



Position Paper on Current Disputes

Quality of Dietary Supplements

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Table of Contents

Quality Dispute.....	2
Cost & Quality	2
How to Choose	2
Internal Quality Control Issues of Raw Materials	3
Minerals	3
Herbs Are of Particular Concern.....	4
Other Important Qualities of Nutraceuticals	5
Disintegration Times (DT)	5
Excipients and Their Quality.....	5

Dietary Supplements

Quality Dispute

Herbal products and nutritional supplements are becoming increasingly more sought out for therapeutic or preventive purposes. In the United States we now spend about \$5.7 billion on dietary supplements, Twenty-four percent of these supplements are obtained from a pharmacy, This trend, however, has attracted companies with less than pristine ethical principles, either intentional or unintentional and the field has been flooded with poor quality products.

For example, a recent study of St. John's Wort found that the levels of hypericin, the active ingredient in the herb, varied greatly among ten different brands tested, including a brand from one of the nation's leading supplement manufacturers.

Cost & Quality

There is a saying in the field, "you get what you pay for". This is as true for food as it is for nutrients. After all, most of them are concentrated food extracts. There is no doubt that cost reflects quality.

Another problem in the field is the ongoing battle with the FDA. Having lost the war on total control of supplements with the passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994, the FDA has, however, retaliated by not allowing us to disclose the real medical purpose of any supplement or even using a name that describes the purpose. You will read on every label the mantra..."this product is not intended to diagnose, treat, cure or prevent any disease." We know this to be a fallacy, but nonetheless the FDA demands it. As a result, we are left with the creative task of educating you, the consumer and ourselves. In a sense, the FDA prohibition has spurred a higher level of sophistication on the part of the consumer.

How to Choose

In choosing any supplement, the first thing that I look for is the reputation and integrity of the manufacturer. Among practitioners, a manufacturer who does not maintain high quality standards, does not last long. The following specific guidelines will assist you in choosing the best.

<p>Look for the label GMP (good manufacturing practices). In this case the FDA comes to our rescue. The FDA has laid down an extensive body of regulations governing the manufacture and sale of dietary supplements. The GMP on the label stands for high standards of production. Some companies, such as the one I am relying on for most of my line of nutraceuticals have gone further and also acquire the OTC (over the counter) label by following even more stringent guidelines in supplement production; the same guidelines by the FDA to OTC drugs.</p>

Internal Quality Control Issues of Raw Materials

Because dietary supplements are very often complex mixtures of many labile ingredients, quality control must always begin at the level of raw material and continue throughout the manufacturing process. A good supplement should have:

- **Quality in raw materials**
- **Quality in formulation**
- **Quality in manufacturing, packaging and handling**
- **Quality in technical support and education**

Some manufacturers, through lack of expertise or pricing philosophy, will use inferior or inexpensive ingredients. This will reflect on results when we use these products for healing purposes.

Minerals

When it comes to minerals, quality can strongly affect the benefits derived from a vitamin-mineral supplement.

Research has shown that dipeptide amino acid chelates (a mineral tied to two amino acids) are better absorbed and more bioavailable than other forms of chelated minerals. Inorganic mineral salts can be more susceptible to inhibition of absorption by phytic acid, fiber and fat. Therefore, when looking for "amino acid chelate" be aware that not all chelates are equal. Always look for dipeptide chelated minerals. The four bonds between the amino acid and the mineral are strong enough to resist disassociation in the stomach and allow the mineral atom to be released by enzymes in the duodenal part of the intestine and be ready for cellular absorption. Albion Laboratories is known in our field for its high quality. The name Albion is a guarantee of pristine manufacturing process.

Microcrystalline Hydroxyapatite Concentrate (MCHC) This is the best form of mineral transport, especially in cases of osteopenia and osteoporosis, conditions we often see in our patient population. The source of MCHC is of the utmost importance in our Center, therefore, we ask for:

- **A Certificate of Analysis, indicating the protein and mineral content.**
- **A collagen analysis, documenting the presence of type I collagen.**
- **An X-ray diffraction analysis verifying the microcrystalline structure.**
- **A Certificate of Edible Origin to assure the material is not animal.**
- **A heavy metal analysis, documenting the lowest levels of heavy metals.**
- **A microbiological analysis documenting freedom from any infection.**

Herbs Are of Particular Concern

Because of the increase in the use of herbs in the health field over the last few years, we are beginning to experience a dwindling of supply. Some unscrupulous manufacturers, therefore, would use herbs that are similar, but not quite the same. The increased usage and consequent shrinking of supply increases the susceptibility of mislabeling. Another unethical practice that is all too common in the case of expensive herbs is that of diluting them with "substitutes" that can be blended into the bulk herb raw material. Unless the manufacturer has a laboratory on-site, the inferior product will be passed on to the consumer.

A reputable manufacturer will ensure that the supplier meets strict standards and the herbs requested, are the ones received. Furthermore, the quality and purity of the herbs should meet the highest standards to assure good results. These standards include:

- ***Organoleptic Evaluation:*** A top manufacturer has a team of highly skilled, in-house researchers who can identify herbs that look alike, but are not the same.
- ***Microscopic Identification:*** This can determine if the powdered or cut herbal materials are the correct specimens and if they have been adulterated. Microscopy also provides additional information when in conjunction with other analytical methods.
- ***Microbiological Analysis:*** Microbiological analysis is important for establishing the safety of the herbal products, to exclude the presence of yeast, mold, fungi, Salmonella, E. coli and insects and their eggs.
- ***Purity Analysis:*** Samples are tested for heavy metals, herbicides, fungicides and pesticides.
- ***Chromatography:*** Chromatography provides a "chemical fingerprint" of the plant and a profile of the active ingredients, both quantitative and qualitative. These tests determine if an extract meets a supplier's potency claim, e.g., percentage of active ingredient in a given herb.

Any company that is willing to follow all these steps will deliver products that guarantee:

- **The herb is the correct one and it contains the highest amount of the active ingredient.**
- **It is not contaminated.**

FAILURE TO FOLLOW ALL THESE STEPS CAN LEAD TO FAILURE OF TREATMENT ON OUR PART.

Other Important Qualities of Nutraceuticals

Disintegration Times (DT)

This is the time it takes for a tablet or capsule to dissolve in the digestive tract. DT has a large impact on absorption and consequent bioavailability. Individual variations in digestive function can also complicate the DT. High quality products are usually manufactured with shorter DTs. The manufacturer we use is willing to give us data on DT.

Excipients and Their Quality

Excipients are the various components that are used in the manufacture of tablets and capsules. They assure that the blended powder has a constancy of flow needed for proper encapsulation and tableting, and that all the ingredients can be combined with uniformity and consistency in appearance. They also assure that the tablet or capsule disintegrates properly. The excipients also have to assure that the tablet does not turn into powder in the bottle and that the coating improves stability and makes it easy to swallow. Excipients, therefore, make up a good part of the product and have very important functions. Because of this, the quality of excipients crucial. Synthetic excipients have been shown to irritate the gastrointestinal tract.^h This might be responsible for some peoples' inability to tolerate nutrients. Inert, nontoxic excipients are available, but of course, more expensive. Reputable manufacturers will use these expensive incipients, but their charge will be reflected in the cost.

While many manufacturers have in-house testing laboratories, others use independent labs and some use both. The latter do a preliminary screening and then send the product to an independent lab which functions as a "watch dog", for approval. This gives us further assurance as for the purity and potency of the products.

In summary, choosing nutrients that are hypoallergenic, non-toxic, and of the highest quality to provide the results that are expected in the field of complementary-alternative medicine, requires knowledge of all the above-described factors. The educated consumer is the best watch dog to maintain high quality in a field that is only partially regulated. I have gone to great lengths to assure our products adhere to the highest standards of quality.

If you wish to check this out, send a written request with a stamped, self-addressed business size envelope and we will be happy to send you a copy of the manufacturer's quality certificate.

AS ALWAYS, TAKE LESS - TAKE THE BEST.