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(54) **Title**: SUGAR-FREE CHEWABLE SUPPLEMENT

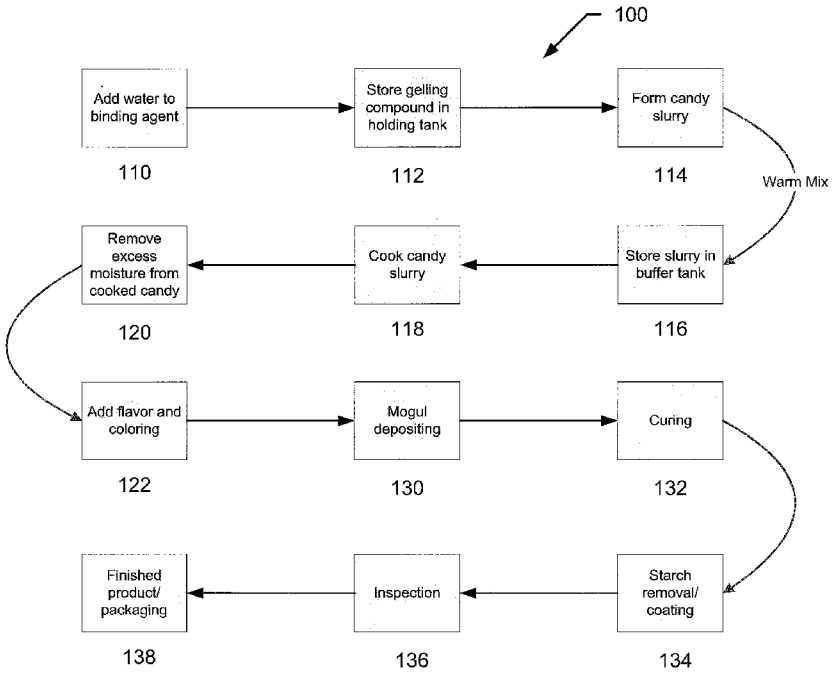

FIG. 1

(57) **Abstract**: A sugar- free chewable composition for delivering dietary supplements and pharmaceutical compounds. The chewable composition includes a sugar-free delivery vehicle and an active ingredient. The delivery vehicle may include a sugar-free gummy candy. The active ingredient may include an over-the-counter drug or a prescription

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drug to provide a desired effect on the user. The active ingredient may also include any combination of nutraceuticals, vitamins, minerals, antioxidants, soluble and insoluble fiber, herbs, plants, amino acids, probiotics, prebiotics, and digestive enzymes.

SUGAR-FREE CHEWABLE SUPPLEMENT

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BACKGROUND OF THE INVENTION

1. Field of the Invention.

[0001] This invention relates generally to a sugar-free chewable supplement, and more particularly, to a sugar-free chewable delivery system for dietary supplements and pharmaceutical compounds, and a method for manufacturing the same.

2. Related Art.

[0002] Recently, chewable supplements have been manufactured and sold in the form a gummy candy supplement. Now a selection of nutritional supplements are being manufactured and sold in a chewable gummy form, including both children and adult supplements. The introduction of gummy supplements into the marketplace has been particularly helpful in getting children to take daily vitamin supplements. For adults that do not like swallowing pills, gummy supplements have also provided a non-pill alternative for adults to get their daily vitamin requirements.

[0003] Although gummy candy was first introduced in 1920 as "gummy bears," it was not until very recently that gummy candy was utilized as a delivery system for supplements. Traditional gummy candy is made from a gelatin base, which is similar to the base found in soft caramels,

marshmallows, foam-filled wafers, licorice, wine gums, pastilles, chocolate coated mallows and a host of other sweets. Gelatin is a protein derived from animal tissue that forms thick solutions or gels when placed in water. Gelatin gives the candy its elasticity, the desired chewy consistency, and a longer shelf life.

[0004] Since gelatin is a tasteless compound, sweeteners and flavorings are typically added to the gelatin base to give the gummy candy its desired taste. In this way, gummy candies are generally made from a blend of corn syrup, sucrose (table sugar), gelatin, coloring, and flavoring.

[0005] When mass produced, gummy candies are made from a gelatin base that's first mixed, and then pumped into a special candy cooker that cooks the gelatin base by a combination of pressure and steam. Once cooked, a vacuum is applied to the cooked candy to remove excess moisture therefrom. The cooked candy then moves to a mixing station where colors, flavors, acids, and fruit concentrates are mixed into the gelatin base. Next, a starch molding machine, commonly known as a mogul, pumps the cooked gelatin stock into starch filled mold boards that shape the candies. After curing, the gummies are removed from the molds and then packaged, delivered, and sold.

[0006] The chewable supplements described above are high in sugar content, and while chewable candies may be utilized as a vehicle for delivering nutritional supplements to consumers, the nutritional value of these supplements may be compromised by the effects of the sugars contained therein. For example, foods with high sugar content have a high glycemic index. The "glycemic index" is a measure, in the form of a number rating, of how a given food affects blood-

glucose levels. The lower the rating, the slower the absorption and digestion process, which provides a more gradual, healthier infusion of sugars into the bloodstream. On the other hand, a high rating means that blood-glucose levels are increased quickly, which stimulates the pancreas to secrete insulin to drop blood-sugar levels. These rapid fluctuations of blood-sugar levels are not healthy because of the stress they place on the body.

[0007] One of sugar's major drawbacks is that it raises the insulin level, which inhibits the release of growth hormones, which in turn depresses the immune system, upsets the mineral relationships in the body, and prevents the body from defending against bacterial infection. In the same way, an influx of sugar into the bloodstream upsets the body's blood-sugar balance, triggering the release of insulin, which the body uses to keep blood-sugar at a constant and safe level. Insulin also promotes the storage of fat, so when one eats foods high in sugar, they may experience rapid weight gain and elevated triglyceride levels, both of which have been linked to cardiovascular disease.

[0008] In addition to the foregoing drawbacks, there are many health risks associated with large intakes of sugar, on a habitual basis. Even moderate sugar intake has been observed to aggravate asthma, affect mood swings, provoke personality changes, hasten hypertension and crankiness in children, cause food allergies, tooth decay, depression, and hormonal imbalance, and increase the risk of blood clots, heart disease, strokes, gallstones, diabetes, and a host of other health issues.

[0009] To date, no one has utilized a sugar-free delivery system for nutritional supplements, and because of growing popularity of chewable supplements, there is a need for a sugar-free delivery system for pharmaceuticals and other nutritional supplements.

SUMMARY

[0010] A sugar-free chewable composition for delivering dietary supplements and pharmaceutical compounds is provided. The chewable composition generally includes a binding agent, a sugar-free sweetener, and an active ingredient.

[0011] According to one implementation, the chewable composition includes a sugar-free delivery system for delivering dietary supplements and/or pharmaceutical compounds to a user's body. The delivery system includes a delivery vehicle in the form of a gummy candy, and a dietary supplement and/or a pharmaceutical compound as active ingredients of the gummy candy. In particular, the delivery vehicle may include a sugar-free gummy candy. The gummy candy may include a sugar-free sweetener, a binding agent, and natural flavors, colors, and preservatives. For example, in one implementation, the gummy candy may include a sugar substitute, gelatin, citric acid, lactic acid, natural colors, natural flavors, fractionated coconut oil, and carnauba wax.

[0012] The active ingredients may include an over-the-counter (OTC) drug or a prescription drug to provide a desired effect on the user. In addition to OTC or prescription drugs, the active ingredients may also include nutraceuticals (*i.e.*, extracts of food purported to have a medicinal effect on human health) such as botanical and herbal extracts and antioxidants, or any combination of food supplements such as vitamins, minerals, soluble and insoluble fiber, herbs, plants, amino acids, probiotics, prebiotics, and digestive enzymes.

[0013] Other devices, apparatus, systems, methods, features and advantages of the invention will be or will become apparent to one with skill in the art upon examination of the following

figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the invention, and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE FIGURES

[0014] The invention may be better understood by referring to the following figures. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. In the figures, like reference numerals designate corresponding parts throughout the different views.

[0015] FIG. 1 shows a flow diagram of an example of a method of manufacturing a sugar-free chewable supplement of the present invention.

[0016] FIG. 2 shows a flow diagram of an example of a method for incorporating a pharmaceutical compound into a delivery vehicle of a delivery system of the present invention.

DETAILED DESCRIPTION

[0017] The present invention relates to a sugar-free chewable delivery system designed to enhance the delivery of dietary supplements and pharmaceutical compounds. The delivery system includes a primary active ingredient to provide a desired effect, and a chewable delivery vehicle to contain the active ingredient for delivery.

[0018] In one implementation of the present invention, the active ingredient may include any combination of vitamins, minerals, antioxidants, soluble and insoluble fiber, herbs, plants, amino acids, probiotics, prebiotics, digestive enzymes, or any other supplements digested to promote the heath and well-being of a person.

[0019] In other implementations, the active ingredient may include a pharmaceutical compound. For example, in one implementation, the pharmaceutical compound may include an OTC drug to treat symptoms of common illnesses. Such OTC drugs may include Benadryl®, Sudafed®, Claritin®, Maalox®, Mylanta®, Tums®, Pepcid® AC, Monistat®, Ex-Lax®, Imodium® A.D., Robitussin®, Chloraseptic®, Thera-flu®, Alka-Seltzer, Motrin®, Dramamine®, and the like, in liquid, powder, or extract form. In another implementation, the pharmaceutical compound may include a prescription drug. Such prescription drugs such may include Lipitor®, Singulair®, Lexapro, Plavix®, Morphine, Hydrocodone (Vicodin®), Demerol®, Codeine, Diazepam (Valium®), Penicillin, Prevacid®, Allegra-D®, Celebrex®, Crestor®, Cialis®, Valtrex®, Ambien CR®, Viagra®, Flomax®, Prozac®, and the like, in liquid, powder, or extract form. In these implementations, in addition to an active pharmaceutical ingredient, the active ingredients of the

delivery system may also include a combination of dietary supplements. The inclusion of dietary supplements with pharmaceutical compounds will depend in part on the supplements compatibility with the pharmaceutical compound.

[0020] As for the dosage, pharmaceutical compounds are generally expressed in terms of grams or milligrams, but may also be expressed in active units, or international unit (IU). As used herein, a "pharmaceutical compound" or "drug" shall include, but is not limited to, any drug, hormone, peptide, nucleotide, antibody, or other chemical or biological substances used in the treatment or prevention of disease or illness, or substances which affect the structure or function of the body.

[0021] The active ingredients are delivered in a delivery vehicle that is palatable and easy to swallow. In one implementation, the delivery vehicle may be a gummy candy to facilitate swallowing. The delivery vehicle may include a binder, sugar-free sweeteners, coloring, and flavoring.

MANUFACTURING OF DELIVERY SYSTEM

[0022] Turning now to FIG. 1, a method **100** for manufacturing a sugar-free delivery system of the present invention is disclosed. In general, the method of manufacturing involves three main phases: (i) compounding (*i.e.*, mixing) and storing; (ii) batching and cooking; and (iii) depositing and curing.

[0023] The first phase of compounding and storing begins with step **110**, where water and a binding agent are mixed in a mixing tank to form a gelling compound. In one implementation, the

mixing tank may include a 1,000 gallon stainless steel planetary mixer, a scrape surface mixer, a holding tank with an agitator, or any other suitable mixer. During production, water and the binding agent are continuously mixed in the mixing tank and the gelling compound is continuously turned in the tank by an agitator to keep the binding agent suspended in water (*i.e.*, to prevent the binding agent from settling on the bottom of the mixing tank). In one implementation, approximately 6,000 lbs to 8,000 lbs of gelling compound may be produced in 8 hours.

[0024] The gelling compound may include cold, warm, or hot water. However, warm or hot water may be used to reduce the hydration time of the gelling compound. For example, about 250 lbs of gelatin mixed with about 250 lbs of warm water may reach a homogenous mixture in about 10 minutes. The hydration rate of the gelling compound may also vary according to the speed of the agitator. For purposes of the present invention, "hydration time" or "hydration rate" refers to the time it takes water to hydrate the binding agent.

[0025] The binding agent may include a pectin gel, gelatin, food starch, carrageenan, or any other suitable binding agent or combination thereof. Depending on the binding agent used, the gelling compound may include, for example only, one of the following formulations:

Table A

GELLING COMPOUND FORMULA

Binding Agent	Binding Agent (% by weight)	Water (% by weight)
gelatin	50%	50%
pectin	2%-3%	97%-98%
starch	7%-10%	90%-93%
pectin/starch	8%-10% (1%-2% pectin / 7%-8% starch)	90%-92%

[0026] In one implementation, a buffer, such as sodium bisulfate or sodium citrate, may be mixed into the gelling compound to regulate the pH of the mixture. In one implementation, the gelling compound may contain approximately 0.01 to 0.03% buffer by weight, or any other suitable amount. The pH of the mixing tank may be adjusted to a range from about 3.2 to about 4.0 to provide adequate gelation and to ensure that the gelling compound does not become unstable (*i.e.*, acidic) during mixing. In implementations where the binding agent includes starch, a buffer may not be necessary to balance the pH of the compound because starch is a stable organic compound.

[0027] At step **112**, the gelling compound may be filtered through a fine mesh, to remove particulates in the compound, and stored in a holding tank. In one implementation, about 140 lbs to 190 lbs of gelling compound may be delivered from the mixing tank to the holding tank every 5 to 10 minutes. The filter may be a 0.034 inch stainless steel basket strainer and the holding tank may be a 1,500 gallon stainless steel tank. In some implementations, the holding tank may include a

moderate agitator (*e.g.*, mixing blades) to mix the compound and prevent the binding agent from settling on the bottom of the holding tank during storage.

[0028] From the holding tank, approximately 125 lbs to 185 lbs of gelling compound may be delivered to a mixing vessel at step **114**, every 5 to 10 minutes, for example. In one implementation, the mixing vessel may be a 5,000 gallon stainless steel planetary mixer. In other implementations, the mixing vessel may be a scrape surface mixer, a holding tank with an agitator, or any other type of suitable mixer.

[0029] In the mixing vessel, water, additives, supplements, and an active ingredient may be added to the gelling compound to form a candy slurry. In one implementation, the additives may include sodium citrate and a sugar substitute, in liquid, powdered, and/or extract form. The sugar substitute may include, but is not limited to, any of the following natural or artificial sugar substitutes:

Maltitol
Sorbitol
Stevia
Sucralose
Acesulfame potassium
Aspartame
Neotame
Honey
Saccharin
Mannitol
Xylitol

Isomalt
Erythritol
Lactitol

[0030] In one implementation, the supplements and/or active ingredient may include vitamins, minerals, herbs, plants, amino acids, probiotics, prebiotics, enzymes or any other supplements digested to promote the heath and well-being of a person. The supplements may include, but not be limited to, any of the following:

Vitamin B1 (Thiamine)
Vitamin B2 (Riboflavin)
Vitamin B3 (Niacinamide)
Vitamin B5 (Pantothenic Acid)
Vitamin B6 (Pyridoxine HCL)
Vitamin B12
Biotin
Folic Acid
Vitamin C (Ascorbic Acid/Activated C)
Calcium
Carotine
Chromium
Choline
Copper
Magnesium
Zinc
Protein

Pomegranate
Inositol
Vitamin D (Cholecalciferol)
Vitamin E (Acetate)
Gingseng
Iron
Vitamin K (Phytonadione)
St. John's Wort

[0031] The above list of raw materials are not exhaustive, but are provided for illustrative purposes only. The length of a list of all available supplements that may be utilized in the chewable supplement of the invention is too lengthy to provide.

[0032] In one implementation, the candy slurry may contain approximately 70% to 85% (sugar-free) sweetener by weight, while the remaining approximately 15% to 30% of the slurry (by weight) may contain the gelling compound and additives. More particularly, the slurry may contain approximately 19% water, 2% sodium citrate, 75% sugar substitute, 3% supplements, and 1% primary active ingredient by weight. In most implementations, the candy slurry may reach a homogeneous mixture in about 5 to 10 minutes.

[0033] The ingredients described above and their compositions are provided by way of example only. Without departing from the spirit and scope of the present invention, the ingredients and the composition of the candy slurry may vary based on the type of formulation desired. For example, corn starch may be added to the candy slurry in an implementation where pectin is added to the gelling compound, to stabilize the product.

[0034] Prior to production, sugar substitute in liquid form may be stored in bulk tanks. In one implementation, the sweetener may be stored in a holding tank at a temperature of approximately 75° F. In the holding tank, the sweetener may be irradiated by ultraviolet light to remove any contaminants in the sweetener. During production, the liquid sweetener may be administered to the mixing vessel manually or by automation.

[0035] Similarly, prior to production, sugar substitute in granular form may be stored in a holding tank. During production, sugar substitute may be fed through an automated feed system that filters the substitute to remove any sediments, weighs the substitute, and delivers a desired quantity of sugar substitute to the mixing vessel. In other implementations, sugar substitute may be added to the mixing vessel manually.

[0036] Turning back to FIG. 1, from the mixing vessel, the candy slurry is processed through a magnetic device, which removes particulates from the slurry, and stored in a storage buffer tank at step **116**. In one implementation, the magnetic device may be a finger magnet or any other suitable magnetic device, and the storage tank may be a 5,000 gallon stainless steel industrial holding tank. In other implementations, the holding tank may include a moderate agitator to suspend the active ingredients in the candy slurry. Prior to reaching the storage buffer tank, the candy slurry may be heated through a series of heat exchangers to a temperature of approximately 150° F to 180° F.

[0037] In one implementation, the storage buffer tank may receive the candy slurry from the mixing vessel at a mass flow rate of approximately 15 lbs/s to 20 lbs/s, and maintain the slurry at a temperature of approximately 150° F to 200° F. Simultaneously, the warm candy slurry may be

continuously fed from the storage buffer tank to a static cooker at mass flow rate of approximately 10 lbs/s to 15 lbs/s, by way of example only.

[0038] In the next phase of batching and cooking, at step **118** the candy slurry mix is received by the static cooker and cooked at a temperature of approximately 220° F to 260° F for approximately 30 sec. to 60 sec., until the slurry is gelatinized (*i.e.*, dehydrated). In one implementation, the static cooker may be a 2,500 gallon high pressure steam jacketed kettle, a vacuum pressure cooker, or any other suitable cooker. In the static cooker, moisture is evaporated out of the candy slurry as the slurry is boiled to a temperature of approximately 250° F. After about a minute of boiling, the slurry may consist of about a 65 to 75 brix solution (*i.e.*, the slurry may consist of approximately 65 grams to 75 grams of sugar substitute per 100 grams of solution).

[0039] After the candy slurry is cooked, a vacuum is applied to the candy at step **120**. In one implementation, the pressure cooker may include a vacuum apparatus. In another implementation, the cooked candy may be delivered to an industrial vacuum chamber or any other suitable enclosure.

[0040] At the vacuum step **120**, moisture is drawn from the cooked candy by suction pressure. In one implementation, the vacuum may draw out approximately 2% to 5% water by weight. At this juncture, the cooked candy may have a brix of approximately 67 to 80, and a pH of approximately 2.8 to 4.0, for example.

[0041] From the vacuum, the cooked candy is filtered into a trough, commonly known as a dosier. In one implementation, the filter may be a 0.034 inch basket strainer.

[0042] At this point in the manufacturing process, the cooked candy mainly consists of a clear gelatin composition. To obtain a desired color and taste, coloring and flavoring may now be added to the cooked candy.

[0043] At step **122**, the cooked candy may be passed through the dosier. In the dosier, water, flavoring, coloring, and food grade acid may be added to the cooked candy to enhance the candy's taste. For example, flavoring such as artificial and/or natural flavoring (*e.g.*, fruit concentrate) may be added to the cooked candy to give the candy a desired flavor. To balance the flavor, food grade acid may be added to the cooked candy. Such food acids may include citric acid, malic acid, lactic acid, adipic acid, fumaric acid, tartaric acid, or any other suitable food acid or combinations thereof. In one implementation, the flavoring, coloring, and acid may be continuously added to (*e.g.*, dripped on) the cooked candy as the candy moves through the dosier to the mogul machine.

[0044] The amount of flavoring, coloring, and acid administered to the cooked candy may vary according the volume of cooked candy passing through the dosier and the desired candy formulation. For example, in one implementation, approximately 1% to 2% flavoring by weight and approximately 0.01 % to 0.03 % acid by weight may be added to the cooked candy composition. However, the amount of acid and flavoring added to the cooked candy formulation must be balanced to insure that the cooked candy will taste good. So, depending on the formulation, more flavoring and less acid may need to be added to the cooked candy for bitter formulations. In some instances, only food acid instead of flavoring may be added the cooked candy.

[0045] In addition to food acid, coloring and titanium dioxide may be added to the cooked candy formulation in the dosier. Coloring may be added to give the candy a desired color or colors. Coloring may include natural coloring such as black carrot, annatto, tumeric, and purple berry concentrate, or artificial coloring such as yellow 5, red 3, and blue 1, or any combination thereof.

[0046] Titanium dioxide may be added to the candy to provide sheen. Titanium dioxide may also stabilize the cooked candy formulation so the coloring does not bleed when it is handled, packaged, or stored.

[0047] In the final phase of depositing and curing, after the cooked candy is passed through the dosier, the candy may be sent to a starch molding machine at step **130**. In one implementation, the starch molding machine may include a mogul machine (simply referred to as a "mogul"). A mogul is a starch molding machine that automatically performs the multiple tasks involved in making gummy candy.

[0048] Gummy candy is produced in the mogul by a continuous process. At the start the process, the cooked candy, or gummy stock, is deposited by depositors (*e.g.*, filling nozzles) onto starch lined trays ("mogul boards") that allow the cooked candy to firm and take on the shape of the tray mold, to produce a series of shaped gummy candies. In one implementation, the depositors are timed to automatically deliver the exact amount of candy needed to fill the trays as the mogul boards are passed under the depositors. In other implementations, the coloring, flavoring, and acids added to the cooked gummy candy at step **122**, may be added to the candy in the depositor.

[0049] A mogul is called a starch molding machine because starch is a main component of the machine. In this machine, starch has three primary purposes. First, it prevents the gummy candy stock from sticking to the mogul boards, which allows for easy removal and handling. Second, starch holds the gummy candy in place during the drying, cooling, and setting processes. Finally, starch absorbs moisture from the candies, giving them the proper texture.

[0050] In some cases, the starch used to coat the mogul boards may include re-circulated starch prepared from re-used starch that is sifted and dried in a starch dryer, and then cooled in a starch cooler. The cooled starch is sifted again and placed in the mogul where it is recirculated through the same process. The recirculated starch may then be sprayed evenly on the mogul board. The cooked candy may then be deposited onto mogul boards coated with the recirculated starch.

[0051] After the cooked candy is deposited onto the mogul boards, the mogul boards may be stacked and then removed from the stack (one-by-one) by a conveyor belt, and placed in a temperature and humidity controlled curing room, where the candy sits and cools (*i.e.*, is cured) for approximately 24 hours to 48 hours (step **132**). Proper curing time is necessary to solidify, or set the gummy product to ensure ease of packaging without breakage and proper yield. In one implementation, the candy may be cured in a curing room with approximately 15% to 25% humidity.

[0052] After curing, the gummy candies, firmed and having proper texture, may be moved to a section of the mogul called the starch buck. In the starch buck, the mogul boards are inverted and the gummy candy is dumped into a tumbler machine at step **134**. In one implementation, the

tumbler may include a 2,000 gallon rotating drum or, in implementations, a vibrating metal sieve. In the tumbler, the gummies may be tumbled together to remove any excess starch that adheres to the gummy candies. Once the starch is removed, the gummies may become sticky, so the gummies may be coated with a polishing compound to prevent the cooked candies from sticking together. Depending on the desired finished product or preferences, the gummies may be polished with fractionated coconut oil, linseed oil, sunflower oil, bees wax, carnauba wax, mineral oil, or any other suitable food grade oil or combination thereof. In other implementations, the gummies may be sanded with a sugar substitute in a drum.

[0053] After the gummies are coated, they are placed on a cooling belt (*e.g.*, a conveyor belt) and transported to an inspection station at step **136**. At step **136**, the gummy candies are placed on an inspector belt where the candy is inspected for food safety and proper organoleptic effects. For example, on the inspector belt the gummy candies may be passed by a detector or x-ray to insure that no particulate or other foreign material has been deposited into the candy during the depositing stage.

[0054] Moving on to step **138**, once the candy passes inspection, the finished gummy product is packaged for distribution.

[0055] The disclosure above only describes one implementation of a method of manufacturing a delivery system of the present invention. Other methods and implementations may be used to manufacture delivery systems in accordance with the present invention.

[0056] The use of sugar substitutes in chewable supplements of the present invention provides several benefits over prior art supplements. For example, the use of sugar substitutes may limit the consumer's food energy intake by replacing high-energy sugar or corn syrup with non-caloric sweeteners having little or no food energy. This allows a user to consume several chewable supplements at one time without having to monitor their caloric intake. Sugar substitutes are tooth-friendly and are not fermented by the microflora of the dental plaque. Diabetic users may regulate their sugar intake with artificial sweeteners, and while some sugar substitutes release energy, they are metabolized at a slower rate than table sugar, thus allowing blood sugar levels to remain more stable over time. And finally, the cost to produce chewable supplement of the present invention may be reduced because many sugar substitutes are cheaper than table sugar.

ADDITION OF PHARMACEUTICAL COMPOUND

[0057] Pharmaceutical compounds may be incorporated into a delivery system of the present invention by one of three methods: (i) as a liquid or solid prior to cooking the gummy composition; (ii) by encapsulation; or (iii) in liquid or extract form after the gummy composition has been cooked. The manner in which a pharmaceutical is incorporated into the delivery system depends on the heat sensitivity and chemical composition of the drug.

[0058] For example, under the first method, a drug may be added to the gelling compound at step **114** (FIG. 1), during the mixing and storing phase. In one implementation, the drug may be poured into the mixing vessel in solid, powdered, extract, or liquid form.

[0059] Because many pharmaceutical compounds are destroyed or degraded when exposed to heat, this method may not be effective for heat-sensitive drugs. For instance, in the mixing phase of the gummy manufacturing process, the gelling compound may be heated to a temperature of 185° F. Thus, the chemical structure of a drug incorporated into the delivery system under this method must be able to withstand temperatures in excess of 200° F.

[0060] For heat-sensitive drugs, such as probiotics, the second method of encapsulation may be applied. Under this second method, the drug may be encapsulated before it is added to the gelling compound at step **114** (FIG. 1). This method may be most effective for drugs, in solid or powdered form, that are moderately resistant to heat.

[0061] Prior to encapsulation, the drug may be pulverized to within a discrete particle size ranging from approximately 10 microns to 300 microns; the smaller the particle size, the more effective the encapsulation. Because the drug is encapsulated, the drug release and absorption capabilities of the delivery system may be controlled depending on the effectiveness of the encapsulation. For example, encapsulation may prevent early release of the drug to the user's system.

[0062] In one implementation, a solvent system containing a filming agent may be mixed with the drug particles and blended at slow speed in a planetary mixer. The solvent may be water or ethanol and the filming agent may be ethylcellulose, gelatin, a water-soluble plasticizer (*e.g.*, glycerin or xylitol), or any other suitable composition. The filming agent solution may be slowly added to the drug particles so that enough individual particles will adhere together to form larger

granules having a size of approximately 300 to 500 microns. The degree of encapsulation may vary depending upon the number of layers of filming agent solution applied. In one implementation, the film coating may have a thickness of about 1 micron or less. There exist various standard pharmaceutical coating techniques that are suitable for use with this invention, depending on the filming agent, type of active ingredient that is to be coated, and the drug release objective, such as immediate release versus sustained release.

[0063] Under the third method, heat sensitive drugs may be added to the cooked candy at step **122**, during the flavoring and coloring phase. In one implementation, a drug in liquid or extract form may be added to the cooked candy in the dosier with the coloring and/or flavoring. While in other implementations, the drug may be added in solid or powdered form, drugs in the form of liquid or extracts are preferred at this stage of the manufacturing process because liquids and extracts are better incorporated into the cooked candy.

[0064] The amount of flavoring added to the cooked candy will vary depending upon the desired flavor and amount of pharmaceuticals added to the gelling compound. Some pharmaceuticals will require differing amounts of flavor, sweetener, color, and citric acid to produce a desirable tasting chewable drug. For example, to mask the flavor of a particular drug, a flavoring agent such as strawberry flavor or cherry flavor may be added to the mixture. The additional flavor would be adjusted based upon the drug. For extra bitter drugs, a flavor masking flavor compound from flavor houses may also be utilized.

[0065] Turning now to FIG. 2, one implementation of a method **200** of incorporating a pharmaceutical into the delivery system of the invention is described. According to this method, the first step (step **210**) is to prepare a test batch of gummy candies adding the drug to the gelling compound in the mixing vessel, at step **114** (FIG. 1) of the manufacturing process. After the gummy candy is cooked, cooled and cured, the candies may be inspected and tested at step **136** (FIG. 1) to validate that the drug composition of the candies meet the desired label requirements (*i.e.*, meet the dosage printed on the product label). If the drug composition is validated, then the chemical formulation of the finished gummy product is set and the gummy candies may be mass produced and packaged using the first method of incorporation described above.

[0066] If the drug composition is not validated (*i.e.*, the drug composition breaks down because the drug is heat sensitive), a second test batch may be produced and tested. This time, the dosage of the drug added to the gelling compound at step **114** (FIG. 1) may be increased to compensate for the drugs broken down during the cooking phase (step **220**). For example, if 100 mg of aspirin is added to the gelling compound in the mixing weigh vessel to produce a 75 mg drug, but only 50 mg of aspirin is measured in the finished product, then 150 mg of aspirin may be added to the gelling compound in the mixing weigh vessel during the second production to compensate for the 25 mg of aspirin dissipated during the manufacturing process.

[0067] Once tested, if the drug composition is validated, then the chemical formulation of the finished gummy product is set and the gummy candies may be mass produced and packaged using the first method of incorporation described above. However, if second batch does not meet the

label requirements, the drug may need to be encapsulated or added at a different stage of the manufacturing process.

[0068] If encapsulation is required, then a third test batch of gummy candies may be produced (step **230**). In this step, the encapsulated drug may be added to the gelling compound in the mixing vessel, at step **114** (FIG. 1) of the manufacturing process, and the gummy candies are tested once again. If the gummy candies meet the label requirements, then the chemical formulation will be set (with an encapsulated drug), and the gummies may be mass produced and packaged using the second method of incorporation described above.

[0069] If the encapsulated gummy candies do not meet the label requirements, then the drug may need to be incorporated into the cooked candy as an oil, extract, or liquid in the flavoring and coloring phase of the manufacturing process (step **240**). In this step, a fourth test batch may be produced where a liquid or extract drug may be added to the cooked candy with the coloring and flavoring at step **122** of the manufacturing process. After the gummy candies are produced, the batch may be tested once again to validate the drug composition of the candies. If the drug composition is validated, then the chemical formulation of the gummy product is set and the gummy candies may be mass produced and packaged using the third method of incorporation described above. If the third batch does not meet the label requirements, the dosage of the liquid or extract may need to be adjusted accordingly at step **122** (FIG. 1).

[0070] The process described above may only apply to drugs generally sold in granule, solid, or powder form. Any drugs generally sold in oil, liquid, or extract form may be automatically added to the cooked candy in the flavoring and coloring phase of the manufacturing process.

[0071] Delivery systems of the present invention not only make drugs palatable, the chewy consistency of the delivery system allows drugs to be easily digested by users of all ages, particularly, those users who have problems swallowing pills. In addition, the formulation of the delivery system enhances the absorption of drugs into the blood stream. Also, for users who cannot digest large drug dosages, the chewable drugs of the present invention will allow these users to administer smaller drug dosages at one time (*i.e.*, the user can take five 10 mg gummies instead of taking one 50 mg drug dosage), which will allow the body to quickly absorb the drug.

EXAMPLES

[0072] The following examples describe particular formulations and concentrations thereof for preparing sugar-free chewable supplements of the present invention. Chewable supplements of the present invention may include non-organic and/or organic compositions. For example, in one implementation, the chewable supplement may include a non-organic or an organic gummy candy. While the process of manufacturing a non-organic gummy and an organic gummy are similar, as described above, the formulations for the two systems differ, as explained in more detail below.

Non-organic Drug

[0073] In one implementation, the delivery system of the present invention may include a non-organic gummy. For example, a 50 mg non-organic chewable aspirin in accordance with the present invention may be prepared using the following formula:

Table B

NON-ORGANIC GUMMY FORMULA

Ingredients	Content (by Weight)
Water	10.3%
Lactic acid	1%
Citric Acid	1%
Maltitol	78%
Gelatin	7%
Aspirin (50 mg)	0.2%
Flavoring (natural/artificial)	1.5%
Colorant (natural/artificial)	1.0%

[0074] In this example, about 50 lbs of warm water may be mixed with about 50 lbs of gelatin in the mixing tank, to form 100 lbs of gelling compound having a homogeneous 50/50 blend of water and gelatin. While gelatin is described as the binding agent in this specific example, pectin, food starch, gum, or any combination thereof may be used as the binding agent in other implementations. About 0.1% to 10% of sodium bisulfate by weight may be added to the gelling compound to reduce the pH of the gelling compound to about 3.5.

[0075] In the mixing weigh vessel, the gelling compound may be mixed with about 6 lbs of water and 78 lbs of Maltitol to form the candy slurry. Because aspirin is not a heat sensitive drug,

about 0.15 lbs to 0.2 lbs of aspirin may be added to the candy slurry at step **114** (FIG. 1). About 0.1% sodium citrate by weight may also be added to the candy slurry to maintain the pH of the slurry at about 3.0 to 3.5.

[0076] Next, the candy slurry may be heated to a temperature of about 180° F prior to being passed through the storage buffer tank, to the static cooker. In the static cooker, the candy slurry may be heated to a temperature of about 240° F to 245° F, dehydrating the slurry to a brix of about 78.

[0077] After the candy is cooked, the cooked candy is sent to the vacuum chamber, where the candy may be further dehydrated to a brix of about 80. After leaving the vacuum, the cooked candy is placed in the dosier where about 1.5% of strawberry flavoring by weight and about 1% of red cabbage coloring by weight may be added to the cooked candy. To balance the flavoring, about 0.1% citric acid by weight and about 0.1% lactic acid by weight may be added to the cooked candy.

[0078] After adding the flavoring and coloring, the cooked candy may be deposited into the mogul machine and then cured. After the candies are cured, they may be added to a tumbling drum to break off any starch that may be remaining on the candies. As the candies are being tumbled, about 1% fractionated coconut oil by weight and about 1% carnauba wax by weight may be poured into the drum to coat the candies to prevent them from sticking together.

[0079] After the candies are coated, they may be inspected to validate that the finished product meets the label requirements, and then packaged.

Organic Vitamin

[0080] In another implementation, the delivery system of the present invention may include an organic gummy. To create an organic gummy, the ingredients used to form the drug must meet the requirements for organic certification. These ingredients may include, but not be limited to, pectin, organic evaporated cane juice, organic tapioca syrup, organic grape juice, citric acid, lactic acid, sodium citrate, natural color (*e.g.*, black carrot, juice concentrate, annatto, turmeric, purple berry concentrate) and natural flavor (*e.g.*, strawberry, orange, pineapple, grape), and a proprietary blend of vitamins, minerals and other functional ingredients.

[0081] For example, a 300 mg organic chewable multi-vitamin, in accordance with the present invention, may be prepared using the following formula:

Table C

ORGANIC GUMMY FORMULA

Ingredients	Content (by Weight)
Water	13.5%
Lactic acid	1%
Citric acid	1%
Erythritol	76%
Pectin	3%
Multi-vitamin blend (300 mg)	3%
Natural flavoring	1.5%
Natural colorant	1.0%

[0082] In this example, about 97 lbs of warm water may be mixed with about 3 lbs of pectin in the mixing tank, to form 100 lbs of gelling compound having a homogeneous 97/3 blend of water and pectin. While pectin is described as the binding agent in this specific example, organic gelatin or starch may also be used as the binding agent in other implementations. About 0.1% to 10% of sodium bisulfate by weight may be added to the gelling compound to reduce the pH of the gelling compound to about 3.5.

[0083] In the mixing weigh vessel, the gelling compound may be mixed with about 6 lbs of water and 76 lbs of Erythritol to form the candy slurry. In addition to sweeteners, about 2.5 lbs to 3 lbs of multi-vitamin blend may be added to the candy slurry at step **114** (FIG. 1). In one implementation, the multi-vitamin blend may include approximately 2500 IU of Vitamin A, 2 mg of Vitamin B-6, 6 mg of Vitamin B-12, 60 mg of Vitamin C, 400 IU of Vitamin D, 16 mg of Magnesium, 15 mcg of Choline, 15 mg of Zinc, 18.4 mg of Calcium, 150 mcg of Iodine, and 15 mcg of Inositol. About 0.1% sodium citrate by weight may also be added to the candy slurry to maintain the pH of the slurry at about 3.0 to 3.5.

[0084] Next, the candy slurry may be heated to a temperature of about 180° F prior to being passed through the storage buffer tank, to the static cooker. In the static cooker, the candy slurry may be heated to a temperature of about 240° F to 245° F, dehydrating the slurry to a brix of about 78.

[0085] After the candy is cooked, the cooked candy is sent to the vacuum, where the candy may be further dehydrated to a brix of about 80. After leaving the vacuum, the cooked candy is placed in the dosier where about 1.5% of strawberry flavoring by weight and about 1% of red cabbage coloring by weight may be added to the cooked candy. To balance the flavoring, about 0.1% citric acid by weight and about 0.1% lactic acid by weight may be added to the cooked candy.

[0086] After adding the flavoring and coloring, the cooked candy may be deposited into the mogul machine and then cured. After the candies are cured, they may be added to a tumbling drum to break off any starch that may be remaining on the candies. As the candies are being tumbled, about 1% fractionated coconut oil by weight and about 1% carnauba wax by weight may be poured into the drum to coat the candies to prevent them from sticking together.

[0087] After the candies are coated, they may be inspected to validate that the finished product meets the label requirements, and then packaged.

[0088] Unlike traditional non-organic gummy candies, organic gummies having a pectin base produce a gummy candy that is both elastic and has a slightly brittle gel texture with a brilliant fracture. Due to the differing properties between pectin and gelatin, different challenges are present during the manufacturing of pectin-based gummy candies. However, due to the properties of organic gummy candy, supplements provided in a pectin-based delivery system may be more easily and quickly digested over non-organic gummies, resulting in a more desirable drug delivery system.

Starch-based Drug

[0089] In another implementation, the delivery system of the present invention may include a pure starch-based gummy. For example, a starch-based chewable drug containing 5 mg of Prilosec OTC®, in accordance with the present invention, may be prepared using the following formula:

Table D

STARCH-BASED GUMMY FORMULA

Ingredients	Content (by Weight)
Water	9.46%
Lactic acid	1%
Citric Acid	1%
Mannitol	77.0%
Corn Syrup	49.0%
Starch	9%
Prilosec OTC® (5 mg)	0.02%-0.04%
Flavoring (natural/artificial)	1.5%
Colorant (natural/artificial)	1.0%

[0090] In this example, about 91 lbs of warm water may be mixed with about 9 lbs of starch compound in the mixing tank, to form 100 lbs of gelling compound having a homogeneous 91/9 blend of water and starch. In one implementation, the starch compound may be corn starch, rice starch, modified starches, or any other suitable starch compound. About 0.1% to 10% of sodium bisulfate by weight may be added to the gelling compound to reduce the pH of the gelling compound to about 3.5.

[0091] In the mixing weigh vessel, the gelling compound may be mixed with about 6 lbs of water and 77 lbs of Mannitol to form the candy slurry. About 0.03 lbs to 0.05 lbs of Prilosec OTC® may be added to the candy slurry at step **114** (FIG. 1). About 0.1% sodium citrate by weight may also be added to the candy slurry to maintain the pH of the slurry at about 3.0 to 3.5.

[0092] Next, the candy slurry may be heated to a temperature of about 180° F prior to being passed through the storage buffer tank, to the static cooker. In the static cooker, the candy slurry may be heated to a temperature of about 240° F to 245° F, dehydrating the slurry to a brix of about 78.

[0093] After the candy is cooked, the cooked candy is sent to the vacuum chamber, where the candy may be further dehydrated to a brix of about 80. After leaving the vacuum, the cooked candy is placed in the dosier where about 1.5% of orange and cherry flavoring by weight and about 1% of annatto and turmeric coloring by weight may be added to the cooked candy. To balance the flavoring, about 0.1% citric acid by weight and about 0.1% lactic acid by weight may be added to the cooked candy.

[0094] After adding the flavoring and coloring, the cooked candy may be deposited into the mogul machine and then cured. After the candies are cured, they may be added to a tumbling drum to break off any starch that may be remaining on the candies. As the candies are being tumbled, about 1% fractionated coconut oil by weight and about 1% carnauba wax by weight may be poured into the drum to coat the candies to prevent them from sticking together.

[0095] After the candies are coated, they may be inspected to validate that the finished product meets the label requirements, and then packaged.

[0096] Starch-based gummies provide an additional benefit over gelatin-based gummies. In particular, because gelatin liquefies when heat is applied, gelatin-based gummies frequently melt when they are exposed to high temperatures during storage and transport. But starch is more stable than gelatin in high temperatures. This is because the semi-crystalline structure of starches do not fully recover once a starch is gelatinized (*i.e.*, becomes a gel when cooked in water) and then cooled, so the starch becomes a thickened paste. If additional heat is applied to the thickened paste, the starch will not liquefy since the starch granules swell and burst during the gelatinization process. Thus, starch-based gummies may retain their gummy shape under high temperature without melting. This is ideal for gummies that are exposed to high temperatures during storage and transport.

[0097] The examples provided above are for illustrative purposes only. Formulations for chewable drugs of the present invention may vary based on the desired dosage of the active pharmaceutical ingredients and the amount of additives, sweeteners, and coloring added to the drug composition. Thus, testing will be required to arrive at a suitable composition for each chewable drug.

[0098] While implementations of the invention have been described with reference to a gummy delivery system, the invention is not limited to this application and may be readily used for any chewable composition that includes a pectin, gelatin, or starch base. For example, implementations

of the invention may also be employed in organic tablets, capsules, or solid candies. The present invention may also apply to other forms of candies such as jelly beans or caramel-based candies. Further, while the dimensions of the holding and mixing vessels are provided herein by way of example only, the actual dimensions of these vessels may vary based on the amount of gelling compound and candy slurry produced in a given time period (*e.g.*, per day).

[0099] The foregoing description of implementations has been presented for purposes of illustration and description. It is not exhaustive and does not limit the claimed invention to the precise form disclosed. Modifications and variations are possible in light of the above description or may be acquired from practicing the invention. The claims and their equivalents define the scope of the invention.

CLAIMS

What is claimed is:

1. A chewable composition comprising:

a binding agent;

a sugar-free sweetener; and

an active ingredient.

2. The chewable composition of claim 1 where the active ingredient is a dietary supplement.

3. The chewable composition of claim 2 where the dietary supplement is a mineral.

4. The chewable composition of claim 2 where the dietary supplement is a vitamin.

5. The chewable composition of claim 2 where the dietary supplement is a plant-based supplement.

6. The chewable composition of claim 2 where the dietary supplement is an enzyme.

7. The chewable composition of claim 2 where the dietary supplement is a probiotic.

8. The chewable composition of claim 2 where the dietary supplement is a prebiotic.

9. The chewable composition of claim 1 where the active ingredient is a pharmaceutical compound.

10. The chewable composition of claim 7 where the pharmaceutical compound is an over-the-counter drug.

11. The chewable composition of claim 7 where the pharmaceutical compound is a prescription drug.

12. The chewable composition of claim 7 further comprising any combination of vitamins, minerals, herbs, probiotics, prebiotics, and enzymes.

13. The chewable composition of claim 1 where the binding agent is pectin.

14. The chewable composition of claim 1 where the binding agent is starch.

15. The chewable composition of claim 1 where the binding agent is gelatin.

16. The chewable composition of claim 1 where the binding agent is carrageenan.

17. The chewable composition of claim 1 where the binding agent includes starch, pectin, gelatin, or carrageenan in any combination.

18. The chewable composition of claim 1 where the composition qualifies as a composition capable of being certified as organic.

19. The chewable composition of claim 1 where the sugar-free sweetener includes a natural and/or artificial sugar substitute.

20. A sugar-free delivery system comprising:

a candy that includes a binding agent and a sugar-free sweetener; and

an active ingredient incorporated into the candy.

21. The delivery system of claim 20 where the active ingredient is a dietary supplement.

22. The delivery system of claim 21 where the dietary supplement is a mineral.

23. The delivery system of claim 21 where the dietary supplement is a vitamin.

24. The delivery system of claim 21 where the dietary supplement is a plant-based supplement.

25. The delivery system of claim 21 where the dietary supplement is an enzyme.

26. The delivery system of claim 21 where the dietary supplement is a probiotic.

27. The delivery system of claim 21 where the dietary supplement is a prebiotic.

28. The delivery system of claim 20 where the active ingredient is a pharmaceutical compound.

29. The delivery system of claim 28 where the pharmaceutical compound is an over-the-counter drug.

30. The delivery system of claim 28 where the pharmaceutical compound is a prescription drug.

31. The delivery system of claim 28 further comprising any combination of vitamins, minerals, herbs, probiotics, prebiotics, and enzymes.

32. The delivery system of claim 20 where the binding agent is pectin.

33. The delivery system of claim 20 where the binding agent is starch.

34. The delivery system of claim 20 where the binding agent is gelatin.

35. The delivery system of claim 20 where the binding agent is carrageenan.

36. The delivery system of claim 20 where the binding agent includes starch, pectin, gelatin, or carrageenan in any combination.

37. The delivery system of claim 20 where the composition qualifies as a composition capable of being certified as organic.

38. The chewable composition of claim 20 where the sugar-free sweetener includes a natural and/or artificial sugar substitute.

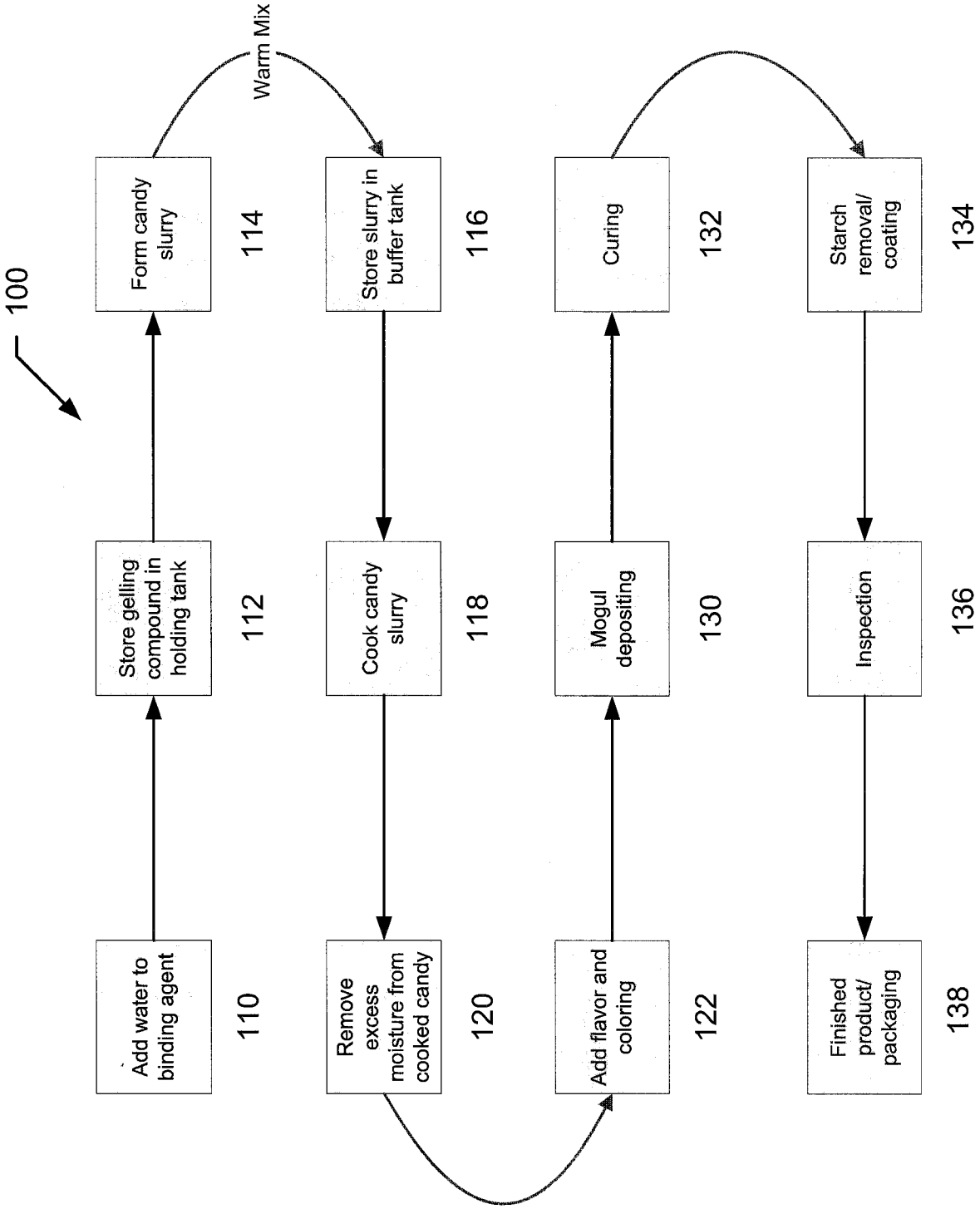
100
Add water to binding agent
110
Store gelling compound in holding tank
112
Form candy slurry
114
Warm Mix
Store slurry in buffer tank
116
Cook candy slurry
118
Remove excess moisture from cooked candy
120
Add flavor and coloring
122
Mogul depositing
130
Curing
132
Starch removal/ coating
134
Inspection
136
Finished product/ packaging
138

FIG. 1

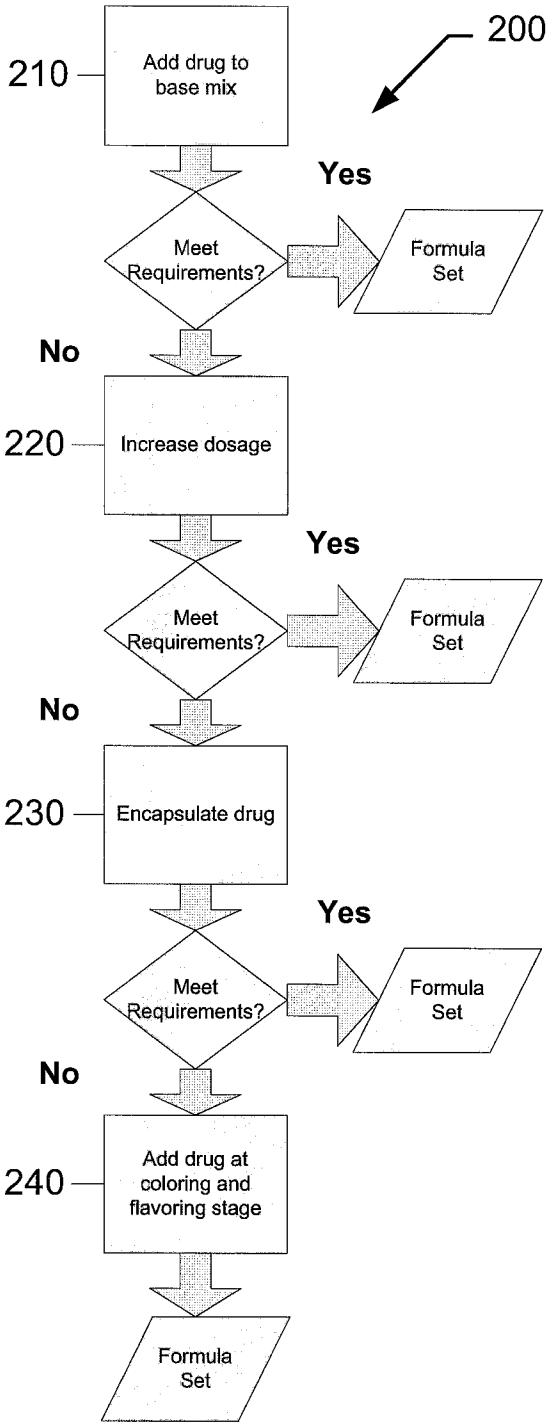
200
210
Add drug to base mix
Yes
Meet Requirements?
Formula Set
No
220
Increase dosage
Yes
Meet Requirements?
Formula Set
No
230
Encapsulate drug
Yes
Meet Requirements?
Formula Set
No
240
Add drug at coloring and flavoring stage
Formula Set

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/40126

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61K 9/68 (2011.01)
USPC - 424/48
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC-424/48

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC-424/48,49,441,725;426/3,6 (see search terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (US Pat, PgPub, EPO, JPO), Google Google Patents (US PAt), Scholar (PL, NPL): chewable composition binding agent sugar-free active ingredient dietary supplement mineral organic certification pectin prebiotic probiotic enzyme delivery agent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 6482465 B1(Cherukri et al.) 19 November 2002 (19.10.2002) col 2, ln 60-col 3, ln 9, col 3, ln 52-55, col 3, ln 65-col 4, ln 23, col 5, ln 40-67, col 6, ln 43-col 8, ln 24, col 9, ln 38-57, col 10, ln 15-col 11, ln 32, col 11, ln 58-66, col 13, ln 47-col 14, ln 18,col 16, ln 18-col 17, ln 7, col 17, ln 28-col 19, ln 2	1-5, 9, 14-17, 19-24, 28-31, 33-36, 38 ---------- 6-8, 10-12, 18, 25-27, 37
X	US 4857331 (Shaw et al.) 15 August 1989 (15.08.1989) title, abstract and entire document, for example col 1, ln 5-30, col 4, ln 18- col 6, ln 18	1, 13, 20, 32
Y	US 2006/0263344 A1 (Skop et al.) 23 November 2006 (23.11.2006) Abstract, entire document, para [0001]-[0025], [0028]-[0049], [0076]-[0077], [0080]-[0097], caims 7, 13-15, 21-24, 30-34	6-8, 10-12, 25-27
Y	US 2009/0197974 A1 (Ahmed et al.) 6 August 2009 (06.08.2009) title, abstract, claims 1-25, para [001]-[0012], entire document	18, 37

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 November 2011 (07.11.2011)	25 NOV 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)