



Pharmaceutical Control and Development Laboratory Co. Ltd.

9. Mexikói Street Budapest, H-1149

Study code: PCDL-0703

FINAL REPORT

Bacterial reverse mutation (Ames) test of VigRX tablet blend

Initiation of the study: February 19, 2007

Experimental period: from February 19 to March 9, 2007

Sponsor:
COFOPEX Ltd.
H-1022 Budapest,
Bimbó út 92.

Contact Person:
István Bara

Study was performed at:
Pharmaceutical Control and
Development Laboratory Co. Ltd.
H-1149 Budapest, Mexikói út 9.

Contact Person:
János Horváth

This report consists of 24 pages plus 5 attachments.

2007

original 2 of 2

Bacterial reverse mutation (Ames) test of VigRX tablet blend**Study code: PCDL-0703****SUMMARY****General information:**

The plate incorporating method was used in the test with five doses in triplicates on four Salmonella (TA98, TA100, TA1535 and TA1537) and one E. coli [WP2 (uvrA)] tester strains, with and without S9 activation. After cytotoxicity test, a definitive assay and a confirmatory repeat assay were made. Doses of test article were up to 5000 µg/plate. Vehicle (distilled water) and suitable positive controls were used. The plates were counted after 3 days incubation.

Evaluation:

There were no revertants exceeding three times the background average either with or without metabolic activation, and there was no dose-related increase over the range tested, so this study gave negative result to VigRX tablet blend as test article.

The results of the definitive assay showed that the test article had no mutagenic effect to any strain used in this test. The results of the repeat assay confirmed the negative results of the definitive assay.

Bacterial reverse mutation (Ames) test of VigRX tablet blend
Study code: PCDL-0703

Statement of Study Director

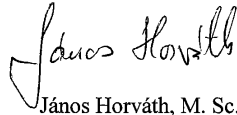
I hereby certify that this study report provides a true and complete record of the data generated and that the study was conducted in accordance with the Principles of Good Laboratory Practice as set forth in the following documents:

1. US Food and Drug Administration Title 21, Code of Federal Regulations, Part 58
Good Laboratory Practice Regulations for Nonclinical Laboratory Studies
2. Good Laboratory Practice Regulations (National GLP, Joint Decree 9/2001. (III.30) EüM-FVM)
3. OECD Principles of Good Laboratory Practice (ENV/MC/CHEM (98)17 as revised in 1997);

There were no deviations from the aforementioned regulations, which affected the quality or integrity of the study or the interpretation of the results in the report.

Date: April 3, 2007

Signature:



János Horváth, M. Sc.

Study Director

Bacterial reverse mutation (Ames) test of VigRX tablet blend**Study code: PCDL-0703****Statement of the Quality Assurance Unit**

This study has been inspected and the report audited by the Quality Assurance Unit of PCDL in compliance with the Principles of Good Laboratory Practice. As far as it can be reasonably established, the methods described and the results incorporated in the report accurately reflect the raw data produced during this study.

Inspections concerning adherence to the protocol were performed:

| Date of Inspection / Audit | Type or Phase of Inspection | Date of Report to the | |
|----------------------------|--|-----------------------|-------------------|
| | | Study Director | Management |
| February 15, 2007 | Protocol audit | February 15, 2007 | February 19, 2007 |
| February 20, 2007 | Experimental procedure - cytotoxicity test | February 20, 2007 | February 20, 2007 |
| February 23, 2007 | Counting procedure - cytotoxicity test | February 23, 2007 | February 23, 2007 |
| February 26, 2007 | Preparation of inoculums - definitive assay | February 27, 2007 | February 27, 2007 |
| February 27, 2007 | Experimental procedure - definitive assay | February 27, 2007 | February 27, 2007 |
| February 27, 2007 | Checking tester strains - definitive assay | February 27, 2007 | February 27, 2007 |
| February 28, 2007 | Evaluation of checking tester strains - definitive assay | February 28, 2007 | February 28, 2007 |
| March 2, 2007 | Counting procedure - definitive assay | March 2, 2007 | March 2, 2007 |
| March 6, 2007 | Experimental procedure - repeat assay | March 6, 2007 | March 7, 2007 |
| March 9, 2007 | Counting procedure - repeat assay | March 9, 2007 | March 10, 2007 |
| April 3, 2007 | Draft report audit | April 3, 2007 | April 3, 2007 |

Date: April 4, 2007

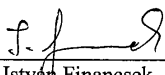
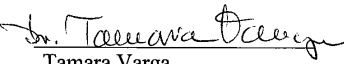
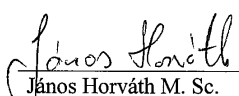
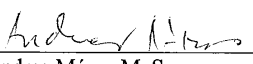
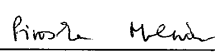
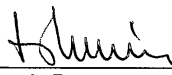
Signature: *Piroska Molnár*

Piroska Molnár, M. Sc.

Biologist

Quality Assurance Unit at PCDL

Staff in Charge

| | Signature | Date |
|--------------------------------------|--|----------------------|
| Director of the Laboratory: |  István Financsek M.D., Ph.D. | <u>04-04-2007</u> |
| Head of the Toxicological Department |  Tamara Varga Ph.D., toxicologist | <u>April 4, 2007</u> |
| Study Director: |  János Horváth M. Sc. food industry engineer, food safety engineer | <u>April 3, 2007</u> |
| Deputy Study Director: |  Andrea Mózes M. Sc. Biologist | <u>April 3, 2007</u> |
| Quality Assurance Unit: |  Piroska Molnár M. Sc. Biologist | <u>April 4, 2007</u> |
| Sponsor: |  István Bara Managing Director COFOPEX Ltd. | <u>April 4, 2007</u> |
| Monitoring Scientist: | _____ Alexander G. Schauss Ph.D. (AIBMR Life Sciences) | _____ |

Staff in Charge


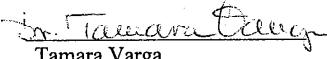
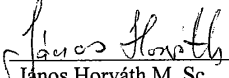
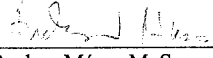
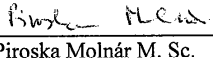
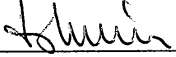
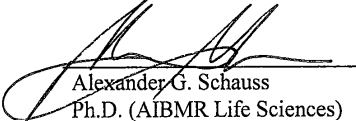
| | Signature | Date |
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| Director of the Laboratory: |  István Financsek M.D., Ph.D. | <u>04-04-2007</u> |
| Head of the Toxicological Department |  Tamara Varga Ph.D., toxicologist | <u>April 4, 2007</u> |
| Study Director: |  János Horváth M. Sc. food industry engineer, food safety engineer | <u>April 3, 2007</u> |
| Deputy Study Director: |  Andrea Mózes M. Sc. Biologist | <u>April 3, 2007</u> |
| Quality Assurance Unit: |  Piroska Molnár M. Sc. Biologist | <u>April 4, 2007</u> |
| Sponsor: |  István Bara Managing Director COFOPEX Ltd. | <u>April 4, 2007</u> |
| Monitoring Scientist: |  Alexander G. Schauss Ph.D. (AIBMR Life Sciences) | <u>April 11, 2007</u> |

Table of contents

| | |
|---|-----|
| Summary | 2. |
| Statement of Study Director | 3. |
| Statement of the Quality Assurance Unit | 4. |
| Staff in Charge | 5. |
| Table of contents | 6. |
| 1. General information | 8. |
| 1.1. Title of the study | 8. |
| 1.2. Objective of the study | 8. |
| 1.3. Type of the study | 8. |
| 1.4. Introduction | 8. |
| 2. Test article | 9. |
| 2.1. Microbiological analysis | 9. |
| 2.2. Chemical analysis | 9. |
| 2.3. Stability control of the test article | 9. |
| 3. Test system | 9. |
| 3.1. Test system description | 9. |
| 3.2. Test system justification | 10. |
| 3.3. Source and storage of test system | 10. |
| 3.4. Identification of test system | 10. |
| 3.5. Preparation of overnight cell cultures | 11. |
| 3.6. Control of bias | 11. |
| 4. Vehicle | 11. |
| 4.1. Formulation of the test article | 11. |
| 5. Dose levels | 12. |
| 5.1. Doses used in the cytotoxicity assessment | 12. |
| 5.2. Doses used in the definitive assay | 12. |
| 5.3. Doses used in the independent repeat assay | 12. |
| 6. Metabolic activation | 12. |
| 6.1. S9 fraction | 12. |

| | | |
|-------|--|-----|
| 6.2. | S9/cofactor mix | 13. |
| 6.3. | Buffer | 13. |
| 7. | Tester strain media | 13. |
| 7.1. | Nutrient broth | 13. |
| 7.2. | Minimal glucose plates | 13. |
| 7.3. | Top agar | 13. |
| 7.4. | Other materials | 14. |
| 8. | Controls | 14. |
| 8.1. | Positive controls (Table 3.) | 14. |
| 8.2. | Negative controls | 14. |
| 9. | Procedures | 16. |
| 10. | Experimental procedures for definitive and repeat assays | 16. |
| 11. | Counting procedure | 16. |
| 12. | Data provided | 16. |
| 13. | Evaluation and interpretation of results | 17. |
| 13.1. | Criteria for a valid assay | 17. |
| 13.2. | Statistical analysis of the data | 17. |
| 13.3. | Evaluation of mutagenicity | 17. |
| 14. | Records maintained | 18. |
| 15. | Schedule of the study | 18. |
| 16. | Results | 19. |
| 16.1. | Cytotoxicity test | 19. |
| 16.2. | Definitive assay | 20. |
| 16.3. | Repeat assay | 22. |
| 17. | Conclusion | 24. |
| 18. | References | 24. |

Attachments:

- E-mail from Dr Alex G. Schauss Ph.D. dated March 16, 2007.
- Materials used in the Ames assay PCDL-0703
- Certificate of Analysis of Viga Rx Plus Tablet (Lot: 120657)
- Certificate of Laboratory Analysis of Powder Blend of Vigra RX Tablet (Lot: 120657)
- Certificate of Good Laboratory Practice (GLP) of PCDL Ltd.

1. General information**1.1. Title of the study**

Bacterial reverse mutation (Ames) test of VigRX tablet blend

Initiation of the study: February 19, 2007.

Experimental period was from February 19 to March 9, 2007.

1.2. Objective of the study

The objective of this study was to evaluate the ability of the test article to induce mutagenic response in four strains of *Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537) and one strain of *Escherichia coli* [WP2 (uvrA)]. The test article was plated in triplicates, at five concentrations both in presence and absence of S9 metabolic activation. A cytotoxicity assessment was performed prior to the definitive study, and an independent repeat assay was conducted to confirm the negative results.

1.3. Type of the study

Preclinical toxicology study in compliance with the principles of the

- Good Laboratory Practice Regulations for Nonclinical Laboratory Studies of the United States Food and Drug Administration (21 CFR 58) ⁽²⁾,
- Good Laboratory Practice Regulations (National GLP, Joint Decree 9/2001. (III.30) EüM-FVM), and
- OECD Principles of Good Laboratory Practice (ENV/MC/CHEM (98)17 as revised in 1997).

The study was set up according to the OECD GUIDELINE FOR TESTING OF CHEMICALS (Guideline No.: 471, adopted: 21st July 1997), Bacterial Reverse Mutation Test. ⁽³⁾

1.4. Introduction

The reverse mutation assay (Ames test) is used to evaluate the mutagenic properties of test articles. The test uses histidine-dependent strains of *S. typhimurium* and tryptophan-dependent strain of *E. coli*. In the absence of an external histidine or tryptophan source, the cells cannot grow to form colonies. Colony growth is evident if a reversion of mutation occurs, allowing the production of histidine or tryptophan to be resumed. Spontaneous reversions occur with each of the strains; mutagenic compounds cause an increase in the number of revertant colonies relative to the background level.

2. Test article

Name⁽¹⁾: VigRX tablet blend,
synonyms: VIGRA RX TABLET BLEND (label),
Viga Rx Plus Tablet⁽⁴⁾,
Powder Blend of Vigra Rx Tablet⁽⁵⁾

Specification⁽⁴⁾: powder of different parts of plants

Manufacturer⁽⁴⁾⁽⁵⁾: VITA-PURE, Inc.
410 W. 1st Avenue Roselle, NJ 07203 U.S.A.

Lot number⁽⁴⁾⁽⁵⁾: 120657

Identification number at PCDL: 2007/03901

Appearance: dark brown powder

Package form: plastic, white bottle, 50g

Storage conditions: at room temperature

Expiration date⁽⁴⁾: December, 2009

For ingredients see Certificate of Analysis attached⁽⁴⁾.

2.1. Microbiological analysis

There were no data available on the stability of the test article when autoclaved in water, it was not possible to get sterile material. Therefore, a microbial limit test by plate-count method was performed on the test article according to the United States Pharmacopeia 30. The total plate count was 10 CFU/g.

2.2. Chemical analysis

Certificate of Analysis provided by the Sponsor is attached to this Final Report. Composition of the test article and the analytical control are the Sponsor's responsibility.

2.3. Stability control of the test article

Stability control of the test article is the Sponsor's responsibility. The product was considered to be stable.

3. Test system

3.1. Test system description

All Salmonella strains used are histidine-dependent. Revertants were identified as colonies that grew in low levels of histidine. The E. coli strain used here is tryptophan-dependent. Revertants were identified as colonies that grew in low levels of tryptophan. Frameshift and base-pair substitution defects are represented to identify mutagens of both types. Additional genetic markers enhance sensitivity of the strains to certain types of mutagens. The DNA repair mutations (uvrB and uvrA) eliminate excision repair, a repair pathway for DNA damage from UV light and certain chemical mutagens. The uvrB mutation, present in strains TA98, TA100, TA1535 and TA1537, and the uvrA mutation, present in strain WP2 (uvrA), was indicated by sensitivity to UV light. The rfa mutation changes the properties of the bacterial cell wall, increasing the permeability of cells to certain types of chemicals. The rfa mutation, present in all Salmonella strains, was indicated by sensitivity to crystal violet. The R factor plasmid (pKM101) present in strains TA98 and TA100 makes them more responsive to a variety of mutagens. The plasmid carries an ampicillin resistance gene, therefore, ampicillin resistance indicated that the strains retain the plasmid.

3.2. Test system justification

The five strains of bacteria that were used in this assay were among those recommended by OECD Guideline 471⁽³⁾ for use in the Ames test. These strains of *S. typhimurium* and *E. coli* have been shown to be reliably and reproducibly responsive between laboratories.

3.3. Source and storage of test system

The Salmonella and E. coli strains used in this study were obtained from Xenometrix GmbH (Gewerbstrasse 25, CH-4123 Allschwill, Switzerland), are maintained as frozen stocks at $-80^{\circ}\text{C} \pm 5^{\circ}\text{C}$.

3.4. Identification of test system

Strains were identified by certain characteristics (see Table 1). The strains also yield spontaneous revertant colony plate counts within the frequency ranges of the historical control data.

Table 1. Characteristics of Salmonella and E. coli strains

| Strain | Gene Affected | DNA repair | LPS | Biotin requirement | Plasmids | Mutational event |
|---------------------|---------------|-------------|------------|--------------------|---------------|------------------------|
| TA98 | <i>hisD</i> | <i>uvrB</i> | <i>rfa</i> | <i>bio</i> - | <i>pKM101</i> | frameshift |
| TA100 | <i>hisG</i> | <i>uvrB</i> | <i>rfa</i> | <i>bio</i> - | <i>pKM101</i> | base-pair substitution |
| TA1535 | <i>hisG</i> | <i>uvrB</i> | <i>rfa</i> | <i>bio</i> - | - | base-pair substitution |
| TA1537 | <i>hisC</i> | <i>uvrB</i> | <i>rfa</i> | <i>bio</i> - | - | frameshift |
| WP2 (<i>uvrA</i>) | <i>trp</i> | <i>uvrA</i> | - | - | - | base-pair substitution |

3.5. Preparation of overnight cell cultures

Frozen stock cultures were grown overnight (for 14-16 hours) at 37 ± 2 °C with shaking in nutrient broth until a cell density of about 10^9 cells/ml was obtained (determined by optical density). Cells were maintained at room temperature until use and during the test.

3.6. Control of bias

In order to control bias, for each day of test system treatment, all test article doses, as well as controls, were plated against cells from homogenous culture, i.e. from a single flask.

4. Vehicle

Sterile distilled water. To enhance dispersion at least two minutes vortexing was used. The vehicle did not affect the spontaneous mutation level and it was recommended for use in this test.

4.1. Formulation of the test article

The necessary amount of the test article (c.a. 500 mg) was weighted and suspended with vortexing in sterile distilled water not earlier than 30 min prior the start of the experimental procedures. For dilution to final doses, sterile distilled water was used with constant vortexing.

5. Dose levels

5.1. Doses used in the cytotoxicity assessment

A cytotoxicity assessment was performed to determine the appropriate dose range for the definitive assay. Test doses (5, 10, 50, 100, 500, 1000 and 5000 µg/plate), along with negative controls, were plated against strain TA100, in triplicates, both with and without S9 activation, as described in Section 10. Experimental procedures.

Cytotoxicity could have been detected by the absence of a confluent bacterial lawn, the presence of pinpoint colonies, and/or a substantial decrease or lack of revertant colonies, but the test article is not cytotoxic material.

As the total plate count had not disturbed the counting procedure in the cytotoxicity assessment, the doses of test article were not reduced in the definitive and repeat assays.

5.2. Doses used in the definitive assay

Five dose levels of test article were evaluated in the definitive test in triplicates. The concentrations for the test article were 50, 100, 500, 1000 and 5000 µg/plate.

5.3. Doses used in the independent repeat assay

As the definitive assay yielded negative results, an independent repeat assay was performed according to OECD guideline 471⁽³⁾. The guideline indicates that study parameters should be modified. There was no other reason for modifying concentration spacing, therefore the S9 content of S9/cofactor mix was increased from 4% to 10%.

6. Metabolic activation ⁽⁶⁾

6.1. S9 fraction

Aroclor™ 1254-induced rat liver S9 (frozen-dried) was purchased from Trinova Biochem GmbH, Kerkrader Strasse 10. D-35394, Giessen, Germany.

6.2. S9/cofactor mix

The S9/cofactor mix contained (for 52.5 ml):

| | Standard mix | Raised mix |
|---|--------------|---------------|
| Rat liver S9 (Aroclor-1254 induced) | 2.1 ml (4%) | 5.25 ml (10%) |
| Salt solution (1.65 M KCl + 0.4 M MgCl ₂) | 1.05 ml | 1.05 ml |
| 1 M glucose-6-phosphate | 0.26 ml | 0.26 ml |
| 0.1 M NADP solution | 2.1 ml | 2.1 ml |
| 0.2 M sodium phosphate buffer, pH 7.4 | 26.25 ml | 26.25 ml |
| Sterile distilled water | 20.74 ml | 17.6 ml |

It was kept on ice during the experiment.

6.3. Buffer

In case S9 mix was not added, sodium phosphate buffer pH 7.4 was used.

7. Tester strain media ⁽⁶⁾**7.1 Nutrient broth**

The broth used for the overnight cultures consisted of 2.5% Oxoid nutrient broth #2.

7.2. Minimal glucose plates

| Ingredient: | Per 0.5 liter | |
|------------------|---------------|----|
| Agar, granulated | 7.5 | g |
| Distilled water | 465 | ml |
| 50X VB salts | 10 | ml |
| 40% glucose | 25 | ml |

Plates consisted of 1.5% agar supplemented with 2.0% glucose and 2.0% Vogel-Bonner buffer.

7.3. Top agar

| | | | |
|-------------|------------------|-----|---------|
| Ingredient: | Agar, granulated | 6 | g |
| | NaCl, a.r. | 5 | g |
| | Distilled water | ad. | 1000 ml |

The top agar consisted of 0.6% agar and 0.5% NaCl. It was supplemented right before use with (10ml/100ml top agar) 0.5 mM solution of histidine and biotin (for Salmonella) or tryptophan (for E. coli).

7.4. Other materials

All the media and solutions were used in this study were prepared in PCDL Co. Ltd. (see Table 2.). Ingredients of these media and solutions are listed in attachment "Materials used in the Ames assay PCDL-0703".

Table 2: List of media and solutions prepared

| Name of media or solution | Lot No. |
|---|------------------|
| Oxoid nutrient broth #2 | A128 |
| Minimal glucose plate | A146, A150, A153 |
| Top agar | A132 |
| 0.5mM Histidine/Biotin | A111 |
| 0.5mM Tryptophan | A131 |
| S9/cofactor mix | A149, A152, A156 |
| 0.2M sodium phosphate buffer pH 7.4 | A136 |
| Sterile distilled water | A137 |
| Sterile DMSO | A144 |
| Histidine/Biotin plate (for control of strains) | A130 |
| Tryptophan plate (for control of strain WP2) | A138 |
| Nutrient agar (for control of strains) | A141 |
| 0.1% Crystal violet (for control of strains) | A142 |
| Ampicillin plate (for control of strains) | A145 |

8. Controls

8.1. Positive controls (Table 3)

Strains were tested with known mutagens to demonstrate that the assay was working effectively and the metabolic activation system was operating. The applied concentrations are listed in Tables 4. and 5.

8.2. Negative controls

All strains were tested for spontaneous revertant counts containing distilled water instead of test article. The characteristic spontaneous revertant counts of the strains are listed in Tables 4. and 5.

Table 3: Positive controls

| Strain | Positive controls (without S9 activation) | Positive controls (with S9 activation) |
|--------|---|---|
| TA 98 | 2-nitrofluorene (2NF) CAS# 607-57-8 | benzo(a)pyrene (BP) CAS# 50-32-8 |
| TA100 | sodium-azide (NaN ₃) CAS# 26628-22-8 | 2-aminoanthracene (2AAn) CAS# 613-13-8 |
| TA1535 | sodium-azide (NaN ₃) CAS# 26628-22-8 | 2-aminoanthracene (2AAn) CAS# 613-13-8 |
| TA1537 | 9-aminoacridine (9AA) CAS# 52417-22-8 | benzo(a)pyrene (BP) CAS# 50-32-8 |
| WP2 | methyl-methansulfonate (MMS) CAS# 66-27-3 | 2-aminoanthracene (2AAn) CAS# 613-13-8 |

Table 4: Controls without S9 mix

| Strain | Positive control | Solvent | Dose (µg,µl/plate) | Spontaneous revertant count ⁽⁶⁾ |
|--------|------------------|---------|-----------------------|---|
| TA98 | 2-NF | DMSO | 2.5 | 10-50 |
| TA100 | NaN ₃ | Water | 1.5 | 60-220 |
| TA1535 | NaN ₃ | Water | 1.5 | 5-50 |
| TA1537 | 9-AA | DMSO | 25 | 1-25 |
| WP2 | MMS | Water | 2.5 | 65-115* |

*Stated based on previous studies.

Table 5: Controls with S9 mix

| Strain | Positive control | Solvent | Dose (µg/plate) | Spontaneous revertant count ⁽⁶⁾ |
|--------|------------------|---------|--------------------|---|
| TA98 | BP | DMSO | 20 | 10-50 |
| TA100 | 2-AAAn | DMSO | 10 | 60-220 |
| TA1535 | 2-AAAn | DMSO | 10 | 5-50 |
| TA1537 | BP | DMSO | 20 | 1-25 |
| WP2 | 2-AAAn | DMSO | 10 | 65-115* |

*Stated based on previous studies.

9. Procedures

The experiments were performed according to the current Standard Operating Procedures of Pharmaceutical Control and Development Laboratory Co. Ltd.

10. Experimental procedures for definitive and repeat assays

The followings were added to each sterile culture tube in triplicates in every dose levels: 0.1 ml of test or control article, 0.5 ml S9/cofactor mix or 0.5 ml phosphate buffer pH 7.4, 0.1 ml of overnight cell culture and 2.0 ml top agar. The tubes were vortexed, poured onto Minimal glucose plates, and evenly distributed. The agar was allowed to harden and the plates were inverted and incubated at $37\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ for 72 ± 4 hours, then scored.

In the repeat assay was the following modification: the S9 concentration in the S9/cofactor mix was increased to 10%. Concentration spacing was not modified.

11. Counting procedure

All plates for all concentrations were counted by hand.

12. Data provided

Results are presented as the number of revertant colonies per plate. For the assays individual plate counts and the mean number with standard deviations of revertant colonies are provided in tabular form.

13. Evaluation and interpretation of results

13.1. Criteria for a valid assay

The study is considered valid if all of the following criteria are met:

- Tester strains TA98, TA100, TA1535, TA1537, and WP2 (uvrA) exhibit sensitivity to UV light.
- All Salmonella tester strains exhibit sensitivity to crystal violet.
- Tester strains TA98 and TA100 exhibit resistance to ampicillin.
- Tester strains exhibit a characteristic number of spontaneous revertant colonies when plated. The mean should be within the range presented in Tables 4. and 5.
- Tester strains exhibit at least a three-fold increase in mutagen-induced revertant colonies (two-fold for strain TA100) when plated with positive control chemicals.

This study is considered valid, because all criteria were met.

13.2. Statistical analysis of the data

There was no test article related increase in average number of revertant colonies relative to the negative control, dose-related increase has not occurred, so it was not reasonable to make statistical (regression) analysis.

13.3. Evaluation of mutagenicity

A test article considered positive if the assay is valid, and if the following conditions are met, considering biological relevance:

- If the background average is below six colonies, the average number of revertants for any test article dose must exceed twenty colonies/plates.
- One test article dose exceeds three times the background average (two times for strain TA100) either with or without metabolic activation, or there is a dose-related increase over the range tested ($p < 0.025$).

A positive result indicates that the test article induces mutations in Salmonella typhimurium or Escherichia coli cells.

A test article for which the results do not meet the above criteria will be considered non-mutagenic in this test.

Negative results indicate that, under the test conditions, the test article does not produce mutations in test cells.

14. Records maintained

The data obtained in the course of the study are collected in a Study File. The Study Protocol, all data generated during and as a result of the study, the documents and all information in connection with the study, a control sample of the test article, and the Final Report will be stored at least for 15 years in the Archives of the PCDL then offered to the Sponsor.

15. Schedule of the study

| | |
|-------------------------|-----------------------------|
| Cytotoxicity assessment | February 19 - 23, 2007 |
| Definitive assay | February 26 – March 2, 2007 |
| Repeat assay | March 5 - 9, 2007 |

16. Results

16.1. Cytotoxicity test

Table 6. Results of cytotoxicity test

| Test article | Dose (µg/plate) | S. typhimurium TA 100 Revertant colonies per plate [Mean ± S.D.] | |
|--------------------------------------|--------------------|---|-----------------------------|
| | | without activation | with 4% S9 activation |
| VigRX tablet blend | 0 ^{a)} | 171 154 167 [164 ± 8.9] | 141 130 148 [140 ± 9.1] |
| | 5 | 157 163 158 [159 ± 3.2] | 136 133 154 [141 ± 11.4] |
| | 10 | 170 158 157 [162 ± 7.2] | 126 149 139 [138 ± 11.5] |
| | 50 | 171 166 176 [171 ± 5.0] | 153 144 123 [140 ± 15.4] |
| | 100 | 177 168 163 [169 ± 7.1] | 152 137 141 [143 ± 7.8] |
| | 500 | 155 169 158 [161 ± 7.4] | 132 155 140 [142 ± 11.7] |
| | 1000 | 166 183 161 [170 ± 11.5] | 131 143 139 [138 ± 6.1] |
| | 5000 | 153 163 157 [158 ± 5.0] | 142 133 157 [144 ± 12.1] |
| Historical negative ^{b)} | - | 60-220 | |

^{a)} Negative (solvent) control, spontaneous revertant number.

^{b)} The historical negative range was formed by reference literature ⁽⁷⁾.

Comments on the cytotoxicity test:

There was normal background lawn with no significant reduction (more than 50%) in the number of revertant colonies.

There was no cytotoxic effect and no precipitation, so in the definitive and repeat assays the dose range was up to 5000 µg/plate.

16.2. Definitive assay

Table 7. Results of definitive assay, without metabolic activation

| Test article | Dose ($\mu\text{g}/\text{plate}$) | Revertant colonies per plate [Mean \pm S.D.] | | | | |
|--------------------------------------|--|--|----------------------------------|---------------------------------|------------------------------|-------------------------------------|
| | | TA98 | TA100 | TA1535 | TA1537 | WP2 (uvrA) |
| VigRX tablet blend | 0 ^{a)} | 45 51 40 [45 \pm 5.5] | 193 174 168 [178 \pm 13.1] | 41 39 47 [42 \pm 4.2] | 14 13 10 [12 \pm 2.1] | 104 78 92 [91 \pm 13.0] |
| | 50 | 40 39 44 [41 \pm 2.6] | 169 171 190 [177 \pm 11.6] | 47 38 39 [41 \pm 4.9] | 16 15 10 [14 \pm 3.2] | 86 75 94 [85 \pm 9.5] |
| | 100 | 45 41 47 [44 \pm 3.1] | 182 171 168 [174 \pm 7.4] | 38 36 50 [41 \pm 7.6] | 13 15 12 [13 \pm 1.5] | 92 102 96 [97 \pm 5.0] |
| | 500 | 45 39 42 [42 \pm 3.0] | 161 187 197 [182 \pm 18.6] | 47 49 41 [46 \pm 4.2] | 16 9 10 [12 \pm 3.8] | 107 93 88 [96 \pm 9.8] |
| | 1000 | 40 49 50 [46 \pm 5.5] | 184 178 195 [186 \pm 8.6] | 48 42 41 [44 \pm 3.8] | 17 12 9 [13 \pm 4.0] | 87 82 110 [93 \pm 14.9] |
| | 5000 | 48 41 46 [45 \pm 3.6] | 166 175 200 [180 \pm 17.6] | 47 44 38 [43 \pm 4.6] | 11 15 10 [12 \pm 2.6] | 88 102 91 [94 \pm 7.4] |
| Positive control | b) | 498 517 461 [492 \pm 28.5] | 884 964 1052 [967 \pm 84.0] | 586 610 696 [631 \pm 57.8] | 81 111 75 [89 \pm 19.3] | 1524 1638 1488 [1550 \pm 78.3] |
| Historical negative ^{c)} | - | 10-50 | 60-220 | 5-50 | 1-25 | 65-115 |

^{a)} Negative (solvent) control, spontaneous revertant number.

^{b)} Dose of the suitable mutagen material, see Table 4.

^{c)} The historical negative ranges were formed by our lab experiences and reference literature⁽⁷⁾.

Table 8. Results of definitive assay, with 4% S9 activation

| Test article | Dose (µg/plate) | Revertant colonies per plate [Mean ± S.D.] | | | | |
|--------------------------------------|--------------------|--|-----------------------------|-----------------------------|------------------------|-----------------------------|
| | | TA98 | TA100 | TA1535 | TA1537 | WP2 (uvrA) |
| VigRX tablet blend | 0 ^{a)} | 41 39 45 [42 ± 3.1] | 189 156 171 [172 ± 16.5] | 40 37 42 [40 ± 2.5] | 12 8 16 [12 ± 4.0] | 102 91 108 [100 ± 8.6] |
| | 50 | 48 44 40 [44 ± 4.0] | 170 161 188 [173 ± 13.7] | 34 36 42 [37 ± 4.2] | 13 10 13 [12 ± 1.7] | 88 91 100 [93 ± 6.2] |
| | 100 | 41 45 39 [42 ± 3.1] | 184 160 170 [171 ± 12.1] | 37 42 45 [41 ± 4.0] | 10 17 11 [13 ± 3.8] | 81 131 106 [106 ± 25.0] |
| | 500 | 43 37 41 [40 ± 3.1] | 159 190 174 [174 ± 15.5] | 40 40 36 [39 ± 2.3] | 17 12 11 [13 ± 3.2] | 93 108 106 [102 ± 8.1] |
| | 1000 | 44 48 35 [42 ± 6.7] | 197 164 181 [181 ± 16.5] | 41 39 33 [38 ± 4.2] | 14 12 10 [12 ± 2.0] | 86 96 92 [91 ± 5.0] |
| | 5000 | 43 31 43 [39 ± 6.9] | 157 166 188 [170 ± 15.9] | 34 41 36 [37 ± 3.6] | 10 16 14 [13 ± 3.1] | 111 94 99 [101 ± 8.7] |
| Positive control | b) | 234 217 264 [238 ± 23.8] | 692 709 803 [735 ± 59.8] | 714 684 756 [718 ± 36.2] | 59 49 57 [55 ± 5.3] | 350 306 386 [347 ± 40.1] |
| Historical negative ^{c)} | - | 10-50 | 60-220 | 5-50 | 1-25 | 65-115 |

^{a)} Negative (solvent) control, spontaneous revertant number.

^{b)} Dose of the suitable mutagen material, see Table 5.

^{c)} The historical negative ranges were formed by our lab experiences and reference literature⁽⁷⁾.

Comments on the definitive assay:

The background lawn was normal at every dose. The positive and negative (solvent) control values were appropriate for the respective strains.

16.3. Repeat assay

Table 9. Results of repeat assay, without metabolic activation

| Test article | Dose (µg/plate) | Revertant colonies per plate [Mean ± S.D.] | | | | |
|--------------------------------------|--------------------|--|-----------------------------|-----------------------------|-------------------------|----------------------------------|
| | | TA98 | TA100 | TA1535 | TA1537 | WP2 (uvrA) |
| VigRX tablet blend | 0 ^{a)} | 37 30 38 [35 ± 4.4] | 169 177 184 [177 ± 7.5] | 27 37 29 [31 ± 5.3] | 13 7 7 [9 ± 3.5] | 63 70 82 [72 ± 9.6] |
| | 50 | 34 32 38 [35 ± 3.1] | 182 178 165 [175 ± 8.9] | 29 29 33 [30 ± 2.3] | 12 6 12 [10 ± 3.5] | 79 61 77 [72 ± 9.9] |
| | 100 | 34 36 40 [37 ± 3.1] | 170 177 174 [174 ± 3.5] | 31 30 36 [32 ± 3.2] | 9 6 16 [10 ± 5.1] | 63 79 67 [70 ± 8.3] |
| | 500 | 31 31 42 [35 ± 6.4] | 181 169 179 [176 ± 6.4] | 20 38 35 [31 ± 9.6] | 8 10 10 [9 ± 1.2] | 61 65 78 [68 ± 8.9] |
| | 1000 | 36 34 32 [34 ± 2.0] | 172 182 177 [177 ± 5.0] | 36 29 28 [31 ± 4.4] | 7 9 11 [9 ± 2.0] | 74 67 64 [68 ± 5.1] |
| | 5000 | 34 34 36 [35 ± 1.2] | 177 172 181 [177 ± 4.5] | 27 32 39 [33 ± 6.0] | 5 13 10 [9 ± 4.0] | 71 76 60 [69 ± 8.2] |
| Positive control | b) | 462 388 558 [469 ± 85.2] | 772 827 889 [829 ± 58.5] | 460 484 590 [511 ± 69.2] | 63 51 41 [52 ± 11.0] | 1340 1488 1124 [1317 ± 183.1] |
| Historical negative ^{c)} | - | 10-50 | 60-220 | 5-50 | 1-25 | 65-115 |

^{a)} Negative (solvent) control, spontaneous revertant number.

^{b)} Dose of the suitable mutagen material, see Table 4.

^{c)} The historical negative ranges were formed by our lab experiences and reference literature⁽⁷⁾.

Table 10. Results of repeat assay, with 10% S9 activation

| Test article | Dose (µg/plate) | Revertant colonies per plate [Mean ± S.D.] | | | | |
|--------------------------------------|--------------------|--|----------------------------------|-----------------------------|----------------------------|-----------------------------|
| | | TA98 | TA100 | TA1535 | TA1537 | WP2 (uvrA) |
| VigRX tablet blend | 0 ^{a)} | 46 40 41 [42 ± 3.2] | 179 166 171 [172 ± 6.6] | 23 24 31 [26 ± 4.4] | 15 11 16 [14 ± 2.6] | 72 67 81 [73 ± 7.1] |
| | 50 | 45 46 39 [43 ± 3.8] | 165 183 177 [175 ± 9.2] | 30 24 26 [27 ± 3.1] | 12 9 14 [12 ± 2.5] | 60 79 64 [68 ± 10.0] |
| | 100 | 41 38 45 [41 ± 3.5] | 169 176 169 [171 ± 4.0] | 25 22 30 [26 ± 4.0] | 14 11 12 [12 ± 1.5] | 71 75 65 [70 ± 5.0] |
| | 500 | 36 38 49 [41 ± 7.0] | 168 179 173 [173 ± 5.5] | 28 25 25 [26 ± 1.7] | 15 13 17 [15 ± 2.0] | 62 65 79 [69 ± 9.1] |
| | 1000 | 39 45 44 [43 ± 3.2] | 167 176 170 [171 ± 4.6] | 21 27 28 [25 ± 3.8] | 15 12 9 [12 ± 3.0] | 65 77 66 [69 ± 6.7] |
| | 5000 | 39 48 38 [42 ± 5.5] | 165 167 178 [170 ± 7.0] | 23 24* 28 [25 ± 2.6] | 16 13 15 [15 ± 1.5] | 74 66 70 [70 ± 4.0] |
| Positive control | b) | 488 415 468 [457 ± 37.7] | 1356 1472 1196 [1341 ± 138.6] | 680 600 602 [627 ± 45.6] | 115 116 111 [114 ± 2.6] | 382 321 356 [353 ± 30.6] |
| Historical negative ^{c)} | - | 10-50 | 60-220 | 5-50 | 1-25 | 65-115 |

^{a)} Negative (solvent) control, spontaneous revertant number.

^{b)} Dose of the suitable mutagen material, see Table 5.

^{c)} The historical negative ranges were formed by our lab experiences and reference literature⁽⁷⁾.

* One colony of mould formed on the plate.

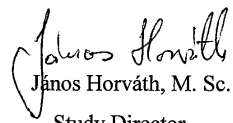
Comments on the repeat assay:

The background lawn was normal at every dose. The positive and negative (solvent) control values were appropriate for the respective strains. The test shows similar results to those of the definitive assay.

17. Conclusion

There were no revertants exceeding three times the background average either with or without metabolic activation, and there was no dose-related increase over the range tested, so this study gave negative result to VigRX tablet blend as test article.

The results of definitive assay showed that the test article had no mutagenic effect to any strain used in this test. The results of the repeat assay confirmed the negative results of the definitive assay.

 April 3, 2007
János Horváth, M. Sc.
Study Director

18. References

- (1) E-mail from Dr Alex G. Schauss Ph.D. dated March 16, 2007 (see attached) and Amendment to the Protocol PCDL-0703 dated March 21, 2007.
- (2) Good Laboratory Practices (GLP) Regulations for non-clinical laboratory studies by the U.S. Food and Drug Administration (21 CFR 58), current versions as of April 2003.
- (3) Organization for Economic Cooperation and Development (OECD) Section 4 of the OECD Guidelines for the Testing of Chemicals: Bacterial Reverse Mutation Test, Guideline 471, adopted 21st July 1997.
- (4) Certificate of Analysis of Viga Rx Plus Tablet, Lot 120657, issued by VITA-PURE, Inc., dated 12/2006 (see attached).
- (5) Certificate of Laboratory Analysis of Powder Blend of Vigra Rx Tablet Lot 120657 issued by Sani-Pure Food Laboratories, dated 1/22/2007 (see attached).
- (6) Maroon, D. and Ames B. (1983) Mutation Res. 113, p.173-215.
- (7) Invittox on line <http://embryo.ib.amwaw.edu.pl/invittox/prot/30.htm>

Financsek Istvan

From: "Alex Schauss" <alex@aibmr.com>
To: "Istvan Bara" <barai@mail.datanet.hu>; "Istvan Financsek, MD, PhD" <financse@t-online.hu>
Sent: 2007. március 16. 5:20
Attach: 0702-EP.DOC
Subject: From Alex Schauss FW: Acute tox VIGRA Rx

Dear Dr. Financsek:

I have a dilemma just discovered. We just noticed that the C of A for the VigRX tablet blend incorrectly reported the name of the product as "Vigra RX". This is incorrect. The name is VigRX. The manufacturer's analytical lab just realized this error and now our client is concerned that the report of the acute toxicity study you are doing will have the wrong name for the product and they can not use the findings because of the error. Can this be resolved before issuing the draft final report? I realize this is difficult because it is a GLP study and you rely on the C of A (from Sani-Pure) to determine the product's name.

Any assistance you to provide or instructions on how this can be solved now would be greatly appreciated. The draft report is scheduled to be released on March 29th.

Regards,

Alex Schauss

----- Forwarded Message

From: Financsek Istvan <financse@t-online.hu>
Organization: GYEL Kft
Date: Tue, 20 Feb 2007 16:13:20 +0100
To: Alex Schauss <alex@aibmr.com>
Cc: Bara Istvan <barai@mail.datanet.hu>
Subject: Acute tox VIGRA Rx

Dear Dr Schauss,

Attached please find the Study Protocol of the VIGRA Rx acute tox study for comments and approval.

Best regards,

I.Financsek

----- End of Forwarded Message

Handwritten signature
2007.03.19.

Materials used in the Ames assay PCDL-0703

| Name of material | Manufacturer | Quality | Lot/Batch No. | Expiry date |
|---|-----------------------------|---|---------------------|-----------------|
| 2-Aminoanthracene | SIGMA Trinova Biochem | for Ames test | 39H0945 | February, 2008 |
| 2-Nitrofluorene | SIGMA- ALDRICH | 98% | S08447-244 | - |
| 9-Aminoacridine | MERCK | for synthesis | S03761 | July, 2011 |
| Agar-agar, granulated | MERCK | purified and free from inhibitors for microbiology | VM603814 | January, 2010 |
| Ampicillin trihydrate | SIGMA- ALDRICH | ≥96% | 035K0521 | April, 2009 |
| Benzo(a)Pyrene | SIGMA Trinova Biochem | for Ames test | 084K1371 | May, 2008 |
| Cristal violet, C.I.42555 | REANAL | for microscopy | 828489 | June, 2008 |
| D(+)-Biotin | MERCK | for biochemistry | D472614 | November, 2007 |
| Dimethyl sulfoxide dried | MERCK | max. 0,05% H ₂ O | K35155131 | September, 2008 |
| Glucose-6-phosphate disodium salt dihydrate | AppliChem | 98.8% | 4T11080 | April, 2008 |
| L-Histidine | MERCK | for biochemistry | K34168851 | December, 2009 |
| L-Tryptophane | MERCK | for biochemistry | K31536974 | November, 2007 |
| Lyoph. SD Rat liver S9, Aroclor 1254 induced | Trinova Biochem | for Ames test | 2057 | September, 2008 |
| Methyl methanesulfonate | FLUKA | purum, ≥98% (GC) | 1098804 24704051 | - |
| NADP-Na ₂ | AppliChem | 97.2% | 6V002232 | January, 2009 |
| Nutrient Broth No. 2. | OXOID | - | 378206 | January, 2010 |
| Sodium azide | MERCK | for synthesis | S4230635 | November, 2009 |
| Sterile distilled water | PCDL | sterile | A137 | April, 2007 |

VITA-PURE, INC.
410 W. 1ST AVENUE
ROSELLE, NJ 07203
TEL: (908) 245-1212 FAX: (908) 245-1999

CERTIFICATE OF ANALYSIS

SF 2226

Our Invoice #
Quantity:
Product: Viga Rx Plus Tablet

Date: 12/06
Lot:# 120657
Exp:# 12/09

PHYSICAL CHARACTERISTICS

Size: 750"
Average Weight: 1200 mg
Disintegration: Within 60 minutes
Hardness: 5KG/CM2
Thickness: 0.320"
Description: Redish Orange Tablet

Shape:Oval

Method-USP
Complies: x
Complies: x

Assay:
Each Tablet Contains:

Label Claim
mg

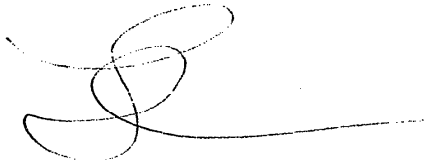
Results
mg

Ingredients:

Korean Red Ginseng (root)
Saw Palmetto (berry)
Hawthorne (berry)
Ginkgo Biloba (leaf)
Damiana (Leaf)
Tribulus Terrestris (vine)
Catuaba 4:1 extract (bark)
Muiru Puama 4:1 extract (bark)
Cuscuta 4:1 extract (seed)
Epimedium 4:1 extract (leaf)
Biperidine

| | |
|--------|---------|
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 75 mg | 75 mg* |
| 50 mg | 50 mg* |
| 50 mg | 50 mg* |
| 25 mg | 25 mg* |
| 15 mg | 15 mg* |
| 5 mg | 5 mg* |

*BASED ON INPUT





Sani-Pure Food Laboratories

CHEMISTS TO THE FOOD INDUSTRIES

178-182 Saddle River Road • Saddle Brook, New Jersey 07663-4619
VOICE (201) 843-2525 • FAX (201) 843-4934 • E-MAIL sanipure.labs@verizon.net

Certificate of Laboratory Analysis FOR INFORMATIONAL PURPOSES ONLY

Vita-Pure, Inc.
410 W. 1st Avenue
Roselle, New Jersey 07203


Date Received: 1/15/2007
Date Reported: 1/22/2007
Lab Number: 07,015,c,130
Purchase Order No. 17455
Page: 1 of 1

Product Identification: Powder Blend of Vigra Rx Tablet
Label: n/a
Net Contents: Plastic Bottle
Lot Number: 120657
Exp Date: n/a

| TEST REQUIRED | RESULT | LIMIT | REFERENCE METHOD |
|-------------------|----------------|-----------------|------------------|
| Total Plate Count | 40 CFU per g | 5,000 CFU per g | USP 29 <61> |
| Salmonella | ABSENT | ABSENT | USP 29 <61> |
| Total Coliforms | ABSENT | ABSENT | USP 29 <61> |
| E. coli | ABSENT | ABSENT | USP 29 <61> |
| Yeasts | < 10 CFU per g | < 500 CFU per g | USP 29 <61> |
| Molds | < 10 CFU per g | < 500 CFU per g | USP 29 <61> |

CFU: COLONY FORMING UNITS

Respectfully submitted,


Ronald A. Schnitzer
Director



ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET
NATIONAL INSTITUTE OF PHARMACY
GENERAL DIRECTOR
H-1051 Budapest V., Zrínyi u. 3.
☎: 1372 POB. 450.
☎/fax: 317-4044, 317-1462
Email: tpaal@ogyi.hu

Budapest, 3rd July, 2006
No.: 239/48/2006
Our ref.: Szilvia Karsai
Annex: -
Subject: GLP Certificate

GOOD LABORATORY PRACTICE (GLP) CERTIFICATE

Based on the Inspection report and the discussion of follow up activities it is hereby certified that the test facility

**Pharmaceutical Control and Development Laboratory Ltd.
Toxicological Department, Microbiological Assay Group
(H-1149 Budapest, Mexikói út 9., Hungary)**

is able to carry out **toxicity, mutagenicity studies** in compliance with the Principles of GLP (Good Laboratory Practice).

Date of inspection: 20-22 February, 2006.

This GLP Certificate is valid for 2 years.



Tamás L. Paál
Prof. Tamás L. Paál
Director-General

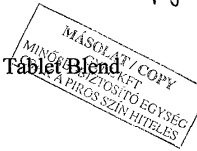
AMENDMENT TO THE PROTOCOL

Study code: PCDL-0703

Title of the study:

Bacterial reverse mutation (Ames) test of Vigra RX Tablet Blend

copy N 05



Number of Amendment: 1.

Type: modification

Reason: In the attached e-mail Dr Alex G. Schauss Ph.D. (monitoring scientist on behalf of the Sponsor) indicated that the name of the test article, Vigra RX Tablet Blend as used in Study Protocol and on all documents generated during and in connection with the study is incorrect. The manufacturer would like to have issued the Report of the study using a name VigRX tablet blend for the test article.

As the lot number 120657 of the test article seems to identify the test article wearing different names on different documents (Ref. 1, 2, 3, 4), we decided to amend the Study Protocol and issue the Report using the suggested name in the Report however listing all synonymous names.

Therefore, the Study Protocol is amended as follows: (Original text: *italics*, altered text: vertical letters)

1.1 Title of the study*Bacterial reverse mutation (Ames) test of Vigra RX Tablet Blend.***1.1 Title of the study**

Bacterial reverse mutation (Ames) test of VigRX tablet blend.

2. Test article

Name:

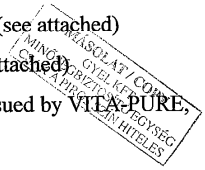
*Vigra RX Tablet Blend (as on the label)***2. Test article**

Name:

VigRX tablet blend,
synonyms: VIGRA RX TABLET BLEND (label),
Viga Rx Plus Tablet ⁽³⁾,
Powder Blend of Vigra Rx Tablet ⁽⁴⁾

References to the present Amendment:

- (1) E-mail from Dr Alex G. Schauss Ph.D. dated March 16, 2007 (see attached)
- (2) Label of the plastic container delivering the test article (copy attached)
- (3) Certificate of Analysis of Viga Rx Plus Tablet, Lot 120657, issued by VITA-PURE, Inc., dated 12/2006 (see attached).
- (4) Certificate of Laboratory Analysis of Powder Blend of Viga Rx Tablet Lot 120657 issued by Sani-Pure Food Laboratories, dated 1/22/2007 (see attached).



Justified by János Horváth Date March 21, 2007
 János Horváth, M.Sc.
 (Study Director) Date

| Informed about the Modification Management: | Signature | Date |
|---|--------------------|-----------------------|
| Head of the Toxicological Dept.: | <u>[Signature]</u> | <u>21-03-2007</u> |
| QAU: | <u>[Signature]</u> | <u>March 21, 2007</u> |
| Sponsor: | <u>[Signature]</u> | <u>20.03.2007.</u> |
| Monitoring Scientist: | <u>[Signature]</u> | <u>March 28, 2007</u> |

Financsek Istvan

From: "Alex Schauss" <alex@aibmr.com>
To: "Istvan Bara" <barai@mail.datanet.hu>; "Istvan Financsek, MD, PhD" <financse@t-online.hu>
Sent: 2007. március 16. 5:20
Attach: 0702-EP.DOC
Subject: From Alex Schauss FW: Acute tox VIGRA Rx

MÁSOLATI COPY
MINOSÍTÉSI ÉRTÉKELÉS
CSÉK A PÍROS SZÍNNI RÉSZT

Dear Dr. Financsek:

I have a dilemma just discovered. We just noticed that the C of A for the VigRX tablet blend incorrectly reported the name of the product as "Vigra RX". This is incorrect. The name is VigRX. The manufacturer's analytical lab just realized this error and now our client is concerned that the report of the acute toxicity study you are doing will have the wrong name for the product and they can not use the findings because of the error. Can this be resolved before issuing the draft final report? I realize this is difficult because it is a GLP study and you rely on the C of A (from Sani-Pure) to determine the product's name.

Any assistance you to provide or instructions on how this can be solved now would be greatly appreciated. The draft report is scheduled to be released on March 29th.

Regards,

Alex Schauss

----- Forwarded Message

From: Financsek Istvan <financse@t-online.hu>
Organization: GYEL Kft
Date: Tue, 20 Feb 2007 16:13:20 +0100
To: Alex Schauss <alex@aibmr.com>
Cc: Bara Istvan <barai@mail.datanet.hu>
Subject: Acute tox VIGRA Rx

Dear Dr Schauss,

Attached please find the Study Protocol of the VIGRA Rx acute tox study for comments and approval.

Best regards,

I.Financsek

----- End of Forwarded Message

WASCO
MINI...
VIGRA RX TABLET BLEND
ROSELLE, NJ 07203

03901
AMES

TO:

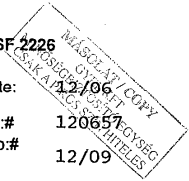
VIGRA RX TABLET BLEND
LOT #120657 w/OUT INACTIVES
NET: 50 GR.

VITA-PURE, INC.
410 W. 1ST AVENUE
ROSELLE, NJ 07203
TEL: (908) 245-1212 FAX: (908) 245-1999

CERTIFICATE OF ANALYSIS

Our Invoice #
Quantity:
Product: Viga Rx Plus Tablet

SF 2226
Date: 12/09
Lot:# 120657
Exp:# 12/09



PHYSICAL CHARACTERISTICS

Size: 750"
Average Weight: 1200 mg
Disintegration: Within 60 minutes
Hardness: 5KG/CM2
Thickness: 0.320"
Description: Redish Orange Tablet

Shape:Oval

Method-USP
Complies: x
Complies: x

Assay:
Each Tablet Contains:

| Label Claim | Results |
|-------------|---------|
| mg | mg |

Ingredients:

Korean Red Ginseng (root)
Saw Palmetto (berry)
Hawthorne (berry)
Ginkgo Biloba (leaf)
Damiana (Leaf)
Tribulus Terrestris (vine)
Catuaba 4:1 extract (bark)
Muir Puama 4:1 extract (bark)
Cuscuta 4:1 extract (seed)
Epimedium 4:1 extract (leaf)
Bioperine

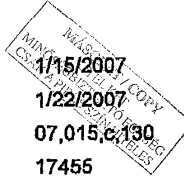
| | |
|--------|---------|
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 100 mg | 100 mg* |
| 75 mg | 75 mg* |
| 50 mg | 50 mg* |
| 50 mg | 50 mg* |
| 25 mg | 25 mg* |
| 15 mg | 15 mg* |
| 5 mg | 5 mg* |

*BASED ON INPUT

Certificate of Laboratory Analysis
FOR INFORMATIONAL PURPOSES ONLY

Vita-Pure, Inc.
410 W. 1st Avenue
Roselle, New Jersey 07203

Date Received: 1/15/2007
Date Reported: 1/22/2007
Lab Number: 07,015,0130
Purchase Order No. 17455
Page: 1 of 1

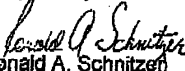


Product Identification: Powder Blend of Vigra Rx Tablet
Label n/a
Net Contents Plastic Bottle
Lot Number 120657
Exp Date n/a

| TEST REQUIRED | RESULT | LIMIT | REFERENCE METHOD |
|-------------------|----------------|-----------------|------------------|
| Total Plate Count | 40 CFU per g | 5,000 CFU per g | USP 29 <61> |
| Salmonella | ABSENT | ABSENT | USP 29 <61> |
| Total Coliforms | ABSENT | ABSENT | USP 29 <61> |
| E. coli | ABSENT | ABSENT | USP 29 <61> |
| Yeasts | < 10 CFU per g | < 500 CFU per g | USP 29 <61> |
| Molds | < 10 CFU per g | < 500 CFU per g | USP 29 <61> |

CFU: COLONY FORMING UNITS

Respectfully submitted,


Ronald A. Schnitzer
Director