THE MAYWAY MAILER

November 2011

Quality Matters

Questions & Answers About Extract Powders/Granules- Part One

By Skye Sturgeon, MSOM, DAOM (candidate)
Quality Assurance Manager, Mayway, USA

There seems to be growing fondness for the use of extract powders or granules to prescribe Chinese herbs by practitioners. They are convenient to use, patient compliance is better, and they lend themselves to tailoring (jia jian). I have noticed this in the student clinics of Chinese medicine colleges, in continuing education classes, and in my doctoral program. Indeed, Mayway's Plum Flower® powdered extract line of single herbs and formulas are quite popular.

I have been curious about these products for some time. Last April, I was fortunate to be able to travel with the Mayway Tour www.maywaytour.com to Anguo, PRC to Mayway Hebei, the GMP facility where Mayway's herbs are identified and processed and many of our products are made. I was able to see extract powder production first-hand and ask a lot of questions of the production manager, Han Gang, about the details of the production of extract powders. Since then, I have spoken to analytical, food, and flavor chemists; plus I have engaged in some research and applied my own knowledge of chemistry and common sense. Enjoy the following, which is a developing list of FAQs regarding extract powders/granules.

1. What are powdered herbs?

Powdered herbs are raw (crude or prepared) herbs that are ground or pulverized into a powder. They may be single herb products or formulas (combinations of herbs). They are not extracted or cooked. When prescribing, one depends on the digestive system to extract the medicinal chemicals from the herbs.

2. What is an extract?

An extract is a liquid mixture obtained from adding a raw material to a solvent such as ethanol or water. In herbal extracts, the raw materials are raw (crude or prepared) herbs. It is not absolutely necessary to cook or heat the solvent to obtain the extraction, although it is common to do so. Extracts may be sold as liquid extracts (e.g. decoctions) or as tinctures (usually containing a large amount of alcohol.) They may also be sold in powder form and these are commonly called extract powders or granules. That is, powders and granules are simply dried decoctions.

Some manufacturers use other solvents such as hexane, chloroform, ether, acetone, or other organic chemical solvents to extract chemical ingredients that are less soluble in water or ethanol or to improve the concentration of a specific marker chemical in order to enhance the ingredient profile of the extract. Often this is done for marketing rather than therapeutic purposes since Chinese medicine is historically based on water extracts. Arguably, one can obtain more of the chemicals within an herb using organic solvents, but many of these chemicals may be undesirable.

3. What is the difference between extract powders and extract granules?

Of course, there are variations and proprietary technologies being employed by some manufacturers. However, I will elucidate some general characteristics of each.

Both forms come from liquid extracts that are dried to make the finished product. The most common method to make a powder is to spray dry the liquid extract. Spray drying is a method of producing a dry powder from a condensed liquid or slurry by rapidly drying with a hot gas such as nitrogen, oxygen or air. This is the preferred method of drying of many thermally-sensitive materials such as foods and pharmaceuticals. The resulting powder has a consistent particle size distribution and generally is free flowing. A disadvantage to this method is that spray dried powders are very hygroscopic and even small amounts of exposure to water vapor (such as that normally found in air) may cause them to clump into a gummy or solid mass.

However, spray drying offers another significant advantage in that the final product can be made with little or no fillers. This means that, gram for gram, spray-dried powders will likely have a higher potency than granules.

In the pharmaceutical industry, granulation refers to the process in which primary powder particles are made to adhere to a carrier to form larger, multi-particle entities called granules. Granulation is the process of collecting particles together by creating bonds between them. Bonds are formed by compression or by using a binding agent. Typical binding agents include disaccharides such as lactose or sucrose, or polysaccharides such as starch, dextrin, and cellulose. Granulation is most commonly and extensively used for the manufacturing of tablets and capsules. Herbal extract granules undergo the same process and can be thought of as stopping the finished product before it is made into a tablet or capsule.

Essentially, there is no difference in potency between extract granules and the tablets or capsules that are made from them. In fact, the main advantage to granules is that they are easier to compress into tablets. They are also superior if one is mixing different constituents together. Some herb granule manufacturers make formulas by mixing extract powders of single herbs together rather than by mixing the herbs first, then cooking them together and then making an extract powder of the entire formula.

In theory, certain herbs must be cooked together to reduce toxicity, harmonize effects, or achieve synergy or potentiation. An additional problem is that single herb extract powders do not really lend themselves to such mixing because the constituent powders could undergo segregation because of the different densities of the individual powders. It's the binding agents used in making granules that insures particles of uniform size and density. The amount of this carrier that is needed depends on the herb used, but typically ranges from 25-50%, so this carrier may constitute a large portion of the product. This is why these carriers are sometimes called diluents in the manufacturing realm.

Two types of granulation technologies are commonly employed, namely, wet granulation and dry granulation. Dry granulation uses powders and is more commonly used to make tablets from materials that may be sensitive to moisture and heat.

When using a type of wet granulation called flow coating, the liquid herb extract solution is atomized and sprayed onto minute particles of a binder. The binder is either some form of starch, or a powdered form of the herb(s) (either a powdered crude herb or the dried, powdered dregs from the extraction process). The process creates a wet mass of product, sometimes called a "slug", which is then milled or forced through a sieve forming uniform granules. The liquid portion of the granules is removed by a drying process such as a drying cabinet or heat tunnel.

4. What is meant when herbal extract powders/granules are called concentrates?

A concentrate is a form of substance which has had the majority of the solvent removed. Typically, this is the removal of water. Think of frozen orange juice concentrate. Usually, the concentrate is re-constituted at the time of usage by the addition of the water. Herbal extract powders/granules are concentrates because the liquid solvent (water) has been removed. They can be re-constituted by dissolving the powder/granules in water. This is a common way that extract powders are consumed by patients, i.e. adding water to reconstitute and then drinking as a "tea".

5. Then, are extract powders/granules "concentrated"?

No. Concentration is the measure of how much of a given substance there is mixed with another substance. This can apply to any sort of chemical mixture, but most frequently the concept is limited to homogeneous solutions, where it refers to the amount of solute in the solvent. The solute in an herbal extract is the amount of dissolved solids obtained from the herbs that appear in the resulting decoction (tang, soup, or tea). The solvent is the water in which the decoction is cooked.

To measure concentration there are three methods:

1) weight/weight (gm/gm) This is common with solid mixtures, e.g. 100gm of 18K rose gold alloy would contain 25gm of copper and 75gm of gold. However, a 5% solution of salt water could be expressed as 5gm NaCl/100gm H_2O.

2) weight/volume (gm/ml) This common with liquids. Using the salt water example above, its concentration could be expressed as 5gm NaCl/ 100ml H_2O.

3) volume/volume (ml/ml) This is commonly used with liquids and gasses and often expressed as percent of the total volume. 100 proof Vodka is 50% alcohol and 50% water. Air is 78% nitrogen, 21% oxygen, 1% other gases.

6. How is concentration determined?

First, a reference is required. Something can be called concentrated only in comparison to something else. To make a solution concentrated, one must add more solute (e.g. herbs), or reduce the amount of solvent (e.g. water). By contrast, to dilute a solution, one must add more solvent, or reduce the amount of solute.

For example, one could take the salt water described above as a reference, which is 5% NaCl. (i.e. 5gm NaCl dissolved in 100ml H_2O). To make a 2X concentration (10% NaCl), one needs to add another 5gm of NaCl to the original solution. To make a 4X concentration (20% NaCl), one needs to add 15gm of NaCl to the original solution, etc. (One could also make a 2X solution by dissolving 5gm NaCl in the water, i.e. 50ml.)

None of this applies to extract powders/granules because all that remains is the solute, that is, the dissolved solids that were obtained from the original liquid extract. If one asserts that they are concentrated, then you must explain, 'In reference to what?' And, 'What is the concentration?' Besides, considering the addition of carriers needed to make granules, it may be more accurate to consider them diluted!

7. Then, what does 5:1 mean?

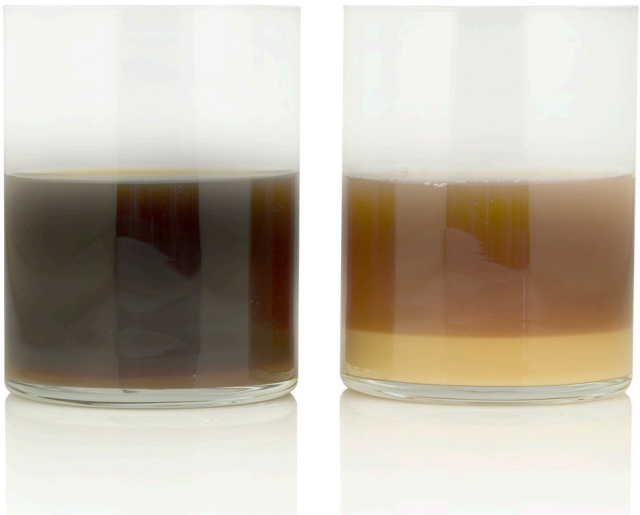
Sometimes referred to as the "industry standard", 5:1 signifies the yield ratio. Yield is the amount of product obtained as a result of the extraction process. A five to one yield means that if you cook 500 kg of herbs, you can expect 100 kg of powder/granules. In this case, the resultant powder represents a 20% yield and thus, a 5:1 yield ratio.

Since this 5:1 represents the yield, then one can imagine that 1gm of powder/granule = 5 gm of raw herb. Unfortunately, it is not as simple as this. This could be true under ideal (i.e. the 5:1 standard) conditions in spray dry powders that are not diluted whatsoever with filler. However, granules are definitely diluted by the extent (25-50%) of binder used to make the granule, so the equivalency does not measure up.

Moreover, even though 5:1 is the "industry standard", most herbs will not necessarily provide a five to one yield ratio. Sometimes, the yield will be 7:1 or 10:1, for example. A 7:1 extract means that it takes 700kg to obtain 100kg of product. A 10:1 extract means that it takes 1000kg to obtain 100kg. These are poorer yields than 5:1, and certainly do not represent a stronger concentration. One is simply getting less out of the extraction process. Another way to understand a 7:1 yield ratio is that if you start with same 500kg of raw herbs in the example above, you will only get 71.4 kg of finished product. With a 10:1 yield ratio, 500kg of raw herbs will yield 50kg, etc.

Plum Flower®
Gou qi zi Extract powder

Major Competitor's
Gou qi zi Extract powder



Three tablespoons of each concentrated powder was stirred into approximately 8 oz of hot water and allowed to sit for 5 minutes.

I think that it is important to reiterate, 7:1 and 10:1 are not stronger than 5:1. It's a little counterintuitive, but 7:1 and 10:1 extracts are less efficient because the yield was smaller.

It is also quite possible that some herbs will result in a higher yield ratio than 5:1, such as 4:1 or 3:1. One example would be if they contain a lot of naturally occurring starch or sugar (e.g. gou qi zi).

The yields of formulas are often above or below this 5:1 standard as well, depending on the combined yields of the various ingredients used in the formulas. An additional complication is that yields of the same herb or formula often differ significantly from batch to batch.

The reasons for poorer yields could be due to characteristics of the herb (i.e. not that much in dissolved solids can be extracted or dissolved from an herb) or it could be that a lower quality herb is being used or there was a variance in the extraction method.

Yields can also differ depending on such factors as:

1. Whether the herbs (especially roots and fruits/seeds) are ground into smaller pieces (increasing the surface area and/or breaking the protective coatings of seeds increase yields).

2. The length of extraction time (longer extraction times are associated with higher yields).

3. The solubility of the herb's ingredients in water.

4. Whether organic solvents are used (e.g. ethanol, acetone, hexane, et al. increase yields but may affect the ingredient profile).

5. pH of the extract solution (e.g. the $CaCO_3$ in mu li is more soluble in water at a lower pH).

6. Whether a temperature gradient is used. Are the herbs subjected to both "military" and "civilian" fire? Different herbs and ingredients presumably require different temperatures for optimal extraction.

7. Seasonality of the herbs (i.e. when they were harvested; immature plants presumably have less material).

Manufacturers often add a filler (also known as a diluent- see above) to make up the difference in poorer yielding herbs or formulas to bring the yield up to the 5:1 standard. Is it possible to make all formulas and herb powders 5:1? Yes. This is easily done by adding fillers.

Common fillers include cellulose (often from the dried, powdered dregs from the extraction process), starch, or dextrin. These are the same diluents that are used as binding agents in the granulation process. Some companies will add raw, i.e. unextracted, herb powders as filler. In a formula extract, this is usually one of the cheaper herbs in the formula rather than a powder of the entire formula.

Fillers are often added mainly in an effort to reach production goals and to achieve a certain price point for the finished product; that is because they artificially increase yield. (In Mayway's Plum Flower® powdered extract line the minimal amount of filler necessary to achieve free-flowing powders is added to its single herb extract powders, and because of the additional ingredients, no fillers are used in the production of formulas.)

One issue surrounding this 5:1 designation is that many "herbs" have ingredients that are relatively insoluble in water. For example, minerals, gelatins, and resins may be easily powdered as a raw herb but cannot be extracted easily into water and thus, their "yield" may be 15:1, 30:1 or worse. In consequence, Mayway's Plum Flower® gelatins and resins are simply powdered herbs since the "herbs" are themselves already extracts.

Bottling extract powders at Mayway Hebei

Finally, an analysis of 71 Plum Flower® formula extract powders from a Dec. 2006 report from our manufacturer, demonstrated a mean yield ratio of 5.88:1 (s = 2.44) and the median was 5.12:1. The range was 2.88- 14.81.

I believe that it is obvious that there is quite a bit of misconception and misleading information being proclaimed in TCM circles about extract powders and granules. Let me know what you think. Email your questions and comments to skyesturgeon@mayway.com. In a subsequent report, I will discuss the implications of this information on the current dosing guidance for extract powders and granules. ▪

Copyright © Mayway Corp. 2011. All rights reserved.

Bio: Skye Sturgeon, MSOM, DAOM (candidate) is the Quality Assurance Manager and Special Consultant for Mayway, USA. Skye is a core faculty member at the American College of Traditional Chinese Medicine where he is also enrolled in ACTCM's doctoral program. Previously, Skye was president of the Acupuncture & Integrative Medicine College, Berkeley. Before making Chinese medicine his career choice, Skye was a clinical biochemist and toxicologist.