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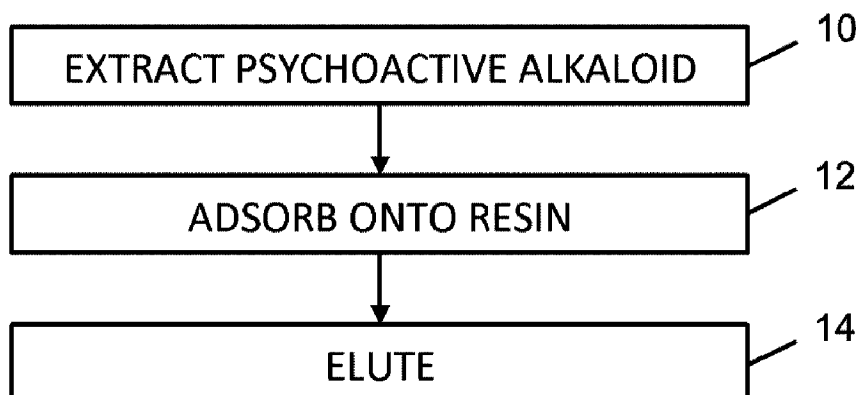
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(54) **Titre :** PROCESSUS D'OBTENTION D'UNE SOLUTION ALCALOIDE PSYCHOACTIVE PURIFIEE

(54) **Title:** PROCESS FOR OBTAINING A PURIFIED PSYCHOACTIVE ALKALOID SOLUTION



(57) **Abrégé/Abstract:**

A psychoactive alkaloid source is used to obtain a psychoactive alkaloid extract. The source may be psychedelic mushrooms, animals or plants or a prior extract therefrom. Psychoactive alkaloids in the extract are adsorbed onto an adsorbent material, from which they are then eluted to provide a purified psychoactive alkaloid solution. The process may be repeated with different adsorbent materials, different pH values and different elution solvents. Solids present in the extract are removed at various stages by filtering or centrifuging. The purified psychoactive alkaloid solution may then be concentrated to a slurry, and then standardized by adding excipients and evaporating the solvent. The resulting standardized extract has a specified psychoactive alkaloid concentration.

ABSTRACT

A psychoactive alkaloid source is used to obtain a psychoactive alkaloid extract. The source may be psychedelic mushrooms, animals or plants or a prior extract therefrom. Psychoactive alkaloids in the extract are adsorbed onto an adsorbent material, from which they are then eluted to provide a purified psychoactive alkaloid solution. The process may be repeated with different adsorbent materials, different pH values and different elution solvents. Solids present in the extract are removed at various stages by filtering or centrifuging. The purified psychoactive alkaloid solution may then be concentrated to a slurry, and then standardized by adding excipients and evaporating the solvent. The resulting standardized extract has a specified psychoactive alkaloid concentration.

Process for Obtaining a Purified Psychoactive Alkaloid Solution

TECHNICAL FIELD

[0001] This application relates to a process of purification. More specifically, the present invention relates to a purification process for obtaining a purified psychoactive alkaloid solution from an extract. Further, the present invention also relates to a process of forming a standardized extract from the purified psychoactive alkaloid solution, wherein the extract has a desired, specific concentration of psychoactive alkaloids.

BACKGROUND

[0002] A psychoactive substance is a chemical substance that changes brain function and may result in alterations in perception, mood, consciousness, cognition, or behavior. Psychoactivity of these substances may include sedative, stimulant, euphoric, deliriant, and hallucinogenic effects. These substances have been used recreationally, to purposefully improve performance or alter one's consciousness, and as entheogens for ritual, spiritual, or shamanic purposes. Some categories of psychoactive compounds have also shown therapeutic value and are prescribed by physicians and other healthcare practitioners.

[0003] The active constituents of the majority of psychoactive plants, fungi, animals, or yeasts fall within a class of basic, naturally occurring, nitrogen-containing, organic compounds known as alkaloids (e.g., nicotine, morphine, cocaine, mescaline, caffeine, ephedrine, psilocin). Alkaloids may provide a wide range of pharmacological activities including antimalarial, antiasthma, anticancer, cholinomimetic, vasodilatory, antiarrhythmic, analgesic, antibacterial, and antihyperglycemic activities. Many alkaloids have found use in traditional or modern medicine, or as starting points for drug discovery. Recently, psychotropic and stimulant activities of psychoactive alkaloids have been gaining interest from researchers as therapeutic agents for treating various conditions such as alcoholism, depression, opioid addiction and pain to name a few.

[0004] However, the general lack of purified, standardized extracts of psychoactive alkaloids having a specific concentration of alkaloids is a major challenge faced by researchers who use natural sources for the psychoactive alkaloids. Potential advantages of natural vs. synthetic sources of these alkaloids include the potential benefits of multiple natural compounds working synergistically (colloquially known as the “entourage” or “halo” effect), increased consumer acceptance of a natural source, and lower cost of production. In addition, the efficacy of some of the single natural compounds is not yet known and requires further research. When psychoactive alkaloids are obtained from natural sources, there may be difficulty in obtaining psychoactive alkaloid extracts with a specific, desired alkaloid content. The content of psychoactive alkaloids in some plants and fungi varies from species to species, and with growing conditions, seasonality, as well as with regular crop-to-crop variations that all natural products suffer from. Furthermore, the concentration of psychoactive alkaloids varies not only from species to species, but also from organism to organism within a given species, subspecies or variety. The same holds true even for different parts of the organism. As a result, one of the biggest challenges in the production of finished products from such naturally produced starting materials is the inconsistency in feedstock material leading to inconsistency in the final product.

[0005] These problems are especially true with respect to extracts of psychedelic mushrooms, for example *Psilocybe* mushrooms and some mushrooms outside the *Psilocybe* genus. The active ingredients are very potent, with a normal dose ranging from only 5 mg to 25 mg. However, when dealing with a low-potency and variable feedstock material, it may be difficult to process the active ingredients to a sufficiently high or consistent percentage content. Thus, there is a need in the art for methods that can consistently allow for the formulation of standardized psychoactive alkaloid extracts with a specific, desired concentration of psychoactive alkaloid.

[0006] This background information is provided to reveal information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF INVENTION

[0007] The present invention relates to a process for obtaining a purified psychoactive alkaloid solution from a psychoactive alkaloid source. The purification process of the present invention allows for producing standardized preparations of psychoactive alkaloids, all while using acceptable solvent and processing systems.

[0008] Standardization is a method that can be used to solve the problem of inconsistency in the finished product. However, when dealing with a low-potency feedstock material, it may be difficult to standardize the active ingredients to a sufficiently high percentage content and achieve the desired therapeutic effects. We therefore need to concentrate the active ingredients beforehand, using a purification process. It may also be desirable to concentrate the active ingredients to a high enough degree that the resulting volume of the final product is sufficiently limited for a specific application, such as to fit into a standard size two-piece capsule.

[0009] A psychoactive alkaloid source is used to provide a psychoactive alkaloid extract. The source may be a species containing psychedelic alkaloids or a prior extract therefrom. Psychoactive alkaloids in the extract are adsorbed onto a resin or other adsorbent material, from which they are then eluted to provide a purified psychoactive alkaloid solution. The process may be repeated with different resins, different pH values and different elution solvents. Solids present in the extract may be removed at various stages by filtering or centrifuging.

[0010] The purification process of the present invention allows for purifying relatively low-potency feedstocks to result in a purified psychoactive alkaloid solution that may have a relatively high concentration of psychoactive alkaloid. Depending on the embodiment, the process may be a purification process that enriches the psychoactive alkaloid content of the final formulation compared to the alkaloid content in the raw materials. Purification may also be the removal of some of the impurities, irrespective of the final alkaloid content. The process of purification in the present invention allows use of the lowest-grade raw materials to obtain a product capable of standardization to a desired specification.

[0011] The purification process of the present invention may be, depending on the embodiment, a relatively simple and robust psychoactive alkaloid purification process, which is suitable for the production of food-grade, nutraceutical-grade, or pharmaceutical-grade standardized extracts, especially of psilocybin, psilocin, baeocystin, norbaeocystin, norpsilocin, aeruginascin, bufotenin, bufotenidine, 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine), N,N-dimethyltryptamine (DMT), ergine (LSA), ergonovine, ergometrine, muscimol, ibotenic acid, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, and/or chanoclavine.

[0012] The present invention also relates to a standardization process for preparation of standardized extracts of psychoactive alkaloids. The standardization process of the present invention allows for standardizing the purified psychoactive alkaloid solution to result in a purified psychoactive alkaloid extract with a specific concentration of psychoactive alkaloids. The standardization process of the present invention may also be a simple and cost-efficient process.

[0013] The standardized psychoactive alkaloid extracts of the present invention can be used in, for example, medical research on the use of psychedelic substances as treatments for addiction, post-traumatic stress disorder, depression, cluster headaches and other illnesses. They may also be used in traditional entheogenic practices or consumed recreationally where such activity is permitted by law.

[0014] Disclosed herein is a process for obtaining a purified psychoactive alkaloid solution, the process comprising: extracting a psychoactive alkaloid from a psychoactive alkaloid source to obtain a psychoactive alkaloid extract; treating the psychoactive alkaloid extract with an adsorbent material to obtain an adsorbed psychoactive alkaloid; and eluting the adsorbed psychoactive alkaloid using a solvent to obtain a purified psychoactive alkaloid solution, wherein the solvent is water, an organic solvent or a combination thereof, under basic, acidic or neutral pH.

[0015] In some embodiments, the process includes: evaporating a portion of solvent from the purified psychoactive alkaloid solution to obtain a concentrated slurry; standardizing the concentrated slurry by adding thereto a quantity of excipient measured to provide a specific concentration of psychoactive alkaloid when the concentrated slurry

is dried; and drying the slurry by evaporating the remaining portion of the solvent to obtain a standardized, purified, powdered psychoactive alkaloid extract having the specific concentration of psychoactive alkaloid.

[0016] This summary does not necessarily describe all features of the invention, and different embodiments thereof may provide at least one but not necessarily all of the benefits described herein.

BRIEF DESCRIPTION OF DRAWINGS

[0017] The following drawings illustrate embodiments of the invention, which should not be construed as restricting the scope of the invention in any way.

[0018] FIG. 1 illustrates the steps of a basic process for obtaining a purified psychoactive alkaloid solution, according to an embodiment of the present invention.

[0019] FIG. 2 illustrates in detail the basic and optional steps of a process for purification of a psychoactive alkaloid extract, according to an embodiment of the present invention.

[0020] FIG. 3 illustrates a process for standardizing a purified psychoactive alkaloid solution to obtain a standardized psychoactive alkaloid extract, according to an embodiment of the present invention.

[0021] FIG. 4 illustrates detailed steps of a process for extracting psychoactive alkaloids from *Psilocybe cubensis*, according to an embodiment of the present invention.

[0022] FIG. 5 is a schematic diagram of an apparatus used for obtaining a purified psychoactive alkaloid solution and standardizing the same to result in a standardized psychoactive alkaloid extract, according to an embodiment of the present invention.

DESCRIPTION

A. Glossary

[0023] To facilitate the understanding of this invention, a number of terms are defined below. Terms used herein have meanings as commonly understood by a person of

ordinary skill in the areas relevant to the present invention, unless otherwise defined. Terms such as “a”, “an” and “the” are not intended to refer to only a singular entity but include the general class of which a specific example may be used for illustration. The terminology herein is used to describe specific embodiments of the invention, but its usage does not delimit the invention, except as outlined in the claims.

[0024] The term “psychoactive alkaloid” as used herein refers to alkaloids that upon ingestion are capable of changing brain function, resulting in alterations in perception, mood, consciousness, cognition or behavior, for example. Psychoactive alkaloids are abundant in nature and can be obtained from sources such as a fungus, an animal, a mycelium, a spore, a plant, a bacterium, or a yeast. Examples of psychoactive alkaloids include, but are not limited to, psilocybin, psilocin, baeocystin, norbaeocystin, norpsilocin, aeruginascin, bufotenin, bufotenidine, 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine), N,N-dimethyltryptamine (DMT), ergine (LSA), ergonovine, ergometrine, ibotenic acid, muscimol, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, and/or chanoclavine. The source of the psychoactive alkaloid can also be an extract or a solution of the psychoactive alkaloid.

[0025] The term “purified psychoactive alkaloid solution” refers to a solution of one or more desired psychoactive alkaloids, where the solution is free of impurities or contains fewer impurities compared to a similar psychoactive alkaloid solution that has not undergone any purification. The purified solution is obtained after a psychoactive alkaloid extracted from its source has been purified by the purification process of the present invention. The impurities that are commonly encountered while extracting psychoactive alkaloids from a natural source include sugars, carbohydrates, chitin, chitosan, fats, minerals, waxes, and/or proteins. The impurities being removed from the psychoactive alkaloid extract will vary depending on the source of the psychoactive alkaloid.

[0026] The term “standardized psychoactive alkaloid extract” is used herein to describe a formulation derived from the purified psychoactive alkaloid solution, which has been standardized using a process described herein. The standardized psychoactive alkaloid extract includes psychoactive alkaloids in a specific concentration.

[0027] The term “resin” as used herein is intended to refer to a solid or highly viscous substance of plant, mineral, or synthetic origin that has been typically converted into a polymer. Resins are usually mixtures of organic compounds. They are typically used in chromatographic techniques as a stationary phase to purify and separate compounds depending on their polarity. Resins can be physically or chemically modified to provide specificity to bind or repel particular molecules within sometimes very complex mixtures. A resin is an example of an adsorbent material.

[0028] As used herein, the term “ion exchange resin” refers to an insoluble organic polymer containing charged groups that attract and hold oppositely charged ions present in a surrounding solution in exchange for counterions previously held. Suitable ion exchange resins to be used herein contain cationic groups that attract and hold anions present in a surrounding solution and are sometimes referred to as “anion ion-exchange resins”. Similarly, other ion exchange resins to be used herein contain anionic groups that attract and hold cations present in a surrounding solution and are sometimes referred to as “cation ion-exchange resins”.

[0029] The term “macroporous resin” as used herein refers to a nonionic, cation or anion resin with very small, highly cross-linked polymer particles with tiny channels. Macroporous resins are generally used for the adsorption of organic constituents due to their hydrophobic properties and are thus used to separate and purify compounds. The adsorption capacity of macroporous resins not only correlates with the physical and chemical properties of the adsorbent, but also with the size and chemical features of the adsorbed substance.

[0030] The term “adsorbed psychoactive alkaloid” refers to one or more alkaloids that are adsorbed onto an adsorbent material such as a resin.

[0031] The term “purification process” may be used herein to refer to the process described herein, i.e. a process for obtaining a purified psychoactive alkaloid solution. The purification process is a separate process to the standardization process.

[0032] The term “standardization process” as used herein refers to the process of obtaining a psychoactive alkaloid extract that has a defined percentage content of psychoactive alkaloids. The standardization process may be applied to an extract that has

gone through a purification process, or to an extract that has not gone through a purification process.

[0033] The term “purified water” includes deionized water, distilled water, reverse osmosis water, or otherwise purified water which is substantially without free ions.

[0034] The term “other adsorbent material” as used herein refers to materials which can be used in place of the resin(s) to adsorb the psychoactive alkaloids. Examples of such materials include, but are not limited to, zeolites, clays, bentonite, minerals, alumina, diatomaceous earth, activated carbon, charred biomass, and others.

B. Basic process

[0035] In one embodiment, referring to FIG. 1, a basic process for obtaining a purified psychoactive alkaloid solution is shown. The process includes the step 10 of extracting a psychoactive alkaloid from a psychoactive alkaloid source to obtain a psychoactive alkaloid extract. The psychoactive alkaloid source may be a fungus, a mycelium, an animal, a spore, a plant, a bacterium, or a yeast. The psychoactive alkaloid source in some embodiments may be a prior extract of one or more psychoactive alkaloids, where the prior extract is to undergo a further extraction process. The psychoactive alkaloid may include, but is not limited to, psilocybin, psilocin, baeocystin, norbaeocystin, norpsilocin, aeruginascin, bufotenin, bufotenidine, 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine), N,N-dimethyltryptamine (DMT), ergine (LSA), ergonovine, ergometrine, muscimol, ibotenic acid, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, and/or chanoclavine. or any combination therefrom. The extract from the psychoactive alkaloid source may be a fluid, as either a liquid or a slurry, or is made into a fluid by the addition of a solvent.

[0036] The solvent in which the extract is carried or dissolved may be a primary aliphatic alcohol, a ketone, water, and any combination therefrom. In one embodiment, the primary aliphatic alcohol is a C1-4 alcohol. In one embodiment, the primary aliphatic alcohol is 5% ethanol. In one embodiment, the primary aliphatic alcohol is ethanol. In one embodiment, the ketone is a C3-4 ketone. In yet another embodiment, the water is selected from

deionized, distilled, reverse osmosis, or otherwise purified water, which is substantially without free ions. In other embodiments, the water is not purified.

[0037] The process then involves adsorbing, in step 12, the psychoactive alkaloid(s) in the extract obtained in step 10 onto a resin to obtain an adsorbed psychoactive alkaloid, which may include one or more adsorbed psychoactive alkaloids.

[0038] In one embodiment, the resin is an adsorbent resin of the macroporous type, such as, a cation or anion ion-exchange resin, a non-ionic resin, or any combination therefrom. Representative pharmaceutical, nutraceutical or food-grade grade resins for use in accordance with the present invention are known to those skilled in the art. For example, pharmaceutical grade non-ionic macroporous resins are commercially available, e.g. Amberlite[®] XAD4. In one embodiment, the resin is a cationic ion-exchange resin or an anionic-exchange resin. The cationic ion-exchange resin may be selected from commercially available cationic ion-exchange resins known in the art, including but not limited to Amberlite[®] MAC-3 H. The cationic ion-exchange resin may be in an H⁺ form or an Na⁺ form. The anionic ion-exchange resin may be selected from commercially available anion exchange resins known in the art, including but not limited to Amberchrom[®] 50WX8. The anionic ion-exchange resin may be in an OH⁻ form or a Cl⁻ form. The resins used may be of any particle size. In some embodiments, the resins may be gel type resins, with any size of gel bead.

[0039] Next, the process involves eluting, in step 14, the adsorbed psychoactive alkaloid using a solvent to obtain a purified psychoactive alkaloid solution. The solvent may be, for example, an organic solvent, an acid, a base, a combination of an organic solvent and a base, a combination an organic solvent and an acid, water, a combination of water and acid, a combination of water and base, or a combination of water and an organic solvent. Usually, the solvent is different from the solvent in which the extract is initially provided, and is either a different type of solvent or a different composition of solvent. It may be at a different temperature than the initial solvent.

[0040] In some embodiments, the solvent used in the elution step 14 may be a primary aliphatic alcohol, a ketone, water, and any combination therefrom. In one embodiment, the primary aliphatic alcohol is a C1-4 alcohol. In one embodiment, the

primary aliphatic alcohol is 5% ethanol. In one embodiment, the primary aliphatic alcohol is ethanol. In one embodiment, the ketone is a C3-4 ketone. In yet another embodiment, the water is deionized, distilled, reverse osmosis, or otherwise purified water, which is substantially without free ions. In other embodiments, the water is not purified.

[0041] In one embodiment, the solvent used in the elution step 14 is a combination of an organic solvent and an acid. In one embodiment, the combination of an acid and an organic solvent is 2% hydrochloric acid and 80% ethanol, for example. In general, any acidic environment will displace some of the ions from the resin, but the rate and optimization of the desorption will be affected by the acid concentration. In one embodiment, the solvent used in the elution step 14 is a combination of an organic solvent and a base. In one embodiment, the combination of an organic solvent and a base is of 2% sodium chloride and 80% ethanol, for example. In general, any basic environment will displace some of the ions from the resin, but the rate and optimization of the desorption will be affected by the concentration of the base.

[0042] All the above solvents and combinations thereof are suitable for the elution step because all of the psychoactive alkaloids of interest are soluble therein and, depending on the choice of resin, they are all capable of pulling the alkaloids of interest off a resin. There are many different resins available, and it is a straightforward matter to select a suitable resin and elution solvent pair.

[0043] In one embodiment, the elution step is carried out at a temperature in the range of 4-75°C. These temperatures are limited by the boiling point of the solvent used, as well as the specifications of allowable food-grade resins, as determined by the manufacturers of the resins and governmental food and drug administrations. In another embodiment, the elution step is carried out at room temperature for convenience, i.e. at 21-25°C.

[0044] In other embodiments, the process for obtaining the purified psychoactive alkaloid solution further includes repeating the steps 12 and 14 with the obtained purified psychoactive alkaloid solution to obtain a further or twice purified psychoactive alkaloid solution. For the repeated steps in these embodiments, the resin may be the same or a different resin, and the solvent may be the same or a different solvent. While the purified

psychoactive alkaloid solution may have a low psychoactive alkaloid content, this may be increased by evaporation of some or all of the solvent.

C. Further processes

[0045] Referring to FIG. 2, additional, optional steps are shown well as the basic steps in the process. In one embodiment, the extraction step 10 is followed by completely or partially concentrating the obtained psychoactive alkaloid extract (or solution) by evaporation of the solvent from the extract in step 22. In other embodiments, step 22 of partially or completely evaporating the solvent may be considered to be part of the extraction step 10. If the solvent from the extract has been completely evaporated in step 22, then reverse osmosis water, more solvent or another solvent is added back.

[0046] In some embodiments, the process includes adding, in step 24, an acid or a base to the psychoactive alkaloid extract obtained in step 10 to obtain a psychoactive alkaloid solution with a specific pH.

[0047] When used, the acid may be acetic acid, adipic acid, ascorbic acid, phosphoric acid, ammonium aluminum sulphate, ammonium citrate dibasic, ammonium citrate monobasic, calcium citrate, calcium fumarate, calcium gluconate, calcium phosphate dibasic, calcium phosphate monobasic, hydrochloric acid, sulphuric acid monobasic, calcium phosphate tribasic, citric acid, fumaric acid, gluconic acid, magnesium fumarate, malic acid, phosphoric acid, potassium acid tartrate, potassium citrate, potassium fumarate, sodium citrate, sodium fumarate, sodium gluconate, sodium lactate, sodium potassium hexametaphosphate, sodium potassium tartrate, sodium potassium tripolyphosphate, sodium pyrophosphate tetrabasic, sodium tripolyphosphate, tartaric acid, and any combination of one or more of these. In some embodiments, the acid is either only hydrochloric acid or only phosphoric acid, for example. It is also envisaged that other acids may be used.

[0048] When used, the base may be ammonium bicarbonate, ammonium carbonate, ammonium hydroxide, calcium acetate, calcium carbonate, calcium chloride, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate dibasic, calcium phosphate monobasic, magnesium carbonate, potassium aluminum sulphate, potassium

bicarbonate, potassium carbonate, potassium hydroxide, potassium lactate, potassium phosphate dibasic, potassium pyrophosphate tetrabasic, potassium phosphate tribasic, potassium tripolyphosphate, sodium acetate, sodium acid pyrophosphate, sodium aluminum phosphate, sodium aluminum sulphate, sodium bicarbonate, sodium bisulphate, sodium carbonate, sodium hexametaphosphate, sodium hydroxide, sodium lactate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic or any combination therefrom. In one embodiment, the base is solely sodium hydroxide, for example. Other bases may be used in other embodiments.

[0049] In one embodiment, the specific pH psychoactive alkaloid solution has a pH ranging from 2.5-4.5, or from 9-10. In other embodiments, the specific pH psychoactive alkaloid solution has a pH of 3, 4, or 9.5. The selection of the pH is chosen in a manner to allow for the efficient adsorption of the psychoactive alkaloids onto the resin(s).

[0050] In one embodiment, the process includes adding phosphoric acid to the psychoactive alkaloid extract to achieve a pH of 4. In another embodiment, the process includes adding hydrochloric acid to the psychoactive alkaloid extract to achieve a pH of 3. In yet another embodiment, the process includes adding sodium hydroxide to the psychoactive alkaloid extract to achieve a pH of 9.5.

[0051] The process includes, in step 26, optionally filtering, centrifuging, or clarifying the psychoactive alkaloid solution or specific pH psychoactive alkaloid solution, as the case may be, and utilizing the obtained filtrate for the next step 12 of adsorption. Clarifying may be performed, for example, by adding an agglomeration agent.

[0052] In step 12, the process involves adsorbing the psychoactive alkaloid(s) in the solution onto the resin to obtain an adsorbed psychoactive alkaloid.

[0053] In step 32, the process involves washing the resin to remove adsorbed impurities from the resin. While not all the impurities are adsorbed onto the resin, some of them may be. The washing step, substantially, does not remove the adsorbed psychoactive alkaloids. The washing solvent may be 100% ethanol, 100% reverse osmosis water, or any other washing solvent used in ion-exchange resin chromatography, provided that the washing removes impurities or by-products that are adsorbed on the resin. Impurities or by-products may include, for example, sugars, carbohydrates, chitin,

chitosan, fats, minerals, waxes, or proteins. There may be one, two or more washing steps depending on the embodiment, and the same or different washing solvents may be used for each wash. In other embodiments, the solvent(s) for washing may include a primary aliphatic alcohol, a ketone, water, and any combination therefrom. In one embodiment, the primary aliphatic alcohol is a C1-4 alcohol. In one embodiment, the primary aliphatic alcohol is 5% ethanol. In one embodiment, the primary aliphatic alcohol is ethanol. In one embodiment, the ketone is a C3-4 ketone. In yet another embodiment, the water is selected from deionized, distilled, reverse osmosis, or otherwise purified water that is substantially without free ions.

[0054] After the washing, the process involves eluting, in step 14, the adsorbed psychoactive alkaloid from the resin using a solvent to obtain a purified psychoactive alkaloid solution. The solvent may be an organic solvent, an acid, a base, or water, a combination of an organic solvent and a base, or a combination of an organic solvent and an acid, a combination of an organic solvent and water, a combination of water and a base, or combination of water and an acid. The result of the elution step is a purified psychoactive alkaloid solution.

[0055] Following the elution, a further washing step 36 may be employed using 100% ethanol, for example, to wash the resin. This may be considered to be a cleaning step, to refresh the resin and make it ready to be used again in a subsequent step or in another process. In other embodiments, the solvent for further washing may be a primary aliphatic alcohol, a ketone, water, and any combination therefrom. In one embodiment, the primary aliphatic alcohol is a C1-4 alcohol. In one embodiment, the primary aliphatic alcohol is 5% ethanol. In one embodiment, the ketone is a C3-4 ketone. In yet another embodiment, the water is selected from deionized, distilled, reverse osmosis, or otherwise purified water that is substantially without free ions.

[0056] The result of the elution is a purified psychoactive alkaloid solution. In one embodiment, the purified psychoactive alkaloid solution has a concentration of 0.07% by weight of a psychoactive alkaloid, which is the concentration before removal of some or all of the solvent. This concentration may be different in other embodiments, depending on the amount solvent used for the elution and the potency of the raw materials. In one

embodiment, the purified psychoactive alkaloid solution is concentrated by evaporating the solvent to form a purified psychoactive slurry that has at least of 5% by weight or more of a psychoactive alkaloid. In another embodiment, the purified psychoactive alkaloid slurry has 5-68% by weight of a psychoactive alkaloid. In yet other embodiments, the purified psychoactive alkaloid slurry has a concentration of psychoactive alkaloid outside these ranges, and, when dried, can be as low as 0.1% or as high as 99% dry wt/wt%.

[0057] Optionally, the obtained purified psychoactive alkaloid solution is further purified by filtering the obtained purified psychoactive alkaloid solution to obtain a filtrate, and then repeating at least steps 12 and 14 with the obtained filtrate.

[0058] Different processes may employ the steps in a different order, and some of the steps may be repeated with the same or different parameters. For example, in one embodiment, starting from a solution of dissolved extract, the order of the steps may be 24, 12, 26, 32, 14, 24, 26, 22, 26, 12, 32 and 14.

D. Standardization

[0059] Referring to FIG. 3, the present invention also relates to a process of obtaining a standardized, purified, psychoactive alkaloid extract. In one embodiment, the process includes, in step 42, concentrating the purified psychoactive alkaloid solution to obtain a purified psychoactive alkaloid slurry. The slurry is then standardized, in step 44, to obtain a standardized psychoactive alkaloid extract.

[0060] In one embodiment, the standardizing step 44 includes adding excipients to the purified psychoactive alkaloid slurry to obtain the standardized psychoactive alkaloid extract. The concentration of alkaloids in the slurry is measured and the proportion of dry weight in the slurry is calculated. Knowing this concentration and the dry weight content, the amounts of excipients are chosen to result in a powder of known alkaloid concentration after the solvent in the slurry has been evaporated.

[0061] The excipients described herein refer to excipients to aid in the manufacturing and/or administration of the compositions described herein. Non-limiting examples of such excipients are well known in the art and include flavorants, colorants, palatants, antioxidants, viscosity modifying agents, tonicity agents, drug carriers, sustained-release

agents, comfort-enhancing agents, emulsifiers, solubilizing aids, lubricants, binding agents, bioavailability-enhancing agents, stabilizing agents and other agents to aid in the manufacturing and/or administration of the compositions. The excipients used in the present invention are acceptable for use in pharmaceutical or nutraceutical applications or as food ingredients.

[0062] In one embodiment, the excipients are selected from silicon dioxide, ascorbic acid, maltodextrin from corn, potato or tapioca for example, gum arabic, microcrystalline cellulose, sodium benzoate, sodium phosphate, sodium citrate, rice hulls, and rice. A combination of any of these excipients may be used.

[0063] Depending on the concentration of the purified psychoactive alkaloid slurry and the quantity of excipients added, the standardized psychoactive alkaloid extract may have a psychoactive alkaloid concentration ranging from 0.1-99% by weight, and the concentration may be specified to two decimal places or two significant figures. For the highest percentage, only 1% of the standardized psychoactive extract will be excipient.

[0064] In exemplary embodiments, the standardized psychoactive alkaloid extracts have psychoactive alkaloid concentrations of 5.00% by weight, 54% by weight and 68% by weight.

E. Extraction

[0065] The extracting step 10 may include, as an example, extracting psychoactive alkaloids from raw, psychedelic mushrooms. The mushrooms are dried and ground to result in a dried biomass. The next step involves heating the dried biomass in a solvent in order for the extraction to occur. The obtained slurry is filtered to obtain a first filtrate and a first residue. The first residue undergoes a second extraction, using a second solvent to obtain a second slurry, which is then filtered to obtain a second filtrate and a second residue. The first filtrate and the second filtrate are mixed to obtain the psychoactive alkaloid extract. More extract can be obtained this way, i.e. by splitting the solvent into two or more batches and using each one sequentially to soak the biomass, compared to using a single volume of solvent.

[0066] The extraction may further include completely or partially concentrating the obtained psychoactive alkaloid extract, by evaporation of the solvent from the combined filtrates.

[0067] In one embodiment, the first solvent and the second solvent are selected from a primary aliphatic alcohol, a ketone, water, and any combination therefrom. In one embodiment, the primary aliphatic alcohol is a C1-4 alcohol. In one embodiment, the ketone is a C3-4 ketone. In another embodiment, the first solvent is an ethanol-water mixture with 3 parts ethanol to 1 part water by weight. In another embodiment, the second solvent is an ethanol-water mixture with 3 parts ethanol to 1 part water by weight. In yet another embodiment, the water is selected from deionized, distilled, reverse osmosis, or otherwise purified water, which has substantially no free ions. The selection of the solvent will depend on the nature of the starting material for extraction and the reaction conditions, according to which a person of skill in the art can make the appropriate solvent selection.

[0068] In one embodiment, the extraction is carried out at a temperature ranging from 5-95°C. The useful temperature range spans most of the liquid state of the solvent used, and upper and lower limits are determined by physical practicalities and limits of the available apparatus. Still, the temperature of the solvent may be outside of this range in other embodiments.

[0069] In another embodiment, the extraction is carried out at a temperature of 70°C. Temperature and pressure, if applied, are generally selected so that the solvent does not boil if elevated temperatures are used. In one embodiment, the extraction is carried out for a time duration ranging from 10 minutes to 12 hours. In yet another embodiment, the extraction is carried out for a time duration of 4 hours.

F. Examples

[0070] In order to further illustrate the present invention, the following specific examples are given with the understanding that these examples are intended only to be illustrations without serving as a limitation on the scope of the present invention.

[0071] Although the examples of the present invention have been formulated specifically using *Psilocybe cubensis* and *Anadenanthera peregrina* as sources to obtain a psychoactive alkaloid extract, the extract including psilocybin and psilocin in the first case and bufotenin, bufotenidine, and 5-MeO-DMT in the second, other sources are possible. A person skilled in the art would appreciate that *Psilocybe cubensis* and *Anadenanthera peregrina* can be readily substituted by other sources of psychoactive alkaloids to obtain a variety of purified psychoactive alkaloids having similar properties, such alkaloids being, besides those mentioned above, baeocystin, norbaeocystin, norpsilocin, aeruginascin, N,N-dimethyltryptamine (DMT), ergine (LSA), ibotenic acid, ergonovine, ergometrine, muscimol, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, and/or chanoclavine, to name a few, and to result in compositions with similar efficacy and efficiency as well. For example, the venom of the toad *Incilius alvarius*, the *Anadenanthera colubrina* tree or the *Amanita muscaria* mushroom may be used as other sources of psychoactive alkaloids. Note that the lists of sources and psychoactive alkaloids are included to provide examples, and are non-exhaustive lists.

Example 1.1: Preparation of psychoactive alkaloid extract

[0072] Referring to FIG. 4, 2.5 kilograms of fresh *Psilocybe cubensis* (caps, stems and gills) was taken (step 50) and dried (step 52) in a forced air oven at 25°C for 5-10 hours. A mass of 140 grams of dried biomass was obtained. The dried biomass was pulverized (step 54) to a size of 200 mesh with a hammer mill to result in a dried, powdered biomass. The dried, powdered biomass was placed in an agitated, heat-controlled extraction vessel with 5 kilograms of a hydro-ethanol mixture, with 3 parts ethanol to 1 part water by weight, as a solvent (step 56). The extraction (step 60) was carried out for 4 hours at a controlled temperature of 70°C to obtain an extract in the form of a slurry. The extraction slurry was filtered (step 62) while it was hot, and filtrate A was collected. The filter residue was retained (step 64) and placed back into the extraction vessel, followed by addition (step 66) of another 5 kilograms of 3:1 ethanol:water mixture by weight as a solvent. The extraction was repeated (step 70). The temperature of extraction was again carried out at 70°C for a duration of 4 hours. The obtained extraction slurry was filtered (step 72) while

hot and filtrate B was collected. Filtrate A and filtrate B from the first and second extractions were mixed (step 74). Using a rotary evaporator the mixture was then partially concentrated by evaporation (step 76) of the solvent from the combined filtrates to provide a 2.5 litre volume of psychoactive alkaloid extract solution. Step 76 is similar to step 22 of FIG. 2.

Example 1.2: Preparation of psychoactive alkaloid extract

[0073] In another example, the process of example 1.1 was followed, except that the combined filtrates A and B were left to cool to room temperature, and any precipitate that formed was filtered out and discarded.

Example 1.3: Preparation of *Anadenanthera peregrina* seed extract

[0074] 1.00 kilogram of dried *Anadenanthera peregrina* seeds were pulverized to a size of 200 mesh with a grinder. The dried powdered biomass was placed into an agitated, heat-controlled vessel with 20 kilograms of solvent. In this embodiment, the solvent was a hydro-ethanol mixture of 4 parts ethanol to 1 part water by weight. The extraction was controlled to a constant 70°C, and the time of extraction was 4 hours. The extraction slurry was filtered while hot, and the filter residue was placed back into the extraction vessel and extracted again with an additional 10 kilograms of 4:1 ethanol:water mixture by weight. The temperature of extraction was again 70°C and the time was 4 hours. The extraction slurry was filtered while hot and the filtrates from the first and second extractions were mixed together. The resulting bulk filtrate was immediately placed into an evaporation still and the solvent was removed until the final volume of the filtrate was reduced to about 6 liters, which resulted in a solids concentration in the filtrate of 6.8%.

Example 2.1: Purifying the psychoactive alkaloid extract using a non-ionic macroporous resin

[0075] The pH of the partially concentrated extract of example 1.1, which was an aqueous extract, was adjusted to pH 4.0 (+/- 0.5) by adding 2 M phosphoric acid and

centrifuged for 15 minutes at 3000g to remove any solid precipitate. The pH of 4 corresponds to the isoelectric point of psilocybin, and psilocin's polarity is such that it is partitioned onto the resin, thus allowing effective binding of the psychoactive alkaloids psilocybin and psilocin to the macroporous resin. Norbaeocystin and baeocystin are phosphorylated and behave in the same way as psilocybin. The supernatant obtained was loaded onto a column of Amberlite® XAD4, a non-ionic macroporous resin (50.34 g of dry resin) at a flow rate of 2 bed volumes per hour, to allow components in the supernatant to be adsorbed onto the macroporous resin. After all 2.5 L of the extract was loaded onto the column of macroporous resin, the column was washed in a single pass with 5 bed volumes of reverse osmosis water at room temperature. This was followed by elution with 5 bed volumes of 5% ethanol (by weight), again at room temperature. Finally, the column was washed in a single pass with 5 bed volumes of 100% ethanol. The elution was performed at room temperature. Each of these three fractions was collected separately. The particular order for the washing steps and the elution was selected to be in the order of the polarity of the solvents. If the order were different, an inferior result may have ensued, such as a lower yield. The first fraction using reverse osmosis water removed the most polar compounds from the resin. The hydroethanol fraction eluted compounds of lesser polarity, and the 100% ethanol solvent removed the least polar compounds. Less polar solvents could also be used to elute less polar compounds.

[0076] The 5% ethanol fraction (i.e. the purified psychoactive alkaloid solution) was then concentrated in a rotary evaporator to form 3.90 g of concentrated aqueous slurry at 30% solids, containing 195.1 mg of total alkaloids, i.e. psilocybin, psilocin, norbaeocystin, and baeocystin. The result was a purified psychoactive alkaloid slurry having a total psychoactive alkaloid concentration of 5.00% by weight.

[0077] As described below, it is possible to replace the solvent with an equivalent weight of excipients to provide a purified extract with a psychoactive alkaloid content of 5.00% dry wt/wt%.

Example 2.2: Purifying the psychoactive alkaloid extract using cation exchange and non-ionic macroporous resins

[0078] The combination of filtrates of example 1.2 was taken as the starting point. The pH of the combined filtrate obtained was adjusted to a pH of 3.0 (+/- 0.5) by adding 1M HCl. It was then mixed with 200 g of Amberlite® MAC-3 H, a strong cationic ion-exchange resin in its hydrogen form, to result in a filtrate-resin mixture, in which components of the psychoactive alkaloid filtrate were adsorbed onto the cation exchange resin. The pH of 3 ensured that the psychoactive alkaloid (i.e. psilocybin) was in its protonated form, and thus adsorbed onto the cationic exchange resin efficiently. The filtrate-resin mixture was agitated for 4 hours at room temperature (21°C – 25°C) and then filtered. The filtrate was discarded, and the resin was rinsed with 2.0 L of 100% EtOH and then 2.0 L of H₂O to remove any impurities. Finally, the psilocybin/psilocin fraction was eluted with 2.0 L of 2% HCl/80% EtOH, for 4 hours at room temperature.

[0079] The eluted fraction was brought to a pH of 4.0 (i.e. the isoelectric point of psilocybin) by adding 2M NaOH. The filtrate was then centrifuged at 3000g to remove any solid precipitate. The resultant filtrate, in form of an aqueous solution, was then placed into a rotary evaporator and the solvent was removed until the aqueous solution reached a volume of 400 mL. The aqueous solution was then again centrifuged for 15 minutes at 3000g to remove any solid precipitate. The supernatant was loaded onto a column of Amberlite® XAD4 macroporous resin (45.53 g of dry resin) at a flow rate of 2 bed volumes per hour. After all the 400 mL of the supernatant was loaded onto the column, it was initially washed with 5 bed volumes of reverse osmosis water, followed by elution with 5 bed volumes of 5% ethanol (by weight) and then washed with 100% ethanol. Each of these fractions was collected separately. The 5% ethanol fraction (i.e. the purified psychoactive alkaloid solution) was concentrated in a rotary evaporator to form 258 mg of solution containing 175 mg of total alkaloids (i.e. psilocybin, psilocin, norbaeocystin, and baeocystin). Thus, a purified psychoactive alkaloid slurry with a total alkaloid concentration of 68% dry wt/wt% was obtained.

Example 2.3: Purifying the psychoactive alkaloid extract using anion exchange and non-ionic macroporous resins

[0080] The combination of filtrates of example 1.2 was taken as the starting point. The pH of the filtrate combination was adjusted to 9.5 (+/- 0.5) by adding 1 M NaOH and then mixed with 150g of Amberchrom® 50WX8 strong anionic ion-exchange resin in its hydrogen form to result in a filtrate-resin mixture, in which components of the psychoactive alkaloid filtrate were adsorbed onto the anion exchange resin. The pH of 9.5 (+/- 0.5) ensured that the psilocybin, psilocin, norbaeocystin, and baeocystin were deprotonated and had a net negative charge for efficient adsorption onto the strong anion exchanger.

[0081] The filtrate-resin mixture was agitated for 4 hours and then filtered out, and the filtrate was discarded. The resin was rinsed with 2.0 L of 100% EtOH and then 2.0 L of H₂O to remove impurities. Finally, the psilocybin/psilocin fraction was eluted with 2.0 L of 2% NaCl/80% EtOH for 4 hours.

[0082] The eluted fraction was brought to a pH of 4.0 with the addition 2 M HCl. The extract was then centrifuged at 3000g to remove any solid precipitate. The resultant extract, in form of a solution, was then placed into a rotary evaporator and the solvent was removed to result in a volume of 400 mL.

[0083] The resultant 400 mL aqueous solution was centrifuged for 15 minutes at 3000g to remove any solid precipitate. The supernatant was loaded onto a column of Amberlite® XAD4 macroporous resin (45.53 g of dry resin) at a flow rate of 2 bed volumes per hour, to allow components of the supernatant to be adsorbed onto the macroporous resin. After all 400 mL of supernatant was loaded onto the column, the column was initially washed with 5 bed volumes of reverse osmosis water, followed by elution with 5 bed volumes of 5% ethanol (by weight) and then a final wash with 100% ethanol was performed. Each of these fractions was collected separately. The 5% ethanol fraction (i.e. the purified psychoactive alkaloid solution) was concentrated in a rotary evaporator to form 325 mg of solution containing 175 mg of total alkaloids (i.e. psilocybin, psilocin, norbaeocystin, and baeocystin). A purified psychoactive alkaloid slurry with a concentration of 54% dry wt/wt% of total alkaloids was therefore obtained.

Example 2.4: Purifying the *Anadenanthera peregrina* seed extract

[0084] The aqueous extract with about 6.8% solids, from example 1.3, was adjusted to pH 4.0 (+/- 0.5) with 2 M phosphoric acid and centrifuged for 15 minutes at 3000g to remove any solid precipitate. The supernatant was loaded onto a column of Seplite® LXA17 macroporous resin (54.21 g of dry resin) at a flow rate of 2 bed volumes per hour. After all 6.0 L of the extract was loaded onto the column, it was initially washed with 5 bed volumes of reverse osmosis water, followed by a second wash with 5 bed volumes of 10% ethanol (by weight) and then eluted with 3 bed volumes of 50% ethanol, and finally the resin was washed with 5 bed volumes of 100% ethanol. Fewer bed volumes of solvent were possible in the elution step than in the washing steps due to the sharper elution peak. This in turn led to a shorter evaporation time than if more bed volumes of the solvent had been used. Each of these fractions was collected separately. The 50% ethanol fraction was concentrated in a rotary evaporator to form 355 g of concentrated aqueous slurry at 30% solids, containing 3.03 g of total alkaloids.

Example 3.1: Process for preparing standardized psychoactive alkaloid extract

[0085] The 3.90 g of purified psychoactive alkaloid slurry with a psychoactive alkaloid concentration of 5.00% by weight that was obtained in example 2.1 was taken and standardized. To achieve this, the concentrated slurry, 0.03 g of SiO₂, 0.02 g of ascorbic acid and 2.55 g of maltodextrin were added and thoroughly mixed to result in a final standardized slurry having a specific concentration of alkaloids. The final standardized slurry was then subjected to spray-drying and a final powdered alkaloid extract with a 5.00% total psilocybin, psilocin, baeocystin and norbaeocystin concentration by dry weight was obtained.

Example 3.2: Process for preparing standardized psychoactive alkaloid extract from *Anadenanthera peregrina* seeds

[0086] The aqueous slurry from example 2.4 was used as the starting point. Next, 0.3g of SiO₂, 0.15g of citric acid and 4.10 g of maltodextrin were added to the slurry, which was thoroughly mixed. The final formulated slurry was then subjected to spray-

drying to yield a final powdered alkaloid extract with a combined bufotenin/bufotenidine/5-MeO-DMT concentration of 20.00% by dry weight.

G. Apparatus

[0087] Referring to FIG. 5, an example of the apparatus is shown schematically. Raw *Psilocybe cubensis* mushrooms were added to a hopper 100, and were released in batches into container 102. The raw fungal material was then dried in a forced air oven 104 to result in dried biomass. The dried biomass was placed into a grinder 106 for grinding.

[0088] The dried powdered biomass was placed into a heat-controlled vessel 110 and solvent (S) was added to the heat-controlled vessel. The vessel 110 was surrounded by an insulating wall 108. Alternately, an insulating jacket may have been wrapped around the vessel. The insulating wall 108 or jacket helps to maintain the contents 112 under a constant temperature (T) between 5 – 95°C. The pressure (P) inside the extraction vessel 110 may be regulated up to 100 MPa (15,000 psig).

[0089] After the extraction, the bottom of the extraction vessel 110 was opened at outlet 114 and the extraction slurry was collected in a container 120. The extraction slurry was then fed into a filter 122 and a first filtrate was collected in container 124. The first filtrate residue 130 was then fed back (R) into the agitated, heat-controlled vessel 110 and more solvent (S) was added for a second extraction. After the second extraction, the extraction slurry was collected in the container 120 and was then fed into a filter 132. After filtration, the obtained second filtrate was collected in container 136.

[0090] After the two filtration stages, the filtrates were mixed in container 140 to obtain a bulk filtrate. In other embodiments, if there is only a single filtration step, this mixing step is not required.

[0091] The bulk filtrate was placed in a rotary evaporator 142 and part of the solvent was evaporated from the bulk filtrate. The resultant extract was transferred to a container 144, where the pH of the extract was adjusted, followed by centrifugation 146 to remove the solid precipitates. The resultant supernatant was loaded onto a column 150 of resin. An initial wash was given to the column with a solvent to remove impurities from the resin,

and fraction 154 was collected. A second wash was given to the column with another solvent to elute the psychoactive alkaloids from the column and result in fraction 156. A final wash was given to the column with another solvent to wash any impurities from the column, to prepare the column for use again, and the fraction 158 was obtained. The elution fraction 156 with the psychoactive alkaloids was then concentrated in a rotary evaporator 160 to result in the purified psychoactive alkaloid solution.

[0092] In a container 164 the purified psychoactive alkaloid solution and desired excipients were added together and thoroughly mixed to result in a final standardized slurry having a specified concentration of alkaloids. The final standardized slurry was then subjected to spray-drying 168 to obtain a final powdered alkaloid extract 170 with a total psilocybin/psilocin concentration defined as a percentage to two decimal places or two significant figures by dry weight.

[0093] In other embodiments, parts of the apparatus may be reused or duplicated. For example, if desired, the elution fraction 156 may be reloaded into the container 144 for pH adjustment and the steps from thereon can be repeated to allow for further purification of the obtained purified psychoactive alkaloid solution.

H. Conclusion

[0094] Throughout the description, specific details have been set forth in order to provide a more thorough understanding of the invention. However, the invention may be practiced without these particulars. In other instances, well known elements have not been shown or described in detail and repetitions of steps and features have been omitted to avoid unnecessarily obscuring the invention. Accordingly, the specification and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

[0095] All parameters, dimensions, materials, quantities and configurations described herein are examples only and may be changed depending on the specific embodiment. Numbers are given to the nearest significant figure, or to 10%, whichever is the greater. Accordingly, the scope of the invention is to be construed in accordance with the substance defined by the claims. The process may be scaled up using larger quantities and a modified apparatus.

[0096] It will be clear to one having skill in the art that further variations to the specific details disclosed herein can be made, resulting in other embodiments that are within the scope of the invention disclosed. Steps in the flowchart may be performed in a different order, other steps may be added, or one or more may be removed without altering the main outcome of the process.

CLAIMS

1. A process for obtaining a purified psychoactive alkaloid solution, the process comprising:

contacting a psychoactive alkaloid extract in liquid or slurry form with an adsorbent material to obtain adsorbed psychoactive alkaloid, wherein:

the psychoactive alkaloid extract in liquid or slurry form comprises a primary aliphatic alcohol, a ketone, water or any combination selected therefrom and has a pH between 2.5-4.5 or 9-10;

the psychoactive alkaloid extract comprises psychoactive alkaloid that is psilocybin, psilocin, baeocystin, norbaeocystin, norpsilocin, aeruginascin, bufotenin, bufotenidine, 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine), N,N-dimethyltryptamine (DMT), ergine (LSA), ergonovine, ergometrine, muscimol, ibotenic acid, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, chanoclavine or any combination selected therefrom; and

the adsorbent material is a gel resin, a first non-ionic macroporous resin, an ion-exchange macroporous resin or any combination selected therefrom;

washing the adsorbent material with a first solvent that is water, a C1-4 primary aliphatic alcohol, a C3-4 ketone or any combination selected therefrom to remove one or more impurities from the adsorbent material; and

eluting the adsorbed psychoactive alkaloid from the adsorbent material using a second solvent different to the first solvent to obtain the purified psychoactive alkaloid solution, wherein the second solvent is water, a C1-4 primary aliphatic alcohol, a C3-4 ketone or any combination selected therefrom, under basic, acidic or neutral pH.

2. The process of claim 1, wherein the pH between 2.5-4.5 of the psychoactive alkaloid extract in liquid or slurry form is obtained by adding an acid to the psychoactive alkaloid extract, wherein the acid is one or more acids selected from the group consisting of acetic acid, adipic acid, ascorbic acid, phosphoric acid, ammonium aluminum sulphate, ammonium citrate dibasic, ammonium citrate monobasic, calcium citrate, calcium

fumarate, calcium gluconate, calcium phosphate dibasic, calcium phosphate, hydrochloric acid, sulphuric acid monobasic, calcium phosphate tribasic, citric acid, fumaric acid, gluconic acid, magnesium fumarate, malic acid, phosphoric acid, potassium acid tartrate, potassium citrate, potassium fumarate, sodium citrate, sodium fumarate, sodium gluconate, sodium lactate, sodium potassium hexametaphosphate, sodium potassium tartrate, sodium potassium tripolyphosphate, sodium pyrophosphate tetrabasic, sodium tripolyphosphate and tartaric acid.

3. The process of claim 1, wherein the pH between 9-10 of the psychoactive alkaloid extract in liquid or slurry form is obtained by adding a base to the psychoactive alkaloid extract, wherein the base is one or more bases selected from the group consisting of ammonium bicarbonate, ammonium carbonate, ammonium hydroxide, calcium acetate, calcium carbonate, calcium chloride, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate dibasic, calcium phosphate monobasic, magnesium carbonate, potassium aluminum sulphate, potassium bicarbonate, potassium carbonate, potassium hydroxide, potassium lactate, potassium phosphate dibasic, potassium pyrophosphate tetrabasic, potassium phosphate tribasic, potassium tripolyphosphate, sodium acetate, sodium acid pyrophosphate, sodium aluminum phosphate, sodium aluminum sulphate, sodium bicarbonate, sodium bisulphate, sodium carbonate, sodium hexametaphosphate, sodium hydroxide, sodium lactate, sodium phosphate dibasic, sodium phosphate monobasic and sodium phosphate tribasic.

4. The process of claim 1, wherein the second solvent has a lower polarity than the first solvent.

5. The process of claim 1, wherein the process comprises further purifying the purified psychoactive alkaloid solution by repeating, with the purified psychoactive alkaloid solution, the contacting step with a different adsorbent material, the washing step with another solvent that is water, a C1-4 primary aliphatic alcohol, a C3-4 ketone or any combination selected therefrom, and the eluting step with yet another solvent that is

water, a C1-4 primary aliphatic alcohol, a C3-4 ketone or any combination selected therefrom.

6. The process of claim 1, comprising:
evaporating a portion of the second solvent from the purified psychoactive alkaloid solution to obtain a purified psychoactive alkaloid slurry.

7. The process of claim 6, wherein the purified psychoactive alkaloid slurry comprises 5% by weight or more of the psychoactive alkaloid.

8. The process of claim 6, comprising:
standardizing the purified psychoactive alkaloid slurry by adding thereto a quantity of excipient measured to provide a specific concentration of the psychoactive alkaloid when the purified psychoactive alkaloid slurry is dried; and
drying the purified psychoactive alkaloid slurry by evaporating the remaining portion of the second solvent to obtain a standardized, purified, powdered psychoactive alkaloid extract having the specific concentration of the psychoactive alkaloid.

9. The process of claim 8, wherein the specific concentration is 0.1-99% by weight.

10. The process of claim 8, wherein the excipient is one or more excipients selected from the group consisting of silicon dioxide, ascorbic acid, maltodextrin, gum arabic, microcrystalline cellulose, sodium benzoate, sodium phosphate, sodium citrate, rice hulls and rice.

11. The process of claim 1, comprising:
prior to the contacting step:
adding an acid to the psychoactive alkaloid extract to bring its pH to 4 ± 0.5 ;
and
removing solids from the psychoactive alkaloid extract;

wherein:

the adsorbent material is the first non-ionic macroporous resin;

the first solvent is water; and

the second solvent is a hydro-ethanol solvent.

12. The process of claim 11, wherein the hydro-ethanol solvent is 5% ethanol.

13. The process of claim 1, comprising:

prior to the contacting step, adding an acid to the psychoactive alkaloid extract to bring its pH to 3 ± 0.5 ;

after the contacting step and before the washing step, washing the adsorbent material with 100% ethanol, wherein the adsorbent material is a macroporous strong cation exchange resin in an H^+ or an Na^+ form; and

after the eluting step:

adding alkali to the purified psychoactive alkaloid solution to bring its pH to 4 ± 0.5 ;

removing solids from the purified psychoactive alkaloid solution;

evaporating a portion of the second solvent from the purified psychoactive alkaloid solution;

removing further solids from the purified psychoactive alkaloid solution;

contacting the purified psychoactive alkaloid solution with a second non-ionic macroporous resin to obtain second adsorbed psychoactive alkaloid;

washing the second non-ionic macroporous resin with purified water; and

eluting the second adsorbed psychoactive alkaloid from the second non-ionic macroporous resin using a hydro-ethanol solvent to obtain a twice purified psychoactive alkaloid solution;

wherein:

the first solvent is purified water; and

the second solvent is 2% hydrochloric acid and 80% ethanol.

14. The process of claim 1, comprising:

prior to the contacting step, adding a base to the psychoactive alkaloid extract to bring its pH to 9.5 ± 0.5 ;

after the contacting step and before the washing step, washing the adsorbent material with 100% ethanol, wherein the adsorbent material is a macroporous strong anion exchange resin in an OH^- or a Cl^- form; and

after the eluting step:

adding acid to the purified psychoactive alkaloid solution to bring its pH to 4 ± 0.5 ;

removing solids from the purified psychoactive alkaloid solution;

evaporating a portion of the second solvent from the purified psychoactive alkaloid solution;

removing further solids from the purified psychoactive alkaloid solution;

contacting the purified psychoactive alkaloid solution with a second non-ionic macroporous resin to obtain second adsorbed psychoactive alkaloid;

washing the second non-ionic macroporous resin with purified water; and

eluting the second adsorbed psychoactive alkaloid from the second non-ionic macroporous resin using a hydro-ethanol solvent to obtain a twice purified psychoactive alkaloid solution;

wherein:

the first solvent is purified water; and

the second solvent is 2% sodium chloride and 80% ethanol.

15. The process of claim 1, wherein the psychoactive alkaloid extract is extracted from a psychoactive alkaloid source that comprises psychoactive fungus, by:

drying and pulverizing the psychoactive alkaloid source to obtain a dried biomass;

placing the dried biomass in a first extraction solvent at a temperature of $5-95^\circ\text{C}$ for a duration of 10 minutes to 12 hours to obtain a first slurry, wherein the first extraction solvent is a primary aliphatic alcohol, a ketone, purified water or any combination selected therefrom;

filtering the first slurry to obtain a first filtrate and a first residue;

placing the first residue in a second extraction solvent at a temperature of 5-95°C for a duration of 10 minutes to 12 hours to obtain a second slurry, wherein the second extraction solvent is a primary aliphatic alcohol, a ketone, purified water or any combination selected therefrom;

filtering the second slurry to obtain a second filtrate and a second residue; and

mixing the first filtrate and the second filtrate to obtain the psychoactive alkaloid extract.

16. The process of claim 1, wherein the psychoactive alkaloid extract is from *Psilocybe* fungus.

17. A powdered composition consisting essentially of:

an extract from one or more mushrooms, the extract comprising psychoactive alkaloid that is psilocybin, psilocin, baeocystin, norbaeocystin, norpsilocin, aeruginascin, bufotenin, bufotenidine, 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine), N,N-dimethyltryptamine (DMT), ergine (LSA), ergonovine, ergometrine, muscimol, ibotenic acid, lysergic acid hydroxyethylamide (LSH), elymoclavine, ergometrinine, chanoclavine or any combination selected therefrom; and

an excipient;

wherein the psychoactive alkaloid has a concentration between a lower limit of exactly 10.5% and an upper limit of 99% by weight in the powdered composition.

18. The powdered composition of claim 17, wherein the excipient comprises ascorbic acid, silicon dioxide, maltodextrin, gum arabic, microcrystalline cellulose, sodium citrate, sodium benzoate, sodium phosphate, rice, rice hulls, or any combination selected therefrom.

19. The powdered composition of claim 17, wherein the concentration of the psychoactive alkaloid is specified as a percentage with a precision of two decimal places.

20. The powdered composition of claim 17, wherein said one or more mushrooms are *Psilocybe cubensis*, *Psilocybe cyanescens*, or both *Psilocybe cubensis* and *Psilocybe cyanescens*.
21. The powdered composition of claim 17, wherein the extract comprises psilocybin, psilocin, baeocystin, norbaeocystin, or any combination selected therefrom.
22. The process of claim 1, wherein the primary aliphatic alcohol in the psychoactive alkaloid extract in liquid or slurry form is a C1-4 alcohol.
23. The process of claim 1, wherein the ketone in the psychoactive alkaloid extract in liquid or slurry form is a C3-4 ketone.
24. The process of claim 8, wherein the specific concentration is 0.1-68% by weight.
25. The process of claim 8, wherein the specific concentration is 5-68% by weight.
26. The process of claim 8, wherein the specific concentration is 0.1-54% by weight.
27. The process of claim 8, wherein the specific concentration is 0.1-16.7% by weight.

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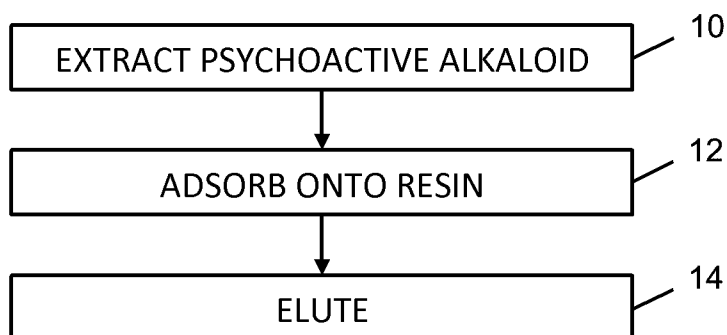


FIG. 1

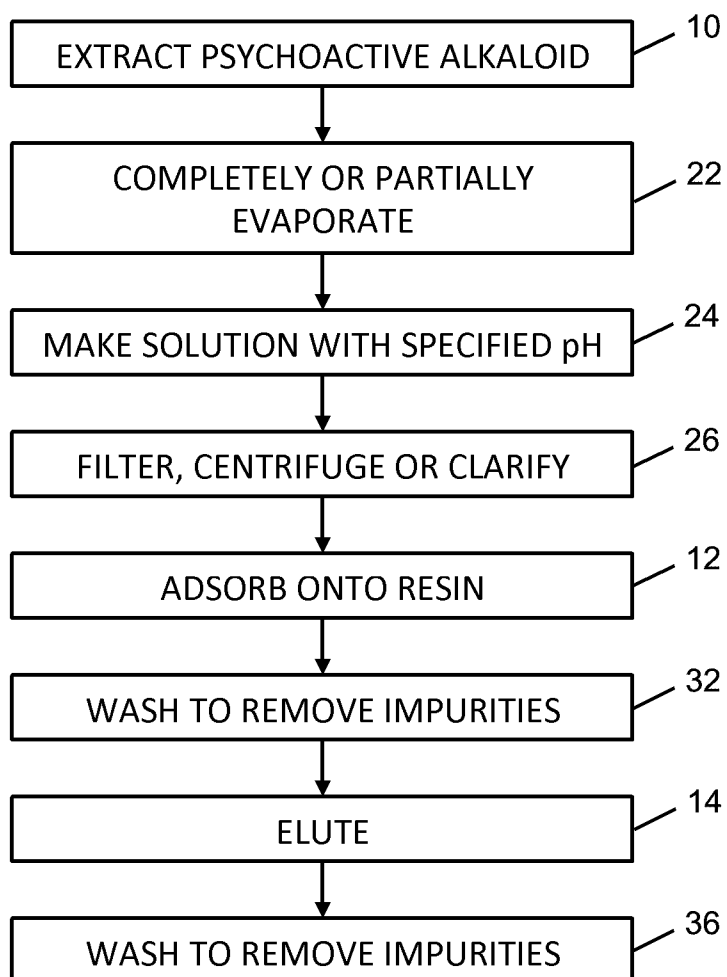


FIG. 2

2/3

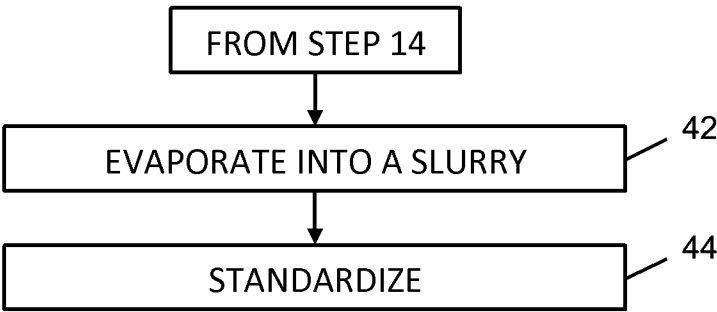


FIG. 3

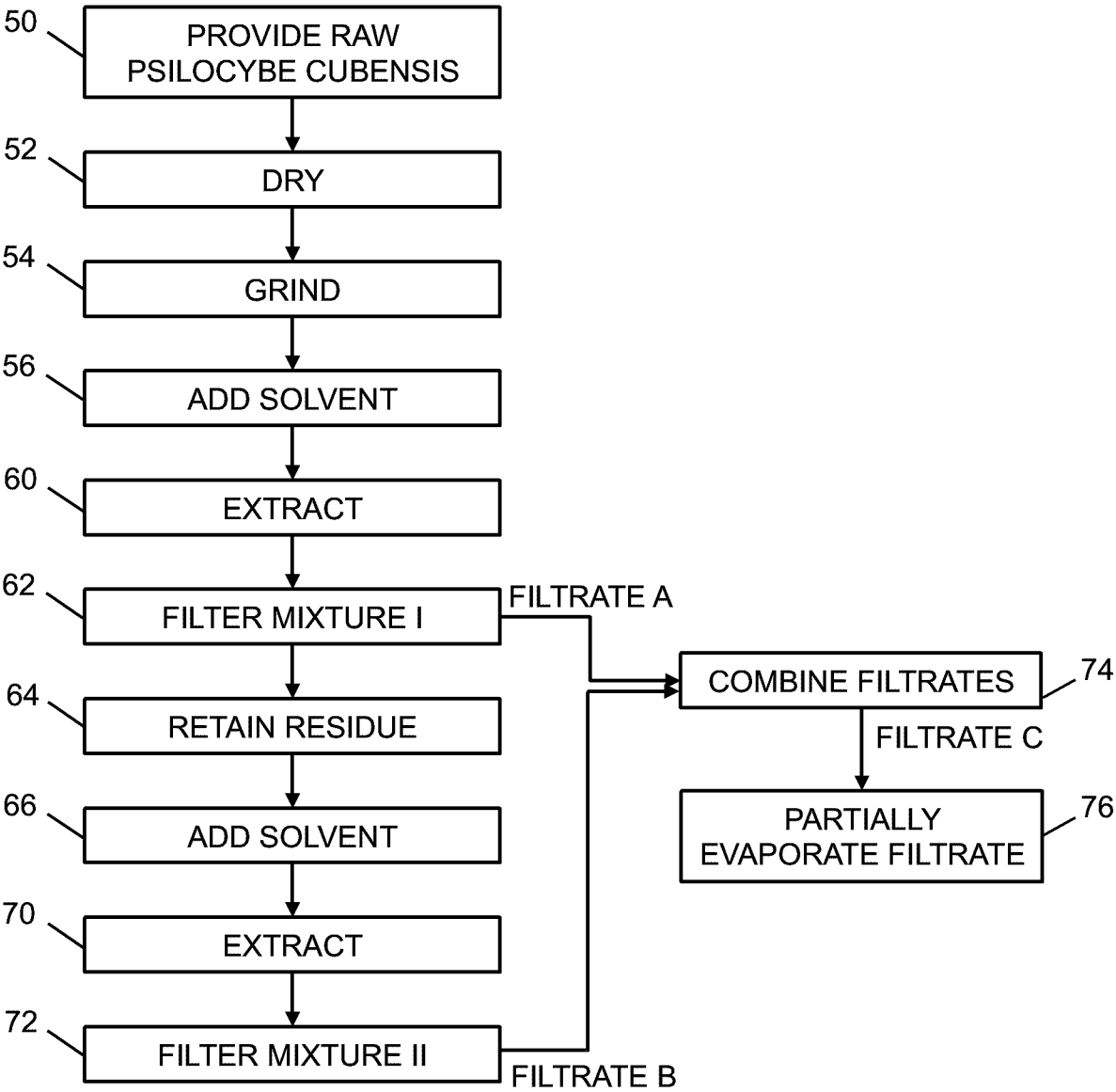


FIG. 4

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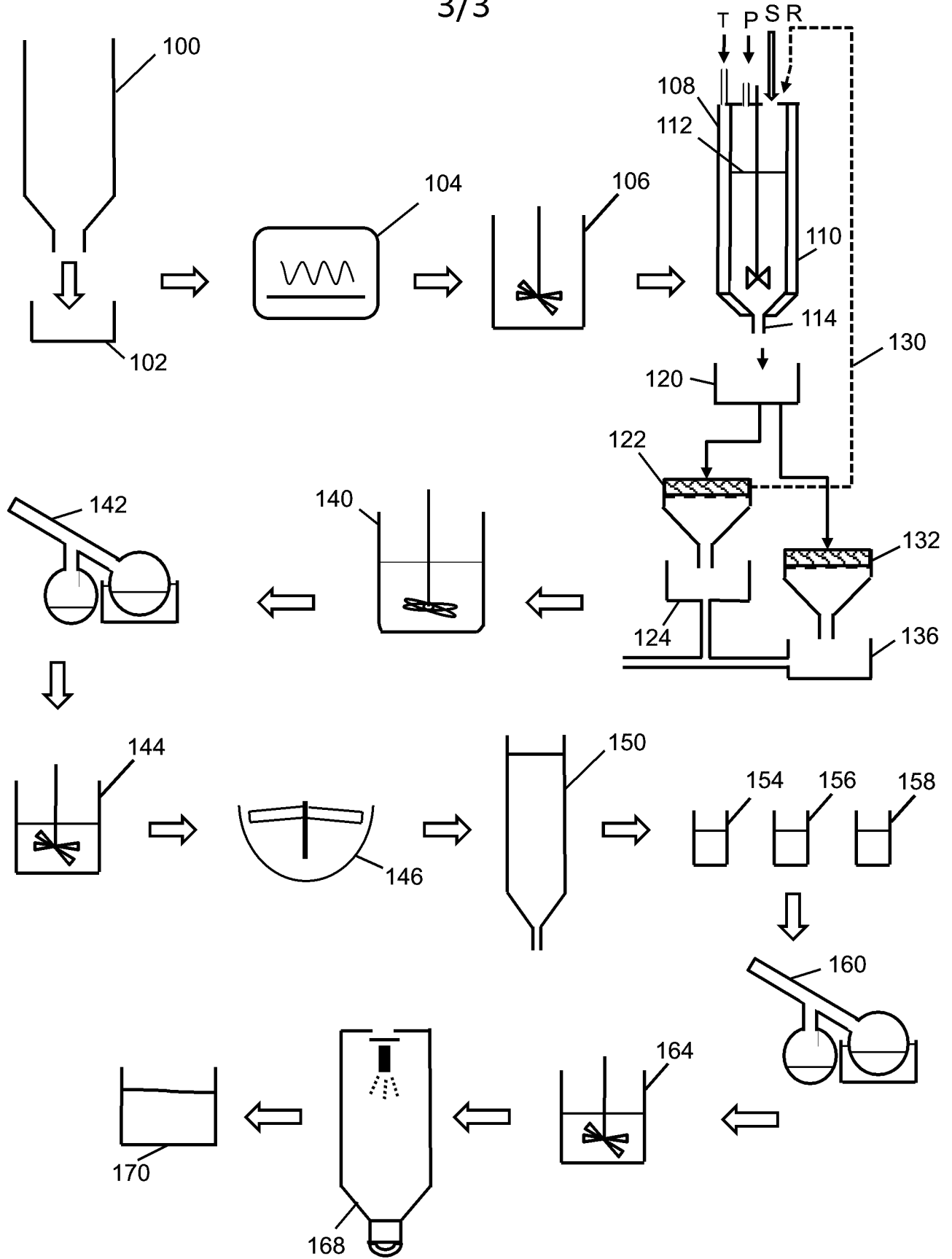


FIG. 5

