Processes for preparing dry extracts from fluid extracts and at least one additional substance by a spray-drying process is effected by adding the additional substance to the spray-drying process in a dry form.
FIG. 2
Ginseng, 3000x

FIG. 3
Glucosamine, 3000x
FIG. 4
St. John's Wort (sole), 10000x

FIG. 5
St. John's Wort, 10000x
PROCESS FOR PREPARING DRY EXTRACTS

RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. application Ser. No. 09/986,116 filed Nov. 7, 2001, which is incorporated herein by reference in its entirety.

[0002] The present invention relates to new processes for preparing dry extracts having superior flow characteristics, and extracts made by such processes.

BACKGROUND

[0003] Biologically, chemically and/or pharmaceutically active agents are often derived from natural sources in liquid form (including solutions, suspensions, emulsions, slurries, pastes or other mixtures, hereinafter, "fluid"). This is particularly the case with plant extracts. Extracts from plant parts and/or plant preparations are widely employed in many industries, including but not limited to the feed, food, functional food, nutraceutical, dietary supplement and pharmaceutical industries. It is often desirable to dry these extracts to reduce their volume and/or to improve their handling and processing characteristics.

[0004] Spray drying is a known and very important method for dehydrating or drying fluids, fluid foods and botanical extracts. In its conventional form, spray drying involves the formation of small droplets of an extract or other fluid to be dried (hereafter, "extract") followed by contacting the droplets with a heated gas to remove moisture. Conventional spray drying typically includes: creation and possibly concentration of a fluid extract; atomization of the extract into droplets; drying the droplets in stream of hot, dry gas such as heated air; separation of the resulting dry powder product from the moistened air; and finally cooling and packaging the product.

[0005] Auxiliary agents such as excipients are often used in the processing of the extract to impart to the extract improved properties, for instance improved tabletting, handling, storage or processing properties. Such auxiliary agents are typically in solid (dry powder) form and are conventionally admixed with the fluid extract. Droplets of the fluid mixture containing the extract and the auxiliary agent are commonly dried in a spray drying process as outlined above. Depending on what use is intended for the thus obtained dry products, further processing steps, such as wet granulation, fluidized-bed drying, compaction, etc., may follow.

[0006] In practice, this form of common spray drying results in products having undesirable characteristics, tending to form hygroscopic (moisture retaining) and therefore "sticky" or "gummy" products. These sticky materials often deposit and build up in layers during the drying process, resulting in product which is unable to trickle as fine particle and flow as powder through subsequent product conveying and packaging steps, for instance product transport through pipes and tubes. Attempts to apply a common spray dry process therefore often fail.

[0007] Auxiliary agents are also commonly mixed in powder form with previously spray dried extract. This mixing of powders is also problematic because these blends still show dust formation, elevated moisture uptake and hygroscopicity, particle separation due to different particle density and size, and inferior compaction and compression properties and thus, also results in mixtures having inferior handling and tabletting properties.

OBJECTS OF THE INVENTION

[0008] In view of the shortcomings of conventional spray drying processes, it is an object of the present invention to overcome the above-described problems and to provide a process for manufacturing free flowing product powders by spray drying.

[0009] It is a further object of the present invention to provide finished products that contain low amounts of auxiliary agents introduced during the drying process or thereafter. Such products would enable further confectionery steps, for instance direct compression to produce tablets or direct compaction to produce granules, without adding large or any amounts of additional excipients.

[0010] Additionally, it is an object of the present invention to provide a particularly simple process for adding further substances in dry form to an extract to be dried, with the goal to obtain material which is more easily handled and processed.

[0011] Finally, it is an object of the invention to provide a process for preparing dry extracts from fluid extracts and at least one additional substance by a spray-drying process, wherein the additional substance is added to the spray-drying process in a dry form during the spray-drying process.

[0012] These and other objects of the invention will become more clear in view of the disclosure of the inventive spray dry technology which follows.

SUMMARY OF THE INVENTION

[0013] The above objects are achieved by a process for preparing dry extracts from a fluid extract and at least one additional substance by a spray drying process, wherein said at least one additional substance is added to the spray drying process in a dry form during the spray drying process.

[0014] That is, the process of the present invention employs the novel and additional feature of dry powder injection. Rather than admixing the powdered auxiliary agent into the fluid extract and thus wetting the auxiliary agent, dry auxiliary agent is injected into a spray dryer contemporaneously with the injection and atomization of the fluid extract.

[0015] The process according to the invention results in adhesion of the auxiliary agents to the extract, thereby forming agglomerated particles. More specifically, wet extract droplets formed by the spraying mix and agglomerate and/or aggregate with at least one additional substance and are dried on their common way through the spray-dryer. The residual moisture of the product of the inventive process is generally below 5%.

[0016] The so formed agglomerated particles possess remarkable and advantageous properties. Due to the outstanding properties of the obtained products, like superior flow characteristics compared to prior art compositions, the new agglomerates allow faster processing for manufacturing final dosage forms including tablet, capsules, granulates and powder blends. Surprisingly, even extract products which
are usually hygroscopic when processed with additional substances according to conventional methods can be obtained as free flowing powder when the inventive process disclosed here is employed.

[0017] Also surprisingly, in this way a homogeneous free-flowing powder can be obtained which can be used, for example, directly for tabletting and/or compaction. Such a product is superior to both one obtained by commonly drying a solution of the extract and auxiliary agent, and one obtained by adding the auxiliary agent to the dried extract, with respect to galenic properties, especially tabletting property. Thus, the proportion of auxiliary agent can be significantly reduced as compared to conventional processes, so that smaller tablets can be produced with the same load of active substance, or more active substance can be introduced in predetermined tablet sizes. Remarkable are the properties of less hygroscopicity, or at least the better flow characteristic with the same moisture uptake, and the improved compressibility with less quantity of added auxiliary agents compared with the conventional obtained botanical extract composition of prior art. The advantages of the present invention are clearly demonstrated within the below detailed description, examples and the presented tables showing comparable data.

[0018] The invention also relates to dry extracts obtained by the inventive "dry" process, and to medications containing such extracts.

[0019] The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] For a more complete understanding of the present invention, reference is now made to the following descriptions taken in conjunction with the accompanying drawings, in which:

[0021] FIG. 1 depicts schematically the spray drying process which is the subject of the present invention.

[0022] FIG. 2 is a scanning electron micrograph of an agglomerated particle comprising extract of Ginseng and silicified/silicated microcrystalline cellulose, magnified at 3,000x.

[0023] FIG. 3 is a scanning electron micrograph of an agglomerated particle comprising extract of Glucosamine and silicified/silicated microcrystalline cellulose, magnified at 3,000x.

[0024] FIG. 4 is a scanning electron micrograph of an agglomerated particle comprising extract of St. John’s Wort and silicified/silicated microcrystalline cellulose, magnified at 10,000x.

[0025] FIG. 5 is a scanning electron micrograph of an agglomerated particle comprising extract of St. John’s Wort and silicified/silicated microcrystalline cellulose, magnified at 10,000x.

DETAILED DESCRIPTION OF THE INVENTION

[0026] A schematic depiction of a spray drying system employed in practicing the method of the invention is shown in FIG. 1. Such a system includes a dry powder injector necessary to obtain the powder products having extraordinary characteristics.

[0027] In particular, and referring to FIG. 1, the inventive spray drying process includes essentially a three-phase drying process involving both particle formation and drying. In a first phase, a fluid extract is flowed through fluid feed 3 and is atomized, via an atomizer 4 into a spray of fine droplets within a drying chamber 6. Contemporaneously, a solid (dry powder) component is injected into the drying chamber from a dry powder feed 1 via a pneumatic feeding system 2. The result is a mixture 13 within the chamber of fine fluid droplets in close and intimate contact with powder particles. A heated gas stream 5 suspends the droplets and powder particles, evaporating the fluid and leaving the solids in essentially their original size and shape. Many droplets in close contact with powder particles agglomerate or aggregate during the drying process, forming new powders with superior flow and other handling characteristics.

[0028] The dried powder is separated from the gas stream and collected. Spent drying gas is either treated and exhausted to the atmosphere or re-circulated to the system. More specifically, the powder is separated from the drying gas at the bottom of the drying chamber. Most often, the gas exits through an outlet duct 11 in the center of the cone portion of the drying chamber. Heavier or coarser particles will be separated at this point, dropping into the cone to be collected through an air lock 8 and into apparatus 10 for further processing. Then, either cyclones 7 or fabric filters 12 (or both) remove the remaining powder from the exit gas and add that collected powder to the further processing apparatus through a second air lock 9. In systems producing a very fine powder, most of the collection takes place at this point.

[0029] The present invention is not limited to the above spray dryer type, but rather includes other types of spray dryers such as a box spray dryer employing the Rogers process, spray-belt dryers, and more.

Drying Conditions

[0030] Precise drying conditions vary in accordance with the extract and auxiliary agents employed. For performing the process, as usual spray-drying plant can be used in which the fluid extract is introduced into a spray tower and drying
air is simultaneously fed. By spraying into a hot-air current, the fluid products are quickly and mildly dried within seconds or fractions of seconds. The fluid extract to be dried typically contains from 5 to 70% of dry substance and is introduced into a spray tower and atomized at a pressure within a range of from 10 to 150 bar through one or more high-pressure nozzles. Usually, the temperature of the fed-in drying air is between 120 and 350°C. In the process according to the invention, the dry additional substance or a mixture of such substances is also introduced into the spray tower using blow conveyance, preferably in the vicinity of the spraying nozzles for the fluid extract.

**Equipment**

**[0031]** The selection and operation of the atomizer is of extreme importance in achieving an optimum operation and production of top-quality powders. Within large capacity spray dryer there can be found at least three main types of atomization:

**[0032]** Centrifugal atomization, the most common, uses a rotating wheel or disc to break the fluid stream into droplets. The rotational speed determines the mean particle size.

**[0033]** Hydraulic-pressure-nozzle atomization forces pressurized fluid through an orifice. Multiple nozzles are used to increase capacity. The particle size depends on the pressure drop across the orifice, so that the orifice size determines the capacity of the system.

**[0034]** Two-fluid pneumatic atomization uses nozzles, as well, but introduces a second fluid, usually compressed air (often called high pressure spray jets), into the fluid stream to atomize it.

**[0035]** After atomization, a disperser brings the heated gas into contact with the droplets. The disperser must accomplish three things: mix the gas with the droplets, begin the drying process, and determine the flow paths through the drying chamber. The drying gas may be heated directly by combustion of natural gas, propane, or fuel oil, or indirectly using shell-and-tube or finned heat exchangers.

**[0036]** In accordance with one embodiment of the present invention, an addition equipment necessary to feed dry auxiliary agent in the top part close to the atomizer and hot air entrance is essential for the process of producing the free flowing and direct compressible product powder.

**[0037]** The drying chamber must be sized to allow adequate contact time for evaporation of all of the fluid to produce a dry powder product. Factors that impact the drying time include the temperature difference between the droplets and the drying gas, and their flow rates. The exact shape of the chamber depends on the drying characteristics and product specifications, but most are cylindrical with a cone-shaped lower section to facilitate collection of the product.

**[0038]** Finally, proper configuration of the atomizer, disperser, and drying chamber is essential for complete drying and to avoid the deposit of wet material on the interior surfaces of the dryer. Designs may use co-current, counter-current, or mixed flow patterns.

**Active Agents**

**[0039]** The invention is not limited to botanical or plant extracts but applicable for all types of food, functional food, dietary supplements, nutraceuticals as well as drugs, pharmaceuticals, and other (bio)active agents for human and animal use. The later, which may be used in accordance with the embodiments described above include therapeutic agents, either systemically or locally applied, biocides, bactericides, pesticides, herbicides, fungicides, fertilizers, repellents, disinfectants, detergents, aromas, fragrances, and others.

**[0040]** The therapeutics may include analgesics, anticonvulsants, anti-diabetic agents, antidotes, antibiosis agent, anti-histamines, anti-inflammatory agents, like amebicides, anthelmintics, and different classes of antibiotics, antifungal, antiviral substances, antineoplastics, antirheumatic and cardiovascular agents, central nervous actives, deodorants, erectile dysfunction enhancer, gastrointestinal agents, homeopathic remedies, hormones, immunoregulators, ophthalmic and osteoporosis agents, psychotherapeutics, respiratory agents, sedatives and hypnotics, skin and mucous membrane agents, uterine tract agents, vaginal preparations, and vasodilators.

**[0041]** Botanical preparations include but are not limited to partial or complete extracts from medical, spice and/or food plants or parts thereof, especially: *Abelmoschus moschatus*, *Acalypanax sessiliflorum*, *Achyrocline sareoides*, *Acorns calamus*, *Aesculus hippocastanum*, *Albizia julibrissin*, *Achyranthes asperulina*, *Aloe vera*, *Aloe arborescens*, *Allium species* (e.g., *A. cepa*, *A. ursinum*, *A. sativum*), *Alpinia officinarum*, *Anethum graveolens*, *Anacardium occidentale*, *Ananas comosus*, *Andrographis paniculata*, *Angelica archangelica*, *Angelica dahurica*, *Angelica formosana*, *Annona muricata*, *Anthemis nobilis*, *Apium graveolens*, *Aralia species*, *Arctium major*, *Arctostaphylos uvaursi*, *Arnica montana*, *Artemisia absinthium*, *Artemisia dracunculus*, *Asparagus officinalis*, *Astragalus membranaceus*, *Arropa belladonna*, *Baccharis genistelloides*, *Banninia forcticata*, *Berberis vulgaris*, *Bertholletia excelsa*, *Betula species*, *Biden pilosa*, *Bixa orellana*, *Boerhavia diffusa*, *Boswellia serrata*, *Brassica nigra*, *Bruneafisa uniflora*, *Bryonia dioica*, *Calycophyllum spruceanum*, *Camellia sinensis*, *Capsicum frutescens*, *Carapa guianensis*, *Carum carvi*, *Cassia occidentalis*, *Cayaponia tayuya*, *Centella asiatica*, *Cetaria islandica*, *Chamomilla romana*, *Chrysanthemum vulgare*, *Cicer arietum*, *Cinncifuga racemosa*, *Cinnamomum species*, *Cissampelos pareira*, *Citrus species*, *Codonopsis pilosula*, *Coffea arabica*, *Cola acuminata*, *Cola nitida*, *Commiphora mukul*, *Copaifera officinalis*, *Copaifera reticulata*, *Copalis chinensis*, *Coricarpus sinensis*, *Coriandrum sativum*, *Crataegus species*, *Croton lechleri*, *Cucurbita pepo*, *Cuminum cyminum*, *Cumcuma species*, *Cusparia officinalis*, *Cynara scolymus*, *Desmodium adscendens*, *Dioscorea villosa*, *Dipterocarpus turbinatus*, *Drosera species*, *Echinacea angustifolia*, *Echinacea purpurea*, *Echinopanax elatus*, *Nakah*, *Elettaria cardamomum*, *Eleutherococcus senticosus*, *Ephedra sinica*, *Equisetum arvense*, *Erythrina malungu*, *Erythrophyllum caudatum*, *Eucalyptus globules*, *Eucumma ulmolodes*, *Fagopyrum vulgare*, *Foeniculum vulgare*, *Funaria officinalis*, *Gandoerma lucidum*, *Gaultheria procumbens*, *Ginkgo biloba*, *Glycyrrhiza glabra*, *Grisola frondosa*, *Guzmania ulmifolia*, *Hamamelis virginiana*, *Harpagopytion procumbens*, *Hederae pulegioides*, *Herni-
aria glabra, Hophea dichotoma, Humulus lupulus, Hyme-
naea courbaril, Hypericum perforatum, Hysopus officinalis, Ilex
paraguariensis, Illicium verum, Liana heliostem, Iris
pelida, Jezanum grandiflorum, Juniperus communis, Lar-
rea tridentata, Laurus nobilis, Lavendula officinalis, Law-
sonia inermis, Leninus edodes, Lepidium meyenii, Lentea
carthamoideae, Levisticum officinale, Malpighia glabra, Mat-
ricaria chamomilla, Maytenus krukovii, Maytenus ilicifolia,
Melaleuca, Melilotus officinalis, Melissa officinalis, Mentha
piperita, Morinda citrifolia, Myrica dubia, Myrica salici-
folia, Myristica fragrans, Myroxylon balsamum perireu-
Myrtus communis, Ocimum basilicum, Ocimum sanctum,
Ocotea sassafras, Oenanthe aquatica, Olea europea, Oli-
barum, Ononis spinosa, Origanum, Orthosiphon stamineus,
Panax ginseng, Panax quinquefolium, Passiflora edulis,
Passiflora incarnata, Paulinia cupana var. sorbilis,
Petroselinum crispum, Pennus boldus, Pflauff paniculata,
Phaeolus vulgaris, Phyllanthus niruri, Physalis angulata,
Pilocarpus jaborandi, Pimenta dioica, Pimpinella anisum,
Piper angustifolium, Piper methysticum, Pogostemon
patchouli, Polypodium lepidopterus, Prunus laurocerasus,
Psidium guajava, Psychophatina olacoides, Rhodiola
crenulata, Rhodiola rosea, Rhus aromatica, Rosmarinus
officinalis, Rubia tinctorum, Rubus fruticosus, Ruscus
aculeatus, Ruia graveolens, Sabal seratula, Salix alba,
Salvia, Sambucus nigra and S. ebulus, Santalum album,
Saratohnus scoparius, Sassafras albidum, Satureja
hortensis, Schinus molle, Schisandra chinensis, Scopoila
camilolica, Scopolia dalics, Serenoa repens, Simarouba
amara, Silybum marianum, Smilax officinalis, Smilax sar-
saparilla, Solarunum paniculatum, Solidago serotina, Sol-
idoa virgaurea, Stachyuthena jaimecensis, Stevia reba-
diana, Symphytum officinale, Syzgium aromaticum,
Tabebula avelanedae, Tabebua impetiginosa, Tanacetum
parthenium, Taraxacum officinale, Theobroma cacao, Thy-
mus serpyllum, Thymus vulgaris, Tilia cordata, Tinospora
cordifolia, Trichopous zeylanicus, Trifolium pratense, Trigo-
nella foenum-graecum, Tumera aphrodiesiaca, Tumera dif-
fusa, Ulmus rubra, Uncaria tomentosa, Uruta dioica, Vac-
cinium macrocarpon, Vaccinium myrtillus, Valeriana
officinalis, Vitex agnus-castus, Vitis vinifera, Withania som-
ufiera, Zingiber officinale, and other herbs, spices, or
medicinal plants.

[0042] The presented invention is extraordinary valuable, if the active agent is hygroscopic, for instance, hygroscopic herbal extracts including but not limited to St. John’s Wort, Artichoke, Valerian, and Ginseng.

[0043] Dietary supplements or nutraceuticals include but are not limited to the groups of amino acids, vitamins, minerals, and trace elements, as well as ergogens and metabolites. These active agent including in particular the non-proteinogenic amino acids Creatine, Taurine, or branch-
chained amino acids, Leucine, Isoleucine, Valine, or neu-
rotransmitter precursors tyrosine, phenylalanine, trypt-
ophane, or Arginine, Ornithine, Citrulline, Glutamine, in
their water-free form, the hydrated or in form of its salt, or
derivatives or metabolites thereof, the purins include espe-
cially are caffeine, theobromine, or theophylline, as sole
substances or in form of their plant origin or extracts thereof,
the vitamins include especially Vitamin A, B-complex, C, D,
E, K, β-carotin, Nicotinamide, Folic acid, Coenzym Q10,
NAD, L-Carnitine, alpha-lipoic acid in free form, salt or
ester form, the minerals and trace elements include espe-
cially Calcium, Magnesium, Sodium, Potassium, Chro-
mium, Iodine, Manganese, Copper, Iron, Zinc, Vanadium,
Phosphorus and Selenium, in physiologically acceptable
form, as well as other groups of nutraceuticals, like Glu-
cosamine, Chondroitin, Phytostrogens, like Flavonoids
(from Soy, Red clover) and Lignans (Flax seeds), Camosine,
Ribose, Choline, Poly-unsaturated fatty acids, Antioxidants
including but not limited to Anthocyan, Proanthocyca-
nides, Carotinoids (lutein, lycopene, astaxanthin, zeax-
anthin), Phytin, Phytic acid, Policosanols, Policosanoic
acids, Montane acids, Phytosterols, Phytostanols, Pyru-
vates, Lecithin, Phosphatidylserine, Phosphatidylcholin,
SAMA, 5-Hydroxytryptophan, Synephrine, prebiotic fibers,
and the like.

Auxiliary Agents

[0044] The process is particularly useful if the fluid extract is the extract of a medicinal plant whose extract is to be administered in the form of tablets. Said at least one addi-
tional substance will then be a galenic auxiliary agent.
Galenic auxiliary agents are known to the skilled person.
There may be mentioned, for example, lactose, maltodextrin,
dextrin, dry glucose, starch, microcrystalline cellulose,
chemically and physically modified microcrystalline cellulose
including silicat/silicated microcrystalline cellulose
or derivatives thereof (e.g., the trademarked product from
Penwest Pharmaceuticals, Inc. Prosolv SMCC 50, 90,
Prosol HD, and other grades), physical blends of microcry-
stalline cellulose and silicon dioxide, Povidone®, polyethyl-
ene glycol, calcium phosphate, magnesium stearate,
precipitated silicic acid, precipitated silica, highly dispersed
silica, sorbitol, mannitol, or mixtures thereof.

[0045] As used herein the terms “silicatied” and “silicated” in the context of microcrystalline cellulose are used inter-
changeably to refer to a class of products which are par-
ticularly useful as a direct compression vehicle. Silicatied/
silicated microcrystalline cellulose is a particulate
agglomerate of coprocessed microcrystalline cellulose and
from about 0.1% to about 20% silicon dioxide particles, by
weight of the microcrystalline cellulose, wherein the micro-
crystalline cellulose and silicon dioxide are in intimate
association with each other. The silicon dioxide has a
particle size from about 1 nanometer to about 100 microns,
based on average primary particle size. Preferably, the
silicon dioxide is a grade of colloidal silicon dioxide.

[0046] Silicatied/silicated microcrystalline cellulose is sold commercially by Penwest Pharmaceuticals, Inc. under
the trademark “ProSolv”, and is described in U.S. Pat.
No. 5,585,115. This application incorporates by reference
the definitions of those terms as defined by the Dictionary.com
internet web site, which is consistent with art recognized
meanings of these terms. Specifically, “silicatied” is defined
as “combined or impregnated with silicon or silica”; and
“silicated” is defined as “converted[ed] into or impregnate[ed]
with silica”. Silicatied microcrystalline cellulose, also called
silicated microcrystalline cellulose, is a preferred auxiliary
galenic agent.

[0047] In accordance with other embodiments of the present invention, the obtained free flowable powders com-
prise agglomerated particles may combined with conven-
tional tableting additives prior to tableting, capsules filling,
or further blending. Those additives may be soluble or
insoluble inert pharmaceutical dithens, lubricants, agents
for enteric, hydrophilic and hydrophobic coating, substances to achieve sustained and controlled release profile of the actives. In particular, the additives are suitable pharmaceutically acceptable carriers include but are not limited to water, salt solutions, alcohols, gum arabic, vegetable oils, benzyl alcohols, gelatin, carbohydrates such as lactose, amylose or starch, magnesium stearate, talc, silicic acid, viscous paraffin, perfume oil, fatty acid monoglycerides and diglycerides, pentaerythritol fatty acid esters, hydroxy methylcellulose and the like. Other additives include, e.g., anti-oxidants and preservatives, coloring, flavoring and diluting agents, emulsifying and suspending agents, such as acacia, agar, algic acid, sodium alginate, bentonite, carborner, carrageenan, carboxymethylcellulose, cellulose, cholesterol, gelatin, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, oleyl alcohol, povidone, propylene glycol monostearate, sodium lauryl sulfate, sorbitan esters, stearyl alcohol, tragacanth, xanthan gum, and derivatives thereof, solvents, and miscellaneous ingredients such as microcrystalline cellulose, citric acid, dextrin, dextrose, fluid glucose, lactic acid, lactose, magnesium chloride, potassium metaphosphate, starch, and the like. Those components may either be co-sprayed or blended together with the product obtained according to the present invention.

[0048] The particle size of the additional substance employed is of less importance. Suitable particle sizes are within a range of 1 to 800 μm, preferably within the range of 1 to 500 μm, more preferably in the range of 100 to 300 μm.

Ratio of Active: Auxiliary

[0049] In accordance with another embodiment of the present invention, the orally applicable product form is provided, which comprises about 45-95%, preferably from 60 to 80%, active agent, in particular, a botanical extract and about 5 to 55%, preferably from 40 to 20%, of a galenic auxiliary agent added as dry powder during the spray drying process.

[0050] The structure of the spray dried powder particles is crucial for its physical characteristics. Thus, the physical properties of spray dried powders is related to the characteristics of the matrix of the shells (outer layer) and the size of the inner core. Using scanning electron microscopy (FIGS. 2-5) it can be shown that the particles obtained according to the present invention possess a shell of the added dry powder. Very impressive is comparison of FIGS. 4 and 5, where the difference of dry St. John’s Wort extract particle (sole) and St. John’s Wort particle produced according to the present invention (so called RediRun) is obvious.

EXAMPLES

[0051] In each of the following examples the products produced according to the invention were processed substantially as follows: A fluid extract is provided in a storage vessel. Also provided separately are dosing scales with the additional substance employed according to the invention in a dry form. The fluid extract or an aqueous solution of the active agent is sprayed into a drying chamber with the finely powdered additional substance at the top of the spray tower through high-pressure nozzles using a pump. Hot air is introduced into the spray tower from below (or top). The exhaust air leaves at the top end (or center) of the spray tower and is optionally conducted to a heat exchanger. The dried product is conducted onto a vibrating bed at the lower end of the spray tower and introduced into the further production process. Alternatively, the product may be fed into a cyclone.

Example 1

[0052] 146.5 kg of St. John’s wort (SJW) extract having a dry content of 47.8% was spray-dried together with 30.00 kg of silicified/silicated microcrystalline cellulose at an air entry temperature of 210°C and under a nozzle pressure of 40 bar to obtain 93.6 kg of dry product.

Comparative Example 1a

[0053] 5.0 kgs of commonly produced St. John’s wort dry extract comprising of 65% native extract and about 35% excipients like Maltodextrin (30%) and silicon dioxide (5%) was added to 2.5 kgs of silicified/silicated microcrystalline cellulose and mixed in a pilot plant blender. The moisture uptake, the powder flowability and the compactability was compared with product of Example 1 in Table 1:

<table>
<thead>
<tr>
<th>Comparison of Properties of St. John’s Wort Products</th>
<th>Flowability</th>
<th>Moisture Uptake</th>
<th>Compactability</th>
<th>Hardness of the Pressed Tablets</th>
<th>Hardness of the Pressed Tablets</th>
<th>Speed of Encapsulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. John’s Wort of Example 1</td>
<td>Very good</td>
<td>Low</td>
<td>Very good</td>
<td>High</td>
<td>High - Nos stop necessary</td>
<td>High - Nos stop necessary</td>
</tr>
<tr>
<td>St. John’s Wort of Comp. Example 1</td>
<td>Good</td>
<td>Fair</td>
<td>Poor</td>
<td>Fair</td>
<td>Poor - Multiple stop for cleaning</td>
<td>Poor - Multiple stop for cleaning</td>
</tr>
</tbody>
</table>

[0054] Speed of encapsulation: comparable trial was performed at standard encapsulation machine (e.g., Bosch 330) to judge over the impact of flowability, dust formation, and moisture uptake on the velocity of capsule filling.

Example 2

[0055] 132.2 kgs of Panax ginseng (PG) extract having a dry content of 43.8% was spray-dried together with 25.0 kgs of silicified/silicated microcrystalline cellulose at an air
entry temperature of 205°C and under a nozzle pressure of 40 bar to obtain 83.6 kg of dry product. of 175-250°C and under a nozzle pressure of about 40 bar to obtain dry product with yields of 85 to 95%.

Comparative Example 2a

[0056] 235.0 kgs of Panax ginseng (PG) extract having a dry content of 39.7% was spray-dried together with 23.3 kgs of physical mixture of microcrystalline cellulose and colloidal silicon dioxide (96% MCC and 4% SiO2, e.g., Aerosil) at an air entry temperature of 215°C and under a nozzle pressure of 36 bar to obtain 83.6 kg of dry product. The moisture uptake, the powder flowability and the compactability was compared with product of Example 2.

Comparative Example 2b

[0057] 2.5 kgs of silicified/silicated microcrystalline cellulose was added to 4.5 kgs of commonly produced Panax ginseng dry extract comprising of 40% native extract and about 60% excipients like Maltodextrin (55%) and silicon dioxide (5%) and mixed in a pilot plant blender. The moisture uptake, the powder flowability, compactability, and hardness of the tablets was compared with product of Example 2.

### Table 2

<table>
<thead>
<tr>
<th>Product</th>
<th>Flowability</th>
<th>Moisture Uptake</th>
<th>Compactability</th>
<th>Hardness of Pressed Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panax of Example 2</td>
<td>very good</td>
<td>Low</td>
<td>very good</td>
<td>high</td>
</tr>
<tr>
<td>Panax of cp. Example 2a</td>
<td>good</td>
<td>Low</td>
<td>good</td>
<td>high</td>
</tr>
<tr>
<td>Panax of Example 2b</td>
<td>poor</td>
<td>High</td>
<td>poor</td>
<td>fair</td>
</tr>
</tbody>
</table>

Example 4

[0059] 5236.8 kg of St. John’s wort extract having a dry content of 38% was spray-dried together with 104.6 kg of highly dispersed silica at an air entry temperature of 200°C and under a nozzle pressure of 40 bar to obtain 2065.8 kg of dry product having a good flowability.

Example 5

[0060] 1819.9 kg of Giant or Late Goldenrod extract having a dry content of 30% was spray-dried together with 221.7 kg of maltodextrin and 23.4 kg of highly dispersed silica at an air entry temperature of 215°C and under a nozzle pressure of 45 bar to obtain 733.6 kg of dry product. The product is a fine powder not sensitive to moisture.

Example 6

[0061] 1640.00 kg of valerian root extract having a dry content of 51.8% was spray-dried together with 332.00 kg of dry glucose and 48.6 kg of highly dispersed silica at an air entry temperature of 230°C and under a nozzle pressure of 80 bar to obtain 1142.8 kg of dry free-flowing extract powder.

Example 7

[0062] 658.5 kg of nettle root extract having a dry content of 32% was spray-dried together with 52.7 kg of lactose at an air entry temperature of 220°C and under a nozzle pressure of 50 bar to obtain 262.4 kg of dry free flowing product having good powder characteristics and is well to handle.

Example 8

[0063] According to Example 1, similar products comprising the dietary supplements Glucosamine and Chondroitin with specialty auxiliary blend were manufactured. 47.6 kgs of Glucosamine sulfate and 38.1 kgs of Chondroitin were dissolved in water to obtain the fluid feed. As dry powder feed a blend of dry silicified/silicated microcrystalline cellulose (11.9 kgs) and colloidal silicon dioxide (Aerosil 200; 2.4 kgs) were mixed. At an air entry tempera-
ture of 220°C and under a nozzle pressure of about 40 bar the fluid and powder feed were co-spray-dried according to the example 1 to obtain dry product with yields of 93%.

Example 9

[0064] The same procedure as described in Example 8 using 45.2 kgs of Glucosamine sulfate and 36.2 kgs of Chromodroitin but a dry powder feed comprise 11.3 kgs of dry silicified/silicated microcrystalline cellulose, 2.3 kgs of colloidal silicon dioxide (Aerosil 200), 3.0 kgs of soy, polysaccharides, 1.5 kgs of Talcum, and 0.5 kgs of sodium stearyl-fumarate were used instead. The yield was 95.3 kgs of dry product. Both products of these examples (8 and 9) were fine, free flowable, and good compactable powder without tendency to lump.

We claim:

1. A process for preparing dry extracts from a fluid extract and at least one additional substance by a spray-drying process, wherein said at least one additional substance is added to the spray-drying process in a dry form during the spray-drying process.

2. The process according to claim 1, wherein said fluid extract is an extract of a medicinal plant.

3. The process according to claim 1 or 2, wherein said at least one additional substance is a galeic auxiliary agent.

4. The process according to claim 1, wherein in that said auxiliary agent is selected from the group consisting of lactose, maltodextrin, dextrin, dry glucose, starch, microcrystalline cellulose, silicified/silicated microcrystalline cellulose, Povidone®, polyethylene glycol, calcium phosphate, magnesium stearate, precipitated silica acid, precipitated silica, highly dispersed silica, sorbitol, mannitol, ir mixtures thereof.

5. The process according to claim 1, wherein the particle size of said at least one additional substance is within a range of from 1 to 500 μm.

6. A dry extract obtained by a process according to claim 1.

7. A medicament containing a dry extract according to claim 6.

8. The medicament of claim 7 in the form of a tablet.

9. A process for preparing agglomerated particles containing an active agent, comprising the steps of:

(a) providing droplets of a fluid, said fluid containing said active agent;

(b) mixing said droplets with dispersed particles of a solid phase component; and

(c) drying said mixture.

10. A process for preparing a dry composition containing an active agent, said process comprising the steps of:

(a) atomizing a fluid which contains said active agent;

(b) dispersing a solid component in the presence of said atomized fluid; and

(c) contacting said fluid and said solid component with a heated gas.

11. A solid dosage form comprising an active agent and an auxiliary agent, the dosage form formed by:

(a) combining said active agent in fluid form with a solid phase component to form agglomerated particles; and

(b) incorporating the agglomerated particles into a solid dosage form.

12. The process of claim 9, wherein said fluid comprises St. John’s Wort, and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

13. The process of claim 9, wherein said fluid comprises ginseng, and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

14. The process of claim 9, wherein said fluid comprises echinacea (Cynara scolymus), and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

15. The process of claim 9, wherein said fluid comprises eleutherooccus (E. senticosiss), and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

16. The process of claim 9, wherein said fluid comprises ginkgo biloba, and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

17. The process of claim 9, wherein said fluid comprises green tea (Camellia sinensis), and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

18. The process of claim 9, wherein said fluid comprises garlic (Allium sativum), and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

19. The process of claim 9, wherein said fluid comprises horse chestnut (Aesculus hippocastanum), and wherein solid phase comprises silicified/silicated microcrystalline cellulose.

20. The process of claim 9, wherein said fluid comprises goldenrod, and wherein said solid phase comprises silica.

21. The process of claim 9, wherein said fluid comprises glucosamine, and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

22. The process of claim 9, wherein said fluid comprises chondroitin, and wherein said solid phase comprises silicified/silicated microcrystalline cellulose.

23. The process of claim 9, wherein said fluid comprises St. John’s Wort, and wherein said solid phase comprises silica.

24. The process of claim 9, wherein said fluid comprises nectar, and wherein said solid phase comprises silica and maltodextrin.

25. The process of claim 9, wherein said fluid comprises valerian root, and wherein said solid phase comprises silica and dry glucose.

26. The process of claim 9, wherein said fluid comprises nectar, and wherein said solid phase comprises lactose.

27. A process for manufacturing agglomerated particles containing an active agent, comprising combining a fluid containing said active agent with a particles of a solid phase component in a dryer to form agglomerated particles.

28. A process for preparing a dry composition containing an active agent, comprising co-spraying a fluid, said fluid containing an active agent, and particles of a solid phase component, to form agglomerated particles.

29. The process of claim 9, further comprising the step of compressing said mixture to form a tablet.

30. The agglomerated particles obtained by the process according to claim 9.

31. The dry composition obtained by the process according to claim 10.
32. The agglomerated particles obtained by the process according to claim 27.

33. The dry composition obtained by the process according to claim 28.

34. The solid dosage form of claim 11, wherein said solid dosage form is selected from the group consisting of tablets, capsules, and entire coated tablets.

35. The agglomerated particles of claim 30 in a solid dosage form, said solid dosage form comprising one or more of tablets, capsules and entire coated tablets.

36. The agglomerated particles of claim 32 in a solid dosage form, said solid dosage form comprising one or more of tablets, capsules and entire coated tablets.

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