PURE NUTRITIONAL SUPPLEMENT MANUFACTURERS, INC.

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12 QUESTIONS TO ASK SUPPLEMENT MANUFACTURERS BEFORE YOU HIRE THEM

PREPARED BY

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Make it Organic with PureNSM

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Questions to Ask Supplement Manufacturers BEFORE You Hire Them

The first question should be the one you ask yourself:

Do you want supplements with additives like magnesium stearate or do you want a clean-label?

Read #3 below to help you decide. In most cases you can get a lower price if you choose magnesium stearate.

You put a lot of thought into figuring out what supplement you want to make. You should long and hard about whom you can trust to make it per the products signed specification sheets provided by your CMO.

How do you go about identifying the best contract manufacturing organization (CMO)? Ask any manufacturer the following questions BEFORE you hire them.

1

Can you manufacture without any Magnesium Stearate? (only ask this question if you want no mag. stearate)

If you don’t mind the magnesium stearate we recommend you keep tabs on how much your manufacturer wants to use. Read the below and you will figure out how to do that.

If you prefer your capsules and tablets to not contain magnesium stearate you better figure out if your manufacturer can live without it. What is their attitude about it? What methods have they developed in order to avoid the use of it? What do they use instead? Do they use rice extracts? Rice flour contains seed oils and is almost as highly processed as magnesium stearate, so that may not be a good alternative.

Because it's so much cheaper to manufacture with a small amount of magnesium stearate, many factories put it in without informing the clients, especially because it does not go against FDA regulations to do so if the factory does it as a matter of routine. For this reason ask if your contract factory offers a monetary guarantee that they will NOT add magnesium stearate to your products. (we offer $10,000)

2

Ask for the COA of the HPMC capsules that will be used in your product, does the COA have the word “carrageenan” in it?

From 1989 to 2022, HPMC capsules commonly contained carrageenan, a fact not widely disclosed. In 2022, new technology enabled the production of HPMC capsules without carrageenan or associated surfactants. Still about 50% of capsules are made with the aid of carrageenan because it's cheaper.

Under FDA regulations (21 CFR Part 101.100), incidental additives like carrageenan, present at insignificant levels without functional effects, are exempt from labeling. This allows manufacturers to omit such ingredients from labels, leaving both brand owners and consumers unaware.

We at PureNSM guarantee that our capsules do not contain a trace amount of carrageenan. We align and augment your commitment to clean label manufacturing.

3

Group of questions about Record Keeping

Ask those questions:

- How many people do you have in your QA and QC departments?
- When will I get the specification sheet for my products?
- Can you please give me the name of a person who can provide me with a copy of my batch records?
- I would like to take a look at the blend and encapsulation records, can you supply the ones used for my particular product batch?
- Do you work on an electronic or paper batch record system?

Note: Your specification sheets flow should be 100% complete before you pay a deposit. However the flow agents in it (natural or not) may change depending on how your powder flows into capsules. You can nuance the specification sheet like follows:

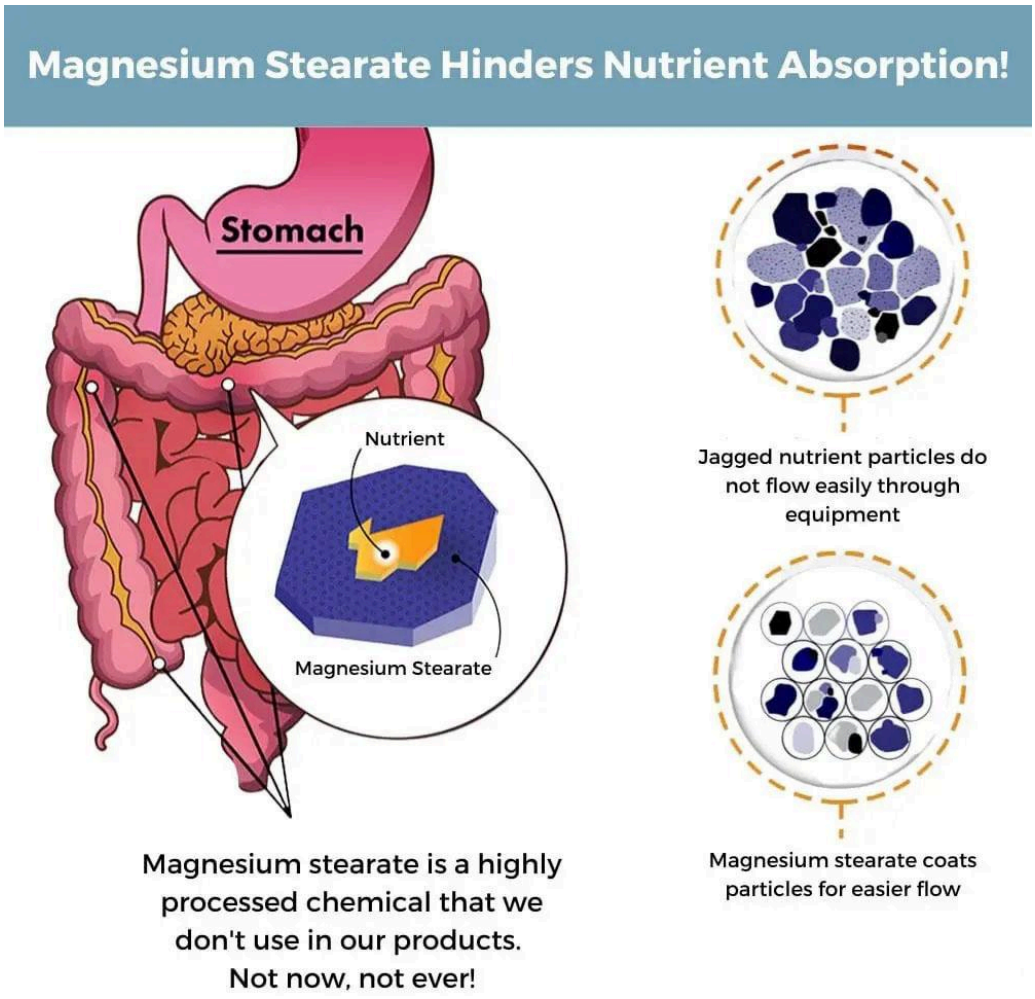
- **If you want magnesium stearate:**
    - Make sure your production records state: If more magnesium stearate is needed, contact the brand owner.
    - For poor flowing and sticky blends expect to see closer to 2%
    - For free-flowing powders, expect to see around 0.25%-0.5%

- **If you don't want magnesium stearate:**
    - Make sure your production records states "no magnesium stearate".
    - In case there are flow problems please try the discussed natural flow agents first and if that does not work suggest to the brand owner how much magnesium stearate to use.
    - Do not proceed with magnesium stearate without contacting the brand owner.

You should have access to your batch records directly from QA as soon as manufacture has taken place.

4

The case against using magnesium stearate:



A popular concern of magnesium stearate in supplements among brands and consumers alike is the potential to hinder the absorption of active ingredients in supplements. Critics argue that magnesium stearate, can form a coating around the particles of active ingredients. This coating may reduce the solubility of the supplement, delaying or even preventing the body from fully

absorbing the nutrients. This could potentially diminish the supplement's effectiveness, especially for individuals relying on it for specific health benefits.

The clean label movement, emphasizing transparency and natural ingredients, has gained momentum, fueled by RFK Jr.'s advocacy against artificial food dyes like Red 40 and Yellow 5, linked to health concerns such as hyperactivity in children. His push has spotlighted the risks of synthetic additives, driving consumer demand for products free from artificial colors and flavors. In response, many brands are reformulating. Many of RFK followers are hyper aware of any ingredient that is hyper processed.

In addition to the two points above, Dr. Mercola has expressed concerns about magnesium stearate. He has highlighted the following potential issues:

1. Immune System Impact: Magnesium stearate may suppress T-cell function, which is crucial for immune response.
2. Biofilm Formation: It could create a biofilm in the intestines, potentially interfering with nutrient absorption.
3. Synthetic Nature and Highly Processed Seed Oils: Dr. Mercola criticizes its synthetic production process, which involves stearic acid and magnesium salts, raising questions about its purity and safety.

The PureNSM Promise: We've been specializing in supplement manufacturing WITHOUT flow agents and other unnecessary excipients since 1993.

Long before the clean label movement was born, we invested in learning how to encapsulate supplements without the need for flow agents such as magnesium stearate, stearic acid, and silicon dioxide. And we've had over 20 years to perfect our skills.

Manufacturing without flow agents does take more time and is more labor intensive, but we believe pure products are more effective and better for your body when they aren't laden with chemical additives.

We can help you avoid putting the following excipients on your supplement label: magnesium stearate, silicon dioxide (silica), cellulose, stearic acid, titanium dioxide, starch, maltodextrin, and more.

Even if you have a troublesome formula that sticks to the equipment, we can use a less controversial and even 100% natural flow agents.

5

What industry certifications does your manufacturing facility have?

The most respected industry certification that you want to see a proof of is the GMP certification. GMP stands for Good Manufacturing Practice. A GMP certification is most frequently issued by UL or NSF that certifies factories to NSF/ANSI standards.

WARNING: Do not accept state-issued GMP (Good Manufacturing Practice) certifications.

- State representatives do not typically visit the factory they issue the certification for. Certainly they don't audit the manufacturing facilities before issuing GMP certifications. UL and NSF certifies factories to NSF/ANSI standards. This is what you are looking for.
- These certifications are primarily used to support exports for American businesses, similar to a Certificate of Good Standing, rather than ensuring actual compliance with GMP standards.

Not all certifications are the same and that is because the first audits are always much easier than the audits you get after 5 years. Look for a CMO with at least a 5 year certification history.

Don't think that PDFs are worth anything! Delete. Go directly to the below links to NSF, UL and NPA websites. This is the ONLY way you should look at the certifications!

We were first GMP certified in 2014. Improving every year since then.

You can verify our UL certification **HERE**.
Search for us under *Nutritional Supplement Manufacturers* or *PureNSM*.

You can verify our NSF certification **HERE**.
Search for us under Manufacturer Name *Nutritional Supplement Manufacturers.*

You can verify our NPA certification **HERE**.
Search for us under *Nutritional Supplement Manufacturers* or *PureNSM.*

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Lets talk about the quality history of your company

Before you ask those questions go to the FDA main warning letter page and google the name of the company and keep that FDA page open if you are having a video call with them.

- Has your company ever changed its name?
- How long have you operated under this name, if so what are those names?
- Do you operate under other similar names?
- Did you ever receive a warning letter from the FDA?

Can I take a tour of your facility?

During either a virtual tour or an actual visit try to notice the following:

- Describe the air pressure differential in your encapsulation rooms. Check if there is a positive outflow out of the room.
- Do you operate a dehumidifier in each of the encapsulation / tableting rooms?
- Do you coat tablets and capsules?
- Is equipment clean, well-maintained, and free of visible dark residue?
- Are cleaning logs for equipment available and up to date? Can we take a look?
- Are raw materials tested for identity, purity, potency, and contaminants (e.g., heavy metals, pesticides)?
- Are deviations documented and addressed promptly?
- Are finished products tested for label accuracy, potency, and contaminants?
- Are stability studies conducted to ensure shelf life?
- Are there designated areas for raw materials, ike high-risk areas for allergin?
- Lets look at your quarantine area
- Lets look at your retained samples area
- Are pest control logs available for review?
- Has the facility been inspected by the FDA, and were there any significant findings?

- Employees not following hygiene protocols (e.g., no handwashing, improper protective gear).
- Raw materials or finished products stored directly on the ground.
- Wooden pallets inside cleanrooms.
- Dirty equipment.
- No validation stickers on their analytical equipment
- No validation sticker on the metal detector
- Not seeing a metal detector even if you ask them to show it to you
- No visible pest control measures.

The PureNSM Promise: We're more than happy to show you our production facility at work. Come see our production, lab, and warehouse staff in action. We'll walk you through the entire production process from the delivery of raw materials to finished product status. We'll even show you examples of production records and raw material test records in line with FDA requirements.

PureNSM operates an FDA-registered production facility under 21 CFR, part 111 of the Federal Code of Regulations (21 CFR111.75). We will gladly furnish proof of our current FDA registration upon request.

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How do you deal with Proposition 65?

You are looking for an answer that protects your brand from lawsuits.

Their inhouse laboratory should be capable of testing for Lead, Mercury, Arsenic, and Cadmium. It's best that they have an inhouse laboratory to take care of that.

You want them to be competent in calculating the total levels in your product every time you manufacture and to warn you if you go over the limits.

If your products are sold or consumed in the state of California, regardless of your physical location, you need to comply with Proposition 65 (Prop 65). In other words, **even if you are located in Iowa** and your brand is sold on the internet, then someone in California could purchase from you. When you ship that product to California you may be liable for big fines.

In 1986, California adopted a stringent law that requires businesses to warn consumers about exposure to various chemicals known to cause cancer, birth defects or other reproductive harm. That list of potentially harmful chemicals is now close to 900 strong.

While good, in theory, to protect consumers from various toxins, Prop 65 does not distinguish between added chemicals and naturally occurring chemicals absorbed from the environment (i.e. lead from a man-made chemical in a pesticide and lead absorbed by a carrot grown in soil get the same treatment under Prop 65).

Additionally, many substances require the Prop 65 warning at levels far lower than the limits set at the federal level.

Prop 65’s limits put supplements at risk, especially if they contain raw, unrefined botanical ingredients.

If your product does not have the Prop 65 warning and contains higher levels than the allowable maximum of any of those 900 or so chemicals, you could face a product recall, costly fines and legal fees, as well as a damaged reputation.

To avoid Prop 65 penalties, work with a contract manufacturer experienced at navigating the regulations.

Always ask a potential manufacturer about their knowledge of Prop 65. And because the most common contaminants in supplements are heavy metals, ask the manufacturer about their methods for heavy metal testing.

The PureNSM Promise: Having operated in the state of California for over 20 years, we've always got an eye on Prop 65 compliance.

As part of GMP regulations and quality assurance procedures, we test all raw materials for heavy metals with an ICP-MS in our state-of-the-art in-house laboratory.

We regularly test for the most frequent contaminants in food and supplements – lead, mercury, arsenic, and cadmium. Upon customer request and according to availability of standards, we can also quantify many other elements such as nickel, copper, chromium, cobalt, molybdenum, osmium, iridium, rhodium, and more.

As one of our clients, you also receive free label reviews from our experts to ensure that your product label is Prop 65 compliant.

8

Will your company make sure my product label meets the current regulations?

Your product label is just as important as the actual product. Your label is often the first place consumers look to answer their questions, and it could be the deciding factor in whether or not they purchase your product.

Although the ultimate responsibility of the label rests in your hands, an experienced contract manufacturer should be able to help you navigate through label compliance standards.

From structure and function claims to the supplement facts box format, your manufacturer should know what's required on the finished product label to steer you away from potential problems with the FDA and sales channels such as Amazon.

The PureNSM Promise: When you partner with us, we include your product label review in your service agreement. Our knowledgeable quality assurance team will make sure any structure and function claims are up to par, and they'll inform you of what documentation you'll need to have on record to substantiate your claims.

We will even help you comply with the new nutrition and supplement facts format requirements taking place between 2019 and 2021.

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Do you test botanical ingredients with HPTLC?

Botanical supplements have not been represented well in the news lately. Accusations of adulterated ingredients and false label claims have landed reputable brands and retail establishments in hot water. And not always rightly so.

You may recall when New York Attorney General Eric Schneiderman called for DNA testing of several herbal supplements available nationwide. The results indicated that the actual ingredients did not match what the label claimed. Supplement skeptics had a field day when the story went public in 2015.

But what is not widely known is that standard DNA testing is NOT an accurate way to identify botanical ingredients.

When botanical ingredients are dried and pulverized into powders, the plant's DNA becomes damaged. Only fragments of DNA are left at this point, rendering DNA testing inaccurate.

The gold standard for identifying botanical ingredients is a method called high-performance thin-layer chromatography or HPTLC. HPTLC is the type of

> *"DNA-based methods are not suitable for materials, such as botanical extracts, that were subjected to processes that denature, degrade and destroy DNA."*
>
> - United States Pharmacopeial Convention; USP Statement on Validation of DNA Test Methods for Regulating the Quality of Herbal Supplements

assurance brand owners need when standard identity testing isn't suitable.

HPTLC can also rule out spent herbs, essentially the leftovers from botanical ingredients that have gone through the extraction process. Unscrupulous vendors may try to pass off spent herbs as their full spectrum counterparts, leaving brand owners who don't test none the wiser.

If you find a contract manufacturer that uses HPTLC, make sure you're able to get copies of the results for your tested ingredients. This type of proof can save your brand's reputation if someone erroneously DNA tested your products, and the results did not come back in your favor.

Don't be sold on HPLC (high-performance liquid chromatography) or FTIR (Fourier-transform infrared spectroscopy) for botanical identity testing either. HPLC measures potency, not identity. And FTIR verifies the identity of amino acids and vitamins, not botanicals.

Knowing what is in your product and having the proof to back up your label claim is essential, especially when people question the regulation of dietary supplements. It is also paramount to make sure you get exactly what you paid for from your raw material suppliers. Even if they provide you with a certificate of analysis, make extra sure that your ingredients have not been adulterated in any way. Otherwise, you're unintentionally scamming your customers.

The PureNSM Promise: We test 100% of all incoming botanical raw materials for identity using HPTLC. After operating this advanced system for several years, we have amassed a library of over 250 botanical standards – and it's still growing.

When we first started using HPTLC, our in-house lab rejected about 30% of the raw materials brought in for identity testing. Once our suppliers caught onto the fact that we test raw materials against the vendor's certificate of analysis, they now know that only the best ingredients will pass our standards.

Although the rejection rate has declined, we still reject about 10% of herbs and botanical extracts because they fail HPTLC identity testing.

When you work with us, we're more than happy to provide you with any test results of your raw materials.

10

What type of testing do you perform?

Having the appropriate tests to back up your product is critical, especially if you ever undergo a product recall.

In accordance with GMP regulations, every new batch of raw material must be tested to ensure that the finished product meets certain safety standards.

When shopping for a contract manufacturer, you'll want to know what types of tests they provide, and also the equipment used to perform the tests. And just as equally important is whether a manufacturer performs testing in-house or if they outsource. Outsourcing can be prohibitively expensive and contributes to longer lead times.

So it's a good sign when you find a contract manufacturer that has its own in-house laboratory. This is proof that they take quality control seriously.

The PureNSM Promise: We offer a full list of tests in accordance with GMP regulations. Before we even prepare your formula, each raw material component undergoes a series of tests.

Test	Method
Heavy Metal Analysis	Inductively coupled plasma mass spectrometer (ICP-MS)
Microbiological Analysis	Neogen Soleris® Next Generation system + testing in plates and sticks
Identity testing	HPTLC, HPLC, GC, FT-IR, ATR-IR and more
Potency Testing	HPLC, FTIR, NIR, GC-MS, NMR, UV-Vis
Finished Product Testing	Micro, Heavy Metal, Potency, Label Review

We invite you to tour our state of the art in-house lab or talk with our QA and QC team to put your mind at ease. We're happy to talk you through the whole production process from when raw materials arrive at our facility to when the finished product is released from the lab and deemed ready to sell.

We're also happy to show you our meticulously-kept lab records.

We firmly believe that knowing your contract manufacturer's capabilities and seeing them in action is key to ensuring that your finished product is fully compliant with current regulations.

11

Will Amazon Accept My Finished Goods From You?

To have finished goods accepted on Amazon, factories must ensure compliance with Amazon's product documentation and regulatory standards. This includes providing authentic and unaltered compliance documents, such as safety certifications and test reports, in non-editable formats like PDFs or JPEGs. These documents verify that the products meet safety and regulatory requirements, ensuring they are suitable for sale on the platform.

Packaging and labeling are critical components of Amazon's requirements. Each product must have a unique FNSKU barcode that corresponds to a single product, along with an exterior scannable barcode or label. Packaging must be robust enough to protect the product during shipping and handling. Additionally, shipping boxes must include essential details like product name, case quantity, weight, and dimensions, along with proper handling instructions to ensure safe delivery.

Factories must also adhere to Amazon's Supplier Quality Assurance Program, which sets baseline expectations for product quality and operational standards. Shipments must follow Amazon's specific routing and labeling guidelines, including the use of Amazon FBA Box ID labels for tracking. By meeting these requirements, factories can ensure their products are accepted and successfully sold on Amazon, maintaining compliance and customer satisfaction.

12

How will your company communicate with me?

Communication between businesses and customers is a given, so you want to work with a manufacturer that is honest and keeps you informed. If there's a delay in the production schedule, will your sales rep alert you as soon as possible? Will they share your formula with other clients?

Your manufacturer should be upfront about lead times, included services, and expectations both before and after you've signed the contract to begin work.

The PureNSM Promise: We offer you a fully transparent experience from start to finish. We honor your trust in us by keeping you informed every step of the way. If there are any issues with raw materials, testing, formulation, production, packaging, labeling, etc., we won't hesitate to let you know. We'll work with you to find the best solutions to whatever problems arise.

We're committed to addressing any concerns promptly before, during, and after the job is complete.