PureNSM
NUTRITIONAL SUPPLEMENT MANUFACTURERS, INC.

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Certified GMP Compliant by NSF
Make it Organic with PureNSM

Certified FDA Registered by Registrar Corp

# Pitfalls to Avoid and Questions to Ask Supplement Manufacturers
## (before you hire them)

**YOUR REVENUE GROWTH LIVES & DIES BY YOUR QUALITY.** Let us help you get your quality down to a science. Reduce your risk and increase customer satisfaction. It all starts with selecting the right contract manufacturer. So here are some of the **pitfalls to avoid** and **questions to ask**.

## Why is GMP Certification Important?

You don't boil your supplements, do you? You don't taste the capsules and tablets you swallow either. Therefore, it's more important for factories that manufacture those items you consume to follow GMP protocols. Furthermore, many herbs are derived from roots that grow in countries that until recently did not regulate against leaded gasoline. This has caused the herbs finding their way to products sold worldwide to be contaminated by lead. Finally, when you purchase herbal supplements, you want them to be "for real", meaning you want what is stated on the label to be what is in the product.

Manufacturing is a complicated business, please let me explain at the bottom of this report the pitfalls that can only be avoided if the supplements are made in a GMP certified facility.

## Sourcing Pure and Potent Raw Materials

Unfortunately, the regulations governing raw material vendors for supplements are subject to a more relaxed (less stringent) regulation called 21 CFR 117 and not 21 CFR 111, which are stricter and govern supplement manufacturing facilities. FDA claims the 21 CFR 117 regulation needs to be less strict because they sell to several different industries, not only the supplement industry, such as foods, cosmetics, and pharmaceuticals. This shifts the burden of quality control of raw materials to the supplement manufacturers. This is exactly why it's so important that they adhere to strict GMP protocols.

## Avoid GMP Certification Bluffing!

It’s dangerous to take a manufacturer's word at face value, it’s not prudent for example to believe a PDF of GMP certifications from UL or NSF for two reasons:

A. GMP certifications from NSF for operating a GMP **warehouse**, GMP **distribution** and a GMP **manufacturing** facility look THE same!
B. GMP certifications frequently expire
C. The GMP certification may be for a different location

# A Warehouse in Manufacturer’s Clothing?



**The NSF Certification for a Warehouse and Manufacturer Looks the Same! Many factories only have a warehouse certification from NSF**

The only way to verify if the factory you are considering contracting with is certified as ***manufacturer*** is to go to the UL and NSF websites and in the case of NSF ***look for the word "Manufacturing Facility"*** above the name of the company.

For some reason, NSF displays the company name and address twice on the same page. You look for the following designations above the 2nd time they display the company name:

- Manufacturing Facility
- Distribution Facility
- Warehouses Facility
- Packaging Facility
- Ingredients Facility

Only the designation of **Manufacturing Facility** is acceptable for anyone you trust to manufacture your products.

Many factories misleadingly display the NSF icon on their websites as they advertise that they are certified as a **supplement manufacturing facility**, when in fact they are not.

If a factory does not have a **GMP Manufacturing Facility certification** from NSF it means they are not inspected the same way. Raw material testing, in process testing, blend stage testing and finished goods testing are not audited! Having a clean warehouse facility is important, however it's more important to have a verified, audited, and certified GMP system in the manufacturing facility itself.

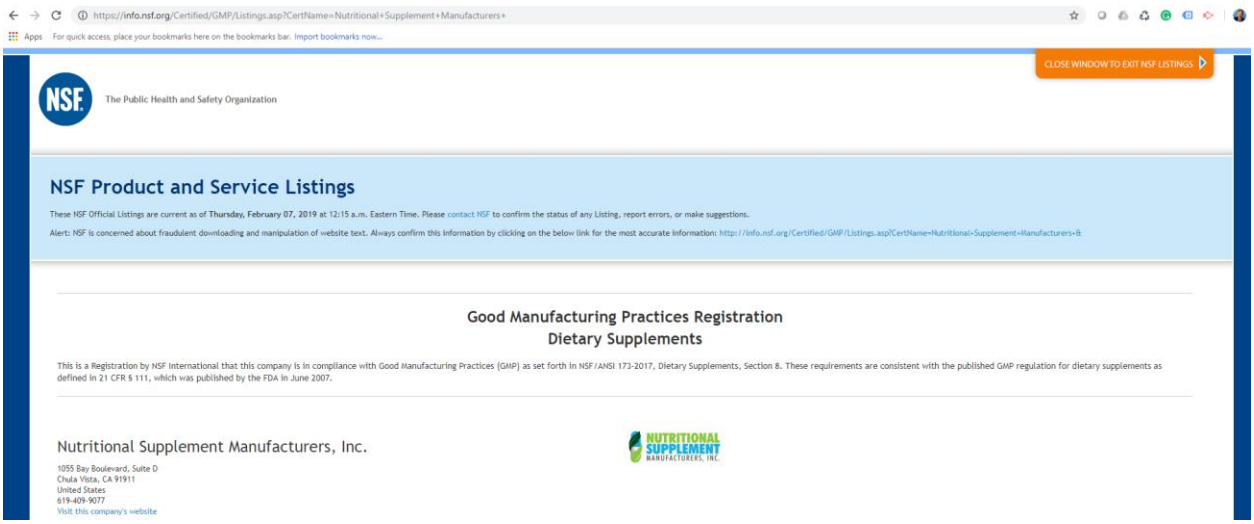
- Your raw material may not be tested for purity, potency and most importantly identity
  - It's common for factories to skip the ID testing for botanicals
  - Those ID tests can only be performed using HPTLC (so ask upfront!)
- Your overages may not be correctly calculated or monitored
  - Your competition can easily find out if you meet label claims
- Your in-process tests may be omitted
- Your finished good testing protocols may be ignored
  - FDA most frequent Warning Letters, called "Form 483" are about failure to perform finished good testing
- Facility may not have BSL-2 microbiology lab

The lack of **GMP Manufacturing Facility certification** can result in adulterated products that don't meet label claims or worse, contaminated products that need to be

recalled. It is therefore important to NOT rely on a PDF of a GMP certification from NSF. The only way to verify a manufacturer is to look them up on the NSF website. You can look us up here:

- **You can verify our NSF certification HERE.**
  Search for us under Manufacturer Name Nutritional Supplement Manufacturers.
  You will see us listed as follows:
    - **Manufacturing Facility**
      Nutritional Supplement Manufacturers, Inc.
      1055 Bay Boulevard Suite D Chula Vista, CA 91911
- **You can verify our UL certification HERE.**
  Click Ctrl+F and search for PureNSM or Nutritional Supplement Manufacturers.

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




# Don’t Fall for Contract Manufactures that only

# Give You a PDF of their NSF Certification!

NSF International

789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA
(800) 673-6275

**Bogus Contract Manufacturer**
**1 My Way, Washington, DC 20500**

has been assessed by NSF International and found to be in compliance with:

**GMP Requirements in**
**NSF/ANSI Standard 173, Section 8**
DIETARY SUPPLEMENTS

Print Date: June 29, 2017
Certificate Number: C0218808 - 05
Initial Certification: June 29, 2017
Expiration Date: December 31, 2017

Cheryl Luther
General Manager, Dietary Supplements and Beverage Quality

## Verify the Location of the Factory

The Sales Executive you talk to must be able to do the following for your quickly:

A. Verify the location of the factory
B. Tell you what name they are certified GMP with NSF and UL, so you can look them up
C. Take you on a quick virtual tour of the factory if they actually have a factory.

**The factory tour:** If the Sales Executive is working from home, she should be able to coordinate with the Production Manager or Supervisors to facilitate a virtual tour.

**Sanitation precautions:** During the tour you should observe carefully that they will be fully "gowned up" with hairnet, gown, shoe covers, and beard-net (if applicable). Some people you talk to won't be able to do that because they actually don't have a factory, they are "middle men".

**Google Map the place:** This is why it's important to google the address and view the aerial map of the address to the factory. Sometimes you end up with a small office in the back of a shopping mall for example. Then you know you are dealing with "middle men".

**Compare address:** Compare the address where you will be **picking the goods up** to the address listed on the NSF website. So before you pay your deposit, ask: "So where will I be picking the finished goods up?"

# Federal Trademarks

Save yourself some time, before you even pick up the phone or email a contract manufacturer make sure they DO NOT display **(1) any unauthorized trademarks from FDA or USDA (2) any made-up GMP icons.**

## Don’t Fall for Unauthorized and Deceitful Use of Federal Trademarks!


If a contract manufacturer displays either the FDA logo or the above USDA trademarked logos, they are doing so WITHOUT a permission.

Registering a company with FDA does not really mean anything, it costs the company 5 minutes and no money to register with the FDA. FDA may not visit that facility because of the registration.

Even if a company registers with FDA it does NOT give them permission to use the FDA or USDA trademarked logos.

# The GMP Bluff


Shutterstock advertises they have 75 "*GMP* icons" to choose from

For those of us who read supplement labels, we have all seen the typical GMP icons that look fancy but don't mean a whole lot. Like these "designer icons". The above icons carry no guarantees of any compliance with GMP protocols! These are simply the opinions of the brand owner, who designs the labels. It's advertising.

amazon

If you need an additional incentive to only manufacture with a certified manufacturer then know that Amazon requires it and is ratcheting up their compliance demand. Here is what they publicly state as requirements for all dietary supplement brands:

A valid **good manufacturing practice (GMP)** certificate issued by an accredited third-party certification body in compliance with 21 CFR 111

Please notice they are not asking for a "valid good warehouse practice" or a "valid good distribution practice".

# Questions to Ask

**We suggest you ask them the following questions:**

# 1. Do you own and operate an HPTLC and do you test 100% of my botanical raw materials on it, and can I get a picture of the results, that show's that my batch has been tested?

**How do you make sure you aren't unintentionally scamming your clients? Do you really know what's in your product?**

If the factory you are hiring does not own and operate an HPTLC system (from CaMag or another comparable brand) and tests 100% of all incoming botanicals, then you may have over **30% chance of not meeting label claims**. Are you sure you want that **liability, karma, reputation**? You put a lot of effort into building a good brand, why not go all the way and ensure your product is up to snuff?

**We reject 10% of all raw herbs and all extracts because the materials fail the HPTLC identification tests. We test 100% of all the botanical raw materials for identity using the HPTLC. This is after operating the system for many years and collecting over 250 standards. When we first installed the system, we rejected about 30% of all raw materials.** You guessed it! Once the suppliers figured out their raw materials would be tested by us, they started shipping us ONLY their best. This means the other stuff goes to the suckers that don't test!

**Understand this: We are buying the very BEST raw materials available from the BEST suppliers in the USA!**

HPTLC is the gold standard for testing herbs for identity. Many of the main US suppliers often get swindled into selling spent herbs. This means they are selling herbs that are left over from the extraction processes. You need to make sure that the manufacturer you choose protects you from this kind of practices.

Also ask the manufacturer how many standards they have on hand to test against on their HPTLC. If they only have 4 standards, then they can only test 4 supplements for identity. We have well over 200 standards and our library is growing.

## ***Ask for a proof!***

Ask to be put in touch with the **Lab Director** and get him/her to email or text you cell phone pictures of your lab results. Please read our report that explains to you in detail what kind of proofs you should be asking for each lot. **If you don't put the time into**

**asking for a proof that your botanical ingredients are tested on an HPTLC, then your product has a 10% chance of being a scam – and you a scam artist! Sorry, but that's the fact of the matter. Ask for the proof!**

## *HPTLC is better than DNA analysis:*

There is a lot of propaganda against supplements, one of the most opportunistic and idiotic propaganda against supplements was when the state of NY tested supplements using DNA analysis. This is not the correct identification test because the DNA is already damaged when the plant has been dried and pulverized into powder. Only fragments of DNA are left at that point. Forbes later explained what happened in this article. https://www.forbes.com/sites/alexmorrell/2015/03/14/did-the-ny-ag-flub-its-testing-in-herbal-supplement-smackdown/#2943c0253114

Therefore, even if a manufacturer claims to verify identity with DNA, do not fall for it. The only way to do so is with HPTLC.

## Don't be fooled!

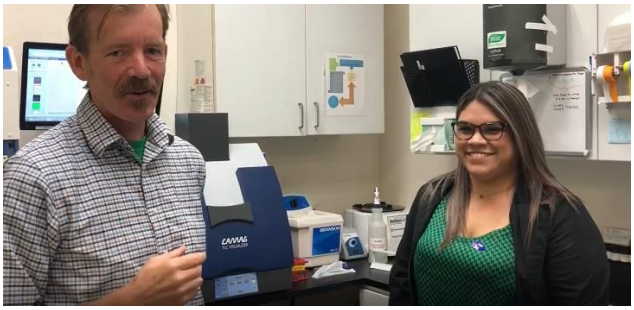
**High-performance thin-layer chromatography = HPTLC = Good for identity testing**

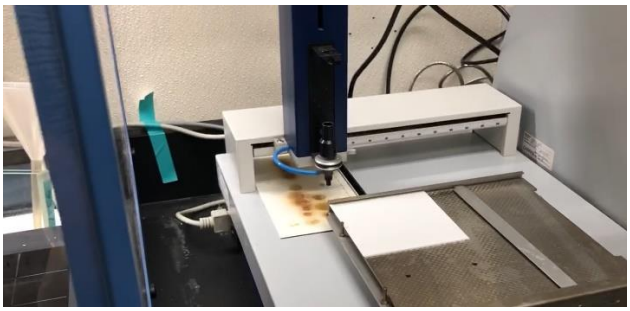
**High-performance liquid chromatography = HPLC = Bad for identity testing (good for potency testing)**

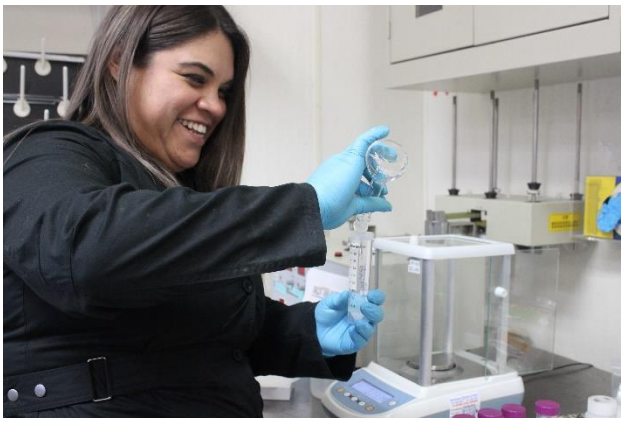
HPLC is used for measuring potency and CANNOT be used for verifying identity of herbs and herbal powders with as much accuracy as the HPTLC system. Further do not be dubbed into the stupidity of verifying botanical ID with FTIR, this should only be used

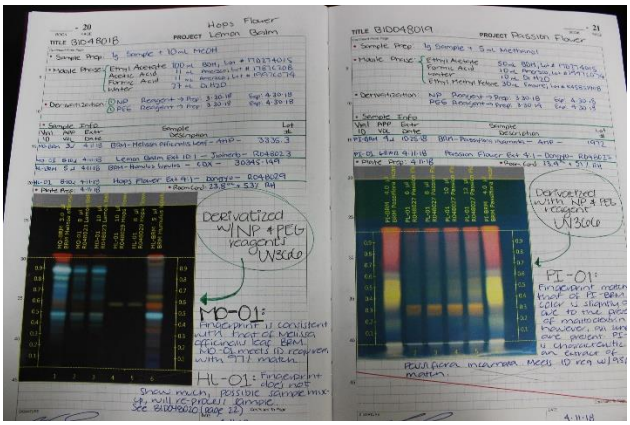
as a secondary method. FTIR is mostly used for verifying ID of amino acids, vitamins and so forth, it should only be used as an auxiliary test method for raw herbs and herbal extracts.

## ***Pictures from our laboratory and office:***









Derivatized w/ NP + PEG reagents UV366
MP-01:
HL-01:
Derivatized w/NP + PEG reagent UV366
PI-01:


UL
CERTIFIED
GMP CERTIFIED FACILITY
Quality Matters. Trust in NSF.
NSF
www.nsf.org
PureNSM

**Read our Report:**
**How to Avoid Dry-Labbing**
***How to ensure your contract factory tests your raw materials and finished goods using correct methods!***
**Dry-Labbing or testing with inappropriate test methods or simply not testing is more common than you think!!!**

## 2. Do you support Organic and Non-GMO Certifications for my brand?

Ask if the manufacturer will support your brand in getting certified. Ask if they are members of the Natural Product Association.

## 3. Do you actually manufacture?

This may sound like a silly question, but we get this question all the time. Some companies that look like large manufacturers are actually “Middle Men” and hire other factories to manufacture the order you may give them.. This causes **longer lead times** but most importantly **loss of control**.

## 4. How many years have you been NSF certified GMP as a Manufacturing Facility?

Another point to consider is that NSF gives a lot of leeway to factories getting their initial NSF certification. Then they make more and more demands as the years progress. WE are on our 8th year with NSF. Case in point, we put enormous emphasis on making sure the overages we put in your product ensure your product meets label claims when tested as finished goods at the end stage of manufacturing. Blending formulas is more complicated than you may initially assume. We have constantly improved our manufacturing processes since 1993.

## 5. Will you work with me to offer my customers a clean label?

There are two types of consumers out there, those looking for best possible price and those that are also concerned about “additional ingredients” that have chemically sounding names, such as Magnesium Stearate”. Many consumers now read the ingredient label backwards and hesitate at point of decision about if they will buy your product or not. They look for words like:

- Magnesium Stearate
- Titanium / Silicon Dioxide
- Cellulose, Silica, Stearic acid and more…

As reported by Natural Foods Merchandiser: “**Consumers want clean labels with words they recognize, and the fewer ingredients the better.**”


## 6. What kinds of testing do you perform inhouse?

It is a good sign if the company has its own in-house lab. It means that they take quality control seriously. However, they also need a Quality Assurance department. Third party testing can be important in some cases, but when it comes to supplement manufacturing a certified laboratory is an absolute must. This is because it increases the speed of manufacturing quality supplements. It also reduces testing costs. You can supplement the testing protocols by opening an account with a testing lab like Eurofins or Dyad Labs and send or have your manufacturer send samples to them for potency testing.

Raw materials must be tested EVERY TIME in accordance with cGMP regulations. Outsourcing all lab tests is prohibitively expensive and time consuming. Therefore, it is a clear sign of poor quality if the manufacturer does not have an in-house lab – and it’s not enough to ask! Get a virtual tour. Ask to look in their lab notebooks. If they say they keep all the information in their computers, then be suspicious. Per GMP you need to keep the info in lab books with numbered pages and each experiment must be signed.

**Questions for Lab Director**

Here are questions to the in-house lab. (Make sure your account representative does NOT answer those questions – insist to talk to the Lab Director).

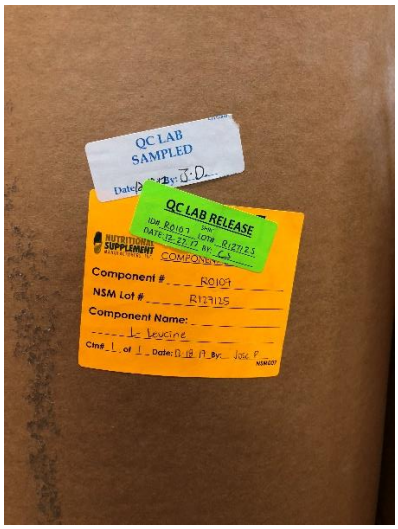
**Question 1:** Who will test my product?
**Question 2:** What equipment will you use when testing for:
1) Identity for raw herbs or herbal extracts?
**ANSWER:** HPTLC note it's not HPLC (if they tell you anything else then run away!!!)
2) Identity for raw materials OTHER than herbs or herbal extracts?
**ANSWER:** FTIR and or HPLC and HPTLC
3) Detection of heavy metals to protect myself from prop 65?
**ANSWER:** ICP-MS (no other answer is good enough)
4) Detection of microbiology
**ANSWER:** Automated Soleris equipment, plate counting in a BSL-2 micro laboratory with 3M system as an option also. If they only have the 3M system then this is not good enough, they can't test for all that is required. Also, Biolumix is out of date and not supported or calibratable anymore.
5) Detection of potency
**ANSWER:** HPLC, UPLC and sometimes we send to 3rd party labs
**More Questions about quality:** Can the Lab Manager give me a tour, virtual or in person, of your laboratory. Can I review your test results that are attached to the production records? Can I inspect your laboratory documentation in your lab book that has numbered pages? Can the Quality Assurance Manager give me a tour of the quarantine system?


## 7. Does your factory follow FDA's cGMP SOPs and MBRs?

**Talk is cheap. Action is golden.** The kind of company you want to work with should painstakingly follow all SOPs and MBRs. Ask to be taken on a tour around the facility and then when you see some production workers taking powder or capsules from a container, do a quick inspection. Check if the container has three stickers on it. All raw materials should have:

- Quarantine Sticker
- Testing Sticker
- Release Sticker

Standard Operating Procedure (SOP) and Master Batch Record (MBR) should be correctly filled out.




Also, ask your contract manufacturer to show you examples of Production Records that have been filled out by their staff.

## 8. What is your company's communication style?

Don't get hooked on a contract manufacturer if they don't communicate with integrity and not on time, are they truthful about their certifications? This would be the first sign.

## 9. Will you protect me against PROPOSITION 65 and the resulting financial losses and recalls?

You don't want to get caught in this trap by working with a company that doesn't know the proper testing to comply with California's Proposition 65. If they don't have an ICP-MS then they can't test your product in-house. Are they able to calculate and inform you about the proper dosage allowed for your formulation? If you sell online your products may find its way to California and this is why you need to comply no matter where you manufacture.

## 10. Will you give me guidance on label regulations?


An experienced contract manufacturer can help you with your label, although the ultimate responsibility of the label rests in your hands, and no one will have studied it more than you.

Ask them if they think your “Structure and Function” claim is up to par. What documentation do you need to have handy to substantiate your claim? Is your supplement box correct?

## 11. Will you drop ship the products for me?

If you ever want them to ship directly to your customers, make sure they can do this for you. The fact is that FedEx, UPS and others do not allow “fulfillment companies” to

charge low shipping rates. Only if the company sold you the products can they charge you the low rates. The carriers do that in order to protect themselves.

As an example, if you take your product to a fulfillment house they will have to charge you $5 whereas if you have your manufacturer send the product they can do so for $3. The savings add up.


## 12. Ask for a Price Match for Same Quality!


We guarantee that the price we quote you is the very best value for money in the industry, please feel free to review our Price Guarantee. You can find a lower price but not for the same safety and quality. If you find a better price, then we will match it. We are generally 10% to 30% below other quality manufacturers.

# Why is GMP Certification Important? Continued

## The Identity Crisis

When you see the VeriGMP icon on your supplements, rest assured that 100% of all incoming botanical raw materials have been tested for identity using the most advanced ID testing methods available, abbreviated HPTLC. Not to be confused with another system used to analyze for potency called HPLC.

We estimate that about 30% of the raw materials sold to manufacturers are adulterated. We know that the only way to protect the consumer from those adulterated herbal raw materials is to test them at the point of manufacture for identity and authenticity.

**For the nerds:** HPTLC stands for High-performance thin-layer chromatography. HPLC stands for High-performance liquid chromatography.

PureNSM uses the HPTLC system from CaMag and has over 300 methods developed. HPTLC is considered by FDA to be better than DNA analysis because it does not rely on fragments of DNA that is frequently damaged when plants have been ground to powder. PureNSM analyzes both raw plant powders and extracts successfully and identifies species, plant parts and if the plant material has been extracted already.

## Bugs in Your Supplements?

You don't wash or boil most supplements; in fact, you swallow most whole. That's precisely why it's so important to only ingest trustworthy supplements. VeriGMP makes sure your supplements have passed the purity test with a battery of microbiological analytical methods.

**For the nerds:** PureNSM uses the Soleris rapid microbiology systems, the traditional plate count methods in a BSL-2 laboratory and the 3M parafilm plate reader. It's not possible to rely on one system and that is why we use all three.

## Heavy Metals in Your Supplements?

Heavy metals are not fun, they are found in food but also in supplements, especially supplements from roots. Heavy metals such as lead find their ways to plant materials from decades of use of leaded gasoline in India and other countries.

**For the nerds:** PureNSM uses ICP-MS from Perkin Elmer.

# Potency Check?

It's important to analyze both raw materials and "finished-goods" for quality (identity, potency, purity). PureNSM tests for potency twice, when we receive the raw materials

and once the product has been manufactured, at the end stage of manufacturing. This is the only way to make sure what is stated on the label is actually in the supplements. This is done with a variety of analytical instruments, HPLC being one of them.

**For the nerds:** PureNSM uses the HPLC system from Agilent, 1100 Series. In addition, PureNSM relies on lab partners such as Dyad and Eurofins.