consumption; certain medications such as steroids and oral contraceptives; distress; enteropathy and other intestinal disorders; and maldigestion and digestive diseases.

Unfortunately, oral intakes of magnesium are difficult for the body to absorb. It is believed that only 3 to 12% of elemental magnesium, typically in the form of magnesium oxide, magnesium sulfate, magnesium carbonate, or other magnesium salt is absorbed for use by the body. Attempts have been made to make complexes to enhance the absorption of magnesium in the human body. For example, U.S. Pat. No. 8,017,160 describes a two part system in which magnesium salts are administered along with choline citrate. However, this system has the drawback in that it is a two part system and not a one part system or single dosage form. Unfortunately, this two part system creates patient compliance issues and stability problems that shorten shelf life. It would therefore be desirable to formulate a magnesium supplement in a single dosage form that would address the deficiencies noted above.

SUMMARY

A single dosage form, for example, a soft gel capsule is disclosed herein. In ~~an illustrative embodiment~~one example, the soft gel is sealed forming a seam in which the gelatin is cross-linked across the seam. This method of sealing the soft gel provides for a better seal that cures the weeping problem that can result from the prior methods of heat sealing soft gel capsules.

The prior methods of heat sealing are generally performed at temperatures in the range of about 65° C to about 70° C. This heat sealing forms a seam or seal extending around the capsule. Unfortunately, this heat sealing process may result in a seal that cannot adequately restrain some small molecules and/or compounds resulting in weeping. For example, if anhydrous ingredients draw water and/or glycerol from the gelatin shell, the seam may rupture. In addition, the fill of soft gels can migrate into the gelatin shell causing cosmetic discoloration and/or shortening of shelf life and/or adverse interaction between pharmaceutical API

and components of the gelatin shell.

In one aspect, there is provided a method of forming a soft gel dosage form, comprising: providing two sheets of a gelatin composition; aligning the two sheets; and sealing edges of the two sheets together forming a seam having cross-linked gelatin across the seam.

In an ~~illustrative embodiment~~example, a method of forming a soft gel dosage form is disclosed. The method may include providing two sheets of a gelatin composition, aligning the two sheets, and sealing edges of the two sheets at a selected temperature range forming a seam having cross-linked gelatin across the seam.

The soft gel may also be cured by drying the soft gel. A fill composition may be disposed between the two sheets prior to completely sealing the edges of the two sheets. The sealing of the edges of the two sheets may include sealing the edges of the two sheets at a selected temperature adapted to allow the formation of the cross-linked gelatin across the seam.

The providing of the two sheets of the gelatin composition may include providing two sheets of the gelatin composition containing one or more of gelatin in an amount of about 65% w/v; glycerol in an amount of about 15% w/v; sorbitol or sorbitan in an amount of about 14% w/v; purified water in an amount of about 5% w/v; and caramel in an amount of about 1% w/v.

In another aspect~~embodiment~~, there is provided a method of forming a soft gel dosage form, comprising ~~is disclosed. The method may include~~ micronizing an anhydrous magnesium powder into a powder having a heterogeneous particle size, suspending the micronized anhydrous magnesium powder in an emulsion forming a fill composition, disposing the fill composition between two sheets of a gelatin composition, and sealing edges of the two sheets together forming a seam having cross-linked gelatin across the seam to form the soft gel.

According to the disclosure, the sealing of the edges of the two sheets may include sealing the edges of the two sheets at a selected temperature adapted to allow the formation of the cross-linked gelatin across the seam. The suspending of the heterogeneous micronized anhydrous magnesium powder in the emulsion may include suspending about 680.8 mg of the micronized anhydrous magnesium powder in the emulsion. The suspending of the micronized anhydrous magnesium powder in the emulsion may include suspending the micronized anhydrous

magnesium powder in about 294.4 mg of medium-chain triglycerides and about 225 mg of a phosphatidyl choline solution.

The gelatin composition may include providing the two sheets of the gelatin composition containing: gelatin in an amount of about 264.6 mg, glycerin in an amount of about 69.3 mg, sorbitol or sorbitan in an amount of about 69.3 mg, purified water in an amount of about 60.1 mg, and caramel in an amount of about 10.7 mg.

In another aspect~~embodiment~~, there is provided a soft gel dosage form, comprising ~~is disclosed. The soft gel dosage form may include~~ a soft gel shell including two sheets of a gelatin composition sealed together forming a seam having cross-linked gelatin across the seam, and a fill composition disposed between the two sheets of the gelatin composition including a micronized anhydrous magnesium powder having a heterogeneous particle size.

The two sheets may be sealed together at a selected temperature adapted to allow the formation of the cross-linked gelatin across the seam. The two sheets of gelatin may include: a gelatin, a glycerin, a sorbitol or sorbitan, a purified water, and a caramel color. The fill composition may further include a medium-chain triglyceride, and a phosphatidyl choline.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of devices, systems, and methods are illustrated in the figures of the accompanying drawings which are meant to be exemplary and not limiting, in which like references are intended to refer to like or corresponding parts, and in which:

FIG. 1 illustrates a block flow diagram of a method of making a soft gel according to aspects of the present disclosure; and

FIG. 2 illustrates a block flow diagram of a method of making a soft gel containing magnesium according to aspects of the present disclosure.