

ORAL DOSAGE DISPENSER**CROSS REFERENCE TO RELATED APPLICATION**

This application claims the benefit of U.S. Provisional Application No. 60/236,224 filed Sep. 28, 2000.

FIELD OF THE INVENTION

The present invention relates to the oral delivery of active agents. More particularly, the invention provides an apparatus for facilitating the oral delivery of an active agent to a patient in need of treatment therewith, which apparatus comprises an active agent mixing chamber, a mixture delivery tube, and at least one liquid delivery tube. The active agent mixing chamber is charged with the active agent, or a pharmaceutical formulation thereof, the apparatus is sealed, and a liquid diluent is drawn into the active agent mixing chamber by a vacuum created therein by suction imparted through the mixture delivery tube, thereby mixing the active agent with the liquid diluent. The active agent/liquid diluent mixture thus formed may then be drawn into the oral cavity of the user from the active agent mixing chamber by continued suction on the mixture delivery tube.

BACKGROUND OF THE INVENTION

Because of age or physical infirmity, many patients encounter considerable difficulty in swallowing solid oral dosage forms. For example, Kikendall et al., *Digestive Diseases and Sciences*, 28:2 (1983), report that there were 221 cases documented between 1970 and 1982 of tablet and capsule induced esophageal injury. The most commonly implicated drug formulations were tetracycline (108 cases), emepromium bromide (36 cases), potassium chloride (16 cases), and ferrous salts (12 cases).

Accordingly, there exists a need for oral dosage forms where the swallowing of a large, solid system is avoided and which forms are facile of use and manufacture. In response thereto, so-called "Dose-Sipping Technology" has been developed. For example, U.S. Pat. No. 2,436,505 discloses a pill douser for administering medicaments in liquid form or in pills or tablets. The device has a bowl at the top for containing the medicament and a tube that can be submerged in a liquid held in a drinking glass. The liquid is drawn upward for administering the liquid together with any pill or tablet present in the bowl. U.S. Pat. No. 2,867,536 discloses an improved drinking straw where a soluble flavoring material is contained within an annular space contained within an inner and outer tube. The inner tube has a bore through which liquid can be drawn. During use, the upper and lower caps are removed, the flavoring material is emptied into the liquid and the flavored liquid is drawn up through the inner tube and into the mouth. U.S. Pat. No. 3,610,483 discloses a dispensing device for liquid medication that is formed in the shape of a straw. A predetermined dose of liquid medication is loaded into the straw which is then capped at both ends until the medication is dispensed, at which point the user removes the caps and sucks air into the device.

Many of the aforementioned devices suffer from certain disadvantages inherent to such delivery systems, including, for example, incomplete and/or non-uniform mixing of the active agent with the liquid diluent prior to ingestion of the formed mixture by the patient, clogging or obstruction of the dosage dispensing tube with undissolved active agent during ingestion of the formed mixture, and the like. Furthermore, certain prior art devices, especially those dispensers com-

prising drinking straw arrangements, suffer from the additional disadvantage of containing and permitting the ingestion of only relatively small amounts of an active agent mixture, i.e. that amount which can be safely and conveniently generated in an apparatus with a tube or bore having the circumference of a drinking straw.

The instant invention obviates the aforementioned disadvantages by providing an apparatus comprising an active agent mixing chamber, a hollow mixture delivery tube, and at least one hollow liquid delivery tube which is capable of containing relatively large amounts of active agent for mixing with a liquid diluent. Because of the relative placement of the mixture delivery tube and the liquid delivery tube inside the active agent mixing chamber, the active agent contained therein may be mixed completely and uniformly with the liquid diluent without presenting the potential of clogging or obstruction during delivery of the active agent solution or suspension to the user of the apparatus.

SUMMARY OF THE INVENTION

The present invention provides an apparatus for facilitating the oral delivery of an active agent to a patient in need of treatment therewith, which apparatus comprises an active agent mixing chamber, a mixture delivery tube, and at least one liquid delivery tube. A mixture formed in the mixing chamber which comprises a combination of an active agent, or a pharmaceutical formulation thereof, and a liquid diluent may be delivered into the oral cavity of the patient from the mixing chamber by suction on the mixture delivery tube.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, reference is now directed towards the embodiments illustrated in greater detail in the accompanying drawings and described hereinbelow by way of examples of the invention.

In the drawings:

FIG. 1 depicts an overhead, fragmentary perspective view of an embodiment of the apparatus of the instant invention.

FIG. 2 illustrates a side, fragmentary perspective view of an embodiment of the apparatus of the invention wherein the apparatus is immersed in a liquid reservoir.

REFERENCE NUMERALS IN THE DRAWINGS

- 1 active agent mixing chamber
- 2 outer wall
- 3 inner wall
- 4 mixture delivery tube
- 5 mixture delivery tube first open end portion
- 6 mixture delivery tube second open end portion
- 7 liquid delivery tube
- 8 liquid delivery tube first open end portion
- 9 liquid delivery tube second open end portion
- 10 mounting means
- 11 liquid reservoir
- 12 sealing means
- 13 surface contour

DETAILED DESCRIPTION OF THE INVENTION

The invention provides an apparatus for the oral delivery of active agents which comprises a sealable active agent mixing chamber, a hollow mixture delivery tube, and at least one hollow liquid delivery tube.

The apparatus comprises a sealable active agent mixing chamber 1 comprising outer 2 and inner 3 walls, wherein the