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Specification

[0001] The invention relates to the field of conditioning and dispensing of liquids, such as pharmaceutical solutions including eye drops. It relates to a container equipped with a dispensing head, which is organized to contain a liquid by protecting it from the outside environment and to deliver this liquid in a controlled manner, particularly drop by drop.

[0002] We know containers for containing a liquid, which are designed to preserve the liquid from the outside environment and to deliver it in a controlled manner, including drop by drop. The applications of such containers are numerous, and a preferred but not restrictive application as to the scope of the present invention, lies in the preservation and dispensing of a pharmaceutical solution, especially eye drops.

[0003] With regard to the preservation of the liquid, it must be protected from the outside environment by avoiding contact with the ambient air which is likely to contain pollutants, in particular bacteria. For the dispensing of the liquid, it is common to give the container a deformable nature which allows reducing its capacity, at least temporarily, in order to evacuate the liquid it contains. More precisely, such containers have a flexible wall to cause evacuation of the liquid from a compression exerted by the user on the wall, and are equipped with a dispensing head to achieve the two objectives that are the preservation and controlled dispensing of the liquid.

[0004] However, the solutions provided to achieve specifically one of these objectives are likely to be antagonistic, and the efforts of creators in the field include the search for a compromise between the different solutions. The aim is to achieve a container with a simple structure, whose manufacturing cost must not be prohibitive in view of its consumable nature, and whose use must be convenient for the user.

[0005] It will be noted at this stage of the description that it is common in the field to use a filtering membrane to prevent the passage of pollutants from outside the container to the liquid it contains. This membrane, placed in the vicinity of a nozzle that includes the dispensing head for discharging the liquid out of the container, allows a passage of the liquid through it under the effect of the compression exerted in the container by deformation of the wall.

[0006] According to a first approach, it was proposed to give the container an irreversible, or almost irreversible, deformable character. An inner wall of the container defining the liquid receiving capacity is organized in a bellow, and is wrapped with an outer sheath. This container further contains a filtering membrane which is impermeable to air, to prohibit an intake of outside air to the liquid contained in the container, under the effect of a withdrawal of liquid delivered. For example, reference may be made to patent documents FR 2 661 401 and FR 2 770 495 (or US Pat. No. 6,336,571), which describe such containers.

[0007] The problem to be solved is the controlled delivery of the liquid. According to the document FR 2,770,495 (US Pat. No. 6,336,571), a microporous pad acting as a

flow regulator is disposed in the dispensing head of a container having a wall with rigorously irreversible deformation. An intermediate reserve is provided downstream of the pad and upstream of an air-impermeable filtering membrane. Such a container has a complex structure, and the manufacturing cost of both the reservoir for containing the liquid to be dispensed and the dispensing head is high. In addition, it is not possible by means of such a container with irreversibly deformed wall to distribute all of the liquid contained in the reservoir. Indeed, the bellows shape does not allow to expel the last drops, so that part of the liquid is wasted.

[0008] According to a second approach, it was proposed to confer on the container a faculty of reversible deformation. In particular, reference may be made to document FR 2 816 600 (or US Patent 2004/0074925), which describes such a container. The structure of the dispensing head of this container is simple. It contains a filtering membrane that aims to preserve the liquid from pollutants that may be present in the ambient air. It is also provided to rigorously preserve the liquid from ambient environment before a first use. For this purpose, the dispensing head is mounted movably on the neck of the container, for the perforation of a cap extemporaneously to a first delivery operation. However, it follows from this arrangement, and more particularly from the mobility of the dispensing head with respect to the container, a risk of a loss of tightness between them after perforation of the lid and assembly by the user of the dispensing head inside a neck of the container, by narrow interlocking in particular. If this risk can be reduced, such an approach tends to increase the complexity of the dispensing head, to the detriment of the primary interest of the simplicity of its structure. In addition, the residual presence of the seal is likely to form an inconvenient obstacle to the controlled delivery of the liquid. The document US 2004/0074925 discloses a container according to the preamble of claim 1. It follows that the designers of the field still face a compromise to be found between simplicity of the dispensing head, preservation of the liquid from pollutants possibly present in the ambient air, metering capacity of the delivered liquid, and optimal use of all the liquid contained in the reservoir

[0009] The present invention is part of this search for a compromise, and aims to provide a container for the conditioning of a liquid to be dispensed drop by drop which offers a solution in answer to such a compromise. The invention more specifically relates to the conditioning of a sensitive liquid, such as a pharmaceutical, biological or similar solution, especially eye drops.

[0010] The inventive step of the present invention was, generally, first to choose a container of the type comprising a reservoir with an elastically reversible deformable wall by admission of air inside the container. This choice is intended to allow delivery of the liquid under the effect of pressure exerted against this wall, and to allow a spontaneous return of the container to its initial conformation after delivery of a liquid dose. Such a reservoir with an elastically reversible deformable wall already has in itself the advantage of a great simplicity of manufacture, compared to reservoirs with irreversible deformation of the prior art, which require a significant number of parts and assembly operations.

[0011] From its general outlook, such a container according to the present invention will be recognized in that it is equipped with a dispensing head comprising a hollowed-out body which is provided with a liquid delivery nozzle and which contains a microporous pad made of hydrophobic material placed downstream of the reservoir

across the body of the dispensing head. Said body is irreversibly assembled inside the neck of the container.

[0012] Furthermore, it is proposed to equip the container with a removable sealing cap for the nozzle which, associated with said microporous pad in hydrophobic material, impedes the spontaneous flow of liquid out of the capacity of the container reserved for its storage towards the nozzle. These provisions are such that the spontaneous passage of the liquid through the hydrophobic microporous pad is not allowed when the cap sealingly closes the nozzle, which happens throughout the use of the container. Conversely, the free flow of the liquid out of the capacity of the container reserved for its storage, through the hydrophobic microporous pad, is authorized when the nozzle is disengaged, for the desired delivery of a dose of liquid by pressure exerted against the container wall. In addition, the passage of air is authorized by suction through the hydrophobic microporous pad to the storage capacity after delivery of a dose of liquid, this suction being caused by the elastic return of the container wall to its initial conformation, return by which the container recovers its original shape notwithstanding the removal of a dose of liquid.

[0013] It should be noted that the microporous pad is preferably made of polyethylene, or similar material, which gives it a hydrophobic nature so that it is not wettable, its microporous nature nevertheless allowing the liquid to pass therethrough provided that the differential of pressure, induced by the pressure exerted by the user, is sufficient.

[0014] Such a configuration of the container according to the invention, and more particularly the combination between the reversible deformation reservoir, the microporous pad and the sealing cap, is quite advantageous. Indeed, when the cap is returned to the closed sealing position of the nozzle, after the suction of air following the delivery of a liquid dose and the elastic return of the container wall to its initial conformation, a pressure difference is created between the parts upstream and downstream of the pad through which a pressure drop is created. This pressure difference prevents the liquid contained in the container from passing through the pad, even if the wall of the container is accidentally pressed, and it ensures that the bottle is sealed, while protecting the liquid contained therein from external contaminations. In addition, such a configuration avoids any stagnation of liquid downstream of the pad, since the non-expelled liquid is sucked back into the capacity of the container.

[0015] The container according to the invention advantageously meets an objective of the invention, which is to ensure optimal use of the entire contents of the reservoir, which is achieved in two different ways. On the one hand, thanks to its elastically reversible deformable wall, the container retains a capacity to expel the intact liquid to the last drop of liquid. Indeed, because air is sucked into the container to replace each dose of liquid expelled, the expulsion pressure available in the bottle is always the same throughout the use, and until the dispensing of the last drop. On the other hand, as it was explained above, there is no drop of liquid downstream of the pad likely to be contaminated by external agents, and such drop should be eliminated before any new dispensing of a clean dose.

[0016] In addition, the microporous pad, through which a pressure drop is created, acts as a flow regulator, which promotes the controlled dispensing of liquid doses. In addition, it prevents the liquid contained in the bottle from flowing when the cap is removed, even when the bottle is in the inverted position, the dispensing head being directed downwards, as long as no pressure is exerted on the wall of the container.

[0017] In the context of an application of the container to a sensitive liquid, a pharmaceutical solution in particular, the dispensing head is preferably equipped with a filtering membrane intended to protect the liquid from an intake of pollutants present in the ambient air, including bacteria. According to the invention, a membrane that is at least partially hydrophilic and at least partially hydrophobic is then chosen to alternatively allow the passage of the liquid and the air therethrough and which is disposed in the dispensing head upstream of the nozzle, between the nozzle and the pad. The partially hydrophilic nature of the membrane allows the liquid to pass therethrough under the effect of the compression exerted in the container by deformation of the wall, while its partially hydrophobic nature allows an entry of the outside air into the container when the latter elastically resumes its initial shape after each compression exerted by the user.

[0018] The membrane further advantageously provides an additional pressure drop, which ensures, in combination with the hydrophobic microporous pad, that no leakage of liquid from the container occurs until the wall of the container is compressed.

[0019] In order to promote the passage of air through the membrane, the invention then provides the possibility to maintain this membrane dry between two liquid deliveries, when the container is in a rested position on its base, thanks to the presence of an intermediate chamber arranged in interposition between the microporous pad and the membrane. Such an intermediate chamber can also be used to constitute a regulation chamber of the delivery of the liquid. For this purpose, it can advantageously be given a volume sufficient to collect at least one drop of liquid to be dispensed during a liquid delivery operation so as to release it drop by drop out of the dispensing head.

[0020] The volume of the intermediate chamber is also, and advantageously, an air reserve which, when the nozzle is closed by the cap, retains a pressure which tends to prevent the liquid from passing through the microporous pad. It should be noted that in combination with the intermediate chamber, the hydrophobic nature of the microporous pad promotes a role of obstacle opposing the passage of the liquid through it.

[0021] The intermediate chamber is also, and advantageously, a capacity to accommodate the liquid that has not yet passed through the membrane when the user ceases to exert pressure on the wall of the container. For this purpose, it is advantageous to ensure that the intermediate chamber extends over the entire surface of the membrane and that it is located at an axial distance from it sufficient to promote the drying of the membrane when the pressure exerted on the wall of the container ceases after delivery of liquid, and that this container is returned to its rest position, placed on its base with the dispensing head at the top. As a result, any residue of liquid which, not having been expelled, remains contained in the intermediate chamber, does not persist in wetting the membrane by capillarity. It should be noted that the hydrophobic nature of the microporous pad also promotes the drying of the membrane.

[0022] Thanks to its different characteristics, as mentioned above and as that they will be more fully defined and described below, the invention has the advantage, in industrial practice, to overcome the complex systems of dynamic closure that were previously used. Thanks to the provisions of the invention, there is no need for a lid or other tear-off separation, or a valve of other shape, or a procedure for opening the bottle by translation or rotation of the dispensing head with respect to the reservoir of the liquid to be dispensed drop by drop.

[0023] In particular, the advantageous combination of the presence of the microporous pad of hydrophobic nature, that of the filtering membrane, and that of the

intermediate chamber between them, which jointly confer on the dispensing head both a function of regularizing the liquid flow during the expulsion of the latter and a closing and drying function of the membrane in combination with the pressure of the air retained in the intermediate chamber due to the sealing of the cap on the dispensing head.

[0024] A microporous pad quite suitable in the context of the invention has, for the passage of the liquid in the longitudinal direction, microchannels whose average pore diameter is between 0.3 and 10 microns.

[0025] Such a range of values is particularly suitable in the preferred field of application of the invention, which is the storage and dispensing of a pharmaceutical solution, especially eye drops.

[0026] In addition, it ensures that the pad will produce a sufficient pressure drop to isolate the membrane from the liquid contained in the container before the first use. This advantageously prevents the membrane from degrading in contact with the liquid during the storage phase of the container before the first use.

[0027] In addition, it is quite advantageous, in the context of the invention, to associate such a microporous pad with a partially hydrophilic and partially hydrophobic membrane whose pore diameter is smaller than that of the pad, in particular between 0.1 and 0.2 microns. As a result, improved sealing and flow control properties of the dispensing head are obtained in particular.

[0028] The membrane may be made of a polymeric material, based for example on polyamide resin or polyether sulfone, which gives it a hydrophilic character. It is then rendered partially hydrophobic by modifying its structure on part of its surface. Such a modification can be carried out in a conventional manner in itself, for example by grafting in the presence of an initiator of radical reactions. The treatment is advantageously carried out so as to render the membrane hydrophobic on a median strip occupying 20 to 50% of its surface which is wetted during the expulsion of the liquid.

[0029] Preferably, the body is assembled inside the neck by interlocking in close contact.

[0030] The body is preferably elastically deformable so as to forcefully introduce it inside the neck of the container, a centering member being preferably formed at the base of the body to facilitate such a forceful introduction. This centering member is preferably constituted by radial wings providing junction by interlocking the body of the dispensing head on the neck of the container, the wings delimiting hollowed-out areas between them.

[0031] To further promote the sealing of the container and the introduction in close contact of the body inside the neck of the container, the outer surface of the body of the dispensing head is advantageously equipped with a peripheral ring derived from said body with which it constitutes a single-piece assembly, this ring being preferably in plurality and axially repeated on the body.

[0032] It will be noted that the body is advantageously obtained by molding, under conditions such that a ring, derived from the joint plane, is radial to its general axis of extension, and, in particular, if appropriate, parallel to the aforementioned peripheral ring. This ring, derived from the joint plane, is more particularly located at the distal end of the body, at the junction limit of the centering member, to promote optimal sealing between the dispensing head and the container.

[0033] The removable cap meanwhile is preferentially fastened on the container by screwing to promote the clamping of the cap on the dispensing head, and therefore the

sealing between these organs.

[0034] For this purpose, the cap advantageously comprises a combination of sealing members associating a pin penetrating inside the nozzle of the dispensing head and a skirt covering this nozzle. The pin and the skirt are advantageously derived from the cap, when obtaining the latter in a single piece, particularly by molding.

[0035] The present invention will be better understood on reading the description which will be made in connection with the figures of the attached plate, in which:

Figure 1 and Figure 2 are diagrams in axial section which illustrate a container for the conditioning of a liquid according to respective variant embodiments of the present invention.

Figure 3 is a sectional view of the container illustrated in Figure 2, taken radially in the region of a centering member that it comprises.

[0036] In Figures 1 and 2, a container for the conditioning of a liquid 1 is provided with spontaneously reversible deformation to allow dispensing the liquid 1 from a manual compression of its wall 2 exerted by a user and a spontaneous return to its original shape by admission of air. This container has a storage capacity 15 of the liquid 1, and is equipped with a dispensing head 3 of the liquid drop by drop. This dispensing head 3 consists mainly of a hollowed-out body 4 provided with a nozzle 5, and a removable cap 6 for closing off the nozzle 5. An antibacterial filtering membrane 7, which is partially hydrophilic and partially hydrophobic, therefore permeable to air but also to the liquid, is disposed upstream of the nozzle 5, to protect the liquid against an unwanted introduction of pollutants possibly present in the ambient air, including bacteria.

[0037] The body 4 of the dispensing head 3 houses in its hollowed-out body a microporous pad 8 which is made of a hydrophobic material, in particular polyethylene, to prevent the passage of the liquid 1 towards the nozzle 5, in the absence of compression on the wall 2 of the container. This microporous pad 8 is disposed upstream and away from the membrane 7 so as to provide between itself 8 and the latter 7 an intermediate chamber 9.

[0038] The chamber 9 extends over the entire surface of the pad so as to constitute a reserve of air which exerts, when the nozzle 5 is closed by the cap 6, a pressure on the entire surface of the pad 8 preventing the liquid 1 to pass through the microporous pad 8 when the nozzle 5 is closed by the cap 6. More specifically, the cap 6 prevents an evacuation of air out of the container, and more particularly out of the intermediate chamber 9. The air being confined downstream of the microporous pad 8, the latter obstructs the passage of the liquid 1 through itself as long as the nozzle 5 is closed by the cap 6. Conversely, for delivery of the liquid 1, the microporous pad 8 does not prevent this delivery as long as the air can be discharged out of the container through the nozzle 5. The intermediate chamber 9 is used to allow a spontaneous regularization of the flow of liquid 1 through the microporous pad 8, prior to its dispensing through the nozzle 5.

[0039] The intermediate chamber 9 extends over the entire surface of the membrane so as to constitute a capacity to collect the liquid 1 away from the membrane 7 when the user stops exerting pressure on the wall 2 of the container and thus to promote the drying of the membrane between two liquid deliveries.

[0040] The body 4 is permanently assembled inside the neck 10 of the container, by forceful interlocking. According to the different variants illustrated in Figure 1 and Figure 2, this interlocking is carried out either directly by close contact between the outer surface of the body 4 and the inner surface of the neck 10, as illustrated in Figure 1, namely, and preferably, by means of O-rings 11 provided at the periphery of the body 4, as illustrated in Figure 2. The preferred presence of a centering member 12, formed at the base of the body 4 to facilitate its introduction inside the neck 10 of the container, should be noted on these exemplary embodiments. The centering member 12, illustrated as an example, is generally constituted by radial wings 13 providing junction by interlocking the body 4 on the neck 10, the wings 13 delimiting hollowed-out areas between them, more particularly visible in Figure 3.

[0041] Finally, the assembly achieved by screwing the cap 6 on the neck 10 of the container, through cooperating reliefs 14, will be noted in the variants shown. To facilitate the screwing of the cap 6 on the container and to strengthen the seal between one and the other, the cap 6 comprises a pin 15 penetrating inside the nozzle 5 of the dispensing head and a skirt 16 covering the nozzle.

PATENTKRAV

1. Beholder til pakning af en væske, der skal dispenseres dråbevis, hvilken beholder omfatter et reservoir med en elastisk deformerbar væg (2), som er reversibel via tilførsel af luft inde i beholderen med henblik på at afgive væsken (1) under indvirkning af tryk udøvet mod væggen (2) og at tillade beholderens spontane tilbagevenden til den initiale konformation efter afgivelse af en dosis væske (1), et dispenseringshoved (3), der omfatter en udhulet krop (4), som er forsynet med en dyse (5) til afgivelse af væske (1), og en antibakteriel filtreringsmembran, der er anbragt opstrøms for dysen, **kendetegnet ved, at** beholderen omfatter en hydrofobisk mikroporøs pude (8), der er placeret nedstrøms for reservoiret inde i kroppen (4), idet kroppen er samlet irreversibelt inde i en hals (10) af beholderen, idet filtreringsmembranen (7) er anbragt mellem dysen og puden, ved, at membranen (7) er en delvis hydrofil membran med henblik på at tillade væsken at passere derigennem under indvirkning af det overtryk, der skabes i beholderen via tryk på væggen, og delvis hydrofobisk med henblik på at tillade luftpassage derigennem under indvirkning af det undertryk, der skabes i beholderen ved frigivelse af det tryk, som udøves på væggen, hvor beholderen endvidere er forsynet med en aftagelig hætte (6) til tætnet lukning af dysen (5), der sammen med den hydrofobiske mikroporøse pude (8) danner en forhindring for væskens (1) spontane strømning ud af det rum (15) i beholderen, som er reserveret til opbevaring deraf, til dysen (5), således at væskens (1) spontane passage gennem den mikroporøse pude (8) for det første forhindres, når hætten (6) på en tæt måde tillukker dysen (5), og således at væskens (1) frie strømning ud af det rum (15) i beholderen, som er reserveret til

opbevaring deraf, og gennem den hydrofobiske mikroporøse pude (8) omvendt for det andet tillades, når dysen (5) fritlægges med hensyn til den krævede afgivelse af en dosis væske (1) via tryk udøvet mod beholderens væg (2), og med henblik på for det tredje at tillade passage af den luft, der er aspireret gennem den hydrofobiske mikroporøse pude (8) til opbevaringsrummet (15) efter afgivelse af en dosis væske (1), via den elastiske tilbagevenden af beholderens væg (2) til den initiale konformation.

2. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 1, **kendetegnet ved, at** den mikroporøse pude (8) er fremstillet ud fra polyethylen med henblik på at tildele puden den hydrofobiske egenskab, idet den mikroporøse egenskab ikke desto mindre tillader væskens passage derigennem under indvirkning af et trykdifferentiale forårsaget af et tryk udøvet af en bruger mod beholderens væg.

3. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 1 eller 2, **kendetegnet ved, at** den mikroporøse pude (8) har mikrokanaler, hvis middelporediameter er mellem 0,3 og 10 mikrometer.

4. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge kravene 1 til 3, **kendetegnet ved, at** dispenseringshovedet omfatter et mellemkammer (9) til regulering af afgivelsen af væsken, hvilket mellemkammer er anbragt indskudt mellem den mikroporøse pude (8) og membranen (7).

5. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 4, **kendetegnet ved, at** kammeret har

tilstrækkeligt volumen til at indsamle mindst én dråbe væske, der skal dispenseres, under en afgivelsesoperation.

6. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 4 eller 5, **kendetegnet ved, at** kammeret strækker sig over hele pudens overflade med et tilstrækkeligt volumen til dannelse af en luftreserve, der, når dysen (5) er tillukket via hættten (6), udøver et tryk, der forhindrer væsken (1) i at passere gennem den mikroporøse pude (8).

7. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge et hvilket som helst af kravene 4 til 6, **kendetegnet ved, at** mellemkammeret (9) strækker sig over hele membranens overflade i en tilstrækkelig aksial afstand til at rumme den væske, som endnu ikke er passeret gennem membranen, når der ikke længere udøves tryk på beholderens væg, og således til at assistere med tørring af membranen mellem to afgivelser af væske.

8. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** kroppen (4) samles inde i beholderens hals (10) ved indsætning i tæt kontakt.

9. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 8, **kendetegnet ved, at** kroppen (4) er elastisk deformerbar til tvangsmæssig indføring deraf inde i beholderens hals (10), idet der er anbragt et centreringselement (12) ved kroppens (4) basis med henblik på at facilitere en sådan tvangsmæssig indføring.

10. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 9, **kendetegnet ved, at**

centreringsselementet (12) består af radiale finner (13) til sammenføjning af dispenseringshovedets krop (4) med beholderens hals (10) via sammenmontering, idet finnerne (13) begrænser udhulede sektorer derimellem.

11. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge et hvilket som helst af kravene 8 til 10, **kendetegnet ved, at** den ydre flade af dispenseringshovedets krop (4) er forsynet med mindst én O-ring (11), der udgår fra kroppen (4), med hvilken den udgør en enkeltstykkесamling, valgfrit en flerhed af aksialt fordelte O-ringe.

12. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** dispenseringshovedets krop (4) opnås ved formstøbning under sådanne forhold, at en ring (17), der opnås ud fra formstøbningsfugeplanet, er placeret ved den distale ende af kroppen (4) i forbindelsesgrænsen for centreringsselementet (1), der assisterer med at opnå en tætnet forbindelse mellem dispenseringshovedet og beholderen.

13. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** den aftagelige hætte (6) fastgøres til beholderen ved påskruning.

14. Beholder til pakning af en væske, der skal dispenseres dråbevis, ifølge krav 13, **kendetegnet ved, at** hætten (6) omfatter en kombination af tætningselementer, der forbinder en spids (15), der trænger ind i dispenseringshovedets dyse (5), og en krave(16), som passer oven på dysen (5).

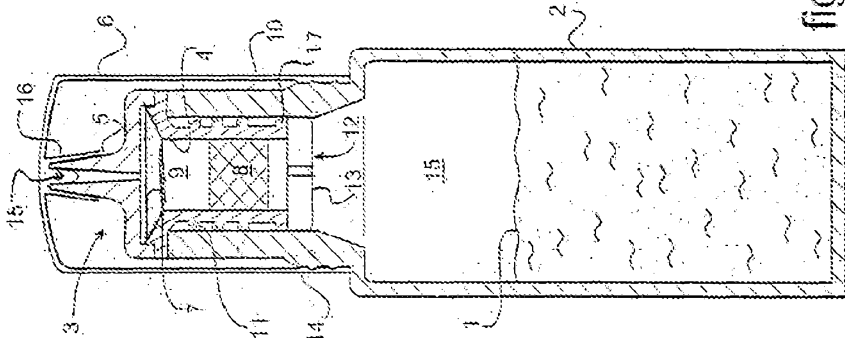


figure 2

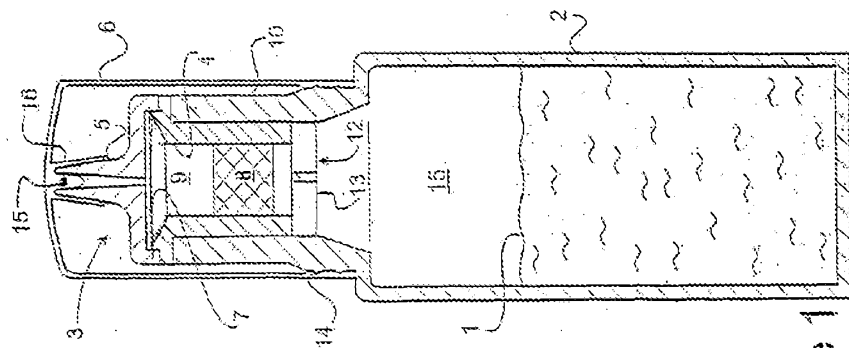


figure 1

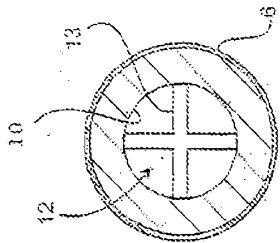


figure 3