

GENERAL INFORMATION

PRODUCT: CISTANCHE TUBULOSA **ID#** 92492
MFG FOR: EARTH ELIXIR **LOT#** 302011 **MFG DATE:** 04/2023 **EXP DATE:** 04/2025

TESTING DATA

ITEM DESCRIPTION	SPECIFICATION	METHOD	RESULT
APPEARANCE	FINE LOOSE POWDER	ORGANOLEPTIC	FINE POWDER
COLOR	BROWN WITH WHITE SPECKS	ORGANOLEPTIC	BROWN WITH WHITE SPECKS
SMELL	SWEET AND EARTHY	ORGANOLEPTIC	SWEET AROMA
IR SPECTRUM	MATCHES REFERENCE 92492 CORRELATION NLT 0.9500	USP<197A>	NO IR REFERENCE

HEAVY METAL ANALYSIS

LEAD (Pb)	NMT 0.625 PPM	USP<2232>	0.0424 PPM
MERCURY (Hg)	NMT 2.500 PPM	USP<2232>	0.1172 PPM
ARSENIC (As)	NMT 4.000 PPM	USP<2232>	0.1455 PPM
CADMIUM (Cd)	NMT 0.625 PPM	USP<2232>	0.0113 PPM

UNIT DOSE

CAPSULE SIZE	1	ORGANOLEPTIC	1
CAPSULE MATERIAL	VEGETABLE (CELLULOSE)	USP<197A>	VEGETABLE
CAPSULE COLOR	NATURAL: COLORLESS	ORGANOLEPTIC	NATURAL
AVERAGE WEIGHT	443.61MG TO 510.39MG	USP<2091>	481.26 MG

MICROBIOLOGY ANALYSIS

TOTAL AEROBICAL COUNT	NMT 10 000 000 CFU/G	USP<2021>	<10,000,000 CFU/G
YEAST & MOLD COUNT	NMT 100 000 CFU/G	USP<2021>	<100,000 CFU/G
ENTEROBACTERIACEAE	NMT 10 000 CFU/G	USP<2021>	<10,000 CFU/G
E.COLI	ABSENT IN 10G	USP<2022>	ABSENT/10G
SALMONELLA	ABSENT IN 10G	USP<2022>	ABSENT/10G
STAPHYLOCOCCUS	ABSENT IN 10G	USP<2022>	ABSENT/10G

FINAL APPROVAL

REPORTED BY: DATE: 06.05.2023
QUALITY CONTROL

RELEASED
 REJECTED BY: DATE: 6/6/23
QUALITY ASSURANCE

COMMENTS:

GENERAL INFORMATION

PRODUCT: CISTANCHE TUBULOSA **ID#** 92492
MFG FOR: EARTH ELIXIR **LOT#** 302011 **MFG DATE:** 04/2023 **EXP DATE:** 04/2025

PRODUCT COMPOSITION

INGREDIENT NAME	AMOUNT PER CAPSULE (MG)	% PER CAPSULE
INGREDIENTS WITH A CLAIMED CONCENTRATION ON LABEL		
None	0	0
INGREDIENTS THAT DO NOT HAVE A CLAIMED CONCENTRATION ON LABEL		
Cistanche Tubulosa Extract 45%	200.00	50.0000
Rice Flour	200.00	50.0000
TOTAL:	400.00	100.0000



Above-listed proprietary blend of botanical ingredients cannot be quantitatively tested in the finished product. As these ingredients are in their natural state any testable phytochemical would have such a wide variance in result that it renders the ingredient untestable. The result of this is that the ingredients in this finished product cannot be quantitatively tested. Input quantities are supported by validated procedures and batch record paperwork.

**NON-ACTIVE INGREDIENTS:	Cellulose (Vegetarian empty capsule)
SERVING SIZE:	2 Capsules
ALLERGEN:	None
DIETARY DECLARATIONS:	Shellfish, Preservative, Sugar, GMO, Gluten & Dairy free.
STORAGE CONDITIONS:	Room temperature. Away from excessive heat and humidity.
SHELF LIFE:	2 years

DOCUMENT CONTROL

SPEC SHEET # QC92492

REV 0

WRITTEN:  **DATE:** 06-05-2023 **APPROVED:**  **DATE:** 6/6/23

GENERAL INFORMATION			
PRODUCT #	92492-180-SP	REV#	0
PRODUCT NAME:	SP Cistanche, 180ct	CUSTOMER:	Earth Elixir

IN-PROCESS CHECK: FINAL BLEND			
SAMPLE RECEIVED:	TIME: <u>6:30AM</u>	DATE: <u>5-5-23</u>	LOGGED BY: <u>JML</u>

CHARACTERISTIC	SPECIFICATIONS	RESULTS	REFERENCE	PASS	FAIL
FORM	Fine Loose Powder	<u>Fine Pwd</u>	ORGANOLEPTIC	<input checked="" type="radio"/>	F
COLOR	Brown with White Specks	<u>Brown w/ white specks</u>	ORGANOLEPTIC	<input checked="" type="radio"/>	F
SMELL	Sweet and Earthy	<u>Sweet aroma</u>	ORGANOLEPTIC	<input checked="" type="radio"/>	F
OVERALL APPEARANCE	Uniform color. No Clumping.	<u>uniform color No clumping</u>	ORGANOLEPTIC	<input checked="" type="radio"/>	F
IR SPECTRUM	MATCHES REF# 92492	CORRELATION: <u>NR</u>	USP<197A>	P	F
	CORRELATION NLT 0.9500				
% MOISTURE	NMT 10%	<u>3.20%</u>	USP<731>	<input checked="" type="radio"/>	F
HEAVY METALS	Lead: NMT 0.625 PPM Mercury: NMT 2.500 PPM Arsenic: NMT 4.000 PPM Cadmium: NMT 0.625 PPM	Lead: <u>0.04248 ppm</u> Mercury: <u>0.11727 ppm</u> Arsenic: <u>0.14552 ppm</u> Cadmium: <u>0.01134 ppm</u>	USP<2232> & Prop 65 REPORT# <u>MICP053001-44</u>	<input checked="" type="radio"/>	F

COMMENTS:

TESTED BY: [Signature] DATE: 05.05.2023

CONCLUSION:

PASS FAIL BY: [Signature] DATE: 6/7/23

DOCUMENT CONTROL			REV 0
WRITTEN: <u>[Signature]</u>	DATE: <u>05-03-2023</u>	APPROVED: <u>[Signature]</u>	DATE: <u>5/4/2023</u>

GENERAL INFORMATION			
PRODUCT #	92492-180-SP	REV#	0
PRODUCT NAME:	SP Cistanche, 180ct	CUSTOMER:	Earth Elixir

IN-PROCESS CHECK: ENCAPSULATION

SAMPLE RECEIVED: TIME: 6:30 AM DATE: 05.05.23 LOGGED BY: JUL

CHARACTERISTIC	SPECIFICATIONS	RESULTS	REFERENCE	PASS	FAIL
CAPSULE SIZE	1	1	ORGANOLEPTIC	Ⓟ	F
INSPECTION	Capsules are completely closed. No damage observed. Polished and free of residues or stains.	<i>capsules completely closed No damage, polished and Free of residues</i>	ORGANOLEPTIC	Ⓟ	F
MATERIAL	Vegetable	<i>Vegetable; 0.975706</i>	USP<197A>	Ⓟ	F
CAPSULE COLOR	Clear, Colorless	<i>Colorless</i>	ORGANOLEPTIC	Ⓟ	F
WEIGHT	TARGET WT: 477.0 mg ACTUAL FILL WT: 400.0 mg EACH CAPSULE MUST WEIGH: 443.61 mg - 510.39 mg	1) <u>480.0</u> 11) <u>466.4</u> 2) <u>490.6</u> 12) <u>480.8</u> 3) <u>499.0</u> 13) <u>463.4</u> 4) <u>487.5</u> 14) <u>486.7</u> 5) <u>469.2</u> 15) <u>481.4</u> 6) <u>485.1</u> 16) <u>483.4</u> 7) <u>475.5</u> 17) <u>480.0</u> 8) <u>477.1</u> 18) <u>472.4</u> 9) <u>475.2</u> 19) <u>480.9</u> 10) <u>479.1</u> 20) <u>465.2</u> AVERAGE: <u>478.9</u>	USP<2091>	Ⓟ	F

COMMENTS: *Caps #1*

TESTED BY: *[Signature]* DATE: 05.05.23

CONCLUSION:

PASS

FAIL

BY: *[Signature]* DATE: 6/7/23

DOCUMENT CONTROL REV 0

WRITTEN: *[Signature]* DATE: 05.03.2023 APPROVED: *[Signature]* DATE: 5/4/2023

GENERAL INFORMATION			
PRODUCT #	92492-180-SP	REV#	0
PRODUCT NAME:	SP Cistanche, 180ct	CUSTOMER:	Earth Elixir

IN-PROCESS CHECK: ENCAPSULATION

SAMPLE RECEIVED: TIME: 6:30 AM DATE: 05-05-23 LOGGED BY: IML

CHARACTERISTIC	SPECIFICATIONS	RESULTS	REFERENCE	PASS	FAIL																						
CAPSULE SIZE	1	1	ORGANOLEPTIC	(P)	F																						
INSPECTION	Capsules are completely closed. No damage observed. Polished and free of residues or stains.	Capsules completely closed No damage, polished and Free of residues	ORGANOLEPTIC	(P)	F																						
MATERIAL	Vegetable	<u>Vegetable; 0.990959</u>	USP<197A>	(P)	F																						
CAPSULE COLOR	Clear, Colorless	<u>Clear, colorless</u>	ORGANOLEPTIC	(P)	F																						
WEIGHT	TARGET WT: 477.0 mg ACTUAL FILL WT: 400.0 mg EACH CAPSULE MUST WEIGH: 443.61 mg - 510.39 mg	<table border="0"> <tr><td>1) <u>500.1</u></td><td>11) <u>490.1</u></td></tr> <tr><td>2) <u>461.8</u></td><td>12) <u>469.5</u></td></tr> <tr><td>3) <u>460.3</u></td><td>13) <u>480.6</u></td></tr> <tr><td>4) <u>464.1</u></td><td>14) <u>488.9</u></td></tr> <tr><td>5) <u>504.8</u></td><td>15) <u>497.6</u></td></tr> <tr><td>6) <u>488.1</u></td><td>16) <u>495.6</u></td></tr> <tr><td>7) <u>481.5</u></td><td>17) <u>487.4</u></td></tr> <tr><td>8) <u>475.5</u></td><td>18) <u>461.1</u></td></tr> <tr><td>9) <u>485.3</u></td><td>19) <u>490.9</u></td></tr> <tr><td>10) <u>493.0</u></td><td>20) <u>483.4</u></td></tr> <tr><td colspan="2">AVERAGE: <u>482.9</u></td></tr> </table>	1) <u>500.1</u>	11) <u>490.1</u>	2) <u>461.8</u>	12) <u>469.5</u>	3) <u>460.3</u>	13) <u>480.6</u>	4) <u>464.1</u>	14) <u>488.9</u>	5) <u>504.8</u>	15) <u>497.6</u>	6) <u>488.1</u>	16) <u>495.6</u>	7) <u>481.5</u>	17) <u>487.4</u>	8) <u>475.5</u>	18) <u>461.1</u>	9) <u>485.3</u>	19) <u>490.9</u>	10) <u>493.0</u>	20) <u>483.4</u>	AVERAGE: <u>482.9</u>		USP<2091>	(P)	F
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AVERAGE: <u>482.9</u>																											

COMMENTS: Caps #2

TESTED BY: [Signature] DATE: 05-05-23

CONCLUSION:

PASS FAIL BY: [Signature] DATE: 6/7/23

DOCUMENT CONTROL		REV 0
WRITTEN: <u>[Signature]</u>	DATE: <u>05-03-2023</u>	APPROVED: <u>[Signature]</u> DATE: <u>5/4/2023</u>

GENERAL INFORMATION			
PRODUCT #	92492-180-SP	REV#	0
PRODUCT NAME:	SP Cistanche, 180ct	CUSTOMER:	Earth Elixir

IN-PROCESS CHECK: <u>ENCAPSULATION</u>			
SAMPLE RECEIVED:	TIME: <u>6:30 AM</u>	DATE: <u>05.05.23</u>	LOGGED BY: <u>TW</u>

CHARACTERISTIC	SPECIFICATIONS	RESULTS	REFERENCE	PASS	FAIL																						
CAPSULE SIZE	1	1	ORGANOLEPTIC	(P)	F																						
INSPECTION	Capsules are completely closed. No damage observed. Polished and free of residues or stains.	<i>capsules completely closed No damage, polished and Free of residues</i>	ORGANOLEPTIC	(P)	F																						
MATERIAL	Vegetable	<i>Vegetable; 0.987395</i>	USP<197A>	(P)	F																						
CAPSULE COLOR	Clear, Colorless	<i>Colorless</i>	ORGANOLEPTIC	(P)	F																						
WEIGHT	TARGET WT: 477.0 mg ACTUAL FILL WT: 400.0 mg EACH CAPSULE MUST WEIGH: 443.61 mg - 510.39 mg	<table border="0"> <tr><td>1) <u>487.6</u></td><td>11) <u>480.1</u></td></tr> <tr><td>2) <u>483.0</u></td><td>12) <u>486.6</u></td></tr> <tr><td>3) <u>494.7</u></td><td>13) <u>459.5</u></td></tr> <tr><td>4) <u>467.0</u></td><td>14) <u>497.2</u></td></tr> <tr><td>5) <u>481.7</u></td><td>15) <u>476.7</u></td></tr> <tr><td>6) <u>491.5</u></td><td>16) <u>488.8</u></td></tr> <tr><td>7) <u>485.9</u></td><td>17) <u>478.9</u></td></tr> <tr><td>8) <u>483.3</u></td><td>18) <u>472.8</u></td></tr> <tr><td>9) <u>474.6</u></td><td>19) <u>492.3</u></td></tr> <tr><td>10) <u>473.8</u></td><td>20) <u>484.2</u></td></tr> <tr><td colspan="2">AVERAGE: <u>482.0</u></td></tr> </table>	1) <u>487.6</u>	11) <u>480.1</u>	2) <u>483.0</u>	12) <u>486.6</u>	3) <u>494.7</u>	13) <u>459.5</u>	4) <u>467.0</u>	14) <u>497.2</u>	5) <u>481.7</u>	15) <u>476.7</u>	6) <u>491.5</u>	16) <u>488.8</u>	7) <u>485.9</u>	17) <u>478.9</u>	8) <u>483.3</u>	18) <u>472.8</u>	9) <u>474.6</u>	19) <u>492.3</u>	10) <u>473.8</u>	20) <u>484.2</u>	AVERAGE: <u>482.0</u>		USP<2091>	(P)	F
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AVERAGE: <u>482.0</u>																											

COMMENTS: *Caps #3*

TESTED BY: *[Signature]* DATE: 05.05.23

CONCLUSION:

PASS FAIL BY: *[Signature]* DATE: 6/7/23

DOCUMENT CONTROL			REV 0
WRITTEN: <u><i>[Signature]</i></u>	DATE: <u>05.03.2023</u>	APPROVED: <u><i>[Signature]</i></u>	DATE: <u>5/4/2023</u>

GENERAL INFORMATION			
PRODUCT #	92492-180-SP	REV#	0
PRODUCT NAME:	SP Cistanche, 180ct	CUSTOMER:	Earth Elixir

IN-PROCESS CHECK: FINISHED PRODUCT

SAMPLE RECEIVED: TIME: 12:00pm DATE: 05.31.2023 LOGGED BY: MPR

CHARACTERISTIC	SPECIFICATIONS	COMPLIES		COMMENTS	METHOD
		YES	NO		
APPEARANCE	Capsules are polished and free of damage. No dust or residue observed in the bottle.	✓			ORGANOLEPTIC
CONTAINER SPECS	200cc Light Amber Bottle PET	✓			ORGANOLEPTIC
CONTAINER EXAM	Containers are free of damage	✓			ORGANOLEPTIC
CAP SPECS	Black Ribbed Skirt Lid w/ Unprinted Pressure Sensitive Liner	✓			ORGANOLEPTIC
CAP EXAM	Lids are tightly screwed. Liner sticks to bottle when opened.	✓			ORGANOLEPTIC
SEAL	Clear Bands No Print	✓			ORGANOLEPTIC
CONTENTS	180ct SP Cistance caps 1ct Rayon Coil	✓			ORGANOLEPTIC
LABEL	Customer's "Cistanche Tubulosa, 180ct" label. Labels are aligned and centered. No damage, wrinkles, or creases observed.	✓			ORGANOLEPTIC
ADDITIONAL SPECS	Lot number and 2 year expiration date are printed on the bottle's bottom Information matches batch record.	✓		LOT# <u>302011</u> EXP: <u>04.2025</u>	ORGANOLEPTIC

MICROBIOLOGY ANALYSIS

EQUIPMENT: Solaris DATES FROM 5.31.23 THROUGH 6.2.23

PARAMETER	SPECIFICATIONS	RESULT	METHOD	P	F
AEROBICAL COUNT	$<10^7$ $<10^6$ CFU/G *	<u>$<10,000,000$</u>	USP<2021>	(P)	F
YEAST & MOLD	$<10^5$ $<10^4$ CFU/G *	<u>$<100,000$</u>	USP<2021>	(P)	F
ENTEROBACTERIA	$<10^4$ $<10^3$ CFU/G *	<u>$<10,000$</u>	USP<2021>	(P)	F
E. COLI	ABS/10G	<u>Absent 10g</u>	USP<2022>	(P)	F
SALMONELLA	ABS/10G	<u>Absent 10g</u>	USP<2022>	(P)	F
STAPHYLOCCOCUS	ABS/10G	<u>Absent 10g</u>	USP<2022>	(P)	F

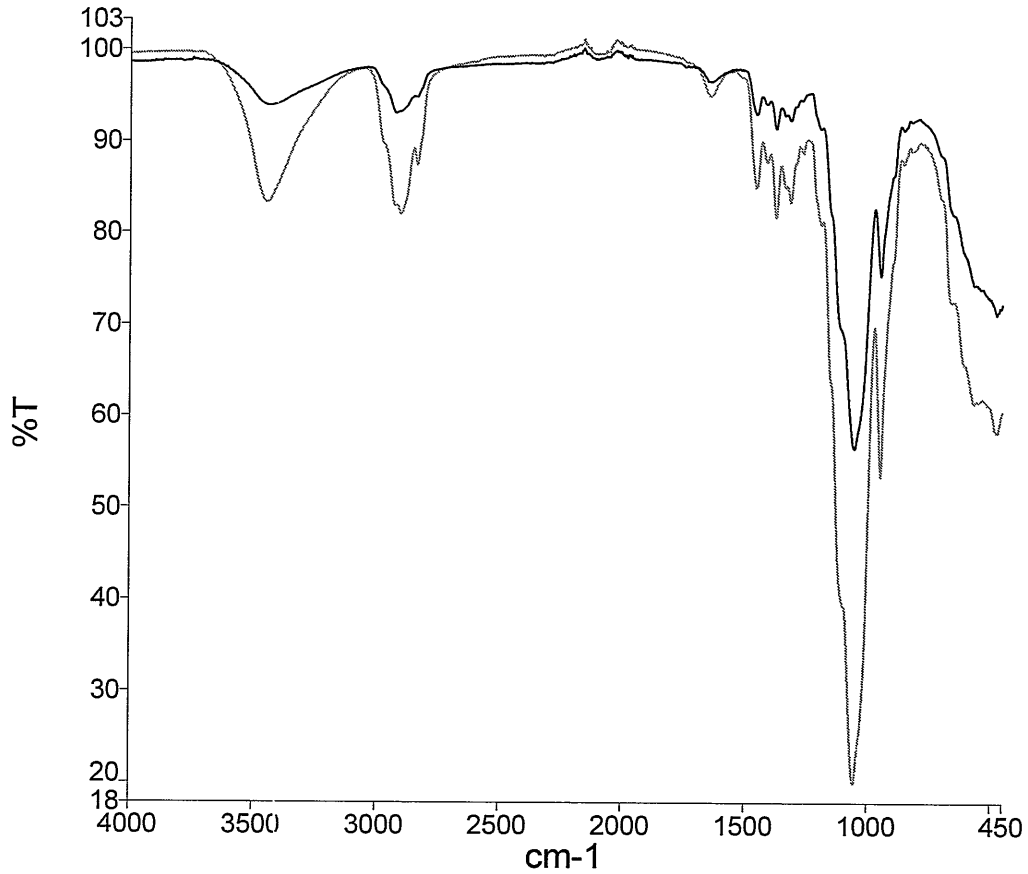
COMMENTS: updating to NSF SPECS. Added Rice Flour to the formula.

TESTED BY: [Signature] DATE: 06.02.2023

FINAL PRODUCT RELEASE:

DOCUMENT CONTROL			
WRITTEN: <u>[Signature]</u>	DATE: <u>05.03.2023</u>	APPROVED: <u>[Signature]</u>	REV 0 DATE: <u>5/9/2023</u>

Analyst Micaela Reichenbach
Date Friday, May 05, 2023 9:58 AM

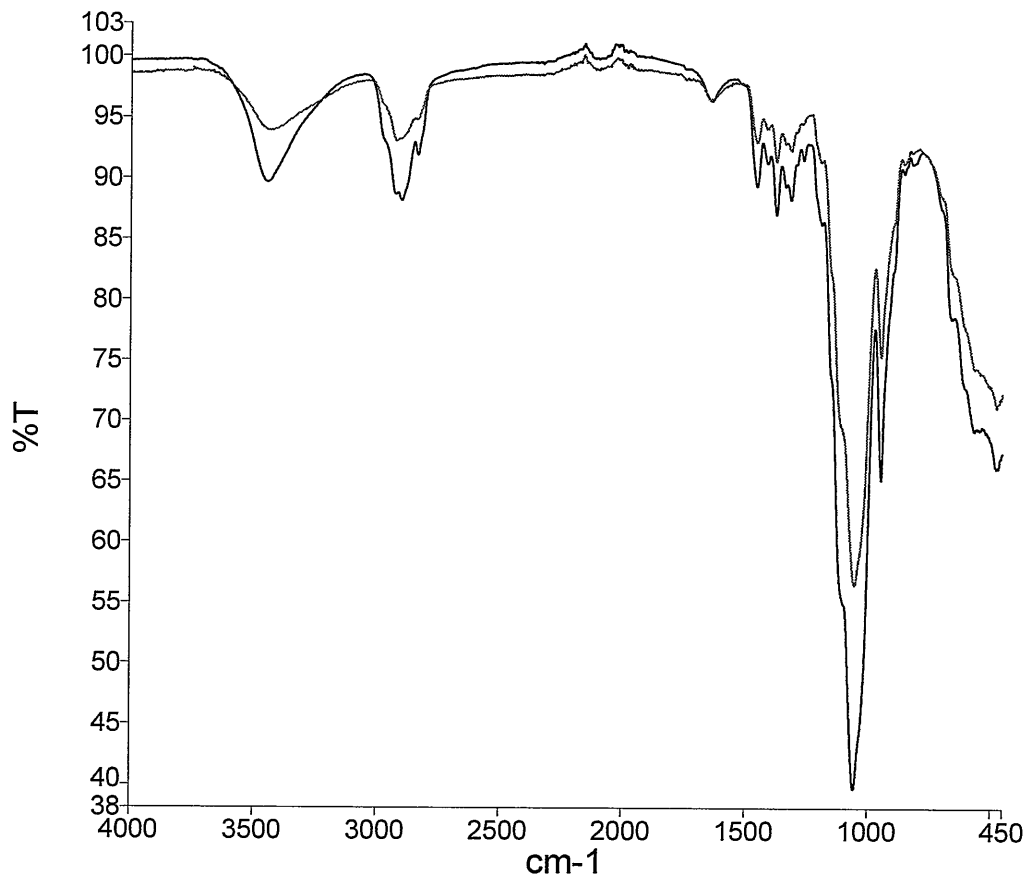


----- 92492-180-SP Cistanche Caps#1 Lot# 302011 Sample 028 By Micaela Date Friday, May 05 2023
 _____ Empty Vegetable Capsule REFERENCE By kvillegas Date Tuesday, January 03 2017

Source Spectra			
Sample Name	Best Hit	Correlation	Pass / Fail
92492-180-SP Cistanche Caps#1 Lot# 302011	C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp	0.975706	Pass

Compared References		
Sample Name	Correlation	Pass / Fail
C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp	0.975706	Pass

Analyst Micaela Reichenbach
Date Friday, May 05, 2023 9:57 AM

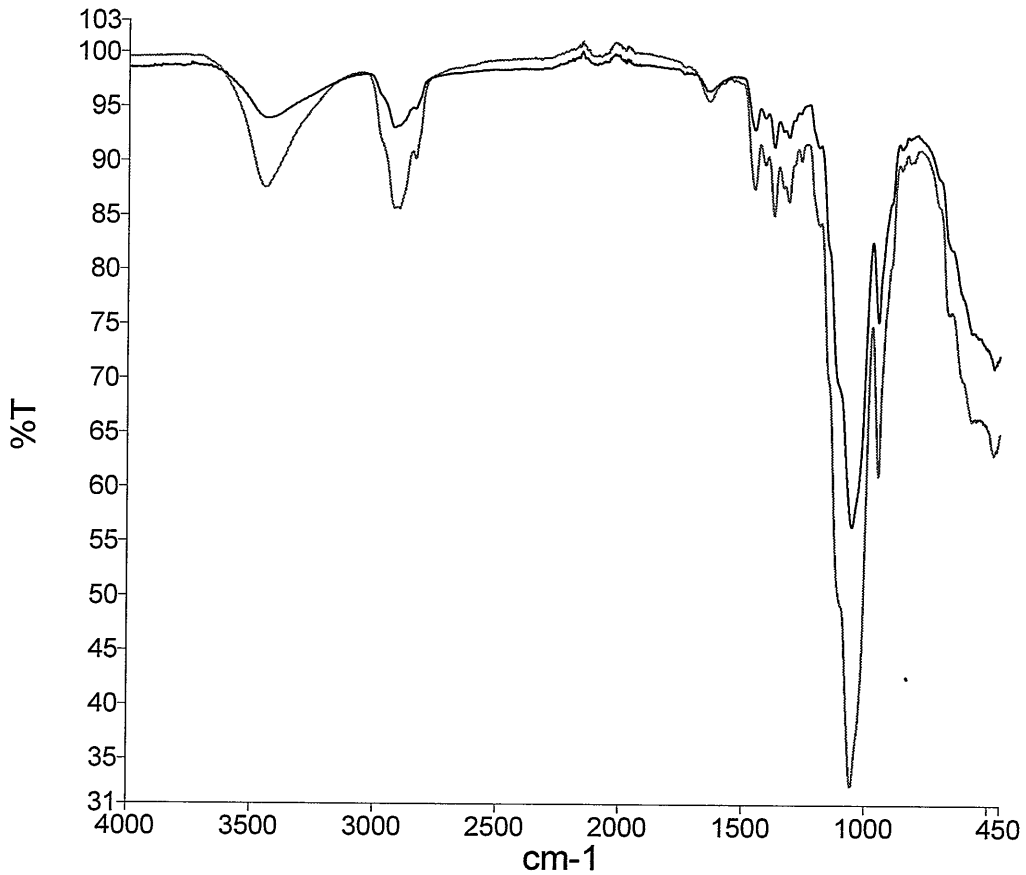


———— 92492-180-SP Cistanche Caps#2 Lot# 302011 Sample 029 By Micaela Date Friday, May 05 2023
 - - - - Empty Vegetable Capsule REFERENCE By kvillegas Date Tuesday, January 03 2017

Source Spectra			
Sample Name	Best Hit	Correlation	Pass / Fail
92492-180-SP Cistanche Caps#2 Lot# 302011	C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp	0.990959	Pass

Compared References		
Sample Name	Correlation	Pass / Fail
C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp	0.990959	Pass

Analyst Micaela Reichenbach
Date Friday, May 05, 2023 10:03 AM



92492-180-SP Cistanche 180ct Caps#3 Lot# 302011 Sample 030 By Micaela Date Friday, May 05 2023
 Empty Vegetable Capsule REFERENCE By kvillegas Date Tuesday, January 03 2017

Source Spectra			
Sample Name	Best Hit	Correlation	Pass / Fail
92492-180-SP Cistanche 180ct Caps#3 Lot# 302011	C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp	0.987395	Pass

Compared References			
Sample Name		Correlation	Pass / Fail
C:\LABFiles\FTIR Spectrum 2 Data\Results\Empty Capsule References\Empty Vegetable Capsule REFERENCE.sp		0.987395	Pass

Certificate of Analysis

Sample ID: **SP Cistanche 302011**

Test Dates: **5/31/2023 - 6/2/2023**

Start Date	Test	Product
5/31/2023 2:07:58 PM	YM 100,000	Yeast & Mold
Stopped Date	Result	Specification / Presence
6/2/2023 2:07:58 PM	Pass	<100,000 cfu/gram
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	

Start Date	Test	Product
5/31/2023 2:09:08 PM	TAC 10,000,000	Raw Botanicals (NSF)
Stopped Date	Result	Specification / Presence
6/1/2023 2:09:08 PM	Pass	<10,000,000 cfu/gram
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	

Start Date	Test	Product
5/31/2023 2:09:08 PM	Entero 10,000	Raw Botanicals (NSF)
Stopped Date	Result	Specification / Presence
6/1/2023 8:09:08 AM	Pass	<10,000 cfu/gram
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	

Start Date	Test	Product
6/1/2023 1:58:25 PM	E.coli	2nd Day
Stopped Date	Result	Specification / Presence
6/2/2023 1:58:25 PM	Pass	Absent/10g
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	

Start Date	Test	Product
6/1/2023 1:58:25 PM	Salmonella	2nd Day
Stopped Date	Result	Specification / Presence
6/2/2023 9:58:25 AM	Pass	Absent/10g
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	Confirmed Negative with reason: Negative Salmonella confirmation test(Reveal 2.0 Immunological Strip)

Start Date	Test	Product
6/1/2023 1:58:25 PM	Staph	2nd Day
Stopped Date	Result	Specification / Presence
6/2/2023 11:58:25 AM	Pass	Absent/10g
Production Lot	User	Confirmation Reason
302011	Idelle Montanez	

Operators:

Idelle Montanez

Idelle Montanez 06/02/2023

Sample ID: SP Cistanche 302011

Test Dates: 5/31/2023 - 6/2/2023

Managers:

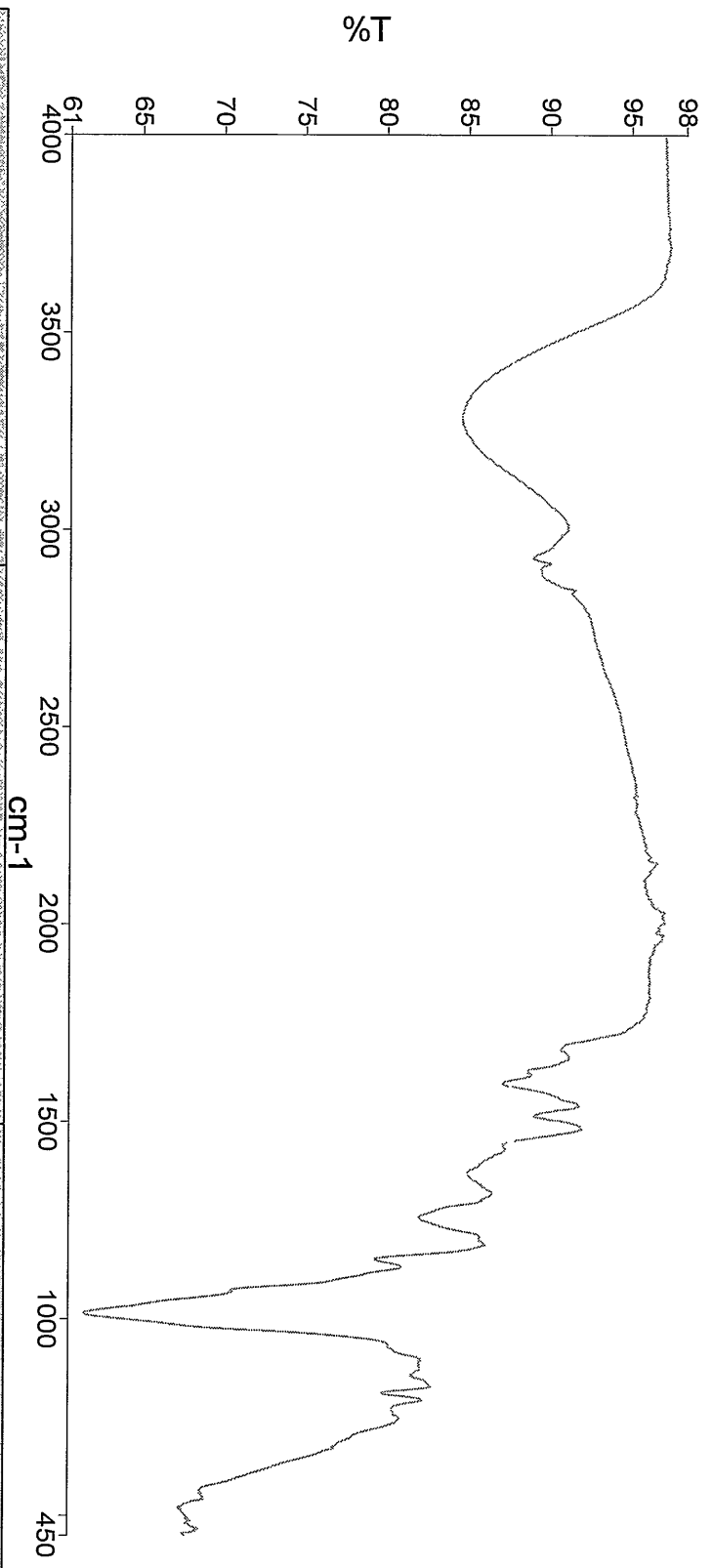
Quality Assurance

G. Veletu 6/7/23

Analyst
Date

Micaela Reichenbach
Friday, May 05, 2023 9:46 AM

PerkinElmer Spectrum Version 10.5.3
Friday, May 05, 2023 9:46 AM



Sample Name	Description	Quality Checks
92492-180-SP Cistanche-180ct lot# 302011	Sample 027 By Micaela Date Friday, May 05 2023	The Quality Checks give rise to a Weak Bands warning for the sample.