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(54) **Drug delivery container having a luer filter**

Behälter mit einem Luer-Filter zur Verabreichung eines Arzneistoffes

Flacon pour délivrer des médicaments comportant un filtre de type luer

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Description

[0001] 1. Field of the Invention. The invention relates to a resealable vial connector assembly that contributes to sterility, which prevents particulate flow to or from the vial, and which controls unintended splash back from the vial.

[0002] 2. Description of the Prior Art. Liquid drugs typically have a shelf life. As a result, liquid drugs typically are stamped with an expiration date, and health care facilities must monitor their inventory to ensure that the drugs are used in a timely manner.

[0003] Many drugs are lyophilized or reduced to a dry powdered form, to increase shelf life and to minimize inventory control problems. The lyophilized drug typically is stored in a sealed glass vial. A measured amount of a liquid solvent may be mixed with the lyophilized during shortly prior to use to produce a drug solution. A selected dose of the drug solution may then be withdrawn from the vial and administered to the patient.

[0004] The prior art has included many structures for sealing glass vials of lyophilized drugs. These prior art structures have attempted to deal with the often conflicting objectives of long term storage and easy access. For example, some prior art vials of lyophilized drugs are sealed with a pierceable membrane. The sealed vial may be used with an adapter having a double ended needle or double ended spike. One end of the needle or spike is urged through the membrane on the vial, and the opposed end is placed in communication with a supply of solvent or with an appropriate drug delivery apparatus. This prior art method and apparatus is undesirable in that small fragments of the membrane can separate when the seal is pierced and can be delivered into the patient.

[0005] Other prior art vials of lyophilized drugs are sealed with a rubber stopper. The stopper is urged into the vial to enable delivery of a solvent to the vial. The rubber stopper is unlikely to generate fragments, and the loose stopper may contribute to efficient mixing of the drug solution. However, the loose stopper can partly block the neck of the vial, and thereby may adversely affect the ability to administer the drug solution to a patient. Additionally, the stopper cannot be used to reseal the vial for preserving unused portions of the drug solution.

[0006] The prior art also includes a connector assembly having a rubber stopper that is securely connected to the proximal end of a spike or a needle. A lumen extends from the pointed distal end of the spike or needle to a location near the stopper. Proximal forces on the spike will urge the stopper proximally beyond the neck of the vial, and permit the solvent to be mixed with the lyophilized drug. The stopper remains affixed to the spike or needle, and therefore will not impede the removal of the drug solution. In some configurations, the spike or needle and the attached stopper may be moved distally to reseal the vial.

[0007] Vial connector assemblies of this type are effective. However, owing to the nature of certain lyophilized medecines, there may be possibility that the all of the lyophilized medecine will not be fully reconstituted, leaving an amount of particulate matter, however small, remaining in the vial. It is preferable that these particles be excluded from delivery to the patient. Moreover, movement of the vial and/or gas pressure generated by mixing the drug solution can cause a splash back of the drug solution when the vial is separated from the supply of solvent and/or from the drug delivery apparatus. Splash back causes a loss of costly drug solution and makes it difficult to monitor the amount of solvent that has been added and the amount of drug solution that has been removed. Splash back also may expose health care workers to the drug.

[0008] Some prior art vials have a luer connector rather than a spike or needle. The luer connector can be threadedly engaged with a supply of solvent or with an appropriate drug delivery apparatus. However, depending on the pressurization inside the vial, the luer connector may allow some splash back, which is preferably avoided.

[0009] WO91/07160 provides a storage bottle which contains a constituent of a medicinal solution and a transfer device for transferring the solution, once it has been mixed with a solvent, into a final-use container. The bottle comprises a constricted neck in which is located, during the storage phase, a sealing device consisting of two elements: a first element consisting of an elastomeric stopper, and a second element consisting of an elastomeric O-ring seal. At least one inlet opens into the space between the first and second elements of the sealing device.

SUMMARY OF THE INVENTION

[0010] According to the present invention, there is provided a vial connection assembly for a vial having a drug receiving chamber, a tubular neck extending from said drug receiving chamber and an open top, said assembly comprising:

a stopper disposed in said vial and being slidably moveable in said neck of said vial;
a luer tube having a distal end disposed externally of said vial and a proximal end rigidly secured to said stopper, said luer tube comprising a lumen extending therethrough from a proximal position substantially adjacent said stopper to said distal end of said luer tube, said luer tube being slidably moveable in said neck of said vial between a distal position where said stopper sealingly engages said neck of said vial and a proximal position where said stopper is in said fluid receiving chamber such that said lumen of said luer tube communicates with said fluid receiving chamber of said vial; and
a filter secured in said lumen of said luer tube, said

filter permitting fluid flow therethrough in response to a pressure differential on opposite respective sides of the filter, whereby said filter acts to prevent particulate flow to or from said vial; and

the assembly further comprises a collar having an inner tubular wall securely engaging said luer tube and an outer wall slidably engaged around said neck of said vial, with an O-ring seal sealingly engaged around said luer tube and sealingly engaged within said neck of said vial, said O-ring seal being disposed distally of said stopper at a position for slidable sealing engagement with said neck of said vial for all sliding positions of said luer tube relative to said vial; and

the assembly comprising one or more ribs between the luer tube and the inner tubular wall of the collar to prevent unwanted rotation between the luer tube and the collar.

DETAILS OF THE INVENTION

[0011] The invention is directed to a vial connector assembly for use with a vial of a lyophilized drug. The vial may be a glass vial having a bottom wall and an upstanding side wall. A shoulder may extend inwardly from the upper end of the side wall and a neck may extend upwardly from the shoulder. The top end of the neck is opened and defines the access to the vial. An enlarged annular rim may extend around the open top end of the neck.

[0012] The connector assembly of the invention includes a luer tube with-opposed proximal and distal ends and a lumen extending continuously therebetween. Portions of the luer tube between the proximal and distal ends may be slidably disposed within the neck of the vial. The proximal end of the luer tube is permanently mounted to a rubber stopper which in turn is slidably and sealably engageable within the neck of the vial. Portions of the luer tube adjacent the stopper include apertures or slots that communicate with the lumen through the tube. The distal end of the luer tube includes a pair of oppositely directed luer projections for threaded engagement with a luer connector on a syringe or on a fitting for delivering a solvent into the vial and for delivering a drug solution from the vial.

[0013] The luer tube further is provided with a filter securely affixed at a location in the lumen intermediate the proximal and distal ends of the luer tube. The filter is selected from known materials that will prevent a flow of solid particulates. Thus, the filter will act to prevent particulate or contaminants from being transported into or out of the vial and will act to prevent an outflow of undesolved lyophilized drug into the patient. The filter also will act to prevent a sufficient impediment to liquid flow for preventing an undesirable splash back of drug solution when the vial is separated from the supply of solvent and/or when the vial is separated from the drug delivery system. However, the filter will permit a flow of solvent under pressure into the vial and similarly will enable an outflow of drug solution from the vial in response to a pressure differential across the filter.

[0014] The connector assembly further includes a collar having opposed proximal and distal ends and a generally annular transverse wall therebetween. The luer tube passes through the annular transverse wall of the collar and is securely mounted thereto. An inner wall is projects proximally from the transverse wall and is dimensioned for slidable insertion into the opened neck of the vial. The inner wall is surrounds portions of the luer tube. An outer wall is dimensioned and configured for slidable movement along the outer circumferential surface of the neck of the vial. However, the outer wall may include latches that are engageable with the enlarged annular rim around the open top of the neck to prevent complete removal of the collar from the vial. Thus, the collar functions to guide the luer tube through a controlled range of movement in the vial.

[0015] One or more ribs is provided between the luer tube and the collar, so as to prevent any unwanted rotation between the two such as may occur, for instance, when a luer syringe is attached to removed from the luer tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016]

Fig. 1 is a side elevational view of a vial and a connector assembly in accordance with the invention.

Fig. 2 is a cross-sectional view of a prior art vial.

Fig. 3 is an exploded perspective view of a vial connector assembly in accordance with the invention.

Fig. 4 is a top plan view of the collar shown in Fig. 3.

Fig. 5 is a cross-sectional view taken along line 5-5 in Fig. 4.

Fig. 6 is a side elevational view of the luer tube shown in Fig. 3.

Fig. 7 is a cross-sectional view taken along line 7-7 in Fig. 6.

Fig. 8 is a cross-sectional view taken along line 8-8 in Fig. 1.

Fig. 9 is a cross-sectional view similar to Fig. 8 showing the vial connector assembly in a condition for introducing solvent to the vial or removing drug solution therefrom.

Fig. 10 is an enlarged view of the connected luer tube and the collar.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0017] A connector assembly in accordance with the subject invention is identified generally by the numeral 10 in Figs. 1, 3, 8 and 9. Connector assembly 10 is used with a prior art glass vial 12 having a bottom wall 14. With reference to Fig. 2, a cylindrical side wall 16 ex-

tends upwardly and substantially orthogonally from bottom wall 14. A shoulder 18 extends inwardly and upwardly from an end of cylindrical side wall 16 remote from bottom wall 14. A cylindrical neck 20 with an inside diameter "a" and an outside diameter "b" extends upwardly from shoulder 18. Neck 20 terminates at an open top 22 and comprises an annular rim 24 projecting outwardly from neck 20 adjacent top 22. Annular rim 24 has an outside diameter "c". Vial 12 contains a drug 26 in dry form, such as a lyophilized drug or a powdered drug, as shown most clearly in Fig. 2.

[0018] Connector assembly 10 functions to protectively seal drug 26 in vial 12 and to permit a solvent to be added to vial 12 for forming a drug solution. Connector assembly 10 further enables connection of vial 12 to a delivery system for administering drug solution 30 to a patient. Connector assembly 10 may then be disconnected from the delivery system and resealed for further use.

[0019] As shown in Figs. 3-5, connector assembly 10 may feature a generally tubular collar 32 having a proximal end 34, a distal end 36 and an annular transverse wall 38 between ends 34 and 36. Annular transverse wall 38 defines an inside diameter less than inside diameter "a" of neck 20 on vial 12 and an outside diameter greater than inside diameter "a" of neck 20. Thus, annular transverse wall 38 can be supported on the top end 22 of vial 12.

[0020] Collar 32 comprises further a tubular inner wall 40 extending proximally from transverse wall 38 toward proximal end 34 of collar 32. Tubular inner wall 40 defines an outside diameter less than inside diameter "a" of neck 20 on vial 12. Proximal portions of tubular inner wall 40 define an outer circumferential step 42 for receiving an O-ring seal as explained further herein. Tubular inner wall 40 further defines an inner generally cylindrical surface having an inside diameter "d" as shown in Fig. 4.

[0021] Collar 32 further includes a outer wall 44 projecting proximally from transverse wall 38 to proximal end 34 of collar 32. Outer wall 44 includes a plurality of distal notches 46 extending proximally from transverse wall 38 to define a plurality of spaced apart resiliently deflectable segments 48 disposed in a generally cylindrical array around transverse wall 38. Outer circumferential portions of segments 48 include detents 50 defining a major outside diameter for collar 32. Outer wall 44 is further defined by a plurality of proximal notches 52 extending distally from proximal end 34. Proximal notches 52 are offset circumferentially from distal notches 46 to define a plurality of circumferentially spaced resiliently deflectable fingers 54 at proximal end 34 of collar 32. Each finger 54 includes an inwardly projecting locking detent 56 having a proximally and inwardly facing cam surface 58 and a distally facing locking surface 60. Opposed locking projections 56 define a minor inside diameter for outer wall 44 which is approximately equal to the outside diameter "b" of neck 20 on vial 12. Portions of outer wall 44 distally of locking projections 56 define an inside diameter approximately equal to outside diameter "c" of rim 24 on vial 12.

[0022] Collar 32 further includes a tubular distal wall 62 projecting distally from transverse wall 38. Tubular distal wall 62 is diametrically greater than tubular inner wall 40 and smaller than outer wall 44.

[0023] Connector assembly 10 further includes a luer tube 64 as illustrated in Figs. 3, 6 and 7. Luer tube 64 has opposed proximal and distal ends 66 and 68 and a passage 70 extending axially therebetween. Proximal portions 72 of passage 70 are substantially cylindrical. Distal portions 74 of passage 70 taper from a major diameter adjacent distal end 68 to a minor diameter spaced therefrom. The taper on distal portions 74 of passage 70 may be configured to conform to a tip on a hypodermic syringe. Passage 70 further includes intermediate portion 76 extending between cylindrical portion 72 and tapered distal end 74. Intermediate portion 76 is tapered in a direction opposite from distal tapered portion 74.

[0024] In order to address the aforementioned difficulties with inadvertent particulate flow or splashback, luer tube 64 further includes a filter 78. Here, filter 78 is shown as securely affixed at the region of dimensional change between cylindrical portion 72 and intermediate portion 76. However, filter 78 may be affixed at another location intermediate proximal and distal ends 66 and 68 of the luer tube. Filter 78 may be formed from a material that will permit a passage of liquid solutions in response to a pressure differential on opposite sides of filter 78. However, filter 78 acts to substantially prevent movement of particulates and acts to prevent flow of liquid if there is no significant pressure differential on opposite sides of filter 78. Thus, filter 78 acts to prevent flow of liquid in response to the above described splash back or mere gravitational flow.

[0025] Proximal end 66 of luer collar 64 comprises a plurality of axially extending slots 80 defining a plurality of resiliently deflectable fingers 82 of length "f". Fingers 82 define an outer diameter "g" along a major portion of their respective lengths. However, fingers 82 comprise outwardly projecting locking detents 84 which define a major outside diameter "h" for fingers 82. Locking detents 84 further comprise a proximally and outwardly facing tapered surface.

[0026] Distal end 68 of luer tube 64 comprises a pair of luer projections 86. Luer projections 86 are dimensioned and configured for threaded engagement with a mateable luer connection, such as a luer collar on a hypodermic syringe. Thus, luer projections 86 enable luer tube 64 of connector assembly 10 to be threadedly, but releasably, engaged with a supply of solvent for mixing with drug 26 and/or for connection to a drug delivery device to enable administration of a drug solution to a patient.

[0027] Outer circumferential portions of luer tube 64 between proximal and distal ends 66 and 68 are dimen-

sioned for slidable insertion in inner tubular wall 40 of collar 32. A step 88 on the outer circumferential surface of luer tube 64 is engageable with the end of tubular inner wall 40 of collar 32 and defines the maximum extent of telescoped engagement between luer tube 64 and collar 32. Luer tube 64 further includes a seal step 90 which cooperates with the step 42 on tubular inner wall 40 of collar 32 for capturing an O-ring seal therebetween.

[0028] Connector assembly 10 further includes an O-ring 92, as illustrated in Figs. 3 and 8-10, which extends between step 42 of tubular inner wall 40 of collar 32 and step 90 on luer tube 64. The O-ring is dimensioned to sealingly engage against both tubular inner wall 40 and luer tube 64. Outer circumferential portions of O-ring 92 are dimensioned for sliding fluid tight and air tight engagement with the inner circumferential surface of neck 20 on vial 12.

[0029] With reference to Figs. 3, 8 and 9, connector assembly 10 further includes a stopper 94 formed from a resiliently deflectable elastomeric material. Stopper 94 is of generally cylindrical shape and includes opposed proximal and distal ends 96 and 98. Outer circumferential surface regions of stopper 94 between proximal and distal ends 96 and 98 comprise a plurality of annular ribs for deflectable sealing engagement with inner circumferential surface regions of tubular neck 20 on vial 12. Proximal end 96 of stopper 94 is substantially continuous entirely thereacross, as shown in Fig. 3, to provide a fluid and air impervious barrier across tubular neck 20 of vial 12. Distal end 98 of stopper 94 comprises a short cylindrical recess 100, as shown in Figs. 8 and 9. Recess 100 defines a depth which is less than the length "f' of fingers 82 on luer tube 64. Recess 100 further defines a diameter approximately equal to the outside diameter "g" on fingers 82 at locations spaced from detents 84. Thus, as shown most clearly in Figs. 8 and 9, proximal end 66 of luer tube 64 can be urged into recess 100 of stopper 94. This insertion of proximal end 66 of luer tube 64 into recess 100 will cause a deformation of the elastomeric material from which stopper 94 is formed and an inward deflection of fingers 32. Upon complete insertion, the elastomeric material of stopper 94 will resiliently return toward its undeformed condition around detents 84, such that detents 84 and the elastomeric material of stopper 94 cooperate with one another for securely retaining stopper 94 on fingers 82 of luer tube 64. The relative depth of recess 100 and length "f" of fingers 82 ensures that portions of slots 80 between fingers 82 will extend distally beyond stopper 94. Thus, stopper 94 will not impede fluid flow through passage 70 of luer tube 64.

[0030] Connector assembly 10 further includes a protective cap 102, as shown in Fig. 1 and 8. Protective cap 102 has a stepped tubular side wall 104 and an end wall 106. The relative dimensions of stepped tubular side wall 104 of protective cap 102 are selected to enable releasable frictional engagement with distal wall 66 of collar 32 and with outer circumferential portions of outer wall 44.

[0031] The above described components of connector assembly 10 are assembled by initially mounting O-ring 92 over proximal end 42 of tubular inner wall 40 of collar 32. The relative position of O-ring 92 on inner tubular wall 40 is precisely controlled by step 42 provided on tubular inner wall 40. Distal end 68 of luer tube 64 is then inserted distally through the proximal end of tubular inner wall 40. After sufficient insertion, step 90 of luer tube 64 will engage against the proximal end of O-ring 92 and will tightly engage within tubular inner wall 40 of collar 32. Proximal end 66 of luer tube 64 may then be urged into recess 100 of stopper 94, such that detents 84 at the ends of fingers 82 lockingly secure stopper 94 to luer tube 64.

[0032] One or more ribs "R" is provided between tubular wall 40 of the collar and outer circumferential portions of luer tube 64 engaging tubular wall 40. See Figures 8 and 10. The purpose of the ribs is to prevent unwanted rotation between the luer tube and the collar that can result, for instance, when a force is exerted upon the luer tube by a luer syringe as it is being attached to or removed from distal end 68 of the luer tube. The ribs can be formed as part of either the collar or luer tube, or both, or they can be separately affixed to either of them. The ribs can be formed from plastics, elastomeric materials, or any other material capable of providing this stated function.

[0033] The assembly of collar 32, luer tube 64, O-ring 92 and stopper 94 are then mounted onto vial 12. More particularly, stopper 94, luer tube 64, tubular inner wall 40 of collar 32 and O-ring 92 all are inserted into open top 22 of vial 12 and are slid proximally along interior regions of neck 20. After sufficient insertion, cam surfaces 58 of locking projections 56 on outer wall 44 of collar 32 engage rim 24 of vial 12. This cammed interengagement will generate an outward deflection of fingers 54 sufficient to permit further proximal movement of collar 32. After sufficient proximal movement, projections 56 will clear annular rim 24 of vial 12 and fingers 54 will resiliently return toward an undeflected condition. Thus, locking surfaces 60 of locking projections 56 will lockingly engage against the proximal surface of annular rim 22 on vial 12. As a result, removal of collar 32 from vial 12 is rendered difficult.

[0034] Connector assembly 10 can be moved in proximal and distal directions relative to vial 12. As shown in Fig 2, connector assembly 10 is in its distal position on vial 12. In this position both O-ring 92 and stopper 94 are sealably engaged with inner circumferential surfaces of neck 20 on vial 12. Thus, drug 26 within vial 12 is contained for long term storage. Sterility of luer tube 64 and distal wall 62 of collar 32 can be assured by frictionally retaining protective cap 102 over collar 32.

[0035] Shortly prior to use of drug 26, protective cap 102 is disengaged from collar 32 by exerting distally directed pulling forces sufficient to overcome the frictional

engagement. Distal end 68 of luer tube 64 then may be threadedly engaged with a supply of solvent. The solvent may be stored in a hypodermic syringe or in some other container that is threadedly engageable with the luer projections 86 on distal end 68 of luer tube 64. The solvent can be directed into vial 12 by urging vial 12 and the supply of solvent toward one another. These forces will overcome the frictional engagement of stopper 94 with neck 20 of vial 12 and will urge stopper 94 proximally into vial 12 as shown in Fig. 9. In this condition, pressure can be exerted on the supply of solvent to urge solvent 28 through filter 78 and through cylindrical portions 72 of passage 70. Solvent 28 will continue to flow through slots 80 between fingers 82 and into vial 12. The solvent will mix with lyophilized drug 26 to produce drug solution 30 illustrated schematically in Fig. 9.

[0036] After delivery of sufficient solvent to vial 12, the supply of solvent may be disengaged from luer tube 64 to permit agitation of vial 12 to ensure that drug solution 30 is adequately mixed. Luer tube 64 may then be connected with a device for delivering drug solution 30 to a patient. More particularly, luer projections 86 at distal end 68 of luer tube 64 may be threadedly engaged with a drug delivery device, such as a hypodermic syringe. Pressure differentials created by the drug delivery device, such as the hypodermic syringe, will cause drug solution 30 to flow distally through filter 78 and into the drug delivery device.

[0037] Filter 78 performs several significant functions. First, filter 78 acts to prevent any extraneous material from flowing into vial 12 and into drug solution 30 after removal of safety cap 102. For example, luer tube 64 may be in the Fig. 9 orientation after separation of connector assembly 10 from the supply of solvent and/or after separation of the connector assembly 10 from the drug delivery device. In this Fig. 9 orientation, extraneous particulate material could migrate into vial 12. Additionally, even slight movements of vial 12, when the connector assembly 10 is in the Fig. 9 orientation, could generate a splash back of drug solution 30. Such a splash back is rendered likely particularly in view of increased pressures that often are created within vial 12 in response to the mixture of solvent 28 with lyophilized drug 26. Filter 78 is operative to permit a pressurized flow of fluid therethrough, but will substantially block low pressure splashing or gravitational flows of drug solution 30 through filter 78. Thus, precise amounts of drug solution can be carefully monitored both for checking the original dosage that may have been delivered to a patient, for checking the approximate concentration of drug solution 30 and for ensuring that a predetermined amount of drug solution 30 is available for a subsequent administration to the patient.

[0038] While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. For example, the relative position of the filter within the luer tube can be varied. Additionally, one preferred assembly of a luer tube, collar and stoppers has been illustrated and described. Other possible assemblies with a filter may also be provided in accordance with the invention as defined by the appended claims.

Claims

1. A vial connection assembly for a vial (12) having a drug receiving chamber, a tubular neck (20) extending from said drug receiving chamber and an open top (22), said assembly comprising:

a stopper (94) disposed in said vial (12) and being slidably moveable in said neck (20) of said vial (12);
a luer tube (64) having a distal end (68) disposed externally of said vial (12) and a proximal end (66) rigidly secured to said stopper (94), said luer tube (64) comprising a passage (70) extending therethrough from a proximal position substantially adjacent said stopper (94) to said distal end (68) of said luer tube (64), said luer tube (64) being slidably moveable in said neck (20) of said vial (12) between a distal position where said stopper (94) sealingly engages said neck (20) of said vial (12) and a proximal position where said stopper (94) is in said fluid receiving chamber such that said passage (70) of said luer tube (64) communicates with said fluid receiving chamber of said vial 12); and
a filter (78) secured in said passage (70) of said luer tube (64), said filter (78) permitting fluid flow therethrough in response to a pressure differential on opposite respective sides of the filter (78), whereby said filter (78) acts to prevent particulate flow to or from said vial (12); and

the assembly further comprises a collar (32) having an inner tubular wall (40) securely engaging said luer tube (64) and an outer wall (44) slidably engaged around said neck (20) of said vial (12), with an O-ring seal (92) sealingly engaged around said luer tube (64) and sealingly engaged within said neck (20) of said vial (12), said O-ring (92) seal being disposed distally of said stopper (94) at a position for slidable sealing engagement with said neck (20) of said vial (12) for all sliding positions of said luer tube (64) relative to said vial (12), **characterised in that**

the assembly comprising one or more ribs (R) between the luer tube (64) and the inner tubular wall (40) of the collar (32) to prevent unwanted rotation between the luer tube (64) and the collar (32).

2. The assembly of Claim 1, further comprising a protective cap (102) releasably engaged over said col-

lar (32) and over said top of said vial (12).

3. The assembly of Claim 1, wherein said filter (78) is disposed at a location in said passage (70) of said luer tube (64) between said proximal and distal ends (66, 68) of said luer tube (64).

4. The assembly of Claim 3, wherein said passage (70) through said luer tube (64) includes a diametrical dimensional discontinuity (76), said filter (78) being secured at said dimensional discontinuity (76) in said passage.

Patentansprüche

1. Ampullenanschlußbaugruppe für eine Ampulle (12) mit einer Arzneimittelaufnahmekammer, einem von der Arzneimittelaufnahmekammer vorstehenden röhrenförmigen Hals (20) und einem offenen Oberteil (22), wobei die Baugruppe folgendes umfaßt:

einen Stopfen (94), der in der Ampulle (12) angeordnet wird und gleitend im Hals (20) der Ampulle (12) bewegt werden kann,
ein Lüer-Rohr (64) mit einem außerhalb der Ampulle (12) angeordneten distalen Ende (68) und einem starr am Stopfen (94) befestigten proximalen Ende (66), wobei das Lüer-Rohr (64) einen Durchgang (70) umfaßt, der durch dasselbe von einer proximalen Position wesentlich angrenzend an den Stopfen (94) zum distalen Ende (68) des Lüer-Rohrs (64) verläuft, wobei das Lüer-Rohr (64) gleitend im Hals (20) der Ampulle (12) bewegt werden kann, zwischen einer distalen Position, in welcher der Stopfen (94) abdichtend mit dem Hals (20) der Ampulle (12) ineinandergreift, und einer proximalen Position, in welcher der Stopfen (94) in der Fluidaufnahmekammer ist derart, daß der Durchgang (70) des Lüer-Rohrs (64) mit der Fluidaufnahmekammer der Ampulle (12) in Verbindung steht, und
einen im Durchgang (70) des Lüer-Rohrs (64) befestigten Filter (78), wobei der Filter (78) als Reaktion auf ein Druckgefälle auf den gegenüberliegenden jeweiligen Seiten des Filters (78) einen Fluidstrom durch denselben ermöglicht, wodurch der Filter (78) wirkt, um einen Teilchenstrom zu oder von der Ampulle (12) zu verhindern, und
die Baugruppe außerdem einen Bund (32) mit einer röhrenförmigen Innenwand (40), die das Lüer-Rohr (64) sicher in Eingriff nimmt, und einer Außenwand (44), gleitend im Eingriff um den Hals (20) der Ampulle (12), mit einer O-Ring-Dichtung (92) dichtend im Eingriff um das Lüer-Rohr (64) und dichtend im Eingriff innerhalb des Halses (20) der Ampulle (12), wobei die O-Ring-Dichtung (92) in distaler Richtung vom Stopfen (94) angeordnet wird, in einer Position zum gleitenden Dichteingriff mit dem Hals (20) der Ampulle (12) bei allen Gleitpositionen des Lüer-Rohrs (64) im Verhältnis zur Ampulle (12), **dadurch gekennzeichnet, daß** die Baugruppe eine oder mehrere Rippen (R) zwischen dem Lüer-Rohr (64) und der röhrenförmigen Innenwand (40) des Bundes (32) umfaßt, um eine unerwünschte Rotation zwischen dem Lüer-Rohr (64) und dem Bund (32) zu verhindern.

2. Baugruppe nach Anspruch 1, die außerdem eine Schutzkappe (102) umfaßt, lösbar im Eingriff über dem Bund (32) und über dem Oberteil der Ampulle (12).

3. Baugruppe nach Anspruch 1, bei welcher der Filter (78) an einer Stelle im Durchgang (70) des Lüer-Rohrs (64) zwischen dem proximalen und dem distalen Ende (66, 68) des Lüer-Rohrs (64) angeordnet wird.

4. Baugruppe nach Anspruch 3, bei welcher der Durchgang (70) durch das Lüer-Rohr (64) eine Abmessungsdiskontinuität (76) des Durchmessers einschließt, wobei der Filter (78) an der Abmessungsdiskontinuität (76) im Durchgang befestigt wird.

Revendications

1. Assemblage de raccord de flacon pour un flacon (12) comportant une chambre de réception d'un médicament, un col tubulaire (20) s'étendant de ladite chambre de réception du médicament vers une partie supérieure ouverte (22), ledit assemblage comprenant:

un bouchon (94), agencé dans ledit flacon (112) et pouvant être déplacé par glissement dans ledit col (20) dudit flacon (12);
un tube luer (64) comportant une extrémité distale (68) agencée à l'extérieur dudit flacon (12) et une extrémité proximale (66) fixée de manière rigide sur ledit bouchon (94), ledit tube luer (64) comprenant un passage (70) le traversant, d'une position proximale pratiquement adjacente audit bouchon (94) vers ladite extrémité distale (68) dudit tube luer (64), ledit tube luer (64) pouvant être déplacé par glissement dans ledit col (20) dudit flacon (12) entre une position distale, dans laquelle ledit bouchon (94) s'engage de manière étanche dans ledit col (20) dudit flacon (12), et une position proximale, dans

laquelle ledit bouchon (94) est agencé dans ladite chambre de réception de fluide, de sorte que ledit passage (70) dudit tube luer (64) communique avec ladite chambre de réception de fluide dudit flacon (12); et
un filtre (78) fixé dans ledit passage (70) dudit tube luer (64), ledit filtre (78) permettant l'écoulement de fluide en réponse à une différence de pression sur les côtés opposés respectifs du filtre (78), ledit filtre (78) empêchant ainsi un écoulement de matières particulaires vers ledit flacon (12) et à partir ce celui-ci; et
l'assemblage comprenant en outre un collier (32) comportant une paroi tubulaire interne (40) s'engageant fermement dans ledit tube luer (64) et une paroi externe (44) engagée par glissement autour dudit col (20) dudit flacon (12), un joint torique d'étanchéité (92) étant engagé de manière étanche autour dudit tube luer (64) et engagé de manière étanche dans ledit col (20) dudit flacon (12), ledit joint torique d'étanchéité (92) étant agencé en un emplacement distal par rapport audit bouchon (94) au niveau d'une position permettant un engagement par glissement étanche dans ledit col (20) dudit flacon (12) pour toutes les positions de glissement dudit tube luer (64) par rapport audit flacon (12), **caractérisé en ce que**;
l'assemblage comprend une ou plusieurs nervures (R) entre le tube luer (64) et la paroi tubulaire interne (40) du collier (34) pour empêcher une rotation indésirable entre le tube luer (64) et le collier (32)

2. Assemblage selon la revendication 1, comprenant en outre un capuchon de protection (102) engagé de manière amovible au-dessus dudit collier (32) et au-dessus de ladite partie supérieure dudit flacon (12).

3. Assemblage selon la revendication 1, dans lequel ledit filtre (78) est agencé au niveau d'un emplacement dans ledit passage (70) dudit tube luer (64) entre lesdites extrémités proximale et distale (66, 68) dudit tube luer (64).

4. Assemblage selon la revendication 3, dans lequel ledit passage (70) traversant ledit tube luer (64) englobe une discontinuité dimensionnelle diamétrale (76), ledit filtre (78) étant fixé au niveau de ladite discontinuité dimensionnelle (76) dans ledit passage.

FIG-1

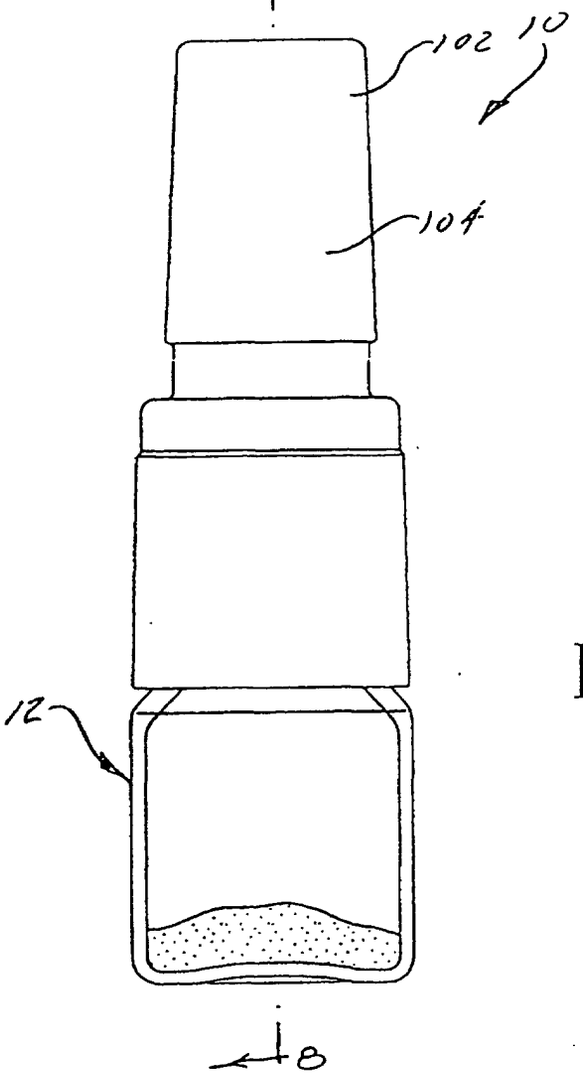


FIG-2 PRIOR ART

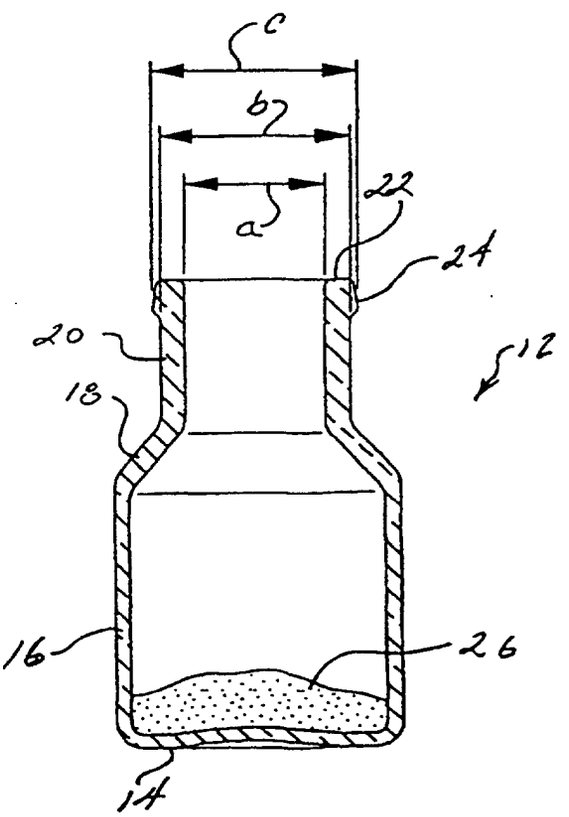


FIG-3

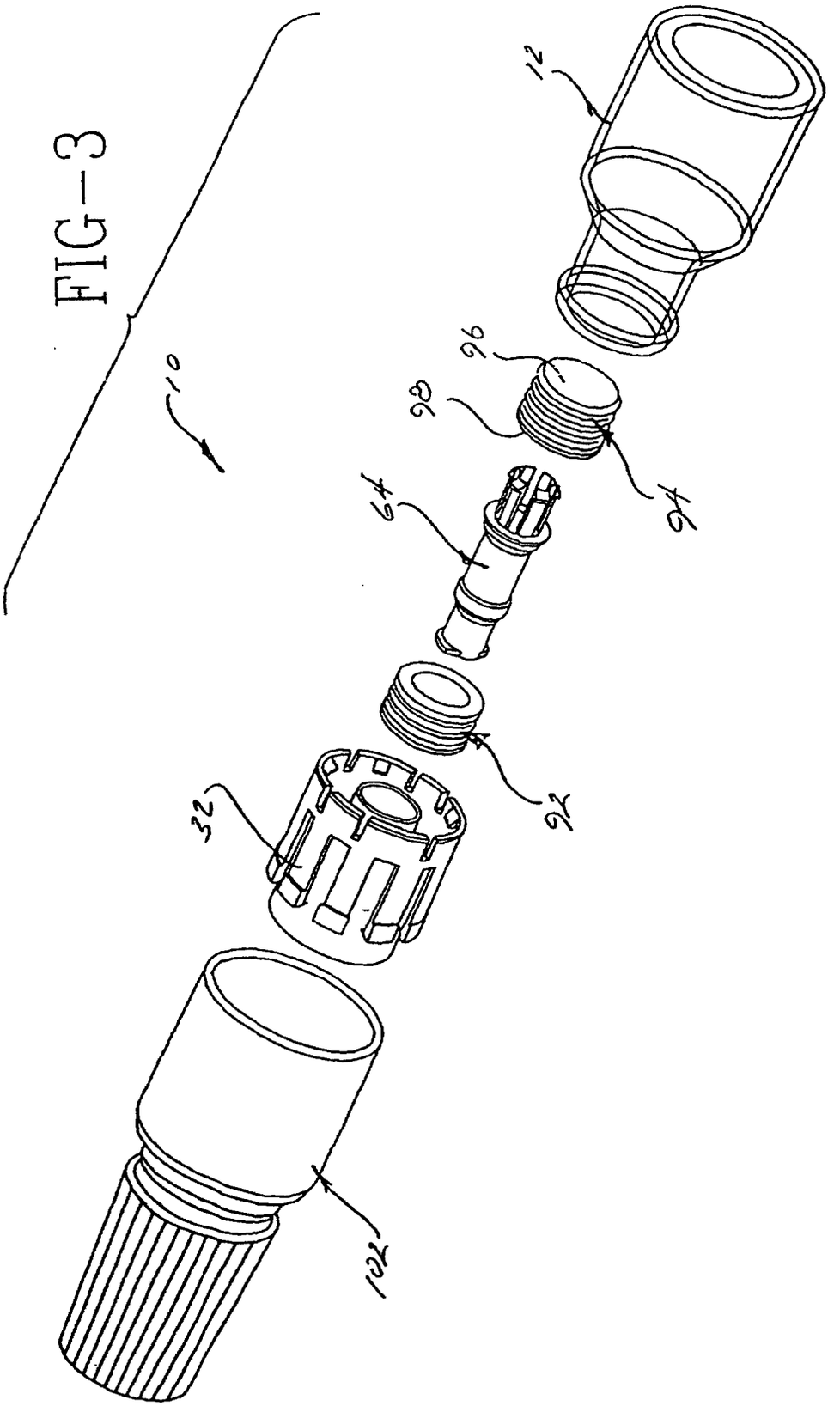


FIG-4

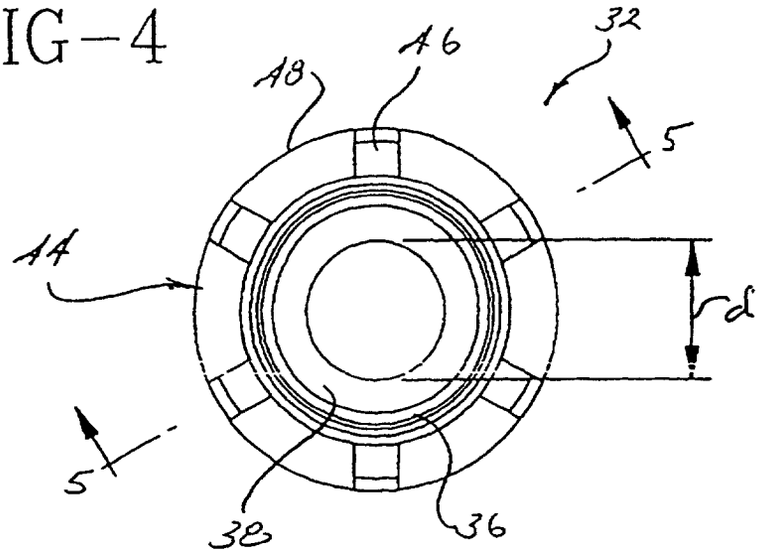
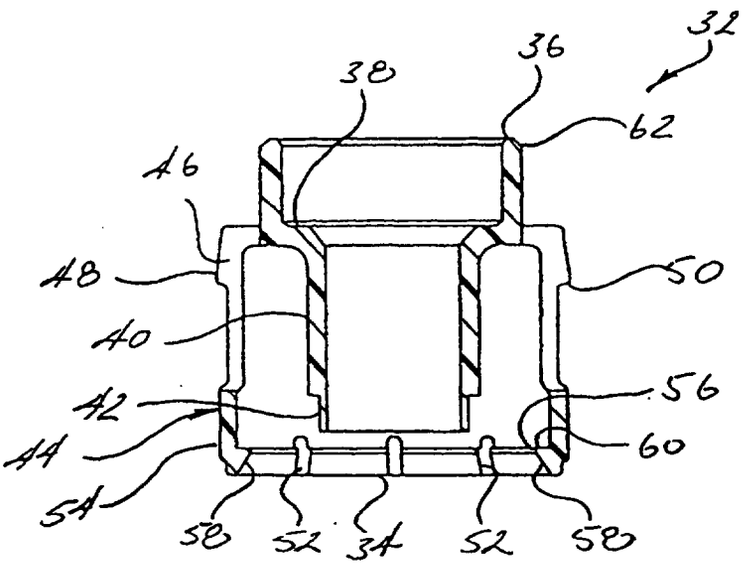

48
46
32
5
44
d
5
38
36

FIG-5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42
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60
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34
52
58

FIG-6

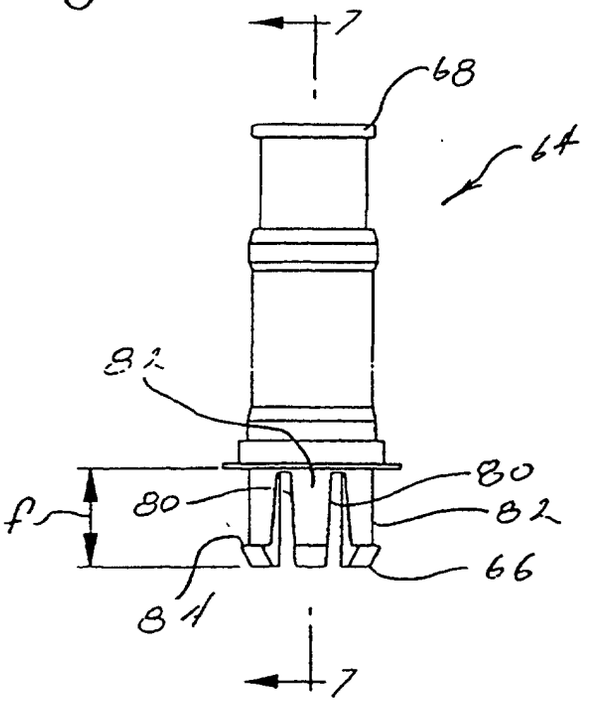
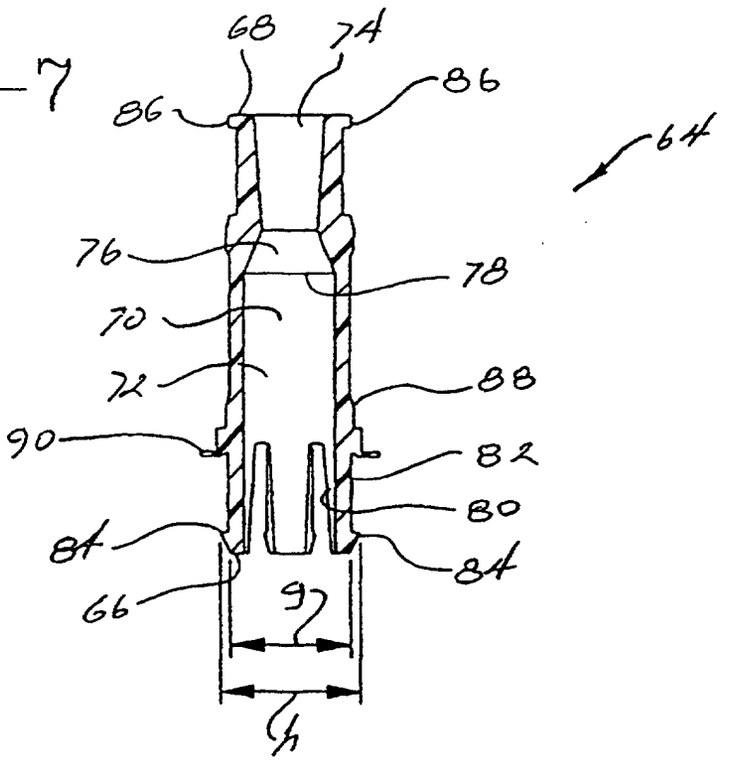

7
68
64
82
80
80
82
f
66
84
7

FIG-7


68
74
86
86
64
76
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72
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90
82
80
84
84
66
92
94

FIG-8

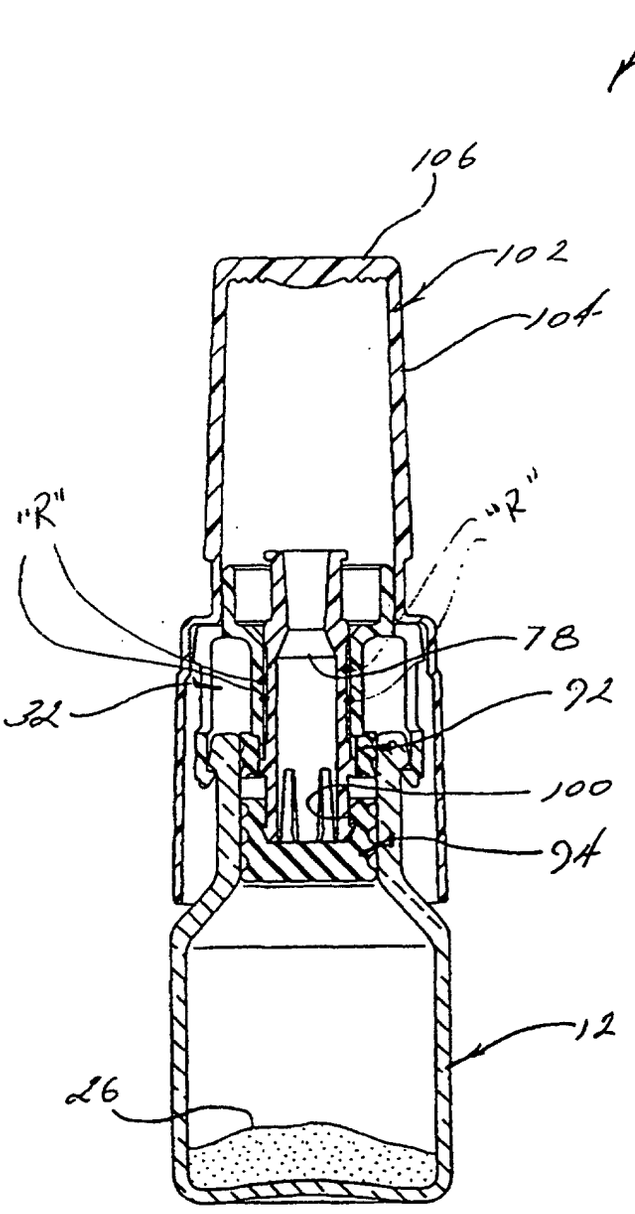

FIG-9

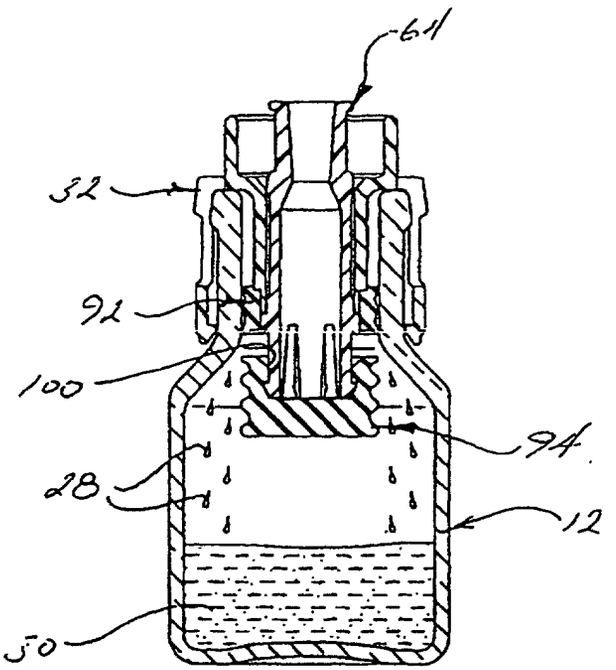

FIG-10