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(57) A packaged liquid-filled plastic tube is provided to achieve a desirably long shelf life. The tube is formed from PET, polypropylene or other known plastics that exhibit high liquid permeability. A liquid additive of a specified volume, concentration and/or solubility is placed in the tube and the tube is sealed. Loss of liquid through the permeable tube is prevented by a moisture barrier film that is sealed around the tube. The moisture barrier film maintains a high relative humidity adjacent said tube and substantially minimizes transport of liquid vapor through the plastic of the tube.

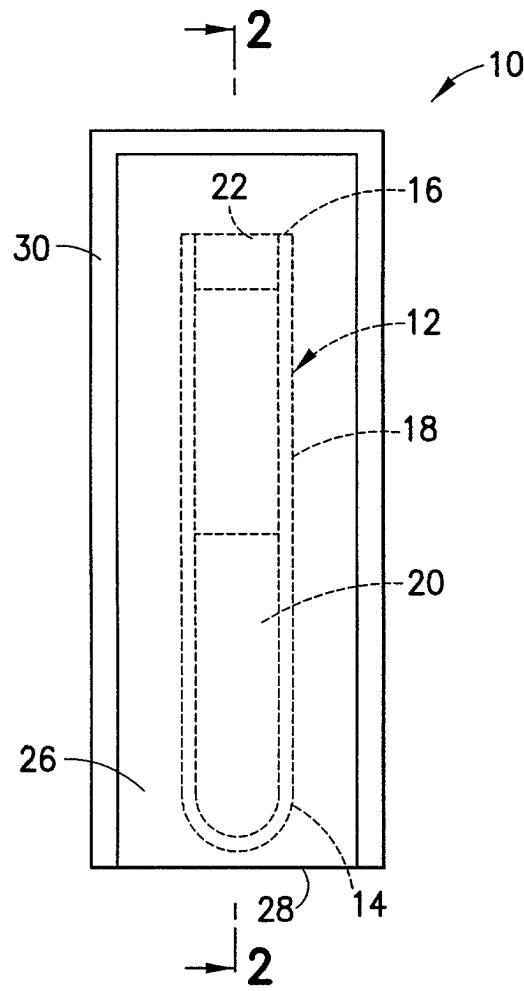


FIG.1

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Description**BACKGROUND OF THE INVENTION****Related Application**

[0001] This application is a non-provisional application of U.S. Provisional Patent Appl. No. 60/376,149 filed April 26, 2002.

1. Field of the Invention

[0002] The subject invention relates to plastic tubes that have been prefilled with controlled volumes and concentrations of liquid, and that are packaged to retain the liquid volume and concentration during storage.

2. Description of the Prior Art

[0003] Many medical procedures require a specified dose of a drug to be administered to a patient. Drugs that are administered intravenously must be in a liquid form. The liquid must be of known volume and concentration to ensure proper dosage.

[0004] Some drugs can be stored for considerable periods of time in a liquid form. Other drugs, however, must be stored in a powdered form, and then must be mixed with a specified volume of a liquid additive shortly prior to administration to the patient. Efficiencies can be achieved if the specified volume of the liquid drug and/or the specified volume of the liquid additive is available in a prefilled tube or other such container. Prefilled containers avoid the need for careful volumetric measuring immediately prior to administering the drug, and hence minimize the chance for error.

[0005] Plastic tubes and other plastic containers are lightweight, relatively inexpensive and relatively unbreakable. As a result, plastic tubes are used for medical applications whenever possible. However, plastic tubes have an inherent permeability to water and other liquids. This high liquid permeability of plastics can significantly affect the volume, concentration and solubility of liquids that are stored for a long period of time in a plastic container. Containers filled with a liquid drug or with a liquid additive for a powdered drug desirably should have a relatively long shelf life. As a result, plastic containers are considered unacceptable for long term storage of liquid drugs or liquid additives for drugs.

[0006] Glass is substantially impermeable to water and other liquids. As a result, liquid drugs or liquid additives for drugs typically are stored in glass tubes or other glass containers. However, glass is much more breakable than plastic. A glass tube can be broken easily while the tube is being manipulated to access the liquid stored therein. Additionally, a small round glass tube can be dropped inadvertently and shattered inadvertently. Sharp edges of a broken glass tube can cut a patient or health care worker, and may create an open

wound that can lead to disease transmission. Fragile glass containers also require protective packaging that typically increases storage space requirements and that may add to costs.

5 **[0007]** The prior art has included attempts to minimize or offset the loss of liquid from plastic tubes. For example, one prior art attempt has bulk packaged a plurality of plastic tubes in a plastic tub. A moisture source also has been placed in the tub to provide a higher vapor content surrounding the bulk packaged tubes, and thereby to impede the outflow of liquid from the tubes. This prior art bulk packaging complicates the packaging process and adds to cost and storage space requirements. Furthermore, vapor from the moisture source is transported through the permeable walls of the plastic tub.

[0008] The prior art also includes tubes that are laminated with foil to prevent liquid loss. Foil lamination of tubes adds significantly to the tube manufacturing complexity and adds to tube manufacturing cost.

3. Summary Of The Invention

[0009] The subject invention is directed to a plastic container in which a liquid drug or a liquid additive solution for a drug has been placed. The plastic container may be formed from a known plastic material, such as polyethylene terephthalate (PET), polypropylene or other plastic material that exhibits liquid permeability. The container may be a tube of prior art construction, and may include a closed bottom, an open top and a continuous side wall extending therebetween. A closure may be securely mounted to the container for closing the open top, and thereby preventing spillage of the liquid drug or the liquid additive stored in the container.

[0010] The subject invention further includes packaging formed from a high moisture barrier material that completely surrounds the container or that completely surrounds a plurality of such containers. The high moisture barrier material may be a film formed from a foil lamination, a metalized polyester, SiO_x coated polyesters, polyester-polyolefins, PVDC or the like. This high moisture barrier material may be a sheet folded around one or more plastic containers of a liquid drug or liquid additive. Edge regions of the sheet then may be sealed in face-to-face engagement with other areas on the sheet. Alternatively a container may be placed between two sheets of high moisture barrier material, and edge regions of the sheets may be sealed. The high moisture barrier packaging material can impede the rate of water vapor transport across the plastic material from which the container is formed by providing and maintaining a high relative humidity environment around the container and inside the package. This enables the volume, concentration and solubility of the liquid in the container to be controlled, and enables a longer shelf life for the liquid therein.

4. Brief Description of The Drawings

[0011] FIG. 1 is a top plan view of a liquid-containing plastic tube packaged in accordance with the subject invention.

[0012] FIG. 2 is a cross-sectional view taken along line 2-2 in FIG. 1.

[0013] FIG. 3 is a cross-sectional view similar to FIG. 2, but showing an alternate package.

5. Detailed Description Of The Preferred Embodiment

[0014] A package in accordance with the subject invention is identified generally by the numeral **10** in FIGS. 1 and 2. Package **10** contains a tube **12** formed from a plastic material, such as polyethylene terephthalate (PET) or polypropylene. Tube **12** includes a closed bottom **14**, an open top **16**, and a cylindrical side wall **18** extending therebetween. A liquid **20** is disposed in tube **12** as shown in FIG. 2. Liquid **20** may be a liquid additive of a specified volume, concentration and solubility that is intended for mixing with a non-liquid drug and for subsequent administration to a patient. Alternatively, liquid **20** may be a liquid drug.

[0015] Liquid **20** is sealingly retained in tube **12** by a closure **22**. Closure **22** comprises a thermoplastic elastomer or a thermoset resin material that is sufficiently deformable and resilient for secure sealing engagement with side wall **18** of tube **12**. Closure **22** may further include a more rigid plastic structure to which the thermoplastic elastomer or thermoset resin is secured to enable closure **22** to be placed in and removed from tube **12** with ease.

[0016] The plastic material of tube **12** is inherently permeable to water. Water vapor permeation through the plastic of tube **12** has the potential for affecting the volume, concentration or solubility of liquid additive **20** stored in tube **12**. To substantially minimize vapor transport through the plastic of tube **12**, package **10** comprises a high moisture barrier film **26** that completely and relatively closely surrounds tube **12**. Film **26** may be a foil lamination comprising a substrate formed from a metallic foil, such as aluminum, and at least one layer formed from a plastic material that is readily sealable. The foil lamination may include an outer layer that is well suited to printing indicia to identify the specific liquid additive in tube **12**. Film **26** alternatively may be a metalized polyester, a SiO_x coated polyester, a polyester-polyoefilin or PVDC, all of which are substantially impermeable to water, particularly in comparison to the PET or polypropylene from which tube **12** is formed.

[0017] Film **26** of package **10** may define an envelope formed from a single sheet that is folded at fold region **28** to closely surround tube **12**. Adjacent registered edges **30** may be bonded in face-to-face relationship as shown in FIG. 2. Alternatively, package **10** may be formed from two separate sheets of film **26a** and **26b** as shown in FIG. 3. Sheets **26a** and **26b** may originally be

in strip form. Tube **12** with liquid **20** therein may be placed on a lower sheet of film **26a**, which may be part of a strip moving longitudinally along a conveying apparatus. Upper sheet of film **26b** may be part of a second

5 strip that is fed into juxtaposed relationship to the strip defining lower sheet of film **26a**. The lower and upper sheets **26a** and **26b** may be sealed along opposed side edges **30a**, and may subsequently be sealed and cut between adjacent tubes to form seals **32**. In this embodiment, the lower and upper sheets of film **26a** and **26b** 10 may be formed from different materials. For example, a lower sheet of film **26a** may be a foil lamination having an only upper layer of a plastic material that will bond well with a lower plastic layer on upper sheet **26b**. Upper sheet **26b**, however, may also include an upper laminated layer that is well suited to receiving printed indicia.

Claims

1. Packaging for liquids of specified volume, concentration and solubility, said packaging comprising:
20 at least one plastic container (12) having a closed bottom (14), an open top (16) and a side wall (18) extending therebetween, said liquid (20) of said specified volume, concentration and solubility being placed in said container (12), a closure (22) sealingly engaged with said open top of said container for retaining said liquid (20) therein, a moisture barrier film (26) completely surrounding said container (12) for preventing vapor transport across said film (26) and maintaining a selected relative humidity between said container (12) and said film (26) for substantially preventing permeation of said liquid (20) from said container (12).
2. The packaging of Claim 1, wherein said container (12) is formed from polyethylene terephthalate or polypropylene.
3. The packaging of Claims 1 or 2, wherein said film (26) is selected from the group consisting of foil laminations, metalized polyesters, SiO_x coated polyesters, polyester-polyoefilins and PVDC.
4. The packaging of any of Claims 1-3, comprising a single sheet of said film (26) folded around said container (12), registered edges of said sheet being secured to one another.
5. The packaging of any of Claims 1-3, comprising first and second sheets of said film (26) having registered edges secured in face-to-face relationship with one another entirely around said container (12).

6. A method for packaging liquids (20) to maintain a specified volume, concentration and solubility, said method comprising:

providing a plastic container (12) having a closed bottom (14), an open top (16) and a side wall (18) extending therebetween; 5

depositing in said plastic container (12) said liquid (20) of said specified volume, concentration and solubility; 10

sealingly enganging a closure (22) with said open top (16) of said container (16) for retaining said liquid (20) therein; 15

providing a moisture barrier film (26) completely around said plastic container (12) and said closure (22) for preventing vapor transport across said film (26) and maintaining a selected relative humidity between said container (12) and said film (26) for substantially preventing permeation of said liquid (20) from said container (12). 20

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7. The method of Claim 6, wherein said step of providing a container (12) comprises providing a container (12) formed from polyethylene terephthalate or polypropylene. 30

8. The method of Claims 6 or 7, wherein said step of providing a moisture barrier film (26) comprises providing a moisture barrier film (26) selected from the group consisting of foil laminations, metalized polyesters, SiOx coated polyesters, polyester-polyolefin films and PVDC. 35

9. The method of any of Claims 6-8, wherein said step of completely surrounding said container (12) with a moisture barrier film (26) comprises folding a single sheet of said film (26) around said container (12) such that edges of said single sheet are substantially registered with one another and securing opposed faces of said sheet to one another adjacent said registered edges. 40

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10. The method of any of Claims 6-10, wherein said step of completely surrounding said container (12) with the moisture barrier film (26) comprises placing said container between first and second sheets of said moisture barrier film (26) and securing opposed faces of said first and second sheets to one another. 50

11. The method of any of Claims 6-10, wherein said step of sealingly engaging a closure (22) with said open top (16) of said container (12) comprises providing a closure (22) formed from a thermoplastic elastomer or a thermoset resin and urging said closure (22) into said open top of said container (12) such that said closure (22) sealingly engages said side wall (18) of said container (12) adjacent said open top (16). 55

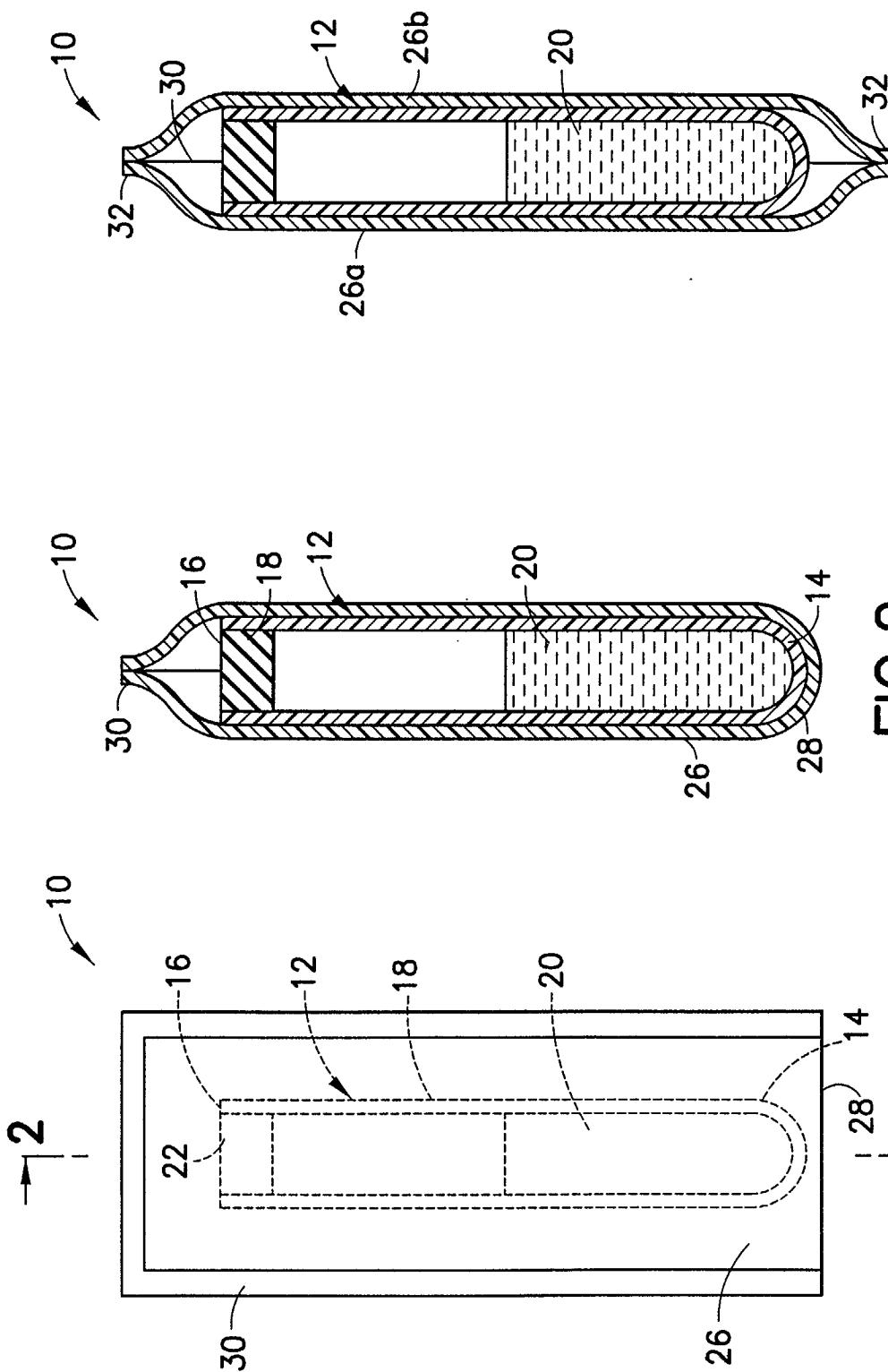


FIG.3

FIG.2

FIG.1



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EUROPEAN SEARCH REPORT

Application Number
EP 02 02 3734

DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)		
X	EP 0 520 443 A (PPG INDUSTRIES INC) 30 December 1992 (1992-12-30) * column 57, line 5 - column 58, line 47 * * column 63, line 11 - column 63, line 28 * * column 64, line 2 - column 64, line 14 * * figure 44 * -----	1-11	B01L3/14 B65D65/40 A61J1/06 B01L3/00		
X	WO 99 22691 A (ABBOTT LAB) 14 May 1999 (1999-05-14) * page 1, line 1 - page 3, line 15 * -----	1-11			
X	EP 0 787 823 A (BECTON DICKINSON CO) 6 August 1997 (1997-08-06) * figure 5 * * page 6, line 4 - page 6, line 15 * -----	1			
A	US 4 038 148 A (HOUNSELL MELVIN WAYNE ET AL) 26 July 1977 (1977-07-26) * the whole document * -----	1-11			
TECHNICAL FIELDS SEARCHED (Int.Cl.7)					
B01L B65D A61J					
The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	21 January 2003	Tiede, R			
CATEGORY OF CITED DOCUMENTS					
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document					
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ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 02 02 3734

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

21-01-2003

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0520443	A	30-12-1992	US	5284570 A	08-02-1994
			BR	9206198 A	29-11-1994
			CA	2072311 A1	27-12-1992
			DE	69216485 D1	20-02-1997
			DE	69216485 T2	17-07-1997
			EP	0520443 A2	30-12-1992
			ES	2099182 T3	16-05-1997
			JP	2607001 B2	07-05-1997
			JP	6201638 A	22-07-1994
			MX	9203532 A1	01-11-1993
			WO	9300582 A1	07-01-1993
			US	5338435 A	16-08-1994
			US	5421981 A	06-06-1995
			US	5342498 A	30-08-1994
			US	5405510 A	11-04-1995
WO 9922691	A	14-05-1999	AU	1117599 A	24-05-1999
			CA	2307848 A1	14-05-1999
			EP	1027026 A1	16-08-2000
			JP	2001521785 T	13-11-2001
			WO	9922691 A1	14-05-1999
EP 0787823	A	06-08-1997	US	5738920 A	14-04-1998
			AU	1231997 A	07-08-1997
			BR	9700733 A	06-10-1998
			CA	2195049 A1	31-07-1997
			EP	0787823 A2	06-08-1997
			JP	3224349 B2	29-10-2001
			JP	9253078 A	30-09-1997
			KR	188291 B1	01-06-1999
			SG	66348 A1	20-07-1999
			US	6013337 A	11-01-2000
US 4038148	A	26-07-1977	CA	1093028 A1	06-01-1981
			DE	2635679 A1	30-06-1977
			ES	451171 A1	01-12-1977
			FR	2336482 A1	22-07-1977
			GB	1586570 A	18-03-1981
			GB	1586569 A	18-03-1981
			JP	1098928 C	18-06-1982
			JP	52079075 A	02-07-1977
			JP	56042903 B	07-10-1981