



108 Coronado Court
Fort Collins, Colorado 80525
Fort Collins: (970) 266-8108
Denver: (303) 530-1169

ROCKY MOUNTAIN INSTRUMENTAL LABORATORIES, INC.

August 21, 2001

Victor Comerchero
RW Young Enterprises
140 Ravenna Way
El Dorado Hills, CA 95762

Dear Mr. Comerchero,

Enclosed is the report regarding the samples of PC SPES, Prostate Formula, sent for DES analysis.

In summary, lots #5430125 (one capsule randomly chosen from the sealed bottle, one from Pacific Toxicology tested), and lot #5436285, definitely contained Diethylstilbestrol (DES). The identity of DES was verified both by library match to a standard reference spectrum from the NIST library, and retention time and spectral match to a known standard of DES run with the samples. The other three lots were not found to contain DES at levels detectable by this assay, which was developed to measure amounts of DES in the range reported by Pacific Toxicology Laboratories. A lower limit of quantitation could be achieved by extracting the material in less solvent. However, such low levels probably would not be of significance.

For this assay, the contents of the sample capsules were placed in screw-top tubes, then 5.0 milliliters of methanol added to each. A measured amount of promazine, to be used as an internal standard, was also added to each. These were then capped tightly, and placed on a shaker plate for 20 minutes to allow the methanol to extract the DES. The tubes were centrifuged to remove the solid materials from solution. A portion of each solution was then injected induplicate onto the GC/MS.

Our GC/MS method was similar, but not identical to, that utilized by Pacific Toxicology. The fact that we obtained similar positive results by use of a different chemistry column is further proof of the presence of DES in those samples in which it was reported positive.

The results reported were obtained by means of an independent analysis by our laboratory, and no one in our laboratory had any contact regarding this analysis with the product manufacturer, or anyone other than yourself and Pacific Toxicology Laboratories. Once the samples were identified in the login process when received, the samples were then identified during the analysis only by our laboratory number. The results were obtained before we were aware that the one sample reported positive was a duplicate of one lot tested by Pacific Toxicology.

Sincerely,

A handwritten signature in cursive script that reads "Patricia L. Sulik Ph.D.".

Patricia L. Sulik, Ph.D.
Associate Director



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ROCKY MOUNTAIN INSTRUMENTAL LABORATORIES, INC.

August 22, 2001

Victor Comerchero
RW Young Enterprises
140 Ravenna Way
El Dorado Hills, CA 95762

Dear Mr. Comerchero,

Enclosed is a second report, dated August 22, 2001, regarding the samples of PC SPES, Prostate Formula, sent for DES analysis. In the earlier report, DES-2 was actually the total of both isomers found. In this report, DES-1 and DES-2 are the individual concentrations of the two isomers, cis- and trans-diethylstilbestrol. I apologize for the confusion.

It is not possible to determine which peak, DES-1 or DES-2, is which isomer by GC/MS, since they give the same mass spectrum. However, if we were able to obtain an isomerically pure standard, we could then determine the identity of the isomers by the GC retention time. It may be that the Pharmaceutical grade DES is a pure isomer rather than a mixture. It may also be possible to use NMR to figure out which is the dominant structure. We would not do this analysis ourselves, but make arrangements with CSU which has the equipment.

As we discussed, some other analyses may be reasonable to characterize the different lots of this product for your group. While a full identification of every component in a botanical could be a project of years duration, a simple "fingerprint" by either LC/MS or LC/Photo Diode Array might be useful. Combining 6-10 capsules from each lot might be useful to reduce the effect of differences between capsules.

I find this project very interesting. I will be happy to discuss any further testing required.

Sincerely,

A handwritten signature in black ink that reads "Patricia L. Sullk, Ph.D.".

Patricia L. Sullk, Ph.D.
Associate Director



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ROCKY MOUNTAIN INSTRUMENTAL LABORATORIES, INC.

LABORATORY REPORT

CLIENT: RW Young Enterprises
Victor Comerchero
140 Ravenna Way
El Dorado Hills, CA 95762

SAMPLE: RML01R1150A-D, received 07-30-2001 from Victor Comerchero, consisting of four bottles of PC Spes, 320 mg capsules, all with their tamper-resistant seals intact. 01R1155A and B, received 08-10-2001 via FedEx from Pacific Toxicology Laboratories, each consisting of five capsules contained in a closed plastic container, and labeled as a specific lot number of PC-Spes.

ANALYSIS: Diethylstilbestrol by GC/MS ANALYSIS DATE: 8/19/01

METHOD: Contents of capsule extracted in 5.0 mls methanol, with promazine added as internal standard. Analysis by GC/MS Varian Saturn 2000, with Varian 3800 GC. Column: Varian CP Sil 8, 30 meters. Carrier gas: He (constant flow). Two isomers of Diethylstilbestrol are present in the standard; results for both are reported. DES-2 is the predominant isomer. Standards were run at 10, 50, 75 and 100 micrograms per capsule; the calibration for DES-2 was not linear above 75 ug.

RESULTS: Diethylstilbestrol in micrograms per capsule

RML ID	SAMPLE ID	DES-1	DES-2
01R1150-A	Lot #5431106 , exp. 04/03	ND	ND
01R1150-B	Lot #5430265, exp. 10/02	ND	ND
01R1150-C	Lot #5430125 , exp. 06/02	15	37
01R1150-D	Lot #5431164 , exp. 06/03	ND	ND
01R1155-A	Lot #5438285 , exp. 03/00	75	>75
01R1155-B	Lot #5430125 , exp. 06/02	13	36
LOQ		10	10

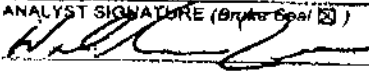
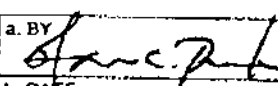
DISCUSSION: Samples containing less than the lowest standard, 10 ug/capsule, the Limit of Quantitation (LOQ), are reported as "ND", none detected. Samples higher than the highest linear standard, 75 ug, are reported as greater than 75. There was excellent consistency between the two capsules of lot #5430125, one received from RW Young Enterprises, and the other from Pacific Toxicology. There is no question that Diethylstilbestrol is present in capsules from the lots indicated.

DES is a synthetic estrogen, and is not naturally occurring.

Robert K. Lantz, Ph.D.

Patricia L. Sulik, Ph.D. 22AUG2001

FLAG Investigational Analysis

ANALYST WORKSHEET		1. PRODUCT PC Spes		2. SAMPLE NUMBER 96196	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8/22/00		5. RECEIVED FROM Eric Ferguson	
7. DESCRIPTION OF SAMPLE One brown paper bag identified in part as "96196 8/10/00 KEJ", containing sample. The sample was further contained in a plastic, whirl-pak bag, officially sealed, in part, as "96196 8/10/00 Katherine E. Jacobitz, CSO". The plastic bag was identified as "Sample #96196 08/10/00 KEJ". The sample consisted of the three subunits individually identified, in part, as "96196 08/10/00 KEJ".					
8. NET CON-TENTS <input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED _____ UNITS EXAMINED		DECLARE/UNIT AMOUNT FOUND % OF DECLARED		9. LABEL-ING _____ ORIGINAL(S) SUBMITTED <input type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS Container: The container was a cylindrical, white, HDPE container with plastic safety-type screw top. The dimensions of the container were: 8.8 cm x 4.6 cm (h x d). Labeling: The label consisted of black, red, green, blue, yellow print on a brown background and black, blue print on white background (attachment F). Code: The lot number, "5430171", was located on the bottom, left-side of the back label. Product: The product was "PC Spes" herbal dietary supplement (attachment F). Analysis (Purpose): Determined the presence of diethylstilbestrol and diethylstilbestrol dipropionate. Method: Analyzed by liquid chromatography(LC)/mass spectrometry(MS). See memo of analysis, page 2. Results: No diethylstilbestrol and diethylstilbestrol dipropionate was detected (page 3).					
11. RESERVE SAMPLE The sample, less the subunit analyzed, was officially sealed as "96196 8/30/00 Walden Lee, Chemist" and returned to Liberty Kaai on 8/30/00.					
12. ANALYST SIGNATURE (By the Seal <input checked="" type="checkbox"/>  042				13. a. BY  b. DATE 8/3/01	
b.				WORK-SHEET CHECK	
c.				14. DATE REPORTED 8/3/01	

Instrument Parameters:

Liquid Chromatograph: Hewlett-Packard 1050, 20 mL sample loop

Time	Flow (mL/min)	%Water	%Methanol
init	.40	40	60
5.00	.40	40	60
15.00	.40	10	90
25.00	.40	40	60
30.00	.40	40	60

Total runtime: 30 minutes.

LC column: Water's XTerra C18, 2.0 x 150 mm

Post column additive: Shidmazu LC 600, MeOH/H2O, 60/40 with .4 % formic acid at .2 mL/min, 1:3 split.

Mass Spectrometer:

Finnigan TSQ 700 triple stage quadrupole mass spectrometer w/ electrospray ionization interface operated in the selected ion monitoring mode. Ions scanned were m/z: 135, 238, 269, 325, 381 (see attachments A1- A2 for conditions).

Memo of Analysis:

From the sample container, 10 capsules were removed. The contents of the 10 capsules were emptied into a glass mortar and thoroughly mixed using a metal spatula. From this mixture, 0.5 g was weighed into a 50 mL polypropylene (PP) centrifuge tube. To the solid, 15 mL of 50% (v/v) ethanol in water was added. The tube was capped and the solution vortexed for 30 seconds. The sample was centrifuged for 10 minutes at 2500 rpm. The sample was filtered through a .45 mcm glass/nylon filter into a 15 mL PP centrifuge tube and injected into the LC/MS system.

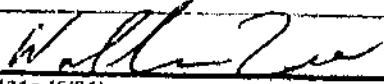
Fortification:

The above method was followed with the following exception. Prior to diluting the sample, the following amounts of each compound was added:

Deethylstilbestrol: 0.7605 mg

Diethylstilbestrol dipropionate: 0.3754 mg

Each compound was detected at 8.12 minutes and 17.68 minutes, respectively (attachment E), when compared with the reference standard injections (attachment C).

ANALYST(S) 	ANALYST NO. 042	PAGE 2 OF 3 PAGES
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GENERAL CONTINUATION SHEET	PRODUCT PC Spes	SAMPLE NO. 96196
<p>Estimated limit of detection (based on S/N 3:1):</p> <p>Diethylstilbestrol 0.0563 mg/mL</p> <p>Diethylstilbestrol dipropionate 0.00834 mg/mL</p> <p>Determination:</p> <ol style="list-style-type: none">1. Inject reference standard (attachment B).2. Inject blank (attachment C).3. Inject sample(attachment D).4. Inject fortification (attachment E). <p>Conclusion:</p> <p>Comparison of the standard chromatogram, attachment C, and the sample chromatogram, attachment D, does not indicate the presence of diethylstilbestrol (retention time: 8.11 minutes) and diethylstilbestrol dipropionate (retention time: 17.42 minutes).</p>		
ANALYST(S) <i>H. H. Zee</i>	ANALYST NO. 042	PAGE 3 OF 3 PAGES

Aug 29, 2001

TO: Victor Comerchero
Susan Domizi

Robert Young.

I have reviewed the FDA report provided by Ms. Domizi. Please note these calculations.

$$1 \text{ gram} = 1000 \text{ milligrams (mg)}$$

$$1 \text{ milligram} = 1000 \mu\text{g (micro) grams.}$$

The FDA took .5 g (500 mg) product, and extracted it with 15 ml solvent.

$$\frac{.5 \text{ g product}}{15 \text{ ml solvent}} = \frac{.033 \text{ g product}}{1 \text{ ml}} = \frac{33 \text{ mg product}}{1 \text{ ml.}}$$

The FDA detection limit is (for DES)

$$\frac{.0563 \text{ mg}}{\text{ml}} = 56 \mu\text{g/ml}$$

Since the amount of DES, if any, ^{extracted} from 33 mg of product is in one ml solvent, then this corresponds to:

$$\frac{56 \mu\text{g DES}}{33 \text{ mg product}} = 1.7 \mu\text{g DES per mg product}$$

as the lowest amount they call positive.

$$\frac{1.7 \mu\text{g}}{\text{mg}} \times \frac{320 \text{ mg}}{\text{capsule}} = \frac{544 \text{ mg DES}}{\text{capsule}}$$



Sent By: RMIL;

303 530 1189;

Aug-24-01 16:24;

Page 2/2

pg 2.

Please note that the amounts reported by RMIL were on the order of 10-200 μ g DES per capsule.

Even at the highest end, these amounts would have been "invisible" in the FDA analysis.

Sincerely,
Patricia L. Subb (PhD)