Pharmaceutical Control and Development Laboratory Co. Ltd.
9. Mexikói Street Budapest, H-1149

Study code: PCDL-0702

FINAL REPORT

Acute oral toxicity study of VigRX tablet blend with 14-day post-treatment observation period in the rat (Limit test)

Initiation of the study: February 22, 2007
Experimental period: from February 22 to March 14, 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:
I. Financsek, M.D.

This report consists of 40 pages plus 4 attachments.

2007

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(Study code: PCDL-0702)

SUMMARY

General information:

Single oral doses of 2,000 mg/kg or 4,000 mg/kg body weight of VigRX tablet blend (Lot number: 120657) were applied to groups of 5 male and 5 female rats by gavage. Animals were weighed, observed for lethality and toxic symptoms for 14 days. Gross pathological examination was carried out on the 15th day.

Lethality, Clinical symptoms:

No lethality, adverse clinical symptoms were noted at single oral limit dose up to 4,000 mg/kg VigRX tablet blend in male and female rats.

Body weight:

None of the animals lost body weight after treatment or during the post-treatment observation period, however, by Day 2, most of the animals did not gain back their initial body weight weighed at randomization (Day -1), but they did by Day 3. During the rest of the observation period, the animals caught up with the body weight, the females slightly slower than the males.

Gross pathology

All animals survived until the scheduled autopsy on Day 15. All organs of all male and female rats proved to be free of treatment related gross pathological changes.

Evaluation:

Single oral LD_{50} proved to be higher than 4,000 mg/kg both in males and females that corresponds to more than 260 fold of the planned human daily dose of VigRX tablet blend as dietary supplement. The "no adverse effect dose" is not much less than 2,000 mg/kg which caused a slight lag in body weight gain in both genders. No other toxic effects were observed.

Contents

Attachments:
Copy of Certificate of Analysis (also showing input of ingredients), issued by Vita-PURE, Inc.,
Copy of Certificate of Laboratory Analysis issued by Sani-Pure Food Laboratories, Inc.,
E-mail from Dr Alex G. Schauss Ph. D. dated March 16, 2007
Copy of GLP compliance Certificate (PCDL)

Staff in Charge

	Signature	Date
Director of the Laboratory:	István Financsek M.D., Ph.D.	04-04-2007
Study Director:	Susan Somfai-Relle M.D., toxicologist	April 4, 2007
Head of the Toxicological Department, Deputy Study Director:	Tamara Varga agronomist, toxicologist, Ph.D.	April 4, 2007
Quality Assurance Unit:	Piroska Molnár M.Sc. biologist	April 4, 2007
Sponsor:	István Bara Managing Director COFOPEX Ltd.	April 4, 2007
Monitoring Scientist:	Alexander G. Schauss Ph.D. (AIBMR Life Sciences)	April 11, 2007

Staff in Charge

	Signature	Date
Director of the Laboratory:	István Financsek M.D., Ph.D.	04-04-2007
Study Director:	Susan Somfai-Relle M.D., toxicologist	April 4, 2007
Head of the Toxicological Department, Deputy Study Director:	Tamara Varga agronomist, toxicologist, Ph.D.	April 4, 2007
Quality Assurance Unit:	Piroska Molnár M.Sc. biologist	April 4, 2007
Sponsor:	István Bara Managing Director COFOPEX Ltd.	April. 4, 2007
Monitoring Scientist:	Alexander G. Schauss Ph.D. (AIBMR Life Sciences)	

Acute oral toxicity study of VigRX tablet blend
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Study Director's Statement

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)
4. Hungarian Act 1998: XXVIII. and Governmental Regulation 243/1998 "Rules of animal experimentation" modified by Governmental Regulation 103/2002, regulating animal protection

Date: April 4, 2007

Signature:

Dr Susan Somfai-Relle

Susan Somfai-Relle, M.D.
Study Director

Acute oral toxicity study VigRX tablet blend
with 14-day post-treatment observation period in the rat (Limit test)
(Study code: PCDL-0702)

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 and completely reflect the raw data produced during this study.

Inspections concerning adherence to the protocol were performed:

Date of Inspection / Audit	Type of Inspection	Date of Report to the Study Director	Management
February 21, 2007	Protocol audit	February 22, 2007	February 27, 2007
February 28, 2007	Formulation of the test article, sampling of the test suspension for concentration and homogeneity check by gravimetry, treatment.	February 28, 2007	February 28, 2007
March 14, 2007	Autopsy	March 14, 2007	March 14, 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

1. GENERAL INFORMATION

1.1. Title of the study

Acute oral toxicity study of VigRX tablet blend with 14-day post-treatment observation period in the rat (Limit test)

Initiation of the study: February 22, 2007
Experimental period: from February 22 to March 14, 2007

1.2. Objective of the study

To develop data on the potential toxicological effects of single oral administration of VigRX tablet blend[(1)] in the rat. The test article is a mixture of several herbs/plants: Korean Red Ginseng root, Saw Palmetto berry, Hawthorne berry, Ginko Biloba leaf, Damiana leaf, Tribulus Terrestris vine and herbal extracts: Catuaba bark, Muira Puama bark, Cuscuta seed, Epimedium leaf as well as Bioperine [(2)]. All ingredients have been traditionally used for centuries. The product is intended to be used as dietary supplement[(3)], it is the manufacturer's responsibility to ensure its safety[(4)].

1.3. Type of the study

Preclinical toxicological 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)
- 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);
- as well as the Hungarian Act 1998: XXVIII. and Governmental Regulation 243/1998 "Rules of animal experimentation" modified by Governmental Regulation 103/2002, regulating animal protection.

The study was set up according to the
- US-FDA, Center for Food Safety and Applied Nutrition: Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food; "Redbook II" - DRAFT, Acute oral Toxicity Tests.1993 [(5)] and the
- OECD GUIDELINES FOR TESTING OF CHEMICALS (Guideline No.: 423, adopted: 17th December, 2001, Acute Oral Toxicity - Acute Toxic Class Method) [(6)].

2. MATERIALS

2.1. Test article

Name:	**VigRX tablet blend**[1], (synonyms: VIGRA RX TABLET BLEND (label), Viga Rx Plus Tablet [2], Vigra Rx Tablet [7])
Manufacturer:	VITA-PURE, INC. 410 W. 1st Avenue Roselle, NJ 07203
Lot number:	#120657
Appearance:	brownish granular powder
Package form:	plastic container
Ingredients by input in 720 mg:	Korean Red Ginseng root 100 mg, Saw Palmetto berry 100 mg, Hawthorne berry 100 mg, Ginko Biloba leaf 100 mg, Damiana leaf 100 mg, Tribulus Terrestris vine 75 mg, Catuaba 4:1 bark extract 50 mg, Muira Puama 4:1 bark extract 50 mg, Cuscuta 4:1 seed extract 25 mg, Epimedium 4:1 leaf extract 15 mg and Bioperine 5 mg; see List of ingredients attached[2]
Purity:	Total plate count: 40 CFU per g, Salmonella, Coliforms, E. coli: absent, Yeasts, molds: < 10 CFU per g [7]
Identification number at PCDL:	2007/03900
pH (in suspension of 175 mg/ml):	5.22 measured at PCDL
Storage conditions:	room temperature
Expiration date:	12/2009[2]

2.1.1. Chemical analysis

Certificates of Laboratory Analysis provided by the Sponsor were attached to this report[2, 7]. Composition of the product and the analytical control were the Sponsor's responsibility.

2.1.2. Stability control of the test article

Stability control of the test article is the Sponsor's responsibility.

2.1.3. Formulation of the test article

The necessary amount of the test article was weighed and suspended in 1% methylcellulose containing distilled water not earlier than 20 min before administration as follows:

Dose 2,000 mg/kg:

10.0 g VigRX tablet blend + methylcellulose of 1% ad 50 ml
(concentration of the suspension: 200 mg/ml)

Dose 4,000 mg/kg:

20.0 g VigRX tablet blend + methylcellulose of 1% ad 100 ml
(concentration of the suspension: 200 mg/ml)

Suspensions were stirred continuously during treatment with a magnetic stirrer type RCT-basic.

2.1.4. Concentration and homogeneity check of the formulated test article

Concentration and homogeneity of the test suspensions were checked by gravimetry. Samples were taken from both suspensions of the formulated test suspension immediately before the dosing procedure: 3 samples of 0.5 ml each were taken from the top, middle as well as bottom regions.

Results of the concentration and homogeneity check

Nominal concentration mg/ml	Sample	Actual concentration mg/ml	Standard deviation mg/ml	Difference %	Date of sampling / measurement
200 prepared for dose group 2,000 mg/kg	top	198.7	2.73	- 0.67	February 28, 2007 / Feb 28- March 01, 2007
	middle	198.7	5.47	- 0.67	
	bottom	203.3	1.03	+ 1.67	
200 prepared for dose group 4,000 mg/kg	top	205.3	2.07	+ 2.67	February 28, 2007 / Feb 28- March 01, 2007
	middle	203.3	2.73	+ 1.67	
	bottom	204.0	0.00	+ 2.00	

The homogeneity and the actual concentration were within the acceptable limits of ± 5%.

2.2. Characteristics of article used for formulation of the test article

Name:	methylcellulose (MC)	MC solution of 1%
Manufactured by:	SIGMA	PCDL Tox. Group
Batch number:	88H0083	M0010107
Storage conditions:	at room temperature	+2°C - + 8°C
Expiration date:	08. 2008	07. 2007

2.3. Characteristics of article used for over-anesthesia before necropsy

Name:	T 61
Ingredients:	0.2 g embutramide, 0.005 g tetracaine hydrochloride, and 0.05 g mébézonium iodide per ml
Manufacturer:	Intervet International B.V.
Batch number:	12 D 012
Storage conditions:	at room temperature, in safety box for poisonous drugs
Expiration date:	11. 2009
Dose:	0.1 ml / 100 g body weight
Administration:	i.v.

3. TEST SYSTEM

3.1. Animals

Species / Strain:	rat, Crl:CD (Br) of Sprague Dawley origin
Age at arrival:	approx. 7 weeks
Body weight at arrival:	males: 204 - 215 g
	females: 151 - 169 g

Number of animals ordered: 24 rats (12 males, 12 females).
Number of animals involved in the study: 20 (10 males and 10 females)

3.1.1. Breeder/Supplier

Charles River Laboratories Hungary Ltd. Isaszeg, Ady Endre u. 47., H-2117

3.1.2. Hygienic class

SPF at arrival, kept in good conventional environment during the study.

3.2. Reason for the selection of species

The rat is commonly used for toxicological studies in accordance with international recommendations. The Sprague Dawley strain is a well-known laboratory model with sufficient historical data.

3.3. Identification and housing of animals

The animals were identified by ear numbering technique and housed in cages by one. The cages were labeled with tags indicating the I.D. numbers of the rats, the study code, the group identification, sex, route of administration, and the starting and ending dates of the experimental period.

3.4. Housing conditions

Hygienic level: good conventional
Type of animal cages: type III H (eurostandard) polycarbonate bottoms with stainless steel wire mesh lids
Size of cage: H x W x D: 17.5 cm x 24.0 cm x 40.5 cm
Cleaning: by changing the bedding material containing bottom of the cages two times a week
Number of animals per cage: 1
Number of animal keeping room: 122

3.4.1. Environmental conditions

Air exchange: approx. 15 times/hour
Temperature: 22 ± 3°C
Relative humidity: 30 - 70 %
Lighting: artificial, 12-hour light-dark cycles.
Environmental conditions were maintained by a regulated air-conditioning system, temperature and relative humidity were continuously recorded. (Results are kept in the study file.)

3.4.2. Feed

Free access to standardized rat and mouse diet ssniff R/M-Z+H, 15 mm, autoclavable except for the overnight fasting period prior to treatment, during treatment as well as for the first two hours of the post-treatment observation.

The composition of the diet and the acceptable level of contaminants were controlled by the Manufacturer ssniff Spezialdiäten GmbH; D-59494 Soest, Germany. The diet was identified by lot number #981 6239 and the date of manufacturing: Sept. 26, 2006; expiry date March 30, 2007.

3.4.3. Drinking

Rats had free access to tap water via drinking bottles. Drinking water is checked monthly by the Microbiological Department of PCDL.

3.5. Acclimatization period

The animals were observed for 6 days prior to the treatment. Only healthy animals, free from any clinical symptoms were used in the study.

3.6. Randomization

Grouping of the animals was made with a random table generated by a computer. The animals were assigned to groups on the basis of their body weight so that their individual body weights should fall in an interval within ±20% of the mean weight of the group at treatment.

4. EXPERIMENTAL DESIGN

4.1. Dose levels, group division

The following doses and animals were used:

Treatment	Group	Dose	Volume	Males		Females	
		mg/kg po.	ml/kg	Number of animals	Identification No's	Number of animals	Identification No's
VigRX tablet blend	1M	2,000	10	5	#1, #2, #3, #4, #5	-	-
	2F	2,000	10	-	-	5	#11, #12, #13, #14, #15
	3M	4,000	20	5	#6, #7, #8, #9, #10	-	-
	4F	4,000	20	-	-	5	#16, #17, #18, #19, #20

4.2. Reason for dose selection

2,000 or 5,000 mg/kg are the limit doses recommended in the OECD Guideline 423 for acute oral toxicity testing of chemicals[6] and 5,000mg/kg is suggested to be given as limit dose of a food additive by the FDA guideline[5]. A food

additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.[8]

Considering that the test article VigRX tablet blend is a mixture of several herbs, plants as well as herb and plant extracts without known individual toxicity[9], it was not expected to produce mortality when administered in high dose to animals, therefore, 4,000 mg/kg, the highest safely applicable dose to rats, has been selected as limit dose . VigRX tablet blend is foreseen to be used as dietary supplement in an oral dose not more than 0.540 gram two times daily i.e. maximum 1.08 g per day[3] corresponding to 15.4 mg/kg body weight calculated with 70 kg body weight of an adult. The suggested 4,000 mg/kg limit dose, will correspond to a safety factor of approx. than 260. The lower limit dose of 2,000 mg/kg corresponds to a safety factor of approx. 130.

The procedure was carried out on rats of both sexes as no information was available about which sex was more sensible to the test article than the other.

5. ADMINISTRATION

5.1. Route of administration and reason for the selection

Application was oral by gavage. The route of application was selected in compliance with international guidelines. The oral route is the anticipated route of human exposure to the test article.

5.2. Frequency and duration of application

Single dose

5.3. Volume of application

The test article was administered in volumes of 10 or 20 ml/kg body weight (see Table in § 4.1.).

5.4. Duration of the experimental period

Six days of acclimatization, treatment's day, 14 days post-treatment observation period including the treatment's day, and the 15th day: autopsy.

6. OBSERVATIONS, EXAMINATIONS

6.1. Lethality

Observations were made twice daily at the beginning and end of the working day and at least once on weekend days.

6.2. General state, external appearance, behavior, and clinical symptoms

Careful clinical observation of the rats was carried out once before the exposure then, after the treatment for 4 hours continuously, and during the subsequent period, animals were checked twice daily for physical signs of toxicity. On week-ends, animals were checked at least once daily. Signs to be observed includeed changes in skin, fur, eyes and visible mucous membranes; occurrence of secretions and excretions and autonomic activity (e.g. lacrimation, piloerection, diarrhea, pupil size, unusual respiratory pattern). Furthermore, potential changes in gait, posture and response to handling as well as the presence of somnolence, trembling, clonic or tonic movements, stereotypes or bizarre behavior were to be recorded.

6.3. Body weight

Animals were weighed at arrival in the laboratory, on the day of randomization (initial weight), on the day of treatment before the treatment, as well as on the 2nd, 8th days, and on the 15th day of the experiment prior to autopsy. Several animals did not gain back their initial weight by Day 2, they were weighed on Day 3 as well, and then they reached their initial weight i.e. the weight on the day of randomization (Day -1) before food withdrawal.

7. PATHOLOGY

7.1. Autopsy

On completion of the post-treatment observation period all rats were exterminated under T61 over-anesthesia and autopsied.

All external and internal lesions were carefully observed and recorded. As no toxic lesions occurred, no tissue samples were taken for histological examination.

8. EVALUATION, STATISTICAL ANALYSIS

Groups of males and females were evaluated separately.

8.1. Parametric values

Individual changes from body weights weighed on Days 1 and 2, Days 2 and 8 as well as Days 8 and 15 were calculated and tabulated (body weight gain). Because of body weight loss on Day 2, additional body weight differences were calculated i.e. differences between weights on Days 2, 3, and 8 compared to the initial weight (weighed on the day of randomization (Day -1) before food withdrawal). Mean values and standard deviations from the individual body weights and body weight changes were calculated. Body weights and body weight changes were compared with statistical methods as follows:
Bartlett's test was used to compare the variances. If the variances of the groups proved to be homogeneous, one-way analysis of variance (ANOVA) followed by Tukey test were performed. If the values in the groups failed Bartlett's homogeneity test, the Kruskal-Wallis nonparametric one-way analysis of variance and Kolmogorov-Smirnov test were performed.

8.2. Non parametric values (lethality and clinical symptoms)

The incidence of lethality and clinical symptoms were tabulated.

9. PROCEDURES

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

10. ANIMAL PROTECTION

In the interests of animal welfare the unnecessary use of animals was avoided. To order the mild extermination of unambiguously moribund animals was the responsibility of the study director. The present method used a reduced number of experimental animals in comparison to other known and acknowledged acute toxicity tests.

11. DATA RECORDING AND ARCHIVATION

All original data were maintained, as dictated by the Standard Operating Procedures, on appropriate forms as follows:

Test Compound weighing
Animal room logbook

Body weight logbooks
Lethality and Clinical observations logbooks
Postmortem records

The data obtained in the course of the study were 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.

12. SCHEDULE OF THE STUDY

Arrival of the animals:	February 22, 2007
Randomization:	February 27, 2007
Treatment's day:	February 28, 2007
Autopsy:	March 14, 2007

13. RESULTS

13.1. Lethality

(see Table 1. and Appendices 1.1.-1.2.)

No death occurred up to 4,000 mg/kg single oral dose of VigRX tablet blend. All males and females survived until the end of the 14-day observation period.

13.2. Clinical symptoms

(see Table 2. and Appendices 2.1.-2.4.)

No treatment related symptoms were observed either on the day of application or throughout the 14-day post-treatment period at any groups of the male and female animals.

13.3. Body weights

(see Tables 3.1.-3.2. and Appendices 3.1.-3.6.)

None of the animals lost body weight after treatment and during the post-treatment observation period, however, by Day 2, most of the animals did not gain back their initial body weight weighed at randomization (Day -1), but they did by Day 3 only.

Group	Treatment mg/kg po.	No of rats that gained back their initial body weight by Day 2	Difference between initial and Day 2 body weights g	No of rats that gained back their initial body weight by Day 3
1M	2,000	2	-1.6	5
3M	4,000	1	-6.2	5
2F	2,000	0	-3.0	5
4F	4,000	0	-7.2	5

The difference between the body weight and body weight gain differences was not statistically significant in the male animals. In the female animals the differences were more expressed than in the males, the lag of the 4,000 mg/kg treated female group was statistically confirmed. The lag of a few animals in both 4,000 mg treated groups reached approx. 10 g (6M, 9 M of Group 3M and 16F, 17F of Group 4F), this is not more than approx. 5% of their initial body weight. During the rest of the observation period, the animals caught up with the body weight, the females slightly slower than the males.

13.4. Gross pathology

(see Table 4. and Appendices 4.1.- 4.2.)

All animals survived until the scheduled autopsy on Day 15. All organs of all male and female rats proved to be free of treatment related gross pathological changes.

Pathological changes not considered to be treatment related:

- Two females: #14F (Group 2F), #19F (Group 4F) out of the 10 female rats had uterine horns distended, containing water-like fluid, the latter slightly hyperemic. Uterine horns of rat #18F (Group 4F) were of normal size but slightly hyperemic. Distended and/or slightly hyperemic uterine horns (hydrometra) are often observed in normal rats and is a slight physiological disorder connected to the uterine cycle.

14. EVALUATION

No death occurred, no body weight loss was observed. Several animals did not gain back their initial body weight by Day 2, during the rest of the observation period, they caught up with their body weight, the females slightly slower than the males. The body weight difference could be partially attributed to the doubled volume given to the high dose animals.

No toxic or other clinical symptoms were apparent. Autopsy revealed no treatment related pathological changes.

Conclusion:

Single oral LD50 proved to be higher than 4,000 mg/kg both in males and females, that corresponds to more than 260 fold of the planned human daily dose of VigRX tablet blend as dietary supplement. The "no adverse effect dose" is not much less than 2,000 mg/kg which caused a slight lag in body weight gain in both genders. No other toxic effects were observed.

Dr Susan Somfai-Relle April 4. 2007

Susan Somfai-Relle, M.D.
Study Director

References:

1. E-mail from Dr Alex G. Schauss Ph.D. dated March 16, 2007 (see attached) and Amendment to the Protocol PCDL-0702 dated March 20, 2007.
2. VIGA RX Plus TABLET; Copy of Certificate of Analysis (also showing input of ingredients), issued by Vita-PURE, Inc., dated 12/06, unreadable signature (see attached).
3. E-mail of Dr Alex G. Schauss Ph.D. forwarded by Mr. Bara on February 15, 2007.
4. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition: Dietary Supplement Health and Education Act of 1994
5. US-FDA, Center for Food Safety and Applied Nutrition: Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food; "Redbook II" - DRAFT, Acute oral Toxicity Tests.1993.
6. OECD GUIDELINES FOR TESTING OF CHEMICALS (Guideline No.: 423, adopted: 17th December, 2001, Acute Oral Toxicity - Acute Toxic Class Method).
7. Certificate of Laboratory Analysis for informational purposes only, Vigra RX Tablet issued by Sani-Pure Food Laboratories, Inc., dated 1/22/2007, signed by Ronald A Schnitzer (see attached)
8. 21 CFR Ch. I (4-1-03 Edition) Subpart B – Food Additive Safety §170.22 Safety factors to be considered.
9. Wikipedia, The Free Encyclopedia http://en.wikipedia.org

Tables

Table 1.

Lethality

Post-treatment observation period (14 days)

	MALES	FEMALES
Treatment	death / number of animals	
Groups 1M / 2F **VigRX tablet blend;** **2,000 mg/kg, po.**	0/5	0/5
Groups 3M / 4F **VigRX tablet blend;** **4,000 mg/kg, po.**	0/5	0/5

Table 2.

Clinical Symptoms

During the first four hours after treatment and
the 14 day post-treatment observation period

	MALES	FEMALES
Treatment	symptom / number of animals	
Groups 1M / 2F **VigRX tablet blend;** **2,000 mg/kg, po.**	0/5	0/5
Groups 3M / 4F **VigRX tablet blend;** **4,000 mg/kg, po.**	0/5	0/5

Table 3.1.

Body Weights

MALES

Group; Treatment	Body weights [g]						
	Day of arrival	Day of randomization (Day-1)	Day 1 prior to treatment	Day 2	Day 3	Day 8	Day 15
Group 1M; VigRX tablet blend; 2,000 mg/kg, po.							
Group size:	5	5	5	5	5	5	5
Mean:	206	291	264	289	300	347	389
± S.D.:	2.4	6.55	6.18	8.98	8.78	15.5	15.8
Group 3M; VigRX tablet blend; 4,000 mg/kg, po.							
Group size:	5	5	5	5	5	5	5
Mean:	209	290	265	284	293	345	387
± S.D.:	3.86	7.58	7.35	10.5	7.41	16.8	21.1

FEMALES

Group; Treatment	Body weights [g]						
	Day of arrival	Day of randomization (Day-1)	Day 1 prior to treatment	Day 2	Day 3	Day 8	Day 15
Group 2F; VigRX tablet blend; 2,000 mg/kg, po.							
Group size:	5	5	5	5	5	5	5
Mean:	158	185	168	182	189	217	234
± S.D.:	6.39	7.08	3.93	4.88	6.34	8.77	12.0
Group 4F; VigRX tablet blend; 4,000 mg/kg, po.							
Group size:	5	5	5	5	5	5	5
Mean:	159	184	169	177	185	205	226
± S.D.:	6.26	9.70	9.53	6.61	9.85	14.6	11.2

Table 3.2.

Body Weight Changes

MALES

Group / Treatment	Body weight changes [g]					
	Day -1 through Day 2	Day -1 through Day 3	Day -1 through Day 8	Day 3 through Day 8	Day 8 through Day 15	Day 1 through Day 15
Group 1M; VigRX tablet blend; 2,000 mg/kg, po.						
Group size:	5	5	5	5	5	5
Mean:	-1.6	8.8	56.4	47.6	42.2	125
± S.D.:	6.7	5.7	11.0	6.9	7.5	10.4
Group 3M; VigRX tablet blend; 4,000 mg/kg, po.						
Group size:	5	5	5	5	5	5
Mean:	-6.2	2.5	54.6	52.1	41.9	122
± S.D.:	5.6	0.4	9.4	9.6	4.6	16.3

FEMALES

Group / Treatment	Body weight changes [g]					
	Day -1 through Day 2	Day -1 through Day 3	Day -1 through Day 8	Day 3 through Day 8	Day 8 through Day 15	Day 1 through Day 15
Group 2F; VigRX tablet blend; 2,000 mg/kg, po.						
Group size:	5	5	5	5	5	5
Mean:	-3.0	4.1	32.0	27.9	17.4	66.2
± S.D.:	2.9	2.9	6.8	7.4	4.2	10.2
Group 4F; VigRX tablet blend; 4,000 mg/kg, po.						
Group size:	5	5	5	5	5	5
Mean:	-7.2	0.8	20.8	20.0	20.5	56.4
± S.D.:	-3.3	0.6	9.4	9.0	7.3	12.3

Table 4.

Gross Pathological Findings

	Animal with findings / number of animals			
	external	internal	external	internal
	MALES		FEMALES	
Treatment / Groups	**Group 1M**		**Group 2F**	
VigRX tablet blend; 2,000 mg/kg, po.	0/5	0/5	0/5	1*/5
Treatment / Groups	**Group 3M**		**Group 4F**	
VigRX tablet blend; 4,000 mg/kg, po.	0/5	0/5	0/5	2*/5

* #14F (Group2F), #19F (Group 4F): uterine horns distended and filled with watery fluid, slightly hyperemic, #18F (Group4F): uterine horns slightly hyperemic

Appendices

Appendix 1.1.

Individual Data of Lethality

MALES

Group / Animal code	DAYS OF OBSERVATION PERIOD														
	Day 1*	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Group 1M: VigRX tablet blend; 2,000 mg/kg, po.															
1	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
2	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
3	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
4	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
5	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
Group 3M: VigRX tablet blend; 4,000 mg/kg, po.															
6	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
7	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
8	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
9	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ
10	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ	θ

Remarks: θ = No Lethality

* Day 1 = Treatment's day

Appendix 1.2.

Individual Data of Lethality

FEMALES

Group Animal code	DAYS OF OBSERVATION PERIOD														
	Day 1*	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Group 2F: VigRX tablet blend; 2,000 mg/kg, po.															
11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Group 4F: VigRX tablet blend; 4,000 mg/kg, po.															
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Remarks: 0 = No Lethality

* Day 1 = Treatment's day

Appendix 2.1.

Individual Clinical Symptoms

during the first four hours after treatment

MALES

Animal code	After treatment min	Observations
Group 1M: VigRX tablet blend; 2,000 mg/kg, po.		
1	0 – 240	Symptom-free. 124 min (feeding time) starts to eat
2	0 – 240	Symptom-free. 125 min (feeding time) starts to eat
3	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
4	0 – 240	Symptom-free. 132 min (feeding time) starts to eat
5	0 – 240	Symptom-free. 126 min (feeding time) starts to eat
Group 3M: VigRX tablet blend; 4,000 mg/kg, po.		
6	0 – 240	Symptom-free. 126 min (feeding time) starts to eat
7	0 – 240	Symptom-free. 122 min (feeding time) starts to eat
8	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
9	0 – 240	Symptom-free. 124 min (feeding time) starts to eat
10	0 – 240	Symptom-free. 122 min (feeding time) starts to eat

Appendix 2.2.

Individual Clinical Symptoms

Post-treatment observation period (14 days*)

MALES

Group	DAYS OF OBSERVATION PERIOD														
Animal code	Day 1*	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Group 1M: VigRX tablet blend; 2,000 mg/kg, po.															
1	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
2	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
3	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
4	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
5	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
Group 3M: VigRX tablet blend; 4,000 mg/kg, po.															
6	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
7	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
8	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
9	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
10	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF

Remarks: SF = Symptom Free

* Day 1 = Treatment's day, symptoms of males observed during the first 4 hours of the treatment's day are shown in App. 2.1 on the previous page

Appendix 2.3.

Individual Clinical Symptoms

during the first four hours after treatment

FEMALES

Animal code	After treatment min	Observations
Group 2F: VigRX tablet blend; 2,000 mg/kg, po.		
11	0 – 240	Symptom-free. 128 min (feeding time) starts to eat
12	0 – 240	Symptom-free. 124 min (feeding time) starts to eat
13	0 – 240	Symptom-free. 122 min (feeding time) starts to eat
14	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
15	0 – 240	Symptom-free. 122 min (feeding time) starts to eat
Group 4F: VigRX tablet blend; 4,000 mg/kg, po.		
16	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
17	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
18	0 – 240	Symptom-free. 123 min (feeding time) starts to eat
19	0 – 240	Symptom-free. 126 min (feeding time) starts to eat
20	0 – 240	Symptom-free. 124 min (feeding time) starts to eat

Appendix 2.4.

Individual Clinical Symptoms

Post-treatment observation period (14 days*)

FEMALES

Group / Animal code	DAYS OF OBSERVATION PERIOD														
	Day 1*	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Group 2F: VigRX tablet blend; 2,000 mg/kg, po.															
11	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
12	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
13	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
14	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
15	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
Group 4F: VigRX tablet blend; 4,000 mg/kg, po.															
16	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
17	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
18	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
19	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF
20	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF

Remarks: SF = Symptom Free

* Day 1 = Treatment's day, symptoms of females observed during the first 4 hours of the treatment's day are shown in App. 2.3 on the previous page

Appendix 3.1.

Individual Body Weights

MALES

Group / Animal code	Body weights [g]						
	Day of arrival	Day of randomi-zation	Day 1, prior to treatment	Day 2	Day 3	Day 8	Day 15
Group 1M: VigRX tablet blend; 2,000 mg/kg, po.							
1	208.9	300.0	269.8	293.1	304.9	356.8	395.4
2	203.9	292.8	268.1	288.7	300.4	350.5	405.3
3	209.0	290.0	265.6	292.0	301.7	352.0	389.1
4	204.5	289.7	263.6	298.0	306.7	356.9	394.0
5	205.9	281.8	254.0	274.3	284.6	319.9	363.2
Group size:	5	5	5	5	5	5	5
Mean:	**206**	**291**	**264**	**289**	**300**	**347**	**389**
± S.D.:	**2.4**	**6.5**	**6.2**	**9.0**	**8.8**	**15.5**	**15.8**
Group 3M: VigRX tablet blend; 4,000 mg/kg, po.							
6	207.9	299.6	272.5	289.5	301.9	363.5	410.7
7	205.8	296.3	266.4	294.9	298.7	361.7	407.7
8	215.3	290.5	269.8	290.6	293.0	341.7	381.1
9	206.1	283.6	254.9	270.7	286.9	329.9	370.9
10	208.1	282.4	259.2	275.7	284.6	328.6	364.7
Group size:	5	5	5	5	5	5	5
Mean:	**209**	**290**	**265**	**284**	**293**	**345**	**387**
± S.D.:	**3.9**	**7.6**	**7.3**	**10.5**	**7.4**	**16.8**	**21.1**

Appendix 3.2.

Individual Body Weights

FEMALES

Group / Animal code	Body weights [g]						
	Day of arrival	Day of randomi-zation	Day 1. prior to treatment	Day 2	Day 3	Day 8	Day 15
Group 2F: VigRX tablet blend; 2,000 mg/kg. po.							
11	157.1	193.2	173.0	185.2	194.5	232.1	253.5
12	168.7	190.8	171.2	187.6	193.3	211.5	224.9
13	156.1	182.8	165.8	181.7	189.0	214.7	236.9
14	151.8	181.0	165.6	179.0	189.0	214.6	231.0
15	155.5	176.1	164.0	175.3	178.4	210.8	224.4
Group size:	5	5	5	5	5	5	5
Mean:	**158**	**185**	**168**	**182**	**189**	**217**	**234**
± S.D.:	**6.4**	**7.1**	**3.9**	**4.9**	**6.3**	**8.8**	**12.0**
Group 4F: VigRX tablet blend; 4,000 mg/kg. po.							
16	164.5	196.2	179.6	185.6	197.8	230.9	242.7
17	162.8	189.2	175.8	179.0	189.8	201.5	216.2
18	153.0	186.7	168.5	179.6	186.7	201.7	229.3
19	161.6	179.0	168.2	174.2	180.1	194.8	215.2
20	150.6	171.0	154.7	167.9	171.8	197.3	225.2
Group size:	5	5	5	5	5	5	5
Mean:	**159**	**184**	**169**	**177**	**185**	**205**	**226**
± S.D.:	**6.3**	**9.7**	**9.5**	**6.6**	**9.8**	**14.6**	**11.2**

Appendix 3.3.

Individual Body Weight Changes

between subsequent weighing days

MALES

Group	Body weight changes [g]				
Animal code	Day 1 through Day 2	Day 2 through Day 3	Day 3 through Day 8	Day 8 through Day 15	Day 1 through Day 15
Group 1M: VigRX tablet blend; 2,000 mg/kg; po.					
1	23.3	11.8	51.9	38.6	125.6
2	20.6	11.7	50.1	54.8	137.2
3	26.4	9.7	50.3	37.1	123.5
4	34.4	8.7	50.2	37.1	130.4
5	20.3	10.3	35.3	43.3	109.2
Group size:	5	5	5	5	5
Mean:	**25.0**	**10.4**	**47.6**	**42.2**	**125**
± S.D.:	**5.80**	**1.33**	**6.89**	**7.50**	**10.4**
Group 3M: VigRX tablet blend; 4,000 mg/kg; po.					
6	17.0	12.4	61.6	47.2	138.2
7	28.5	3.8	63.0	46.0	141.3
8	20.8	2.4	48.7	39.4	111.3
9	15.8	16.2	43.0	41.0	116.0
10	16.5	8.9	44.0	36.1	105.5
Group size:	5	5	5	5	5
Mean:	**19.7**	**8.74**	**52.1**	**41.9**	**122**
± S.D.:	**5.28**	**5.78**	**9.61**	**4.63**	**16.3**

Appendix 3.4.

Individual Body Weight Changes

between subsequent weighing days

FEMALES

Group	Body weight changes [g]				
Animal code	Day 1 through Day 2	Day 2 through Day 3	Day 3 through Day 8	Day 8 through Day 15	Day 1 through Day 15
Group 2F: VigRX tablet blend; 2,000 mg/kg; po.					
11	12.2	9.3	37.6	21.4	80.5
12	16.4	5.7	18.2	13.4	53.7
13	15.9	7.3	25.7	22.2	71.1
14	13.4	10.0	25.6	16.4	65.4
15	11.3	3.1	32.4	13.6	60.4
Group size:	5	5	5	5	5
Mean:	**13.8**	**7.08**	**27.9**	**17.4**	**66.2**
± S.D.:	**2.24**	**2.79**	**7.39**	**4.20**	**10.2**
Group 4F: VigRX tablet blend; 4,000 mg/kg; po.					
16	6.0	12.2	33.1	11.8	63.1
17	3.2	10.8	11.7	14.7	40.4
18	11.1	7.1	15.0	27.6	60.8
19	6.0	5.9	14.7	20.4	47.0
20	13.2	3.9	25.5	27.9	70.5
Group size:	5	5	5	5	5
Mean:	**7.90**	**7.98**	**20.0**	**20.5**	**56.4**
± S.D.:	**4.11**	**3.45**	**9.00**	**7.32**	**12.3**

Appendix 3.5.

Individual Body Weight Changes
referring to initial weight*

MALES

Group	Body weight changes [g]			
Animal code	Day -1 through Day 2	Day -1 through Day 3	Day -1 through Day 8	Day -1 through Day 15
Group 1M: VigRX tablet blend; 2,000 mg/kg; po.				
1	-6.9	4.9	56.8	95.4
2	-4.1	7.6	57.7	112.5
3	2.0	11.7	62.0	99.1
4	8.3	17.0	67.2	104.3
5	-7.5	2.8	38.1	81.4
Group size:	5	5	5	5
Mean:	**-1.6**	**8.8**	**56.4**	**98.5**
± S.D.:	**6.7**	**5.7**	**11.0**	**11.5**
Group 3M: VigRX tablet blend; 4,000 mg/kg; po.				
6	-10.1	2.3	63.9	111.1
7	-1.4	2.4	65.4	111.4
8	0.1	2.5	51.2	90.6
9	-12.9	3.3	46.3	87.3
0	-6.7	2.2	46.2	82.3
Group size:	5	5	5	5
Mean:	**-6.2**	**2.5**	**54.6**	**96.5**
± S.D.:	**5.5**	**0.4**	**9.4**	**13.8**

* Initial body weight = weight on the day of randomization (Day -1) before food withdrawal

Appendix 3.6.

Individual Body Weight Changes
referring to initial weight*

FEMALES

Group	Body weight changes [g]			
Animal code	Day -1 through Day 2	Day -1 through Day 3	Day -1 through Day 8	Day -1 through Day 15
Group 2F: VigRX tablet blend; 2,000 mg/kg; po.				
11	-8.0	1.3	38.9	60.3
12	-3.2	2.5	20.7	34.1
13	-1.1	6.2	31.9	54.1
14	-2.0	8.0	33.6	50.0
15	-0.8	2.3	34.7	48.3
Group size:	5	5	5	5
Mean:	**-3.0**	**4.1**	**32.0**	**49.4**
± S.D.:	**2.94**	**2.88**	**6.80**	**9.70**
Group 4F: VigRX tablet blend; 4,000 mg/kg; po.				
16	-10.6	1.6	34.7	46.5
17	-10.2	0.6	12.3	27.0
18	-7.1	0.0	15.0	42.6
19	-4.8	1.1	15.8	36.2
20	-3.1	0.8	26.3	54.2
Group size:	5	5	5	5
Mean:	**-7.2**	**0.8**	**20.8**	**41.3**
± S.D.:	**3.28**	**0.59**	**9.41**	**10.3**

* Initial body weight = weight on the day of randomization (Day -1) before food withdrawal

Appendix 4.1.

Gross Pathological Findings

MALES

Group Animal code	Day 15	
	external	internal
Group 1M: VigRX tablet blend; 2,000 mg/kg; po.		
1	No Finding	No Finding
2	No Finding	No Finding
3	No Finding	No Finding
4	No Finding	No Finding
5	No Finding	No Finding
Group 3M: VigRX tablet blend; 4,000 mg/kg; po.		
6	No Finding	No Finding
7	No Finding	No Finding
8	No Finding	No Finding
9	No Finding	No Finding
10	No Finding	No Finding

„No Finding" stands here for:

external: Animal of average development. Skin. fur. visible mucous membranes are intact.

internal: Organs are without pathological changes. Gastric mucosa: intact.

Appendix 4.2.

Gross Pathological Findings

FEMALES

Group	Day 15	
Animal code	external	internal
Group 2F: VigRX tablet blend; 2,000 mg/kg, po.		
11	No Finding	No Finding
12	No Finding	No Finding
13	No Finding	No Finding
14	No Finding	The uterine horns are distended. diam. approx. 3 mm, filled with clear water-like fluid, slightly hyperemic. The rest of the organs: intact.
15	No Finding	No Finding
Group 4F: VigRX tablet blend; 4,000 mg/kg; po.		
16	No Finding	No Finding
17	No Finding	No Finding
18	No Finding	The uterine horns slightly hyperemic. The rest of the organs: intact.
19	No Finding	The uterine horns slightly distended. diam. approx. 3 mm, filled with clear water-like fluid, slightly hyperemic. The rest of the organs: intact.
20	No Finding	No Finding

„No Finding" stands here for:

external: Animal of average development. Skin. fur. visible mucous membranes are intact.

internal: Organs are without pathological changes. Gastric mucosa: intact.

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
Disintergration: 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:

Ingredients:	Label Claim mg	Results mg
Korean Red Ginseng (root)	100 mg	100 mg*
Saw Palmetto (berry)	100 mg	100 mg*
Hawthorne (berry)	100 mg	100 mg*
Ginkgo Biloba (leaf)	100 mg	100 mg*
Damiana (Leaf)	100 mg	100 mg*
Tribulus Terrestris (vine)	75 mg	75 mg*
Catuaba 4:1 extract (bark)	50 mg	50 mg*
Muira Puama 4:1 extract (bark)	50 mg	50 mg*
Cuscuta 4:1 extract (seed)	25 mg	25 mg*
Epimedium 4:1 extract (leaf)	15 mg	15 mg*
Bioperine	5 mg	5 mg*

*BASED ON INPUT

MEMBER ACIL

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

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

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.

ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET

Prof. Tamás L. Paál
Director-General