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(54) CUPS AND CONTAINER ASSEMBLIES FOR STORING AND DISPENSING LIQUID PHARMACEUTICAL FORMULATIONS

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(57) **ABSTRACT**

The present invention provides cups for storing and dispensing liquids, such as liquid pharmaceutical formulations, having a bowl with an open top and a curved inner surface with an annular base extending from a bottom portion of the bowl, and a rim circumscribing the upper portion of the bowl. The present invention also provides unit dose container assemblies including cups according to the present invention and lids enclosing the open top, and container package assemblies for storing and dispensing liquid pharmaceutical formulations.

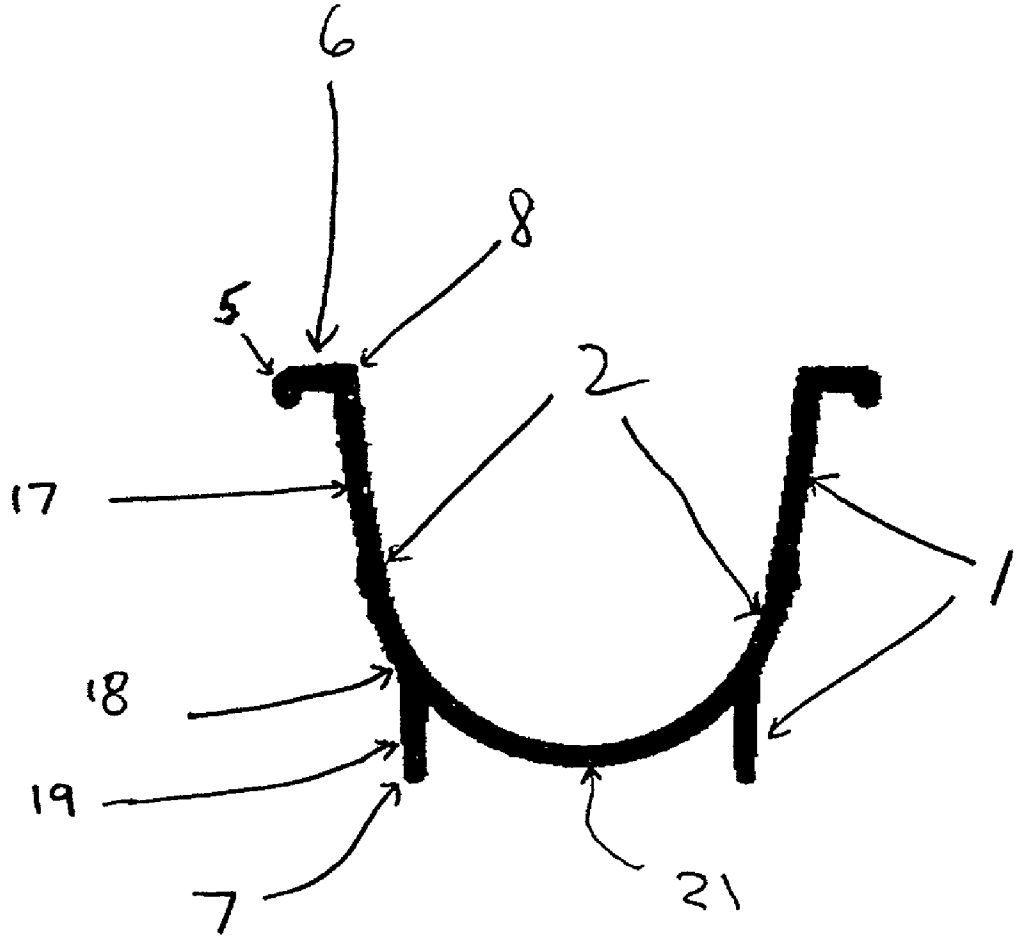
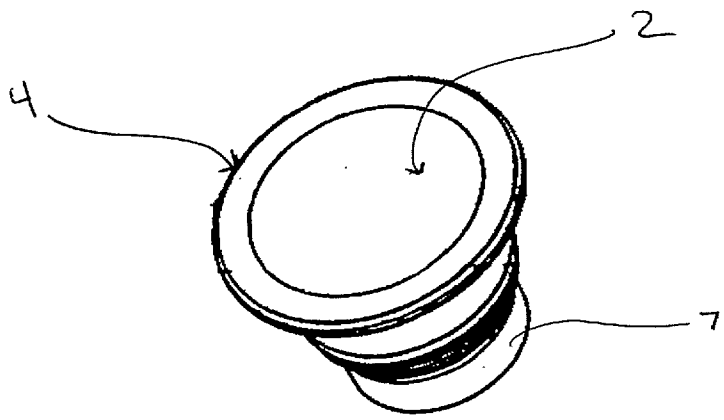


FIG. 1



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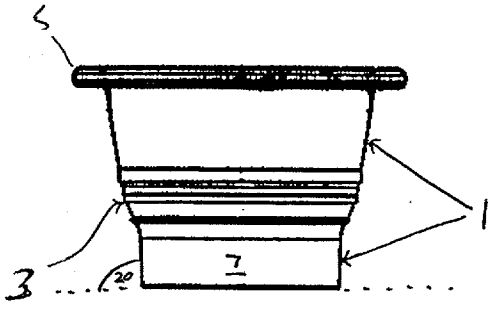

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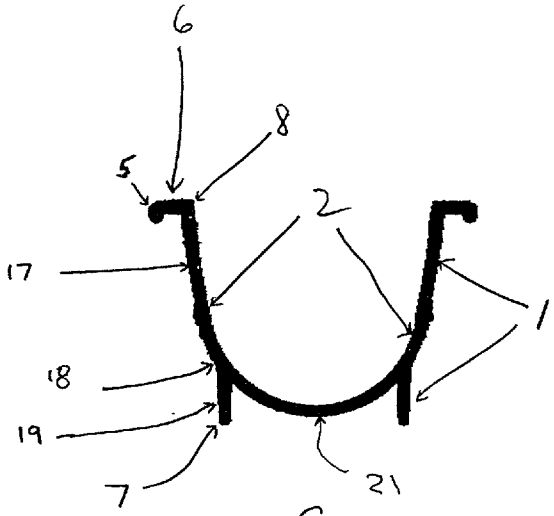

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FIG 2

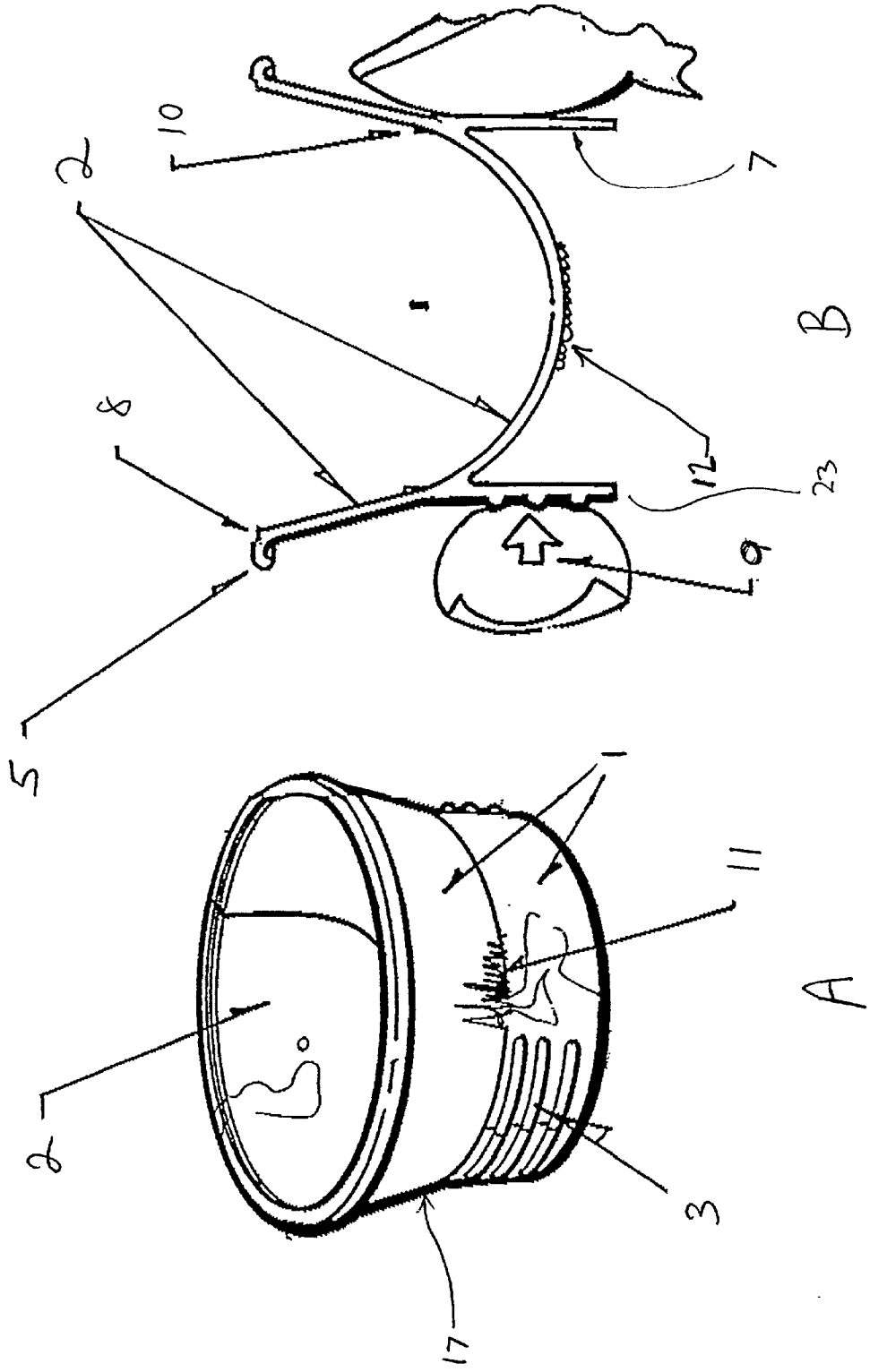
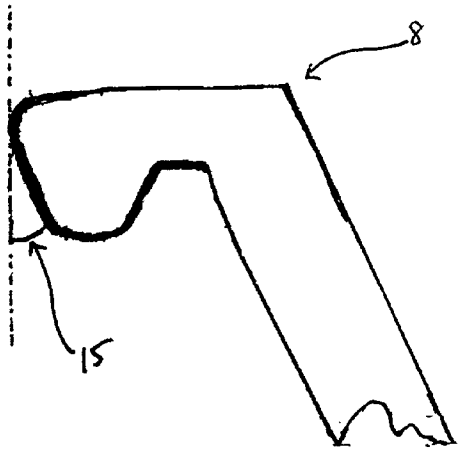


FIG. 3



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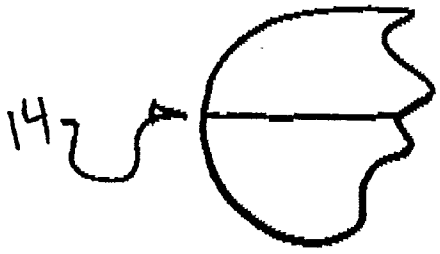

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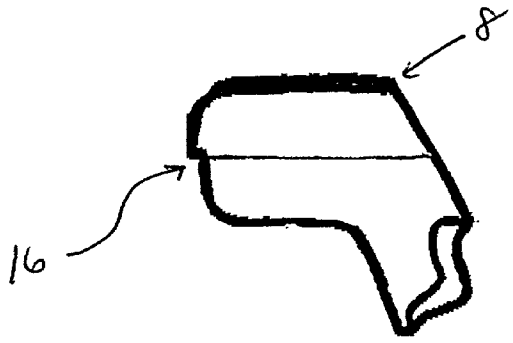

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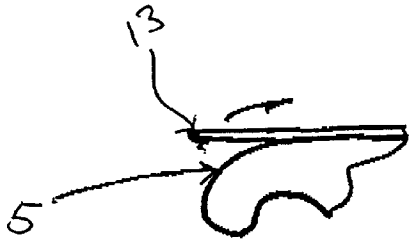

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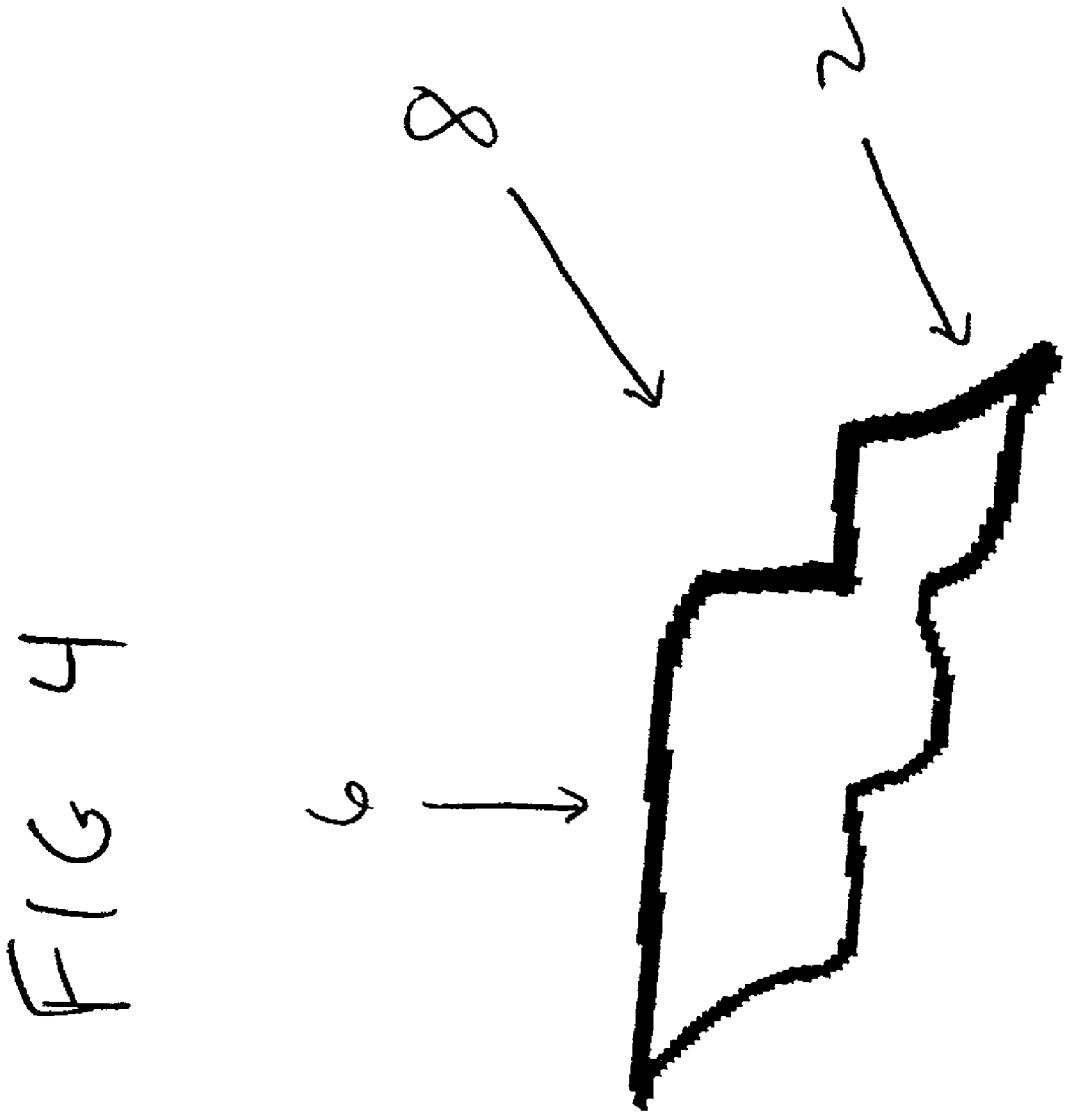


FIG 4

FIG 5

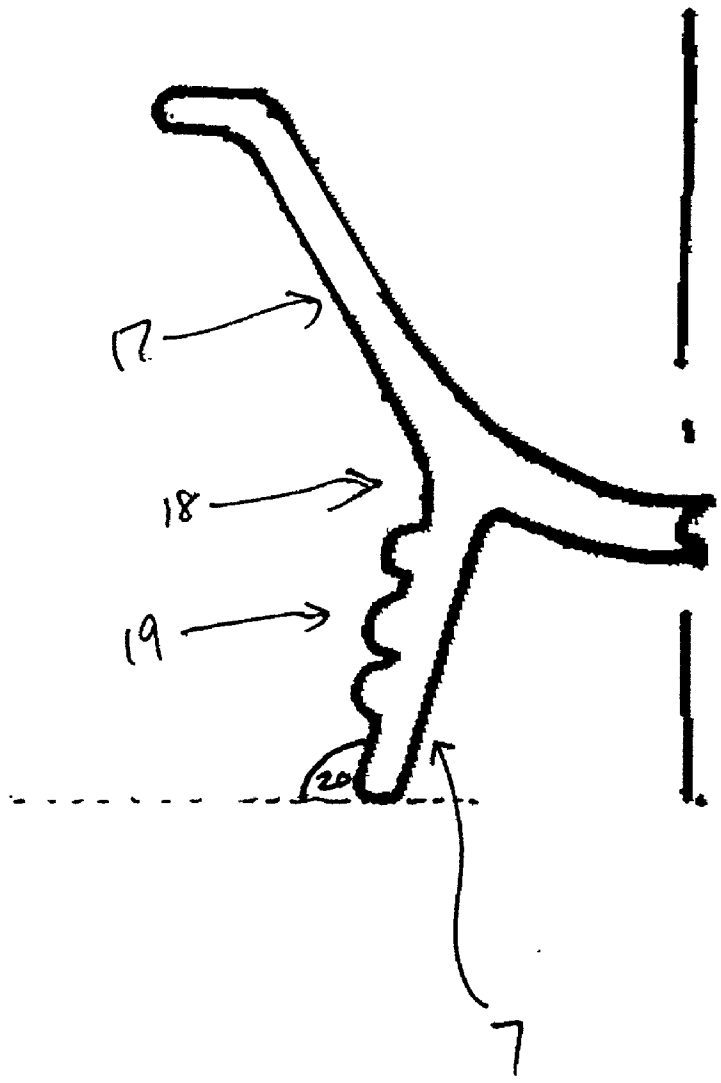
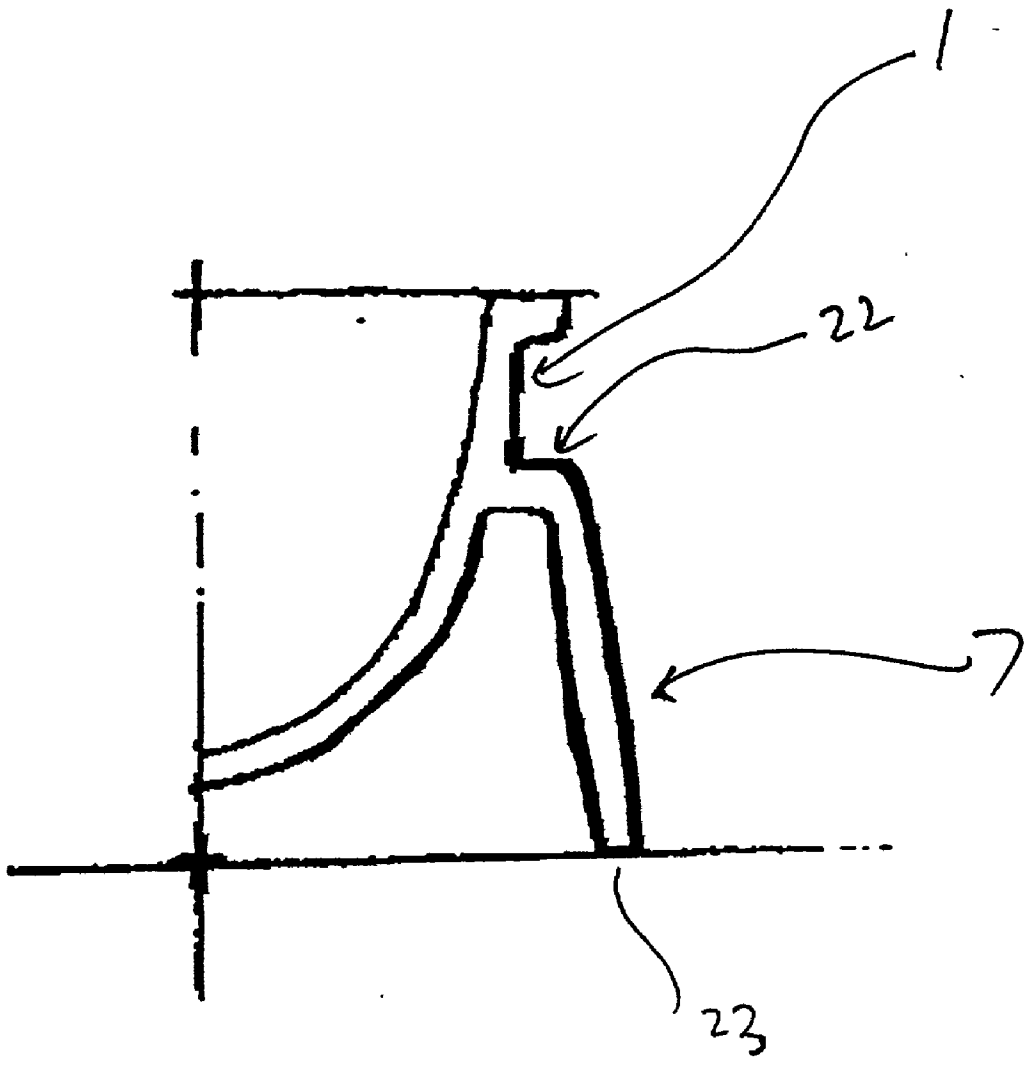


FIG. 6



CUPS AND CONTAINER ASSEMBLIES FOR STORING AND DISPENSING LIQUID PHARMACEUTICAL FORMULATIONS

FIELD OF THE INVENTION

[0001] The field of this invention is cups and containers for storing and dispensing liquid pharmaceutical formulations.

BACKGROUND OF THE INVENTION

[0002] Liquid pharmaceutical formulations, such as oral syrups, are typically stored or contained in bottles, with individual doses being dispensed by pouring a portion of the stored syrup into a spoon or measuring cup from which the patient then drinks. The spoon or cup is then rinsed or washed to remove medicine adhering to the inner surface, so the spoon or cup can be reused in the future. The bottle containing the remaining undispensed formula is then closed and stored until another dose is to be administered. This cycle of dispensing and storing is typically repeated until all of the formulation has been used, too little remains in the bottle to be useful as an effective dose, or the formula remaining in the bottle has become contaminated, has expired, or has otherwise become unsuitable for safe or effective use as a medicament.

[0003] Currently marketed measuring cups, which are often cups or caps provided or sold with the bottle as a separate part of the packaging, are typically manufactured by vacuum-formation. In such a process, a thin sheet of plastic, typically a styrene, is laid over an open mold or female half. The thin plastic sheet is heated, then vacuumed into or over the mold, forming the cup. Cups formed by such methods typically have common characteristics, including, among others, a flat bottom, rounded outer edges which contribute to instability, and a lack of durability. Markings are frequently added to a sidewall of the cup to serve as a target demarcation to guide the patient or treatment provider in administering a dose of the liquid pharmaceutical formulation.

[0004] Various vacuum-formed cups are known in the art for dispensing oral liquid pharmaceutical formulations. However, the vacuum-forming process has limitations which impact on the properties and usefulness of the resulting cup. For instance, the choice of material available for use in the process is limited, and typically results in weak or thin-walled products. The cups are also typically flat-bottomed with inner edges that, along with the material used, result in adherence of the liquid to the inner surface and therefore incomplete or inadequate dispensation of the liquid formulation. The flat bottom of a vacuum-formed cup can be made larger to enhance its stability. However, enlarging the bottom results in diminished evacuation efficiency. The vacuum-forming process moreover is not optimal for producing cups with consistent or precise volumes. Such inconsistency and imprecision can result in inaccurate doses of medicine.

[0005] In addition to vacuum-formation of plastic cups, other materials such as pliable metals have been bent into shape to produce cups. Metal cups have many of the same or similar limitations as those produced by vacuum-formation. Metal can easily dent or become misshapen, resulting in inaccurate cup volume, and thus inaccurate dosing. As with vacuum-formed cups, metal, flat bottomed cups also do not adequately release liquid formulations upon dispensing. Moreover, typical use of any of the prior art cups provides excessive opportunity for human error. Because a patient or treatment provider allocates a unit dose, typically by attempting to hit the target demarcation included on the cup, spillage or under- or over-shooting the mark is common, if not likely. Moreover, reuse of the same cup can lead to contamination of the medicine remaining in the storage bottle from which the dose is poured.

[0006] It should therefore be appreciated that there is currently a need for a device which overcomes these limitations. In particular, there is a need for a stable, durable device for containing and delivering a liquid pharmaceutical formulation with precision and efficiency of evacuation, and particularly a cup which can store and accurately dispense a unit dose of such formulation.

SUMMARY OF THE INVENTION

[0007] The present invention provides devices, including cups and container assemblies, for storing and dispensing liquid pharmaceutical formulations which have numerous advantages over the prior art. The present invention provides a durable cup which has a smooth inner surface so as to reduce or eliminate adherence of the pharmaceutical formulation when the cup is inverted or the formulation is otherwise dispensed.

[0008] Cups according to the invention include a bowl, an annular base and a rim. The bowl has an open top, a curved bottom which is concave on at least a portion of its inner surface, and an annular wall which forms an upper sidewall for the cup. An annular base circumscribes the concave bottom of the bowl and forms a lower sidewall for the cup. The cups include an annular rim circumscribing the open top of the bowl. The rim has a top surface extending outward from the upper sidewall of the cup. In another embodiment the cups further include a lid removably affixed to the rim and enclosing the open top. The cup has a concave inner surface of the bowl that is without edges and sufficiently smooth to prevent a liquid from adhering to the inner surface when the liquid is dispensed. Such an inner surface may be injected molded from materials such as high density polyethylene, polypropylene, and cylic olefin copolymer barrier material.

[0009] As used herein, "dispersed,""dispensing" and modifications thereof refer to manipulation of the open cup's position so as to allow the liquid to be poured from the cup. Typically, dispensing occurs by tilting or inverting the open cup so that a patient can drink a liquid pharmaceutical formulation.

[0010] The cups of the present invention can be used as unit dose cups for storing and dispensing a unit dose of a pharmaceutical formulation, and can also be used as measuring and dispensing cups either alone or packaged together with another container, which contains a liquid pharmaceutical formulation. As used herein, "unit dose" refers to an amount predetermined to be an effective single dose for the intended patient. When the cups of the present invention are employed as unit dose cups they are provided enclosed with a removable lid, thus providing for long term storage and protection of the pharmaceutical formulation contents from environmental conditions.

[0011] Additional features and advantages of the invention will be set forth in the description and figures which follow and will be apparent from the description or may be learned by practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1A** is a perspective view of a cup in accordance with the present invention. **FIG. 1B** is a side elevational view of the cup of **FIG. 1A**. **FIG. 1C** is a vertical cross sectional view of the cup.

[0013] **FIG. 2** depicts an alternate embodiment of a cup of the present invention in perspective view, **FIG. 2**A, and vertical cross sectional view, **FIG. 2B**.

[0014] FIGS. **3**A-D illustrate various embodiments and features of rims of cups in accordance with the present invention.

[0015] **FIG. 4** depicts the top inner edge of an alternate embodiment of a cup in accordance with the present invention.

[0016] **FIG. 5** depicts an alternate configuration of the annular base of a cup in accordance with the invention.

[0017] **FIG. 6** depicts another alternate configuration of the annular base of a cup in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Reference will now be made in detail to embodiments of the invention, which serve to explain the principles of the invention. It is to be understood that application of the teachings of the present invention to a specific problem or environment will be within the capabilities of one having ordinary skill in the art in light of the teachings contained herein.

[0019] The present invention provides devices, including cups and containers, for dispensing a liquid, including a liquid pharmaceutical formulation. The devices have a bowl with an open or a sealingly closeable top and a curved bottom which is concave on its inner surface. The devices are composed of a material which renders the concave inner surface sufficiently smooth to prevent liquid contents, such as pharmaceutical suspension and syrup formulations, from adhering to the surface when dispensed. The devices of the invention are particularly useful with viscous syrup and suspension formulations, but can also be used with solutions and any other liquid pharmaceutical or other liquid product.

[0020] The cups according to the invention include an annular base circumscribing the outer surface of the bowl's bottom. The cups can also have a rim circumscribing the open top. The rim includes a top surface extending outward from the top inner edge of the cup.

[0021] The present invention further provides unit dose cups for storing and dispensing a liquid pharmaceutical formulation. Unit dose cups according to the invention have an open top and a curved, for example, a hemispherical, bottom which is concave on its inner surface. The unit dose cups can include a foil, plastic, laminate or other suitable material for sealingly enclosing the open top.

[0022] The cups of the present invention are composed of a material which renders the cup's inner surface sufficiently smooth and slick to prevent the liquid contents from adhering to the cup when dispensed. Such a material preferably has a small molecular structure and prevents liquids from intermingling on a molecular basis. Cups according to the invention may be manufactured by any suitable method, including vacuum forming, injection molding, or any combination of the two. A preferred manufacturing method is injection molding to obtain smooth surfaces and high compressive strength. In the injection molding process a mold, typically with two halves, is set together with a space between them which corresponds to the shape of the object to be formed. Plastic or other suitable material is forced into the space through an opening. The material then hardens and the halves are separated, releasing the formed object. The injection molding process may use molds suitable for straight draw molding or molds with side action. Preferred materials for composing cups according to the invention are high density polyethylene or polypropylene. Alternatively, a cyclic olefin copolymer (COC) barrier material may be used. The cup may be of a color or shade which visually identifies or distinguishes the cup. The cup may be transparent or opaque.

[0023] The liquid contained or measured within the cup will typically be a liquid pharmaceutical formulation present in a unit dose amount. The liquid pharmaceutical formulation may be indicated for oral administration and may be, for example, a solution, syrup, or a suspension. The liquid pharmaceutical formulation is typically a suspension, but may be any other liquid, including any other liquid suitable for ingesting a pharmaceutically active product. Various pharmaceutical products for use in accordance with the present invention include, by way of example only, oral formulations containing lactulose, nystatin, phenytoin, sulfatrim, ibuprofen, or megestrol acetate, together with a pharmaceutically acceptable carrier.

[0024] Various embodiments according to present invention will now be described with reference to the accompanying drawings, wherein like reference numerals correspond to like components. Referring to **FIGS. 1 and 2**, the illustrated cup includes a bowl **2** having a smooth concave inner surface, which may be hemispherical or non-spherical. The inner surface does not include any sharp edges, which are typically present with prior art flat bottom cups. The bowl **2** is supported by an annular base **7**, which provides a stable resting platform or surface for the cup. The sidewall of the bowl forms an upper sidewall **17** for the cup, while the base **7** forms the lower sidewall **19** of the cup. The lower sidewall **19** extends even with, or preferably beyond, the outer bottom portion **21** of the bowl so that the cup can stably rest on the table, shelf, hospital tray, or other surface.

[0025] The angle **20** between the annular base and the table, shelf or other horizontal surface can be 90°, resulting from a cylindrical base, or any other suitable angle, such as from a conical or frustoconical base. The angle **18** between the upper and lower sidewalls **17**, **19** is typically less than or equal to 180° and, may be about 120° to 150°, for example. The angle **18** may be, but need not be, gradual or rounded to form a smooth outer surface, so long as the concave inner surface of the cup does not contain any corners or angles where residual liquid contents might otherwise adhere after the bulk liquid is dispensed.

[0026] The bowl **2** and annular base **7** can be manufactured with any suitable dimensions selected depending on

the dosage or other end use application of the cup. The bowl **2** will typically be wider, i.e., have a larger maximum diameter, than the annular base **7**. The ratio of height to diameter for the bowl **2** may be, for example, in the range of about 1.5:1 to 1:1. The height of the base **7** is preferably just sufficient to raise the bottom **21** of the bowl **2** off of the table, shelf, or other surface. The ratio of height to diameter of the base **7** may be, for example, about 1:3 to 1:5.

[**0027**] The upper **17** and lower **19** portions of the sidewall **1** can provide for improved stability and grip. The raised gripping surface or ribs **3** shown in the embodiment illustrated in **FIG. 1** provide additional grip enhancement. **FIG. 2** illustrates an alternate configuration for gripping surfaces **3**. Numerous other configurations of gripping surfaces can be used in accordance with the present invention. A gripping surface may encircle the cup entirely or only partially and may be rounded or have defined edges. The gripping surface may be molded or formed as part of the cup or may be affixed to the cup after the molding or forming process. The gripping surface may be textured to enhance friction between the user's fingers and the cup sidewall.

[**0028**] The concave shape of the inner surface of the bowl **2** promotes evacuation of the cup's contents in that it preferably includes no internal corners or edges. The concave configuration may be of a variety of shapes and dimensions including, by way of example only, those yielding hemispherical or hemi-oblong shapes. The shape of the inner surface may be one in which a pure or 100% radius is achieved. Numerous materials can be used to render the cup's inner surface sufficiently smooth to further prevent or minimize any residual liquid contents from adhering to it when dispensed. These materials include, by way of example only, high density polyethylene and polypropylene.

[**0029**] In the illustrated embodiments, the cups also include a rim **4**, with a top surface **6**, and an outer edge which forms a rounded continuous surface **5**. This rim configuration can facilitate removal of an optional flexible, disposable lid **13**, as shown in **FIG. 3D**. Lid **13** may contain a label indicating on its surface unit dose quantity and other characteristics of the cup's contents. Lid **13** may be a laminate having a paper layer and a foil underside with a seal that adheres to the cup's rim **4**. The lid may alternately be a rigid lid. Suitable lids may be opaque or transparent and may contain a tab or other grip for facilitating removal. Various suitable processes for affixing lid **13** include, by way of example, the use of perforated labels on a roller, blowing the lid onto the cup, or a "pick and place" method in which a robotic arm places the lid onto the cup.

[**0030**] The rim's rounded edge shape also serves to eliminate the hazards to a patient's lips associated with rougher edges. The top surface **6** of the rim will typically have a relatively small dimension to aid in keeping the surface clean and dispensing the contents.

[**0031**] Referring now to **FIG. 3**A, the outer edge of the rim may be manufactured with a reverse draft angle **15** to facilitate removal of the cup from an injection mold. The angle **15** is preferably greater than or equal to 0° and more preferably, between about 1° and 45°.

[**0032**] **FIG. 3B** shows a parting line **14** which may occur during a molding process at the point where two molds meet. A phenomenon known as flash may occur if the two molds do not fit together precisely. Flash can result in sharp, irregular edges and occurs when liquid squirts between the ill-fitting molds. In one embodiment of the present invention, a step **16**, illustrated in **FIG. 3**B, is included at the parting line to reduce or eliminate the occurrence of flash.

[**0033**] **FIGS. 3A and 3C** illustrate the top edge **8** of the cup of a preferred embodiment of the invention. Top edge **8** occurs where the surface **6** of the rim meets the inner surface of the upper sidewall **17** of the cup. The sharp demarcation created by the surface of the rim and the inner surface of the cup provides for enhanced content removal with a minimum of residue spilling on and clinging to the top surface of the rim during dispensing of the cup's contents. In an alternate embodiment, the edge **8** may include a step as shown in **FIG. 4**. This configuration helps to prevent liquid contents from spilling out upon lid removal by allowing the liquid to drain back into the cup.

[**0034**] **FIGS. 5 and 6** illustrate embodiments having alternate annular base configurations **7**. In the embodiment illustrated in **FIG. 5**, the annular base is frustaconic, with the angle **18** formed by upper sidewall **17** and lower sidewall **19** being less than 180° and angle **20** being greater than 90°. The configuration illustrated in **FIG. 5** can be achieved via an injection molding process by using a mold with movement or side action. A straight draw mold may be used in the manufacture of cups having annular base configurations in which angle **20** is about 90°.

[**0035**] The alternate embodiment illustrated in **FIG. 6** includes a base **7** which includes a lateral hip extension **22** at its top which extends outward from sidewall **1** of the cup. Hip extension **22** may be substantially horizontal or may extend slightly upward or downward.

[**0036**] Numerous alternative base configurations may be used in accordance with the present invention. Such configurations include, by way of example only, bases having multiple concentric annular portions. In configurations with multiple concentric annular base portions, each individual portion may be at the same or at a different angle in relation to a horizontal surface. Any of the bases suitable for use in the present invention may be friction enhanced on its bottom surface **23**. Such friction enhancement may be a texture or other suitable enhancement produced during the manufacturing process of the cup. Alternatively, the friction enhancement may be a surface affixed to the base after the cup is molded or formed. The annular base **7**, preferably has a rectangular lower edge **23**, which promotes stability for the cup to remain upright when placed on a surface such as a hospital tray, shelf, or table during use or storage, or while the cup is being filled, or a lid is being affixed during production. In the embodiment illustrated in **FIG. 2**B, the outer sidewall **1**, formed in part by the annular base, provides for superior strength against radial compression **9**.

[**0037**] The upper portion **17** of the outer sidewall also allows for the inclusion of a conspicuously placed marking **11**, if desired. The marking may be a design, a symbol, a word or group of words, or other graphic marking, including a measurement scale for determining the liquid volume of the cup's contents. The space provided on the outer surface of the cup's bottom **12** may accommodate additional markings or writing. The markings may be raised. Markings can be used in marketing the product or identifying its origin.

[**0038**] The embodiment illustrated in **FIG. 2B** includes optional stacking vanes **10**. These stacking vanes allow a

plurality of cups to be stacked with minimal distance between them to improve packing efficiency and accommodate space limitations.

[0039] The above description and examples are illustrative of alternative embodiments which achieve the objects, features, and advantages of the present invention, and it is not intended that the present invention be limited thereto.

What is claimed is:

1. A cup for dispensing a liquid comprising:

a bowl having an open top, a curved bottom portion which is concave on at least a portion of its inner surface, and an annular wall forming an upper sidewall for said cup;

an annular base circumscribing the bottom portion of said bowl and forming a lower sidewall for said cup; and

an annular rim circumscribing the open top of said bowl and having a top surface extending outward from the upper sidewall of the cup.

2. The cup of claim 1 further comprising a lid removably affixed to the rim and enclosing the open top.

3. The cup of claim 1 wherein the inner surface of said bowl comprises a material selected from the group consisting of high density polyethylene, polypropylene, and cylic olefin copolymer barrier material.

4. The cup of claim 1 wherein said cup is formed by injection molding.

5. The cup of claim 1 wherein said annular rim has a rounded edge.

6. The cup of claim 1 wherein said annular base extends beyond the bottom of said bowl.

7. The cup of claim 1 wherein said annular base is cylindrical.

8. The cup of claim 1 wherein said annular base is frustoconical.

9. The cup of claim 1 wherein said annular base has a lateral hip extension.

10. The cup of claim 1 wherein said rim comprises a reverse draft angle.

11. The cup of claim 1 wherein said rim comprises a step.

12. The cup of claim 1 wherein said rim top surface meets said bowl inner surface at an angle.

13. The cup of claim 1 further comprising a step between the top of said rim and the inner surface of said bowl.

14. The cup of claim 1 wherein said concave bowl bottom portion is hemispherical.

15. The cup of claim 2 wherein said lid is a flexible, disposable lid.

16. The cup of claim 2 wherein said lid comprises a laminate.

17. The cup of claim 2 wherein said lid comprises a tab for facilitating removal of the lid.

18. The cup of claim 2 wherein said lid comprises a label.

19. The cup of claim 1 further comprising a stacking vane affixed to the inner surface of the bowl.

20. The cup of claim 1 wherein the upper sidewall further comprises a gripping surface.

21. The cup of claim 1 further comprising a liquid pharmaceutical formulation present within the bowl of said cup.

22. The cup of claim 21 wherein said liquid pharmaceutical formulation is indicated for oral administration.

23. The cup of claim 21 wherein said liquid pharmaceutical formulation is present in a unit dose amount.

24. The cup of claim 21 wherein said liquid pharmaceutical formulation is selected from the group consisting of solutions, syrups, and suspensions.

25. The cup of claim 21 wherein the liquid pharmaceutical formulation is a suspension.

26. The cup of claim 21 wherein the liquid pharmaceutical formulation comprises a pharmaceutically active ingredient selected from the group consisting of lactulose, nystatin, phenytoin, sulfatrim, ibuprofen, and megestrol acetate.

27. A package assembly for storing and dispensing a liquid pharmaceutical formulation comprising the cup of claim 1 and a reservoir containing a liquid pharmaceutical formulation.

* * * * *