

Dietary Supplement Quality Guide

A Conversation on Quality

When practitioners are asked why they sell dietary supplements to patients, the number one response is to offer patients access to safe, high-quality products. For many patients however, convenience and price rank very high in their decision-making.

This discrepancy between practitioner and patient beliefs about the importance of quality helps explain why so many patients end up going elsewhere for refills and ongoing purchases. If patients could understand the importance of product quality to their health, they might rank trust in practitioner recommendations above all else.

Ultimately, there are 3 things both practitioners and patients want from dietary supplements:

1. That the products are safe
2. That the products work
3. That the products are worth the cost

Most people assume dietary supplements are regulated and quality controlled by the FDA. Unfortunately, FDA regulations do little to ensure authenticity, purity, safety and efficacy due to lack of oversight and enforcement. So how can consumers be sure the products they purchase are safe, effective and authentic?

The answer is to buy products only from high-quality brands, through reputable distributors. When it comes to dietary supplements, quality really does matter.

This guide provides information on what distinguishes a high quality supplement manufacturer from the rest, and how to choose the right brands and products for your patients.

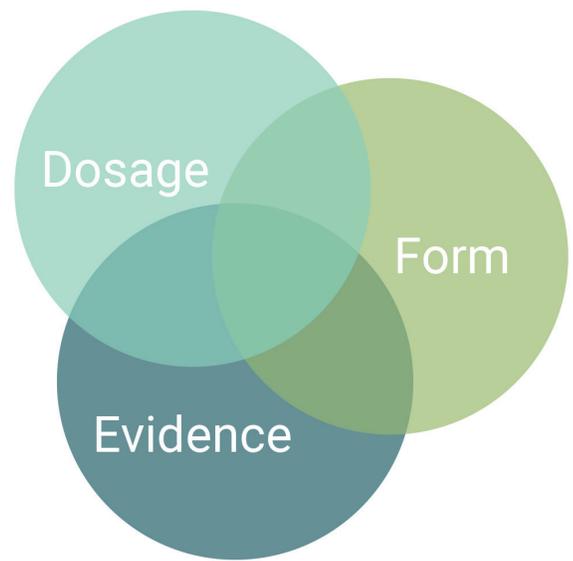


Ingredients Quality Checklist

When it comes to finding good quality supplements for your patients, there are some key questions you should be asking.

Identify the Key Ingredients and Ingredient Forms You Are Looking For

- **Form:** Any special ingredient forms you are looking for based on clinical evidence and experience?
- **Dosage:** What dose range is acceptable for your purposes?
 - Is the dose form optimized for absorption and bioavailability? Many cheaper brands use the cheapest ingredients which are not optimal from a bioavailability perspective (For example, magnesium oxide versus magnesium citrate have different bioavailability)
- **Evidence:** Do the ingredients have clinical data to support their use for the population and purpose you are after?



Review the Supplement Label

- Does the product contain your desired ingredients and dosages?
 - Are there any ingredients that are contraindicated for your patient?
 - Does the product contain other ingredients that are unacceptable to you?
- Does the product design and dosing make sense? How many capsules would be required to meet your desired dosage and will this work for your patient?
- Does the product fully disclose ingredients, including
 - Plant parts used (for herbs)
 - Extracts strength noted with amount of marker compound
- Does the label contain any “too good to be true” claims that may indicate they are not aware of regulations and quality?
 - Treat, cure, or prevent a disease

- Does the label contain all information required?
 - Name of the supplement
 - Supplier name & contact info
 - Ingredients & serving size
 - Allergens, warnings, and other considerations for use

Allergen Statements

By law, manufacturers are required to disclose the presence of the eight most common food allergens

- | | |
|------------------------|-------------|
| • Crustacean Shellfish | • Wheat |
| • Fish | • Tree Nuts |
| • Egg | • Peanuts |
| • Dairy | • Soy Beans |

A declaration of "Allergen free" requires that companies test for the absence (or presence below an acceptable limit) of that specific allergen. For example, gluten free must be <20ppm of gluten upon testing.

Supplement Facts			
Serving Size 1 Tablet			
Amount per Serving		% DV	
FoodState Nutrients <small>•</small>			
Vitamin A	(45 mg†; carrot)	2250 IU	45
As Alpha & Beta Carotene with Mixed Carotenoids (Cryptoxanthin, Lutein, Zeaxanthin)			
Vitamin C	(240 mg†; organic orange)	60 mg	100
Vitamin D3	(8 mg†; <i>S. cerevisiae</i>)	400 IU	100
Vitamin E	(64 mg†; organic brown rice)	16 IU	53
Vitamin K	(3 mg†; cabbage)	30 mcg	38
Thiamine (B-1)	(12 mg†; <i>S. cerevisiae</i>)	3 mg	200
Riboflavin (B-2)	(20 mg†; <i>S. cerevisiae</i>)	2 mg	118
Niacinamide	(80 mg†; <i>S. cerevisiae</i>)	20 mg	100
Vitamin B-6	(20 mg†; <i>S. cerevisiae</i>)	4 mg	200
Folate	(40 mg†; broccoli)	400 mcg	100
Vitamin B-12	(2 mg†; <i>S. cerevisiae</i>)	10 mcg	167
Biotin	(21 mg†; organic brown rice)	105 mcg	35
Pantothenic Acid	(40 mg†; <i>S. cerevisiae</i>)	10 mg	100
Calcium	(20 mg†; <i>S. cerevisiae</i>)	1 mg	<1
Iron	(90 mg†; <i>S. cerevisiae</i>)	4.5 mg	25
Iodine	(10 mg†; <i>S. cerevisiae</i>)	150 mcg	100
Magnesium	(20 mg†; <i>S. cerevisiae</i>)	1 mg	<1
Zinc	(280 mg†; <i>S. cerevisiae</i>)	14 mg	93
Selenium		(15 mg†; <i>S. cerevisiae</i>)	15 mcg 21
Copper		(20 mg†; <i>S. cerevisiae</i>)	200 mcg 10
Manganese		(20 mg†; <i>S. cerevisiae</i>)	1 mg 50
Chromium (GTF)		(30 mg†; <i>S. cerevisiae</i>)	60 mcg 50
Molybdenum		(15 mg†; <i>S. cerevisiae</i>)	30 mcg 40
Potassium		(792 mg†; <i>S. cerevisiae</i>)	4 mg <1
Boron		(50 mg†; <i>S. cerevisiae</i>)	500 mcg **
Rejuvenating and Balancing Blend 81 mg **			
Organic Chaste Tree Berry, Organic Red Clover Flower, Organic Saw Palmetto Berry, Organic Ashwagandha Root, Organic Ginkgo Leaf, Organic Hawthorn Berry, Organic Sacred Basil Leaf, Organic Turmeric Root, Organic Milk Thistle Seed, Organic Ginger Root, Organic Nettle Leaf			
Immune Health Blend 34 mg **			
Organic Astragalus Root, Organic Eleuthero Root, Organic Whole Orange (natural source bioflavonoids), Organic Blueberry (natural source anthocyanins), Organic Cranberry (natural source proanthocyanidins), Organic Schisandra Berry, Organic Shiitake Mushroom			

*Full spectrum of mixed tocotrienols and tocopherols ** % Daily Value (DV) not established †Total Weight FoodState Nutrient to Deliver Daily Value

Other Ingredients: Plant Cellulose, Silica, Vegetable Lubricant.

Suggested Use: 1 tablet daily. May be taken anytime throughout the day, even on an empty stomach.

Proprietary Blends: Do they provide enough info for you?

Supplement Facts		
Serving size 1 capsule		
Servings per container 180		
Amount Per Serving		%DV
Pantothenic acid (as calcium pantothenate) (B ₅)	150 mg	3,000%
Asian ginseng (<i>Panax ginseng</i>) extract (root) (standardized to contain 5% total ginsenosides)	150 mg	*
Eleuthero (<i>Eleutherococcus senticosus</i>) extract (root) (standardized to contain 0.8% eleutherosides)	100 mg	*
Ashwagandha (<i>Withania somnifera</i>) extract (root) (standardized to contain 2.5% withanolides)	150 mg	*
Rhodiola (<i>Rhodiola rosea</i>) extract (root) (standardized to contain 3% total rosavins and 1% salidroside)	50 mg	*
Astragalus (<i>Astragalus membranaceus</i>) extract (root)	150 mg	*

* Daily value (DV) not established

Other ingredients: vegetarian capsule (cellulose, water)

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

- Supplement Facts is the name given to the nutrition information panel of a dietary supplement product.
- Serving size is the manufacturer's suggested serving expressed in the appropriate unit (tablet, capsule, softgel, packet, teaspoonful, etc.)
- Servings Per Container tells the net content of the dietary supplement.
- Amount Per Serving heads the listing of dietary ingredients in the supplement and the quantity of each.
- Percent Daily Value (DV) tells what percentage of the recommended daily intake for each nutrient is contained in each serving. The DVs are for adults and children ages 4 and up, unless otherwise indicated.
- All dietary ingredients contained in the supplement are identified by their common or usual name. A dietary ingredient can be a vitamin, mineral, botanical, amino acid, or other dietary substance, as well as a concentrate, metabolite, constituent, extract, or combination of any of the above.
- The amount of dietary ingredient in each serving is declared in metric units. Milligram (mg) and microgram (mcg) are common units.
- A symbol, such as an asterisk, placed under the % Daily Value heading indicates that the Daily Value has not been established for that dietary ingredient.
- A footnote contains explanations for symbols, such as the asterisk, placed under the % Daily Value heading. Explanations may include "Daily Value not established."
- The list of all ingredients in the supplement, including any ingredient that is the source of a dietary ingredient, in decreasing order by weight.

1 Supplement Facts		
2 Serving Size 1 Tablet		
3 Servings Per Container 100		
	4 Amount Per Serving	5 % Daily Value
Vitamin A (50% as beta-carotene)	900 mcg	100%
6 Vitamin C	7 250 mg	278%
Vitamin D	20 mcg	100%
Vitamin E	75 mg	500%
Vitamin K	120 mcg	100%
Thiamin	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin	16 mg	100%
Vitamin B6	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B12	2.4 mcg	100%
Biotin	30 mcg	100%
Pantothenic Acid	5 mg	100%
Choline	550 mg	100%
Calcium	260 mg	20%
Iron	18 mg	100%
Phosphorus	250 mg	20%
Iodine	150 mcg	100%
Magnesium	210 mg	50%
Zinc	11 mg	100%
Selenium	25 mcg	45%
Copper	0.9 mg	100%
Boron	150 mcg	8 *

9 * Daily Value not established.

- 10** Other Ingredients: Choline bitartrate, calcium carbonate, ascorbic acid, dicalcium phosphate, magnesium oxide, microcrystalline cellulose, dl-alpha tocopherol acetate, ferrous fumarate, niacinamide, zinc oxide, magnesium stearate, d-calcium pantothenate, vitamin A acetate, pyridoxine hydrochloride, potassium iodide, boron citrate, phylloquinone, thiamin mononitrate, copper sulfate, d-biotin, sodium selenate, cholecalciferol, and cyanocobalamin.

Brand Quality Checklist

When it comes to finding good quality supplements for your patients, there are some key questions you should be asking.

Evaluate the Brand

- Is the brand 3rd party certified/registered as compliant with cGMP (current Good Manufacturing Practices)? This provides a reasonable assurance that the manufacturer is manufacturing according to FDA guidelines and their adherence is verified by an independent party. Some credible organizations include:
 - NSF (nsf.gov)
 - US Pharmacopeia (usp.org)
 - UL (ul.com)
 - Natural Products Association (npanational.org)
 - Therapeutic Goods Administration of Australia (tga.gov.au)
- How does the brand test to ensure the product contains what it says and is free of contaminants?
 - How do they qualify a new material (ingredient)? How do they test it and how frequently do they test?
 - How do brands test for purity, potency, and identity of ingredients along with contaminants?
 - How frequently does testing occur?
- Has the brand ever undergone an FDA audit and were there any “483s” (the name for formal findings by the FDA)



REAL CERTIFICATIONS

Qualifying a new brand or new product to use in your clinic can be time-consuming, but is important for the safety and health of your patients.

- If performed on the same day as the patient’s visit, the clinician may now be able to bill and code for the time spent doing this (in practices that accept insurance).

Emerson Quality Program EQP®

The Emerson Quality Program (EQP) is a service we offer for practitioners to do this evaluative process for you! The Emerson Medical and Quality teams conduct regular audits of brands including reviewing Standard Operating Procedures (SOPs), employee training, manufacturing processes, testing protocols and more. The team conducts virtual paper audits, on-site audits of manufacturing facilities and labs, and even conducts independent lab verification of the brands' products to ensure top quality of the brands in the program.

The standards for achieving EQP Partner designation highlight quality practices consistent with the production of superior quality dietary supplements. The standards for each Partner level include:

- **Emerson Distributed Brand:** Current Good Manufacturing Practices (cGMP) compliance; acceptable third party, Emerson or agency audit
- **Silver Partner:** EQP Partner standards; use of the most appropriate testing methodologies; potency testing; and a validated risk-based approach to testing adulterants and contaminants. Stability testing may be accelerated
- **Gold Partner:** EQP Silver Partner standards; testing every batch for identity, potency (label claim), microbiological and other applicable contaminants; a real-time stability program in place; plus demonstrated evidence of research and product development, clinical trial support and sustainable environmental practices.

EQP® Mechanics

Phase I: Proprietary Supplier - Questionnaire

- GMP, Raw material testing, Finished product testing
- Manufacturer Quality Highlight Table
- EQP Overview Chart to summarize the supplier's quality practices
- Review and approval by both Emerson and supplier
- Successful completion = EQP Applicant designation

Phase II: Documentation audit with benchmark quality practices

- Extensive document audit to determine that the supplier's practices and manufacturing controls meet the standards for EQP Silver Partner or EQP Gold Partner.

Phase III: Product Testing

- To proceed to the next phase, Emerson selects products to send for independent confirmatory lab testing
- Higher risk products selected and confirmed for identity, potency, and/or purity.
- Sent to Emerson's qualified laboratory partners

Phase IV: On-Site Audit and Batch Record Verification

- On-site audit to determine that the supplier has met the standards for EQP Silver Partner or EQP Gold Partner.
- Successful completion = EQP Partner designation

Phase V: EQP Partner Re-verification

- Random product testing quarterly to verify critical quality control check points
- cGMP assessment form completed annually
- Complete document and/or on site audit every 3 years

EQP Evaluation

We solicit information on 3 key areas

1. cGMP (current Good Manufacturing Practice)
 - State of cGMP compliance (dietary supplements, food, pharmaceutical) and status of third party cGMP certification
 - Qualifications of the Quality unit and sufficient SOPs
 - Frequency of internal audits, cGMP training, and production control processes
 - Clean manufacturing processes
 - Adverse event reporting and product recall procedures
2. Raw Materials Testing Raw material supplier and COA qualification procedures
 - Confirmatory testing for identity for every raw materials
 - Frequency, specifications, results and testing methodology for potency
 - Frequency, specifications, results and testing methodology for purity regarding heavy metals, microbes, herbicide/fungicide/pesticide residues, chemical solvent residues, melamine, aflatoxin
3. Finished Product Testing
 - Frequency, methodology, specifications, and results for potency, heavy metals, microbial contamination, chemical solvent residues, stability profiling and shelf-life validation
 - Contract manufacturer qualification program

<p>Emerson Qualified Supplier (EQS)</p> <p><i>Required of all brands</i></p>	<ul style="list-style-type: none"> • Third party/agency audit (NSF, USP, NPA, TGA, FDA, etc.) verifying cGMP compliance of the Brand within the most recent 2-year period. • If a third party certificate is not available than a SOP index that minimally includes procedures for supplier qualification, analytical testing, product recalls, HACCP (as applicable) and adverse event reporting. • If the Brand uses contract manufacturers (CM), a 3rd party certification of cGMP compliance or an FDA audit report with acceptable findings must be provided for each CM that collectively manufactures at least 80% of the total product line. • Product labels that demonstrate compliance with FDA and FTC labeling and adverting requirements.
<p>EQP Silver Partner</p> 	<ul style="list-style-type: none"> • EQS requirements AND: • Use of most appropriate testing methodologies when testing for identity, microbiologicals, heavy metals, pesticides/herbicides (for botanicals), aflatoxins, melamine, and residual solvents. • In addition to supplier CoA, identity is tested on each batch of raw materials or finished product and all other analytical tests (microbiology, heavy metals, pesticides/herbicides (non-organic), solvents (concentrates) are completed on at least every 5th batch/lot or if less than 5 lots, at least once annually. • Re-qualification of Contract Manufacturer by questionnaire and/or site audit at east every 3 years. • Potency testing procedure for finished products in place and in use • Demonstration of reliable in-process controls to provide batch to batch consistency in potency and purity • Evident industry knowledge of common adulterants and contaminants, and sufficient testing to guarantee the absence of these adulterants and contaminants in Finished Products and disqualification of Suppliers of adulterated ingredients
<p>EQP Gold Partner</p> 	<ul style="list-style-type: none"> • EQS requirements AND: • Analytical testing on each batch of Raw Material or Finished Product for: identity, potency (label claim), and microbiological contaminants as well as other applicable analytical tests on ingredients at high risk for certain impurities (ie.: solvents for concentrates; pesticides for non-organics; melamine for animal proteins; aflatoxin for high risk herbs/foods; adulterants) • Demonstration of product holds, recalls, reformulations and/or supply chain changes in response to discovered failure to meet product specifications for qaity reasons. • A real time stability program is in use to esnure that all Finished Products meet label claim throughout their shelf life • Products contain active ingredients in sufficient quantities to be clinical effective • Evidence of Total Quality (such as: research and product development, product formulation, sustainable enviromental practices, clinical trial support, good business practices)



We would like to thank Dr. Robert Luby, MD (Director of Medical Education Initiatives, Institute for Functional Medicine) and Dan Lukaczer, ND (Director of Medical Education Programs, Institute for Functional Medicine) for lending clinical insights and instructional design recommendations in the developmental stage of this project and for providing a clinical review of the guide.

Grantor acknowledges the use of the IFM name, logo and trademark does not infer a co-brand relationship. Emerson Ecologics is a wholesale distributor of professional-grade vitamins and supplements to the functional medicine community.