PureNSM
NUTRITIONAL SUPPLEMENT MANUFACTURERS, INC.

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How to Avoid Dry Labbing

Ensuring That Your Contract Manufacturer Tests Your Raw Materials and Finished Goods Using the Correct Methods

There's a lot of hard work that goes into creating a new dietary supplement. Each step from the idea phase to finally selling your product requires planning and thoughtful decision-making. Choosing the right contract manufacturer is just one piece of the puzzle. But you're risking your brand's reputation and more if you're putting so much trust in your contract manufacturer that you don't ask about pre- and post-production testing procedures.

Dry labbing, or the act of supplying fictional yet plausible results in lieu of performing an assigned experiment, is a shady business practice that puts unsuspecting supplement brand owners at risk of ruin. The only way to know that you're not being duped is to demand proof of testing from your contact manufacturer. Whether the testing is done on-site at your manufacturer's facility or they outsource it to an independent lab, make sure you get copies of those test results.

Even if your contact manufacturer is registered with the FDA or certified by NSF, it's no guarantee that your products will be tested correctly. A contract manufacturer's inefficient or deceitful business practices that went into making an inferior product won't cover up a brand owner's neglect to ensure that proper testing was done. As a brand owner, you're 100% liable.

Dietary supplements are no stranger to lawsuits and lengthy court battles. When this happens, the product in question's manufacturing records are thoroughly scrutinized. Raw material records from the supplier and those from the manufacturer are put under the microscope. Production records are analyzed thoroughly. And testing methods and their results are dissected with precision. More often than not, the fault lies in testing. Either insufficient testing or no testing at all.

If your product has been implicated in someone's death, you could be facing manslaughter charges. How? Something as innocuous as vitamin D can be dangerous, and even deadly, if the potency per dose was not tested properly. If your finished product had a higher vitamin D potency than what you claimed on the label, you could be implicated in causing a customer's kidney failure, or worse.

Not quite as dramatic but equally tarnishing to your band's reputation, if your product is found in violation of California Proposition 65 you could face fines of up to $2,500 per day per dose. So, if you sold 10,000 bottles with 30 doses each, the fine quickly adds up to $750 million.

California Proposition 65 (Prop 65)

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.

If your products are sold or consumed in the state of California, regardless of your physical location, you need to comply with Prop 65.

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.

When your products reach the open market, they are subject to testing by federal and state FDA, or anyone who wants to check your label claims for accuracy – that the potency per dose is spot on and that the ingredients listed on the label are a true representation of what's actually in your product.

Have Your Raw Materials Tested the Right Way

You don't have to be a scientist or a doctor to formulate supplements. But you do want to ensure that your finished product is safe when taken as directed. Part of that safety is having each ingredient in your formula tested with the proper method. Here's a breakdown of different raw materials most likely to be in supplement form and the most accurate way to test them.

Botanicals & Non-Standardized Botanical Extracts

Identity: Fingerprinting botanical ingredients needs be done with HPTLC (high performance thin layer chromatography). Avoid any contract manufacturer or independent lab that tells you they can skip HPTLC and test identity using HPLC (high

performance liquid chromatography) or FTIR (Fourier-transform infrared spectroscopy) instead.

Some raw material suppliers claim they identity test their botanicals using FTIR; however, all botanicals look the same under FTIR. There's no way to differentiate one from another based on their infrared spectrum. HPTLC offers the most accurate fingerprint, showing all the characteristic metabolites for each botanical. So steer clear of suppliers and contract manufacturers who only use FTIR to identify herbs.

Microbiology: Nowadays there are many alternative methods to the classic plate count assessment. The Biolumix or Soleris systems offer rapid microbiology analysis that is validated against US Pharmacopeia's microbiology requirements for nutritional and dietary supplements. Each is an automated system that gives accurate results within 48 hours compared to the conventional manual plate count method, which can be inaccurate and subjective while requiring considerably more time.

At a minimum, your products need to be tested for total aerobic microbial count, total yeast and mold count, Enterobacteria, Coliforms, E. coli, Salmonella, and Staphylococcus.

Heavy Metals: The ideal test for presence of heavy metals is ICP-MS (inductively coupled plasma mass spectroscopy). It's also the method of choice of the US Pharmacopeia Convention. Some suppliers may report heavy metal results as "not detected". This is often a sign that they're using instruments that are not sensitive enough to detect trace amounts of harmful heavy metals. Inferior methods such as atomic absorption spectroscopy or ICP-OES (inductively coupled plasma optical emission spectroscopy) may not hold up if your product were to be tested the by the FDA using ICP-MS.

Standardized Botanical Extracts

Standardized exacts need to undergo the same identity, microbiology, and heavy metal testing as their non-standardized counterparts, but they also need potency analysis. You want this done using HPLC instead of UV spectroscopy or titration.

Why is the method of potency testing so important? Here's proof from our own lab: One of our suppliers sent us Boswellia serrata with 65% boswellic acids (according to them), but they did not disclose their testing methods. When we tested the material using HPLC, our results showed only 18% boswellic acids. When we confronted the supplier about the discrepancy, they explained that using the titration method would yield a result of 65% boswellic acids.

Nutraceuticals, Vitamins & Amino Acids

For these types of nutrients, insist on microbiology testing on either a Biolumix or Soleris system. Heavy metals should be tested with ICP-MS. Unlike botanicals, however, FTIR is a suitable method to test identity. For purity and potency testing, use HPLC and gas chromatography.

Minerals

For minerals, you want microbiology done with Biolumix or Soleris systems, heavy metals and potency done with IPC-MS, and identity done with FTIR.

Enzymes

Enzymes need to be tested for activity levels. We highly suggest that this is done by a US laboratory. From our experience, enzyme assays done in China or India frequently exaggerate the true enzyme activity compared to testing done in the US. This is why it's crucial that your contact manufacturer tests your enzyme material before the production phase, even if the raw material supplier provides their own assessment of enzyme activity. The extra testing can prevent you from making inaccurate label claims.

Probiotics

Probiotics are somewhat fragile because they are live microorganisms, and they can be harmed if conditions are not right. Probiotics need to be tested for potency or activity levels (colony forming units) of the strains indicated. And they need microbiology contamination testing as well.

Don't Forget About Finished Product Testing

Even if every single raw material in your product was tested on its own before production, you still need to ensure that the finished product is tested as well. This ensures you and your customers that no contamination happened during the production phase.

Finished products need to be tested for microbiology and heavy metals. You also need to make sure that your contract manufacturer tests your product against your label claims. That means they're verifying the amount of each ingredient per serving and the ingredients themselves to make sure your finished product matches what is stated on your label.

Unfortunately, many manufacturers skip this important step. If the FDA were to inspect your contract manufacturer's facility and found that they haven't been performing

finished product testing on each lot or batch, the FDA would issue them a Form 483, an official notice that the facility is in violation of the Food Drug and Cosmetics Act.

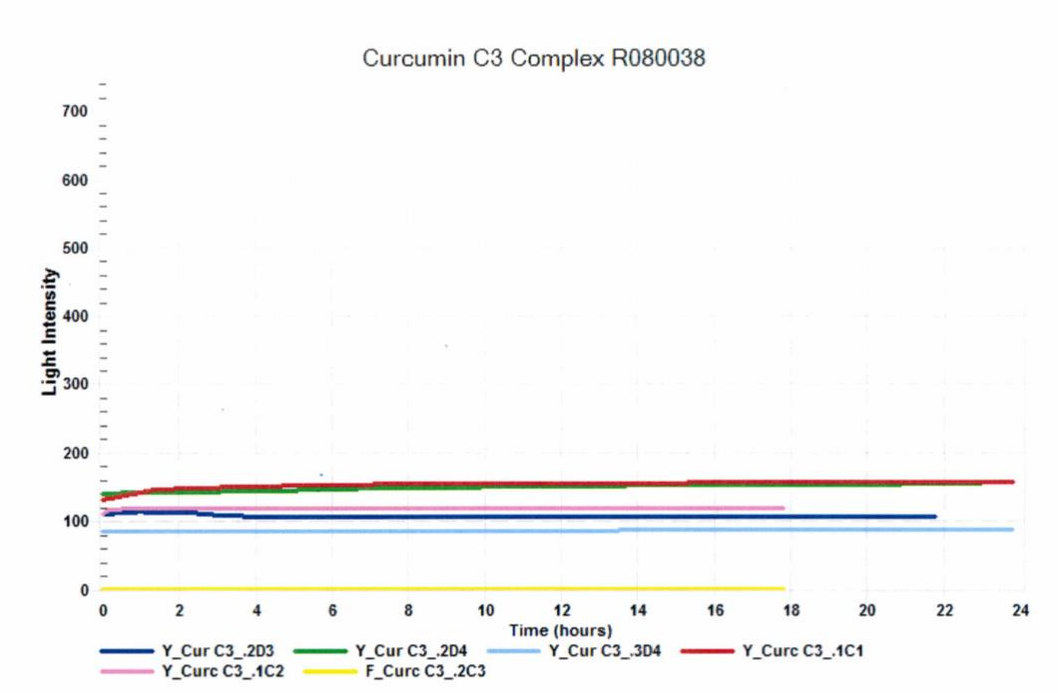
What Proof of Testing Should You Ask For?

Ultimately, it's your product and your reputation at stake if the proper testing procedures are not followed. You have the right to receive proof of **all** testing done on your product. In fact, for your first two or three production jobs with a new manufacturer, ask for copies of all testing done on each raw material and finished product. If you stick with the same manufacturer, continue to ask for proof from time to time.

As previously stated, the type of raw materials in your product will dictate what tests should be done. Keep the following proof of testing in mind and request the ones applicable to your product.

Microbiology
Request either photo, print or scanned results for the following microbiology tests: total aerobic microbial count, total yeast and mold count Enterobacteria, E. coli, Salmonella, Staphylococcus.

If your contract manufacturer uses the Biolumix system, your test proofs may look something like this example of curcumin that shows no spike in CO2 to indicate microbial growth.



Microbiology Certificate of Analysis

Make sure you also ask for the Certificate of Analysis (COA) for the microbiology test for the individual raw materials in your product. Here's an example of what a COA looks like.

23-Mar-2020

Certificate of Analysis

Pure NSM Inc.
Microbiology Research and Quality Control

Sample (Product) ID: Mg Citrate

Product (Group): Nutraceutical
Batch/Lot: R030034
Source: GW
Test Dates: 3/16/2020 - 3/23/2020

Assay(Test)	Result (CFU/g)	Status
Yeast&Mold	<100	Pass
TAC 100	<100	Pass
Enterobacteria	<100	Pass
Ecoli	<0.1	Pass
Salmonella	<0.1	Pass
Staphylococcus	<0.1	Pass

* Absent in 10 units is indicated by <0.1

Analyst
3/23/2020
Date

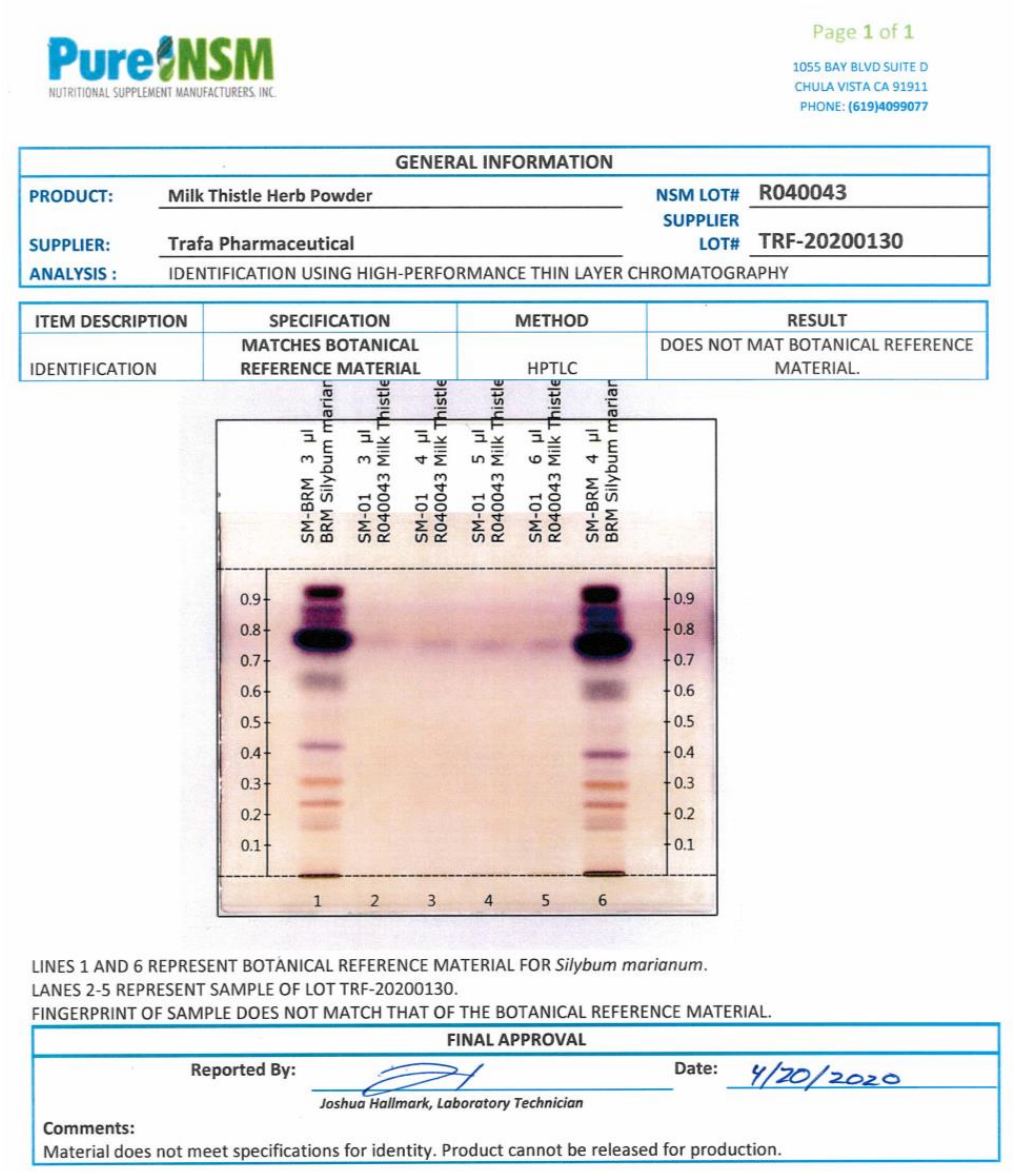
Reviewer
3.30.2020
Date

Botanical Identity

Identity testing of botanical ingredients needs to be performed 100% of the time – no exceptions.

The test results should be precisely documented in a laboratory book. Each botanical should include a six-column printout of the HPTCL reading: the furthest columns on the left and right represent a verified raw material sample; the four middle columns represent the botanical being tested. The match can never be more than 99% and never below 90%. Ask for either a copy of the lab book page or a printout of the test results including the HPTCL reading.

Here's an example of botanical sample that failed identity testing on HPTLC.



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1055 BAY BLVD SUITE D
CHULA VISTA CA 91911
PHONE: (619)4099077

GENERAL INFORMATION			
PRODUCT:	Milk Thistle Herb Powder	NSM LOT#	R040043
SUPPLIER:	Trafa Pharmaceutical	SUPPLIER LOT#	TRF-20200130
ANALYSIS :	IDENTIFICATION USING HIGH-PERFORMANCE THIN LAYER CHROMATOGRAPHY		

ITEM DESCRIPTION	SPECIFICATION	METHOD	RESULT
IDENTIFICATION	MATCHES BOTANICAL REFERENCE MATERIAL	HPTLC	DOES NOT MAT BOTANICAL REFERENCE MATERIAL.

LINES 1 AND 6 REPRESENT BOTANICAL REFERENCE MATERIAL FOR *Silybum marianum*.
LANES 2-5 REPRESENT SAMPLE OF LOT TRF-20200130.
FINGERPRINT OF SAMPLE DOES NOT MATCH THAT OF THE BOTANICAL REFERENCE MATERIAL.

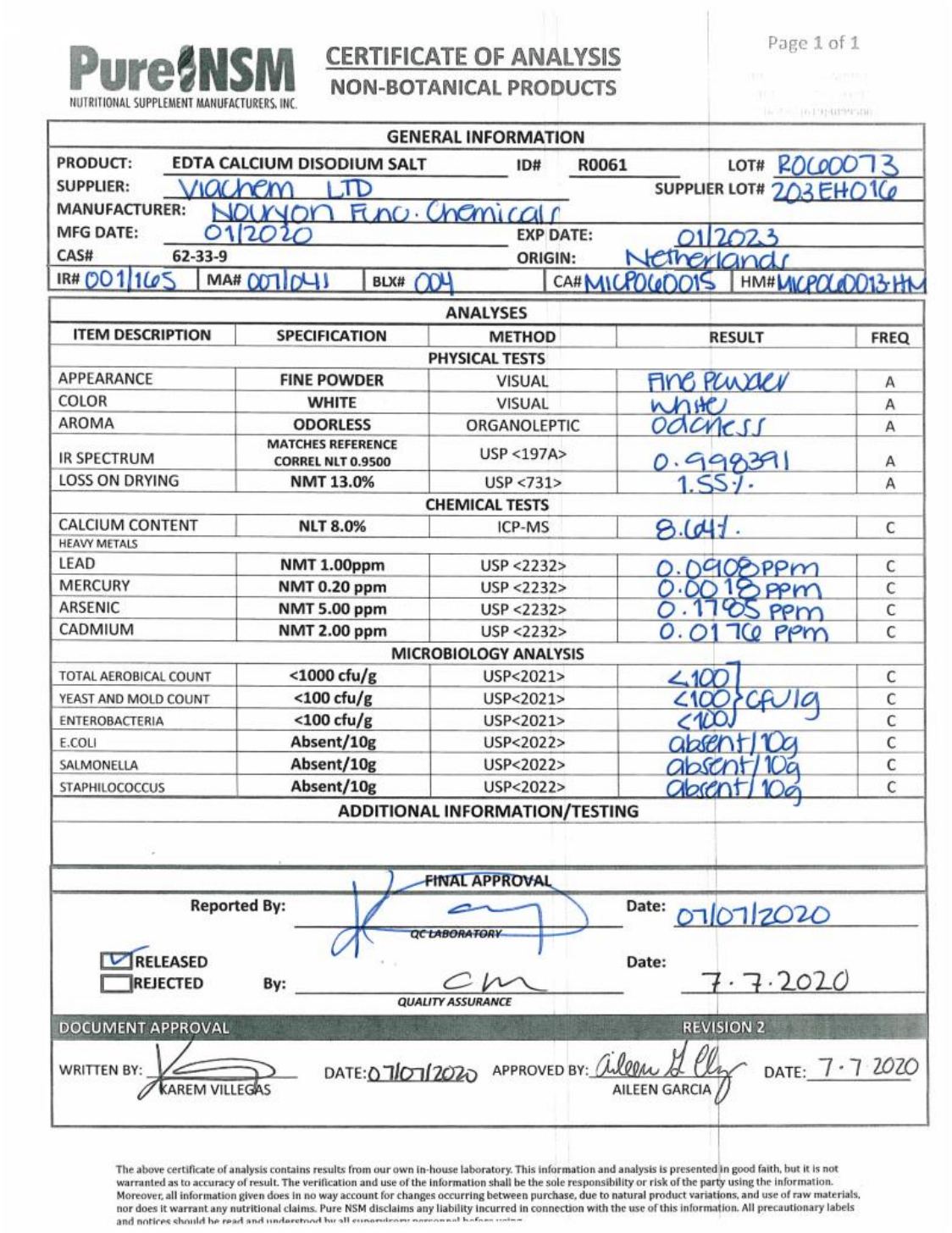
FINAL APPROVAL

Reported By: *Joshua Hallmark, Laboratory Technician* Date: 4/20/2020

Comments:
Material does not meet specifications for identity. Product cannot be released for production.

Raw Material Certificate of Analysis

Whether you're dealing with botanicals, vitamins, minerals, or other nutritional ingredients, ask for a copy of each raw material's COA. The COA is a snapshot of both the physical and chemical identity as well as the microbiology and heavy metal analysis. You can expect to get something like this:



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CERTIFICATE OF ANALYSIS
NON-BOTANICAL PRODUCTS

Page 1 of 1

GENERAL INFORMATION

PRODUCT:	EDTA CALCIUM DISODIUM SALT	ID# R0061	LOT# R0C00073
SUPPLIER:	Viachem LTD		SUPPLIER LOT# 203EH016
MANUFACTURER:	Nouryon Func. Chemicals		
MFG DATE:	01/2020	EXP DATE:	01/2023
CAS#	62-33-9	ORIGIN:	Netherlands
IR# 001/165	MA# 007/041	BLX# 004	CA# MICP0C00015 HM# MICP0C00013 HM

ANALYSES

ITEM DESCRIPTION	SPECIFICATION	METHOD	RESULT	FREQ
		PHYSICAL TESTS		
APPEARANCE	FINE POWDER	VISUAL	Fine Powder	A
COLOR	WHITE	VISUAL	White	A
AROMA	ODORLESS	ORGANOLEPTIC	Odorless	A
IR SPECTRUM	MATCHES REFERENCE CORREL NLT 0.9500	USP <197A>	0.998391	A
LOSS ON DRYING	NMT 13.0%	USP <731>	1.55%	A
		CHEMICAL TESTS		
CALCIUM CONTENT	NLT 8.0%	ICP-MS	8.64%	C
HEAVY METALS				
LEAD	NMT 1.00ppm	USP <2232>	0.0908 ppm	C
MERCURY	NMT 0.20 ppm	USP <2232>	0.0018 ppm	C
ARSENIC	NMT 5.00 ppm	USP <2232>	0.1795 ppm	C
CADMIUM	NMT 2.00 ppm	USP <2232>	0.0176 ppm	C
		MICROBIOLOGY ANALYSIS		
TOTAL AEROBICAL COUNT	<1000 cfu/g	USP<2021>	<100	C
YEAST AND MOLD COUNT	<100 cfu/g	USP<2021>	<100 cfu/g	C
ENTEROBACTERIA	<100 cfu/g	USP<2021>	<100	C
E.COLI	Absent/10g	USP<2022>	absent/10g	C
SALMONELLA	Absent/10g	USP<2022>	absent/10g	C
STAPHILOCOCCUS	Absent/10g	USP<2022>	absent/10g	C

ADDITIONAL INFORMATION/TESTING

FINAL APPROVAL

Reported By: _____ QC LABORATORY Date: 07/07/2020

☑ RELEASED
☐ REJECTED

By: _____ QUALITY ASSURANCE Date: 7.7.2020

DOCUMENT APPROVAL REVISION 2

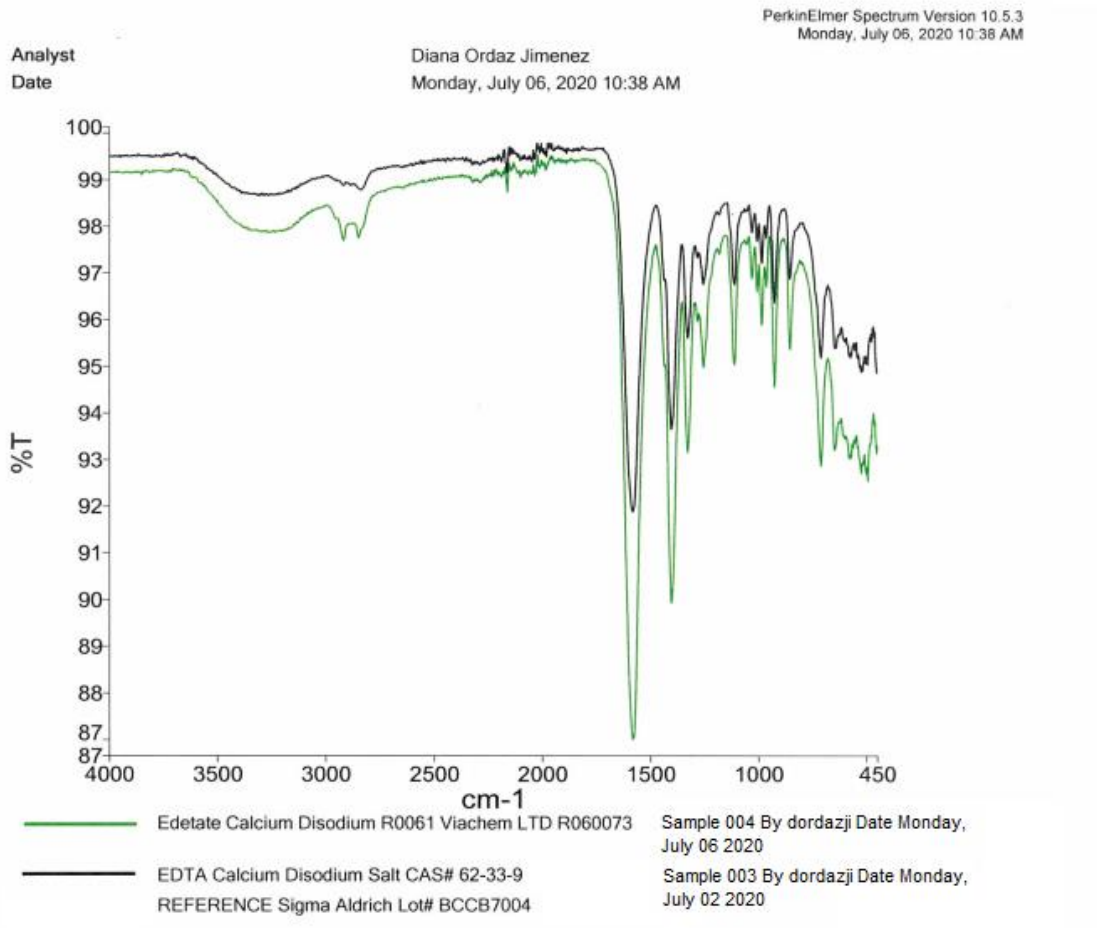
WRITTEN BY: _____ KAREM VILLEGAS DATE: 07/07/2020

APPROVED BY: _____ AILEEN GARCIA DATE: 7.7.2020

The above certificate of analysis contains results from our own in-house laboratory. This information and analysis is presented in good faith, but it is not warranted as to accuracy of result. The verification and use of the information shall be the sole responsibility or risk of the party using the information. Moreover, all information given does in no way account for changes occurring between purchase, due to natural product variations, and use of raw materials, nor does it warrant any nutritional claims. Pure NSM disclaims any liability incurred in connection with the use of this information. All precautionary labels and notices should be read and understood by all supervisory personnel before using

FTIR Results

Remember, if your contact manufacturer only tests botanical ingredients with FTIR, the test results may not be accurate. If they supply FTIR analysis of botanicals, demand that they follow up with HPTLC as well. FTIR is more likely the type of test result you'll receive for amino acids, vitamins, and minerals. Here's what you can expect:

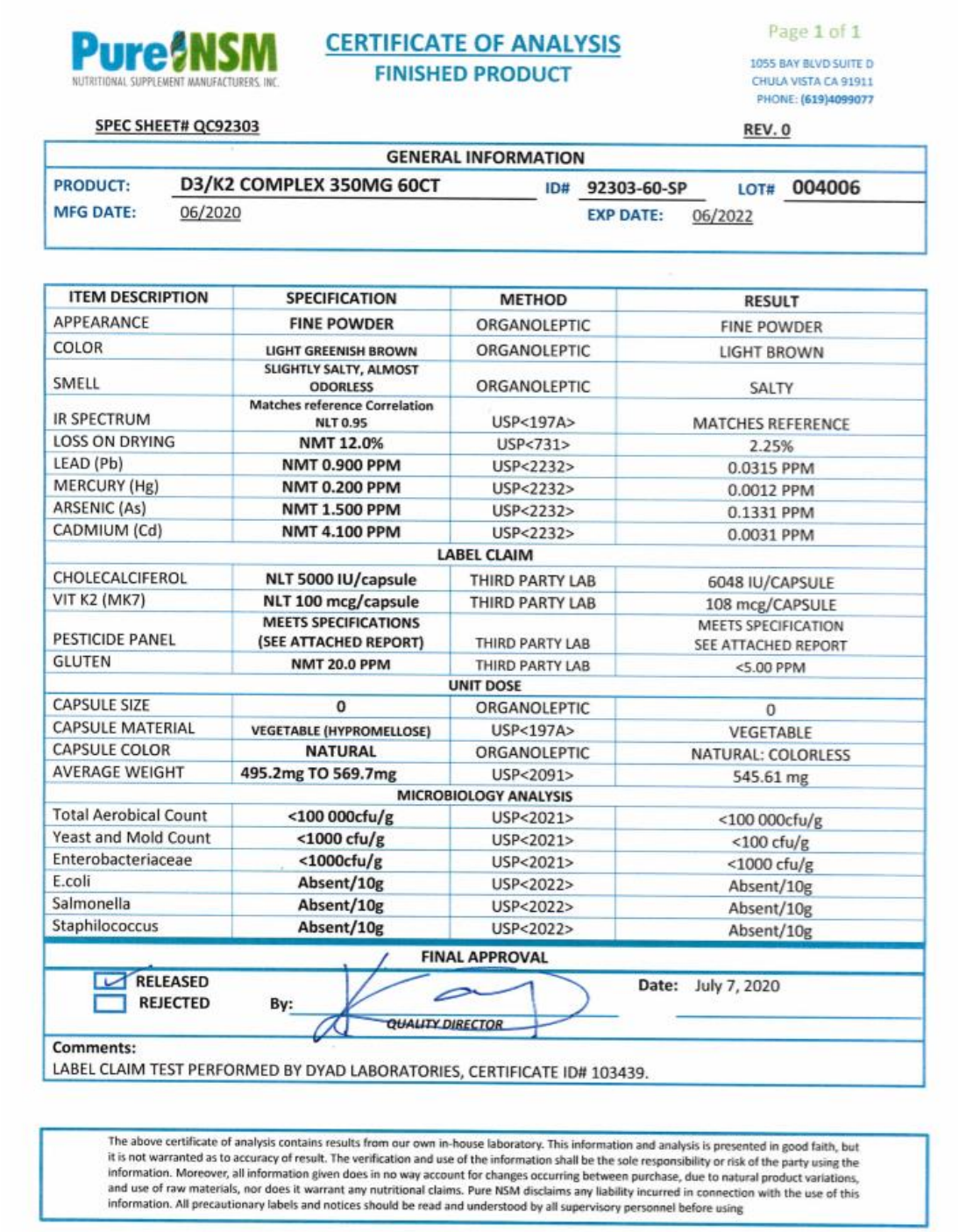


Source Spectra			
Sample Name	**Best Hit**	**Correlation**	**Pass / Fail**
Edetate Calcium Disodium R0061 Viachem LTD R060073	M:\Laboratory Files\FTIR Spectrum 2 Data\Results\Raw Material References\EDTA Calcium Disodium Salt CAS# 62-33-9 REFERENCE Sigma Aldrich Lot# BCCB7004.sp	0.998391	Pass

Compared References		
Sample Name	**Correlation**	**Pass / Fail**
M:\Laboratory Files\FTIR Spectrum 2 Data\Results\Raw Material References\EDTA Calcium Disodium Salt CAS# 62-33-9 REFERENCE Sigma Aldrich Lot# BCCB7004.sp	0.998391	Pass

Finished Product Certificate of Analysis

Even though you've asked your contract manufacturer to supply test results for each raw material, it's always a good idea to ask for proof of finished product testing as well. A finished product COA should include your product name, lot number, manufacture date, expiration or best by date, physical description, label claims, heavy metal analysis, and microbial analysis. Here's an example of what one looks like:



Pure NSM
NUTRITIONAL SUPPLEMENT MANUFACTURERS, INC.

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Page 1 of 1

1055 BAY BLVD SUITE D
CHULA VISTA CA 91911
PHONE: (619)4099077

SPEC SHEET# QC92303 REV. 0

GENERAL INFORMATION

PRODUCT: D3/K2 COMPLEX 350MG 60CT ID# 92303-60-SP LOT# 004006
MFG DATE: 06/2020 EXP DATE: 06/2022

ITEM DESCRIPTION	SPECIFICATION	METHOD	RESULT
APPEARANCE	FINE POWDER	ORGANOLEPTIC	FINE POWDER
COLOR	LIGHT GREENISH BROWN	ORGANOLEPTIC	LIGHT BROWN
SMELL	SLIGHTLY SALTY, ALMOST ODORLESS	ORGANOLEPTIC	SALTY
IR SPECTRUM	Matches reference Correlation NLT 0.95	USP<197A>	MATCHES REFERENCE
LOSS ON DRYING	NMT 12.0%	USP<731>	2.25%
LEAD (Pb)	NMT 0.900 PPM	USP<2232>	0.0315 PPM
MERCURY (Hg)	NMT 0.200 PPM	USP<2232>	0.0012 PPM
ARSENIC (As)	NMT 1.500 PPM	USP<2232>	0.1331 PPM
CADMIUM (Cd)	NMT 4.100 PPM	USP<2232>	0.0031 PPM
LABEL CLAIM			
CHOLECALCIFEROL	NLT 5000 IU/capsule	THIRD PARTY LAB	6048 IU/CAPSULE
VIT K2 (MK7)	NLT 100 mcg/capsule	THIRD PARTY LAB	108 mcg/CAPSULE
PESTICIDE PANEL	MEETS SPECIFICATIONS (SEE ATTACHED REPORT)	THIRD PARTY LAB	MEETS SPECIFICATION SEE ATTACHED REPORT
GLUTEN	NMT 20.0 PPM	THIRD PARTY LAB	<5.00 PPM
UNIT DOSE			
CAPSULE SIZE	0	ORGANOLEPTIC	0
CAPSULE MATERIAL	VEGETABLE (HYPROMELLOSE)	USP<197A>	VEGETABLE
CAPSULE COLOR	NATURAL	ORGANOLEPTIC	NATURAL: COLORLESS
AVERAGE WEIGHT	495.2mg TO 569.7mg	USP<2091>	545.61 mg
MICROBIOLOGY ANALYSIS			
Total Aerobical Count	<100 000cfu/g	USP<2021>	<100 000cfu/g
Yeast and Mold Count	<1000 cfu/g	USP<2021>	<100 cfu/g
Enterobacteriaceae	<1000cfu/g	USP<2021>	<1000 cfu/g
E.coli	Absent/10g	USP<2022>	Absent/10g
Salmonella	Absent/10g	USP<2022>	Absent/10g
Staphilococcus	Absent/10g	USP<2022>	Absent/10g

FINAL APPROVAL

☑ RELEASED
☐ REJECTED

By: QUALITY DIRECTOR

Date: July 7, 2020

Comments:
LABEL CLAIM TEST PERFORMED BY DYAD LABORATORIES, CERTIFICATE ID# 103439.

The above certificate of analysis contains results from our own in-house laboratory. This information and analysis is presented in good faith, but it is not warranted as to accuracy of result. The verification and use of the information shall be the sole responsibility or risk of the party using the information. Moreover, all information given does in no way account for changes occurring between purchase, due to natural product variations, and use of raw materials, nor does it warrant any nutritional claims. Pure NSM disclaims any liability incurred in connection with the use of this information. All precautionary labels and notices should be read and understood by all supervisory personnel before using

Hopefully, you now realize how essential testing is when making dietary supplements. If your product comes under fire for harming someone, not meeting label claims (adulterated ingredients, inaccurate potency, unlisted ingredients, etc.) or violating Prop 65, you will need accurate proof of testing to plead your case. Working with a trustworthy contract manufacturer with meticulous testing protocols is your first step in avoiding legal trouble.

Partner with **PureNSM** if you're looking for a contract manufacturer that is completely transparent about testing procedures. Our on-site, state-of-the-art lab is run by a team committed to helping you create a product that fully complies with quality and safety standards.