßöffnung (2) versehen ist, wobei alles aus dem thermoplastischen Material gebildet ist, und wobei die Auslaßöffnung (2) den Spezifikationen eines genormten Innenkonus entspricht und die konisch geformte äußere Oberfläche (8) den Spezifikationen eines entsprechenden genormten Außenkonus einer Spritze entspricht, und wobei die Wand des Behälters so dünn und nachgiebig ist, daß der Behälter in sich zusammenfällt, wenn die Injektionslösung durch eine Spritze herausgezogen wird, und wobei der Behälter (1) weiters 1-50 ml faßt.

2. Dosiseinheitsbehälter (1) nach Anspruch 1, dadurch gekennzeichnet, daß die Auslaßöffnung (2) das Behälters (1) den Spezifikationen für einen genormten Luer-Innenkonus entspricht.

3. Dosiseinheitsbehälter (1) nach Anspruch 1, dadurch gekennzeichnet, daß die Auslaßöffnung (2) einen maximalen Öffnungsdurchmesser von weniger als 1,0 cm hat.

4. Dosiseinheitsbehälter (1) nach einem der Ansprüche 1-3, dadurch gekennzeichnet, daß die Kappe (4) einen Querfortsatz (5) umfaßt, der ein erhöhtes Drehmoment beim Aufbrechen des Verschlusses ermöglicht.

5. Dosiseinheitsbehälter (1) nach einem der Ansprüche 1-4, dadurch gekennzeichnet, daß der Behälter (1) einen Fortsatz (6) aufweist, der als Hilfe beim Aufbrechen des Verschlusses zu verwenden ist.

6. Dosiseinheitsbehälter (1) nach einem der Ansprüche 1-5, dadurch gekennzeichnet, daß der Behälter in einem feuchtigkeitsundurchlässigen Beutel aus einem Laminat aus Metall und Plastik eingeschlossen ist.

7. Dosiseinheitsbehälter (1) nach einem der Ansprüche 1-6, dadurch gekennzeichnet, daß eine kapillare Einschnürung (7) unter der Öffnung vorgesehen ist.

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