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TESTOFENTM

Fenugreek Extract standardized for FENUSIDETM

Anabolic & Androgenic Activity



Gencor Pacific Inc.

920, E.Orangethorpe Avenue, Suite B, Anaheim, CA - 92801

Animal Study on Aphrodisiac Activity of **TESTOFEN**TM (Fenugreek Extract standardised for **FENUSIDE**TM)

Swiss Wistar rats of weight 160 - 220 grams were used for this study.

The rats were separated into 5 groups as below.

- 1.] Group 0 : 7 pairs of male and female. This was the control group [placebo] where normal food was fed to the rats.
- 2.] Group 1 : 7 pairs of male and female. The male rats were given orally 5 mg / kg body weight of **TESTOFEN**TM daily .
- 3.] Group 2 : 7 pairs of male and female. The male rats were given orally 10 mg / kg of body weight of **TESTOFEN**TM daily.
- 4.] Group 3 : 7 pairs of male and female rats. The male rats were given orally 25 mg / kg of body weight of **TESTOFEN**TM daily.
- 5.] Group 4 : 7 pairs of male and female rats. The male rats were given orally 5 mg / kg of body weight of **Sildenafil Citrate** daily.

The animals were kept in special observation cages and the sexual behaviour was observed to note the following during 8 hours from 10 a.m. to 6 p.m.

- 1.] MF - Mounting Frequency
- 2.] IF - Intromission Frequency
- 3.] ML- Mounting Latency
- 4.] IL- Intromission Latency
- 5.] EL - Ejaculation Latency
- 6.] PEI - Post Ejaculation Interval
- 7.] Testosterone Levels

These readings were compared with placebo and with the positive control with Sildenafil Citrate. The observations were as follows. Statistical significance was measured by ANOVA parameters.

Summary of Results Observed

- 1.] All the three test groups showed statistically significant activity over the placebo group. Mounting frequency and intromission frequency increased, mounting latency and intromission latency decreased, ejaculation latency increased and post ejaculation interval levels decreased.
- 2.] The 25 mg / kg body weight fed test group, showed comparable activity to the positive control group with Sildenafil Citrate.
- 3.] Testosterone levels increased significantly in the entire test group compared to the placebo group. Testosterone levels did not increase in the positive control group, which were fed with Sildenafil Citrate.
- 4.] Androgenic Activity increase was observed in the test group, which were significantly higher than the placebo group and the positive control group.
- 5.] There was no blood pressure drop in either the test groups or the placebo group. There was a 23 % drop in blood pressure in the positive control group due to side effects of the drug Sildenafil Citrate.
- 6.] Muscle mass increase was observed in the entire test group.

Tables of the observations are given in the next page.

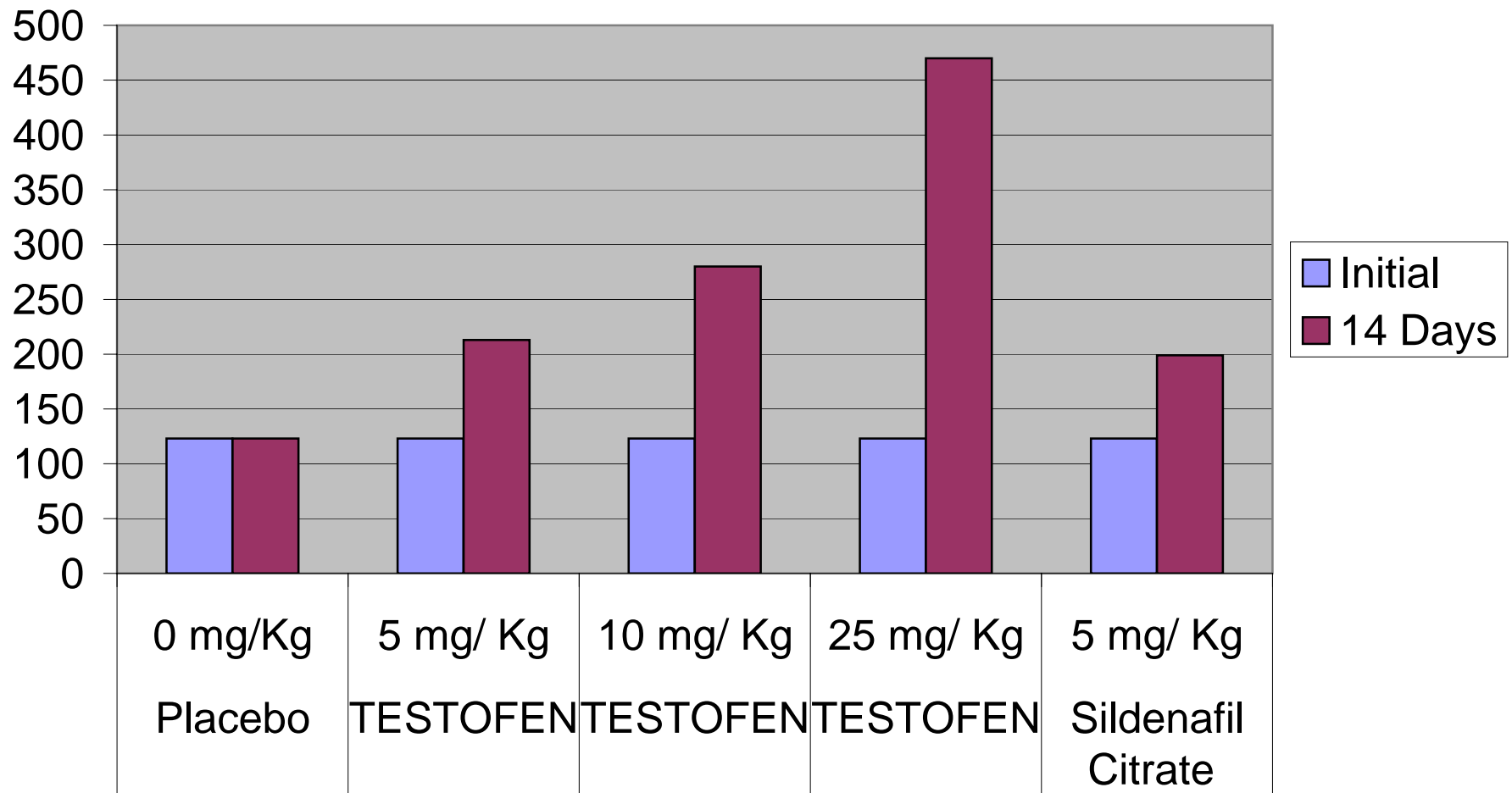
OBSERVATIONS TABLE

Aphrodisiac activity of **TESTOFEN**TM

Readings as on the 14th day

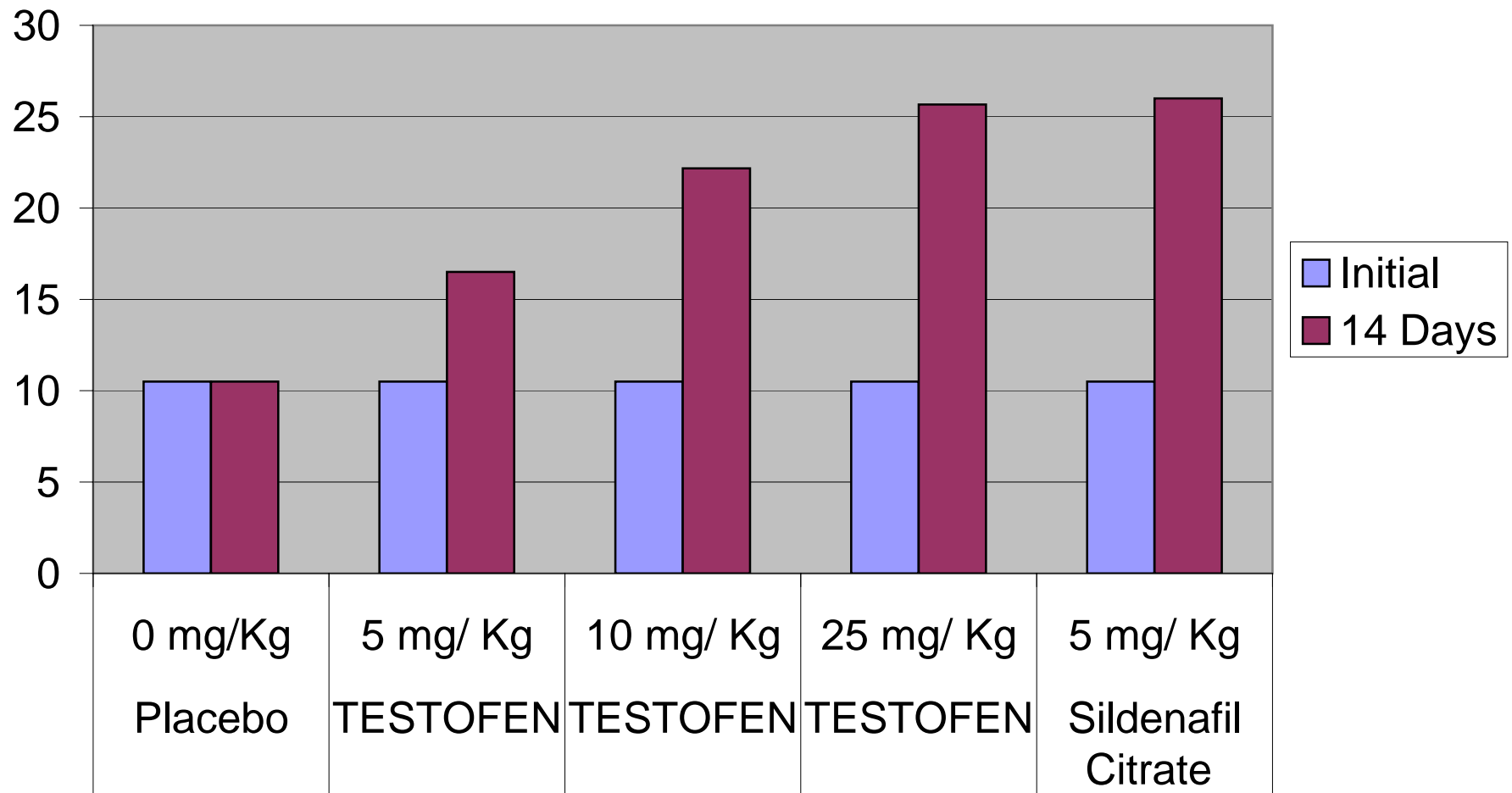
Group	MF	IF	ML	IL	EL	PEI	Testosterone
Group-0 Placebo N=7 No drug	10.50	6.5	136.83	201.17	211.50	330.33	123
Group-1 Substance treated N=7 5 mg/kg TESTOFEN TM	16.50	13.5	87.83	109.17	262.17	241.17	213
Group-2 Substance treated N=7 10mg/kg TESTOFEN TM	22.17	18.00	58.67	84.17	283.67	200.67	280
Group-3 Substance treated N=7 25mg/kg TESTOFEN TM	25.67	21.17	38.17	67.17	318.67	133.33	470
Group-4 Positive Control N=7 5 mg/kg Sildenafil Citrate	26.00	21.00	33.83	58.00	332.17	103.83	199

TESTOFEN™ Animal Study: Testosterone level



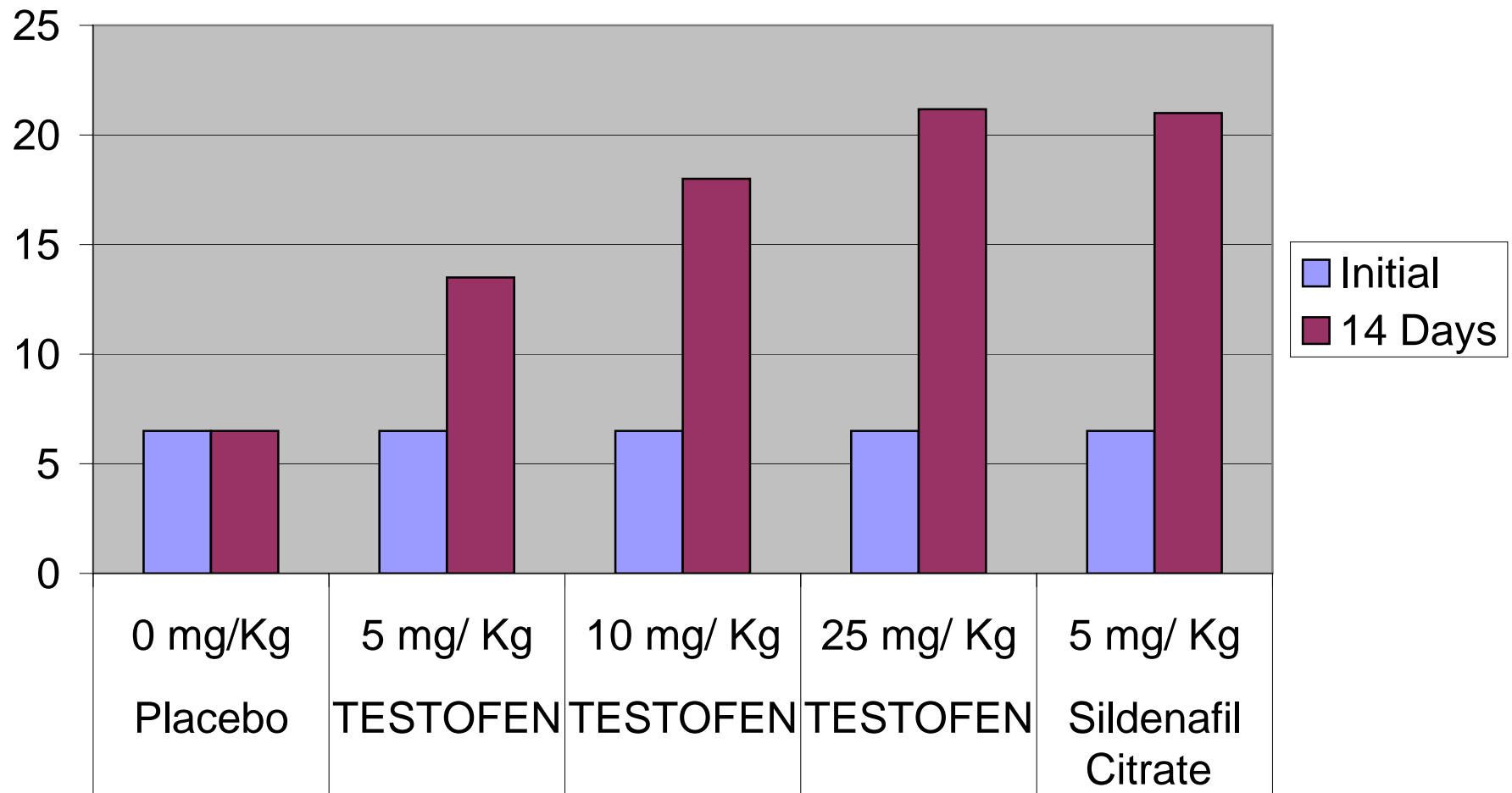
Gencor Pacific, Inc.			
Animal Study of TESTOFEN TM :			
Increase in Testosterone Level			
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	123	123
TESTOFEN	5 mg/ Kg	123	213
TESTOFEN	10 mg/ Kg	123	280
TESTOFEN	25 mg/ Kg	123	470
Sildenafil Citrate	5 mg/ Kg	123	199

TESTOFEN™ Animal Study : Mounting Frequency



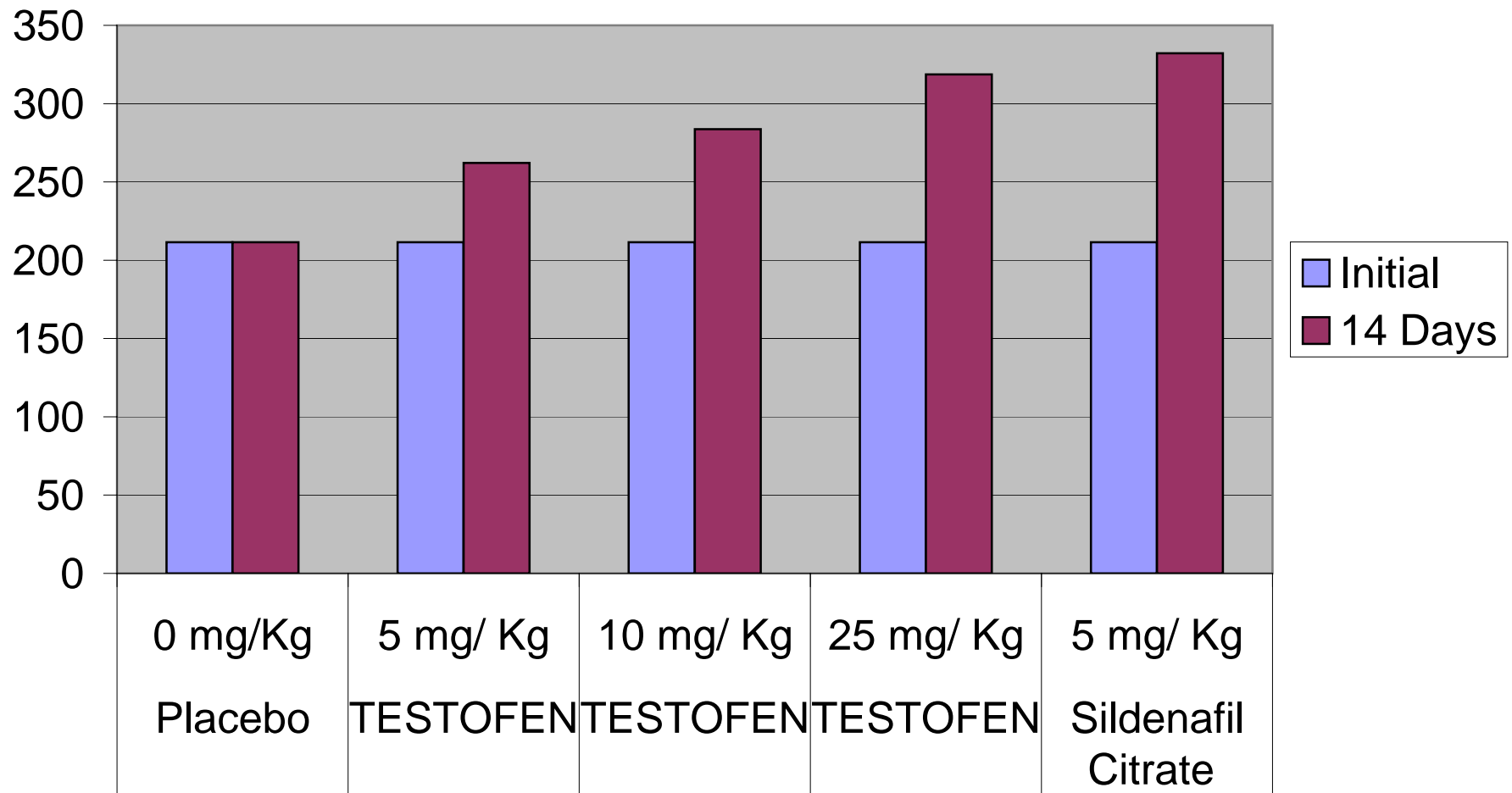
Gencor Pacific, Inc.			
Animal Study of TESTOFEN [™] :			
Increase in Mounting Frequency			
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	10.5	10.5
TESTOFEN	5 mg/ Kg	10.5	16.5
TESTOFEN	10 mg/ Kg	10.5	22.17
TESTOFEN	25 mg/ Kg	10.5	25.67
Sildenafil Citrate	5 mg/ Kg	10.5	26

TESTOFEN™ Animal Study: Intromission Frequency



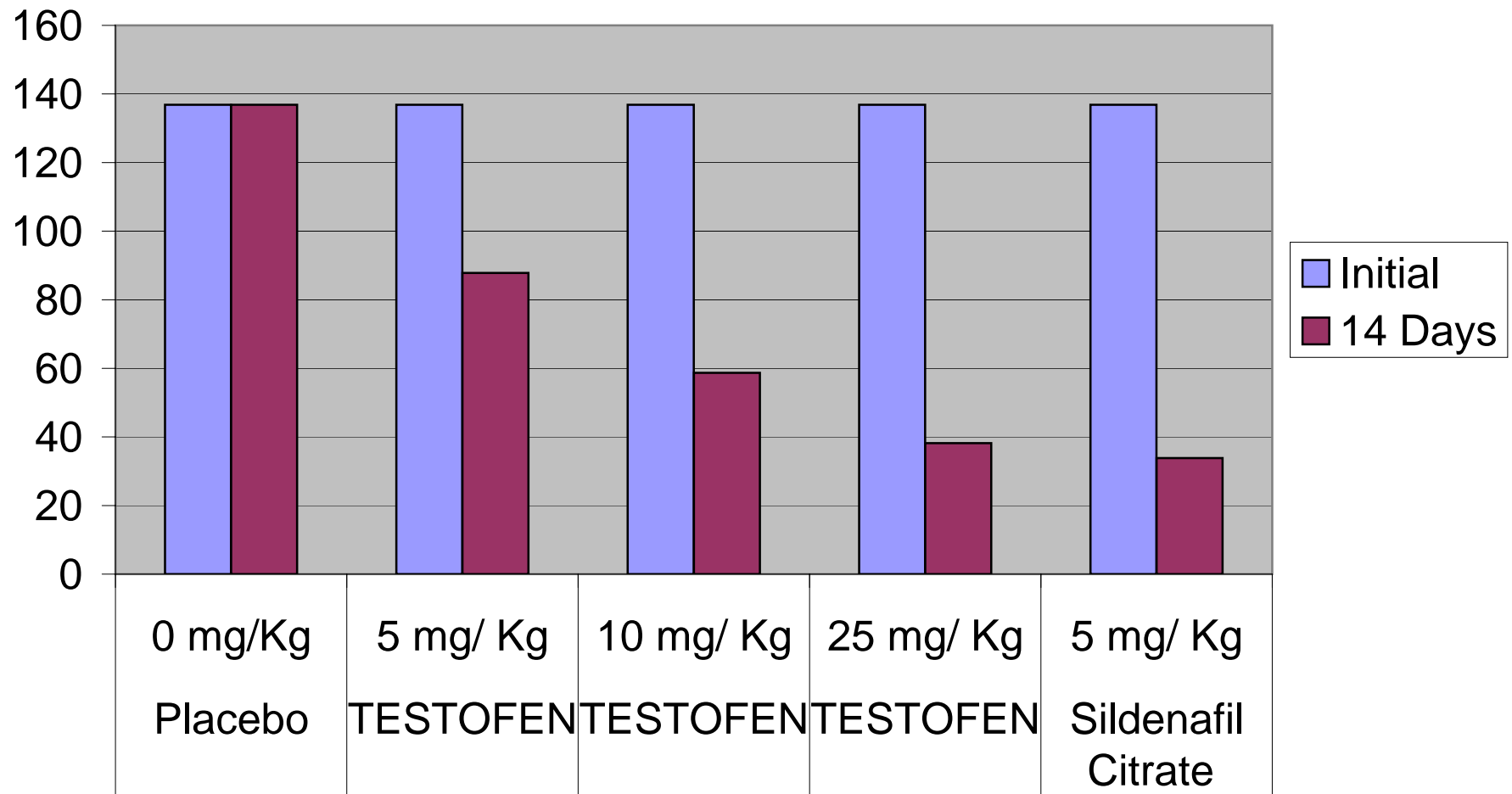
Gencor Pacific, Inc.			
Animal Study of TESTOFEN™ :			
	Increase in Intromission Frequency		
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	6.5	6.5
TESTOFEN	5 mg/ Kg	6.5	13.5
TESTOFEN	10 mg/ Kg	6.5	18
TESTOFEN	25 mg/ Kg	6.5	21.17
Sildenafil Citrate	5 mg/ Kg	6.5	21

TESTOFEN™ Animal Study: Ejaculation Latency



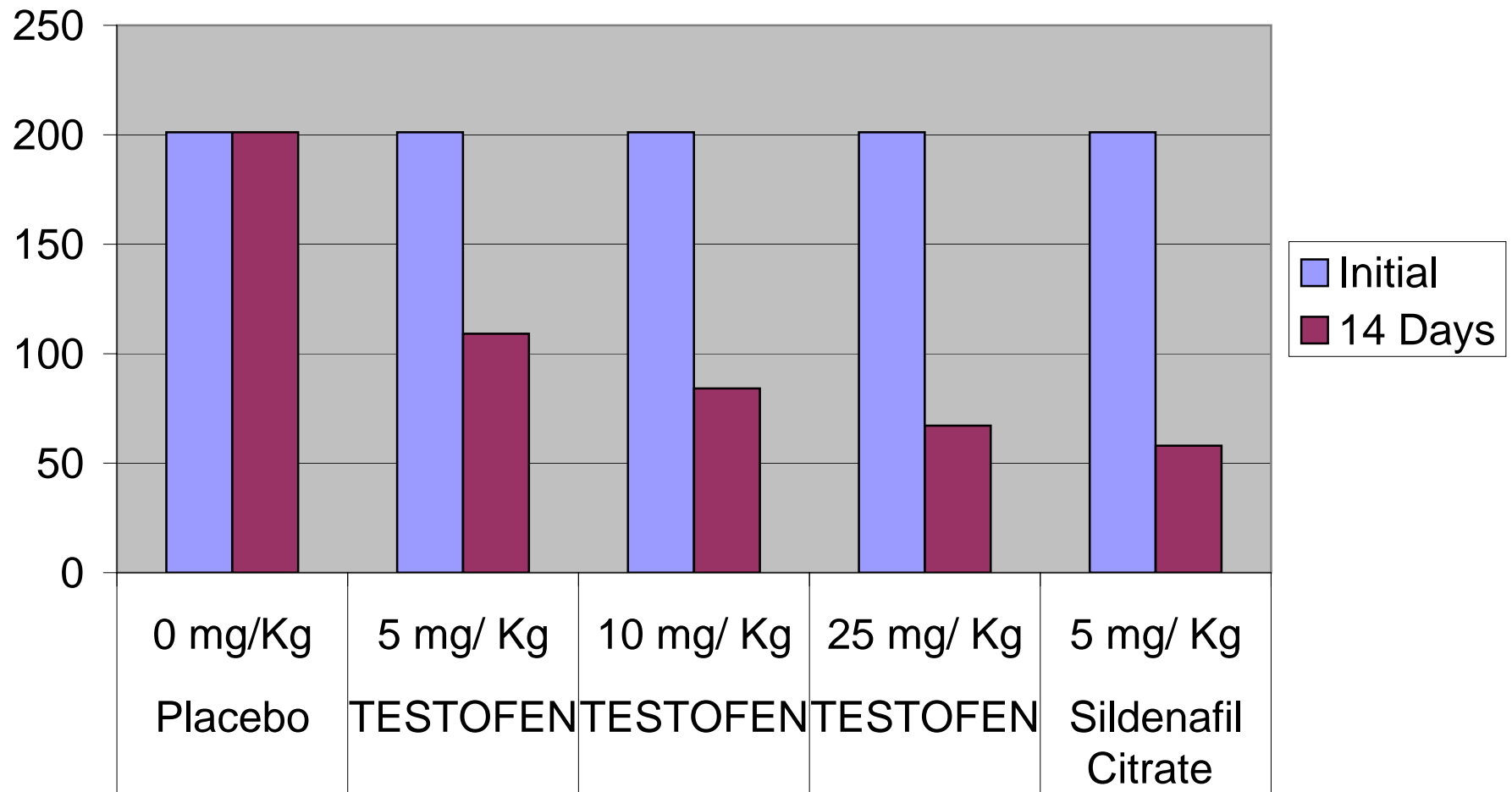
Gencor Pacific, Inc.			
Animal Study of TESTOFEN [™] :			
Increase in Ejaculation Latency			
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	211.5	211.5
TESTOFEN	5 mg/ Kg	211.5	262.17
TESTOFEN	10 mg/ Kg	211.5	283.67
TESTOFEN	25 mg/ Kg	211.5	318.67
Sildenafil Citrate	5 mg/ Kg	211.5	332.17

TESTOFEN™ Animal Study: Mounting Latency



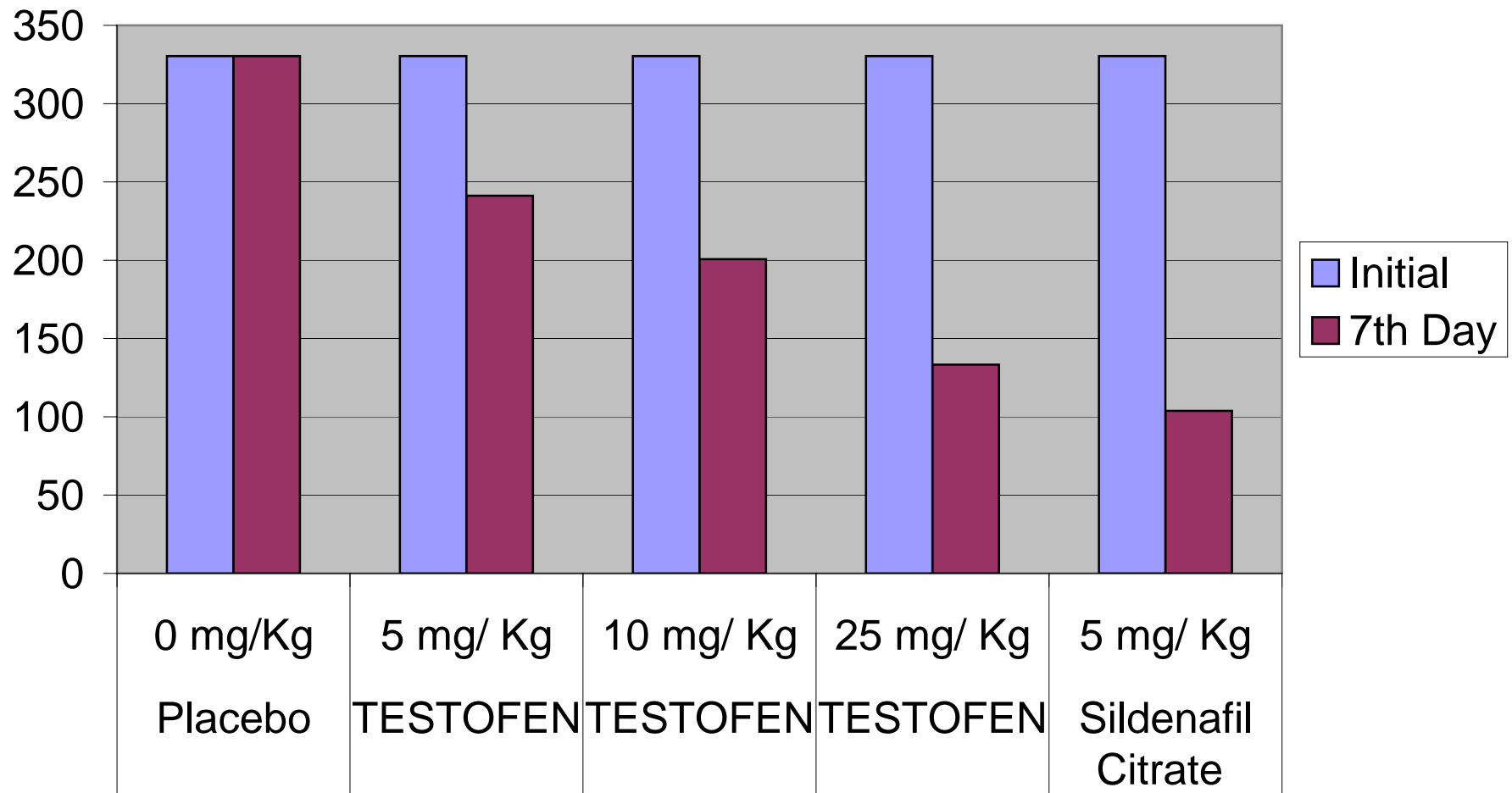
Gencor Pacific, Inc.			
Animal Study of TESTOFEN TM :			
Reduction in Mounting Latency			
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	201.17	201.17
TESTOFEN	5 mg/ Kg	201.17	109.17
TESTOFEN	10 mg/ Kg	201.17	84.17
TESTOFEN	25 mg/ Kg	201.17	67.17
Sildenafil Citrate	5 mg/ Kg	201.17	58.00

TESTOFEN™ Animal Study: Intromission Latency



Gencor Pacific, Inc.			
Animal Study of TESTOFEN™ :			
	Decrease in Intromission Latency		
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	136.83	136.83
TESTOFEN	5 mg/ Kg	136.83	87.83
TESTOFEN	10 mg/ Kg	136.83	58.67
TESTOFEN	25 mg/ Kg	136.83	38.17
Sildenafil Citrate	5 mg/ Kg	136.83	33.83

TESTOFEN™ Animal Study: Post Ejaculation Interval



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Animal Study of TESTOFEN™ :			
	Reduction in Post Ejaculation Interval		
Compound Fed Orally	mg/kg Body Wt.	Initial	14th Day
Placebo	0 mg/ Kg	330.33	330.33
TESTOFEN	5 mg/ Kg	330.33	241.17
TESTOFEN	10 mg/ Kg	330.33	200.67
TESTOFEN	25 mg/ Kg	330.33	133.33
Sildenafil Citrate	5 mg/ Kg	330.33	103.83

Safety of TESTOFEN™

Following functions were observed for all the animals involved in the trial

- 1.] Metabolic Functions
 - a) Blood Glucose
 - b) Cholesterol
- 2.] Renal Function
- 3.] Hepatic Function
- 4.] Differential Leucocyte Count
- 5.] Blood Functions
 - a) Haemoglobin
 - b) Platelet Counts
 - c) WBC
 - d) RBC
 - e) PVC
 - f) MCV
 - g) MCH
 - h) MCHC
- 6.] Histopathology
 - a) Heart
 - b) Liver
 - c) Kidneys
 - d) Testes

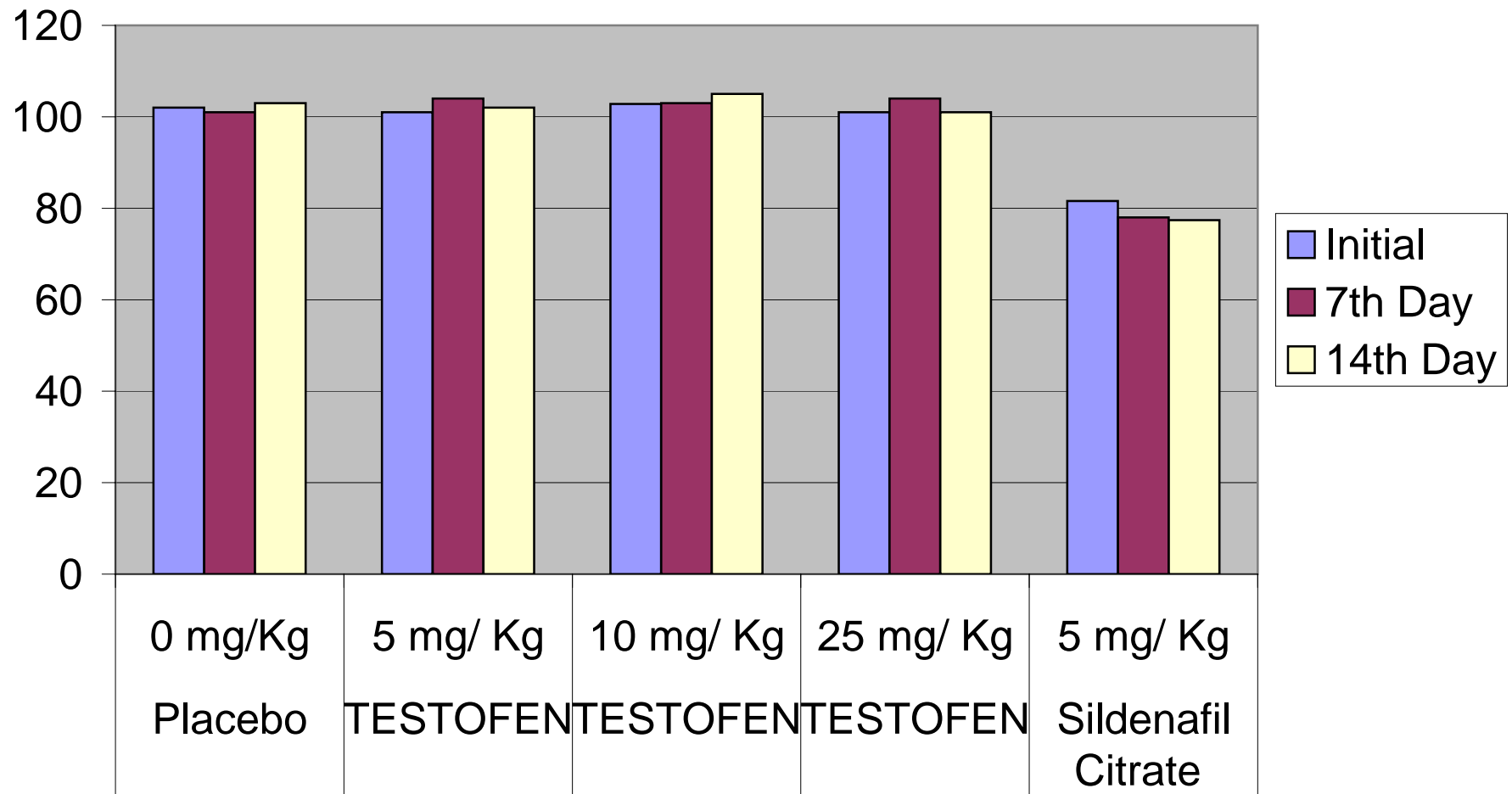
7.] Blood Pressure

All functions except Blood Pressure were normal in the test group, placebo group and positive control group. Blood Pressure was normal in the placebo and test groups and there was 23 % drop in Blood Pressure observed in the positive control group.

Blood Pressure:- Blood pressure before feeding was 101-102 for all the groups.

Group	Pressure 1'st day	7'th day	14'th day
Control	102	101	103
Substance treated 5 mg/kg	101	104	102
Substance treated 10 mg/kg	102.8	103	105
Substance treated 25 mg/kg	101	104	101
Sildenafil Citrate treated 5 mg/kg	81.6	78	77.4

TESTOFEN™ Animal Study: Blood Pressure Changes





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PROPOSED MECHANISM OF ACTION OF GENCOR'S TESTOFEN™

Testofen™ seems to have a dual mechanism of action. It seems to act in two ways

1. Testofen™ seems to have mode of action through the Adrenal Cortex. It seems to stimulate the secretion of Corticotropin Releasing Hormone [CRH] from the Hypothalamus in the brain.
2. The CRH reaches the Anterior Pituitary Gland and stimulates it to produce Adrenocorticotrophic Hormone [ACTH]. ACTH then acts on the cells of the Adrenal Cortex stimulating them to produce Androgens. Androgens are precursors to Testosterone with Testosterone like activity, the common one being Androstenedione. Testosterone itself has 19 carbons and such a steroidal skeleton in general is called as an Androgenic Skeleton.
3. Testosterone and Androstenedione are interconvertible in our body, especially in the peripheral sites of action like muscles where Androstenedione converts more into Testosterone than the reverse.
4. Some amount of Testosterone gets converted into 5-Alpha DHT in the body. Later, Testosterone, 5-Alpha-DHT and Androstenedione get metabolised in the GI tract and get flushed out of the system. Structural chart of this Androgen metabolism is shown below.
5. In sexually mature males, the quantity of such Testosterone produced through the ACT stimulation is much lower than in the testes to have much physiological significance.
6. But it helps in simulating Luteinizing Hormone [LH] secretion. LH is secreted by the pituitary glands in response to negative feedback from Testosterone.

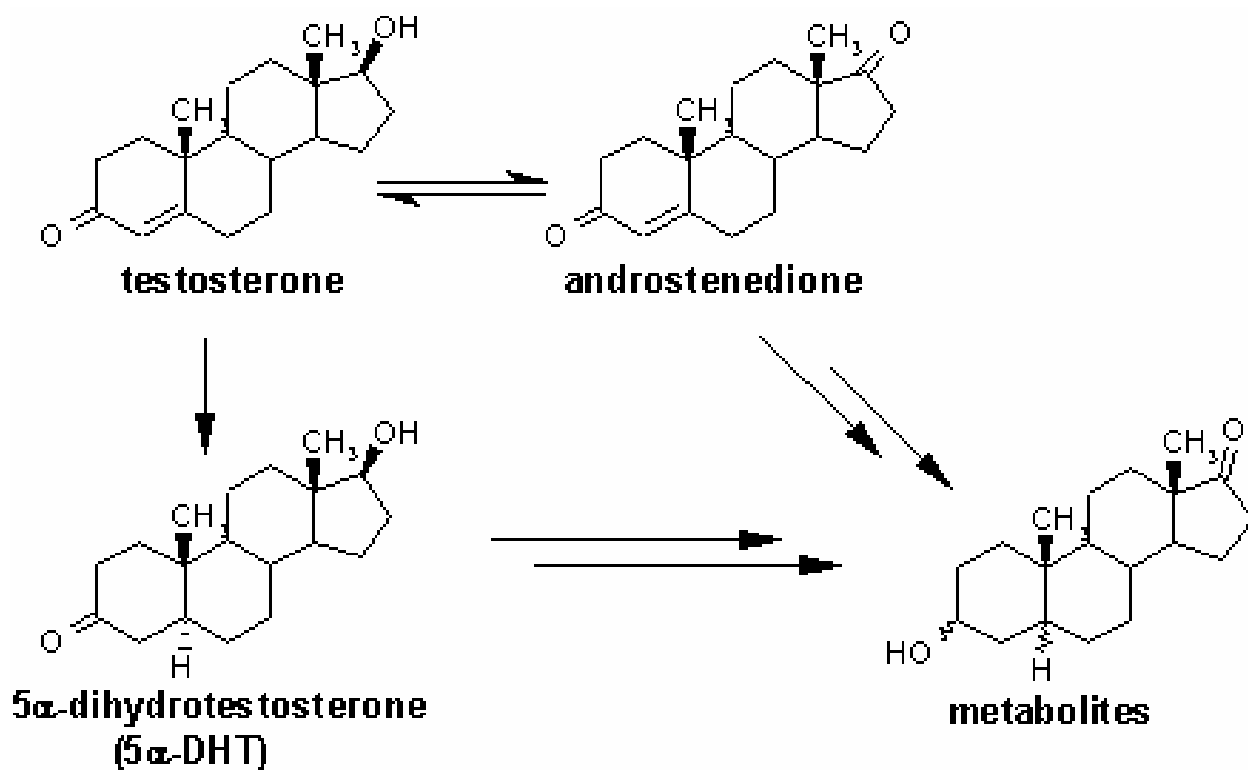
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7. The negative feedback effect of Testosterone is actually produced by the conversion of Testosterone to 5-Alpha Reduced Androgens like 5-Alpha-DHT.
8. So LH then stimulates the Interstitial Cells of Leydig in the testes to produce Testosterone. Testosterone then produces 5-Alpha-DHT and the cycle goes on.

Testosterone has anabolic and androgenic activities. Anabolic Activity relates to role played in development of Muscle Mass. Androgenic Activity relates to role played in development of sexual characteristics of the human body like growth and development of male sex organs, male sexual drive and performance, spermatogenesis etc.

Testofen[™] has shown Testosterone boosting activity which leads to Anabolic and Androgenic activity consistent with the above hypothesis.

2.] **Testofen**[™] also seems to have Testosterone like properties on its own. It seems to bind to the Testosterone receptor sites in the body and seems to stimulate anabolic and androgenic activity. This has been verified by studies done on castrated male Swiss Wistar rats wherein administration of **Testofen**[™] has led to anabolic and androgenic activity similar to Testosterone.





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Anabolic & Androgenic Activity of Gencor's **Testofen**™

Procedure Followed –

1. Immature male wistar rats weighing about 55 gm (\pm 5gm) were taken for the study.
2. These rats were castrated after anesthetizing them and giving a small transversal incision in the skin on the ventral site over the symphysis.
3. The testes lying in the scrotum was gently pushed into the abdominal cavity. With a pair of fine forceps, the abdominal wall was opened.
4. Testes with epididymis was pulled out. The ductus deferens with the testicular vessels were crushed with a pair of artery forceps and the testes together with epididymal fat pad were cut off with a pair of fine scissors.
5. The control group (A) received distilled water only. On the 11th day, the animals were sacrificed and the seminal vesicles, the ventral prostate, and musculus levator ani were carefully dissected and weighed.
6. Testosterone was given subcutaneously in 0.2 ml sesame oil suspension daily over a period of 10 days in the following doses to a different set of rats
 - (B). 0.02 mg per animal
 - (C) 0.1 mg per animal
 - (D) 0.5 mg per animal
7. After a gap recovery period (2-3 days), the animals were administered Gencor's **Testofen**™ orally for a period of 10 days in the following doses –
 - (E). 5 mg / kg body weight
 - (F). 10 mg / kg body weight
 - (G). 25 mg / kg body weight

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Increase in the weight of the seminal vesicles (which was optimal for the production of maximal isovolumetric contractions and) and ventral prostate indicates androgenic activity.

Whereas increase in the weight of musculus levator ani indicates anabolic activity.

It could be clearly seen that the Gencor's **Testofen™** at 25 mg per kg produced Anabolic activity almost equivalent to 0.5 mg Testosterone administration. This is very significant in muscle building applications.

DATA SHEET

Control (Placebo) Group : A

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	55	103	25	23.5	154
2	53	99	24	17	163
3	57	101	31	19	152
4	56	96	30	21	171
5	55	98	27	18	160
6	58	102	32	21	159
Avg	55.67	99.83	28.17	19.92	159.83
St. Dev.	1.75	2.64	3.31	2.38	6.79

Group B - Testosterone 0.02 mg given subcutaneously in 0.2 ml sesame oil suspension daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	58	105	35	27.8	175
2	55	101	37	30.8	181
3	59	111	29	25	178
4	53	104	36	23	163
5	58	109	41	28	173
6	53	100	36	22.3	167
Avg	56	105	35.67	26.15	172.83
St. Dev.	2.68	4.34	3.88	3.28	6.77

Group C – Testosterone 0.1mg given subcutaneously in 0.2 ml sesame oil suspension daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	55	105	49	38	189
2	54	102	52	33.4	184
3	58	112	56	38.6	195
4	59	109	59	40	193
5	52	106	63	41	188
6	57	105	50.6	36	193
Avg	55.83	106.50	54.93	37.83	190.33
St. Dev.	2.64	3.51	5.39	2.77	4.08

Group D – Testosterone 0.5mg given subcutaneously in 0.2 ml sesame oil suspension daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	54	106	72	51	198
2	58	110	74	42	201
3	57	115	81	49	207
4	53	102	78	46.5	203
5	60	114	83	53	211
6	54	101	77	49.8	199
Avg	56	108	77.5	48.55	203.17
St. Dev.	2.76	5.97	4.14	3.86	5.00

Group E - Gencor's Testofen™ 5 mg / kg given orally daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	53	100	27	19	164
2	54	99	31	21	158
3	57	104	28	23	170
4	57	105	28.3	24	167
5	58	109	30.4	23.6	164
6	55	98	29	21	162
Avg	55.67	102.50	28.95	21.93	164.17
St. Dev.	1.97	4.23	1.51	1.93	4.12

Group F - Gencor's Testofen™ 10 mg / kg given orally daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	54	102	36	27	178
2	56	106	38	29	184
3	59	111	42	31	186
4	58	109	34.5	27	191
5	55	108	39	28.7	181
6	54	100	42	26.5	179
Avg	56	106	38.58	28.2	183.17
St. Dev.	2.10	4.24	3.07	1.70	4.88

Group G - Gencor's Testofen™ 25 mg/kg given orally daily

s. no.	Body Weight (gm)		Wt of the Organs (mg)		
	Initial	Final	Prostate	Sem. Ves.	Lev. Ani.
1	58	115	59	39.7	204
2	55	113	58.3	38.6	191
3	57	114	58.6	40.7	200
4	54	110	63	41	198
5	53	109	65	43	194
6	59	117	64	42.3	206
Avg	56	113	61.32	40.88	198.83
St. Dev.	2.37	3.03	3.01	1.62	5.74

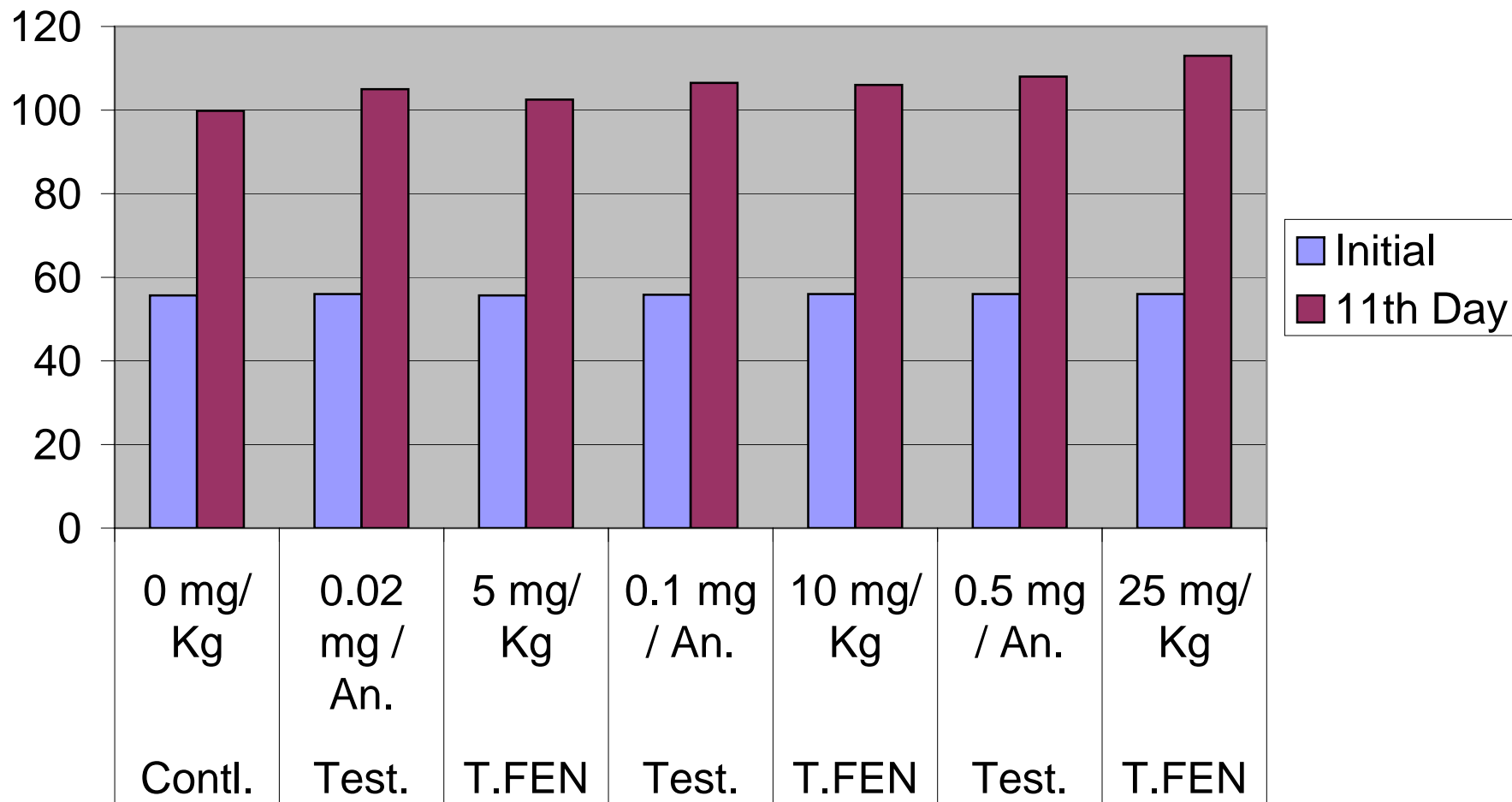
The above tables demonstrate clearly that Gencor's **Testofen™** at a dosage of 25 mg / kg body weight of Swiss Wistar Rats (Group G) exhibits Anabolic and Androgenic Activity **comparable to** 0.5 mg Testosterone (Group D).

The Anabolic and Androgenic activity exhibited as shown by above data, is also **statistically significant** both in the 10 mg per kg body weight group (F) and 5 mg per kg (E) body weight group when compared to the control [placebo] group.

In both above cases P values are less than 0.05. Under ANOVA parameters they represent statistical significance.

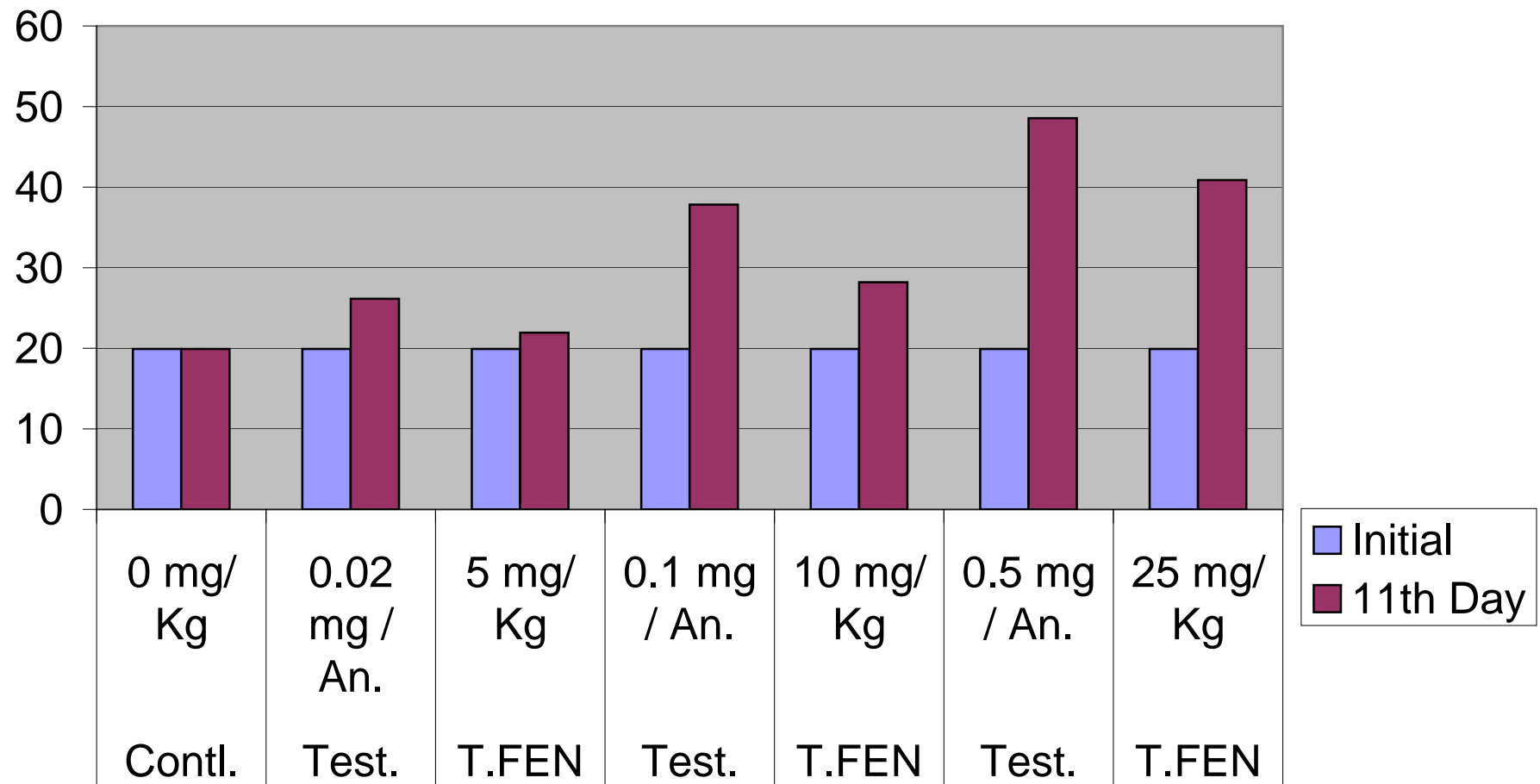
Gencor Pacific, Inc.				
Comparision of Anabolic & Androgenic activity				
of TESTOFEN TM and Testosterone :				
		Increase in Body Weight		
Compound Fed				
			Initial	11th Day
Control	Contl.	0 mg/ Kg	55.67	99.83
Testosterone	Test.	0.02 mg / An.	56	105
TESTOFEN	T.FEN	5 mg/ Kg	55.67	102.5
Testosterone	Test.	0.1 mg / An.	55.83	106.5
TESTOFEN	T.FEN	10 mg/ Kg	56	106
Testosterone	Test.	0.5 mg / An.	56	108
TESTOFEN	T.FEN	25 mg/ Kg	56	113

Comparision of Anabolic & Androgenic Activiry Increase in body weight



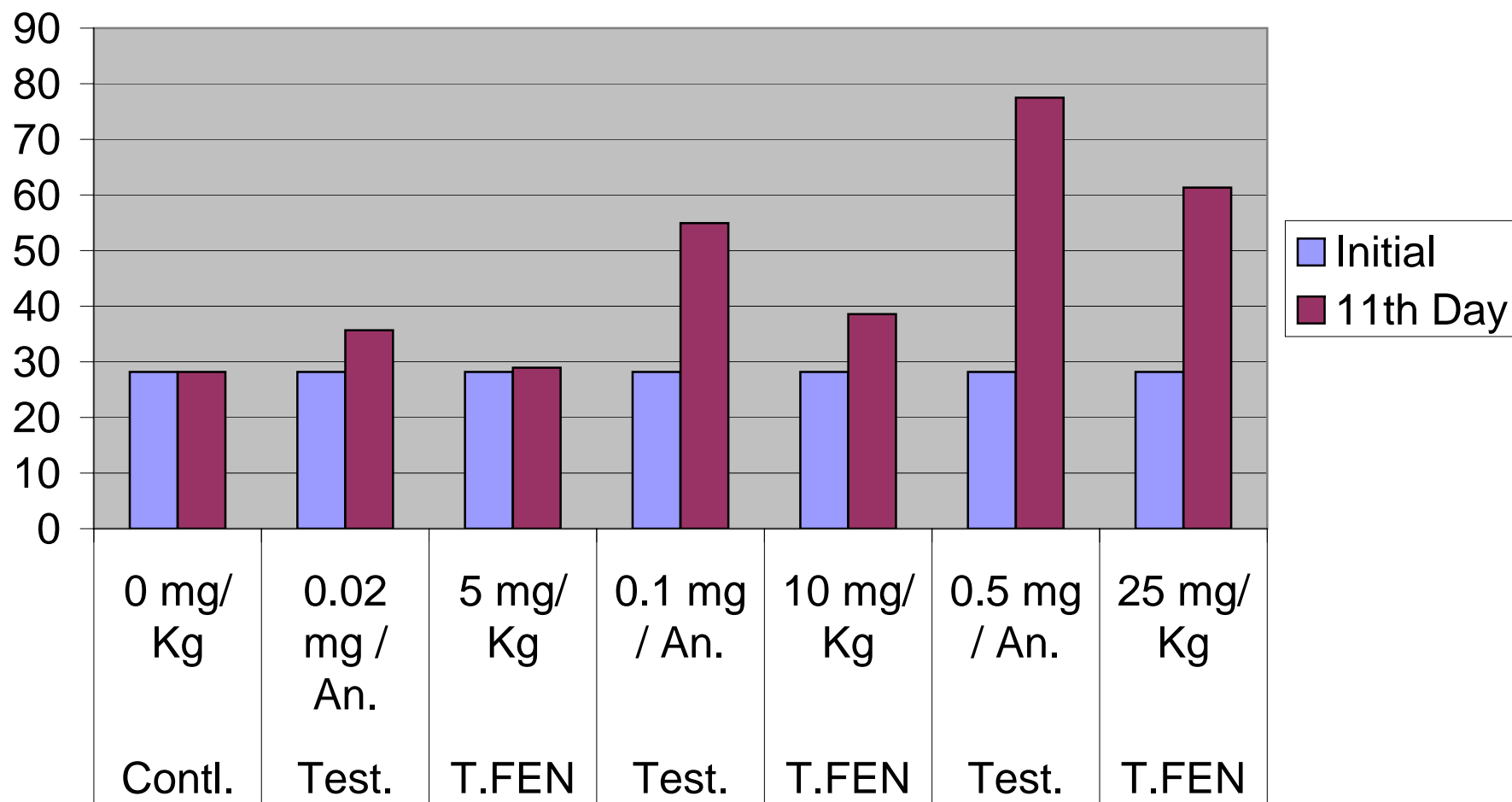
Gencor Pacific, Inc.				
Comparision of Anabolic & Androgenic activity				
of TESTOFEN TM and Testosterone :				
		Increase in Seminal Vesicles		
		(For Androgenic activity)		
Compound Fed				
			Initial	11th Day
Control	Contl.	0 mg/ Kg	19.92	19.92
Testosterone	Test.	0.02 mg / An.	19.92	26.15
TESTOFEN	T.FEN	5 mg/ Kg	19.92	21.93
Testosterone	Test.	0.1 mg / An.	19.92	37.83
TESTOFEN	T.FEN	10 mg/ Kg	19.92	28.2
Testosterone	Test.	0.5 mg / An.	19.92	48.55
TESTOFEN	T.FEN	25 mg/ Kg	19.92	40.88

Comparision of Anabolic & Androgenic Activiry Increase in Seminal Vesicles



Gencor Pacific, Inc.				
Comparision of Anabolic & Androgenic activity				
of TESTOFEN TM and Testosterone :				
		Increase in Ventral Prostate		
		(For Androgenic activity)		
Compound Fed				
			Initial	11th Day
Control	Contl.	0 mg/ Kg	28.17	28.17
Testosterone	Test.	0.02 mg / An.	28.17	35.67
TESTOFEN	T.FEN	5 mg/ Kg	28.17	28.95
Testosterone	Test.	0.1 mg / An.	28.17	54.93
TESTOFEN	T.FEN	10 mg/ Kg	28.17	38.58
Testosterone	Test.	0.5 mg / An.	28.17	77.5
TESTOFEN	T.FEN	25 mg/ Kg	28.17	61.32

Comparision of Anabolic & Androgenic Activiry Increase in Ventral Prostate



Gencor Pacific, Inc.				
Comparision of Anabolic & Androgenic activity				
of TESTOFEN TM and Testosterone :				
		Increase in Musculus levator ani		
		(For Anabolic activity)		
Compound Fed				
			Initial	11th Day
Control	Contl.	0 mg/ Kg	159.83	159.83
Testosterone	Test.	0.02 mg / An.	159.83	172.83
TESTOFEN	T.FEN	5 mg/ Kg	159.83	164.17
Testosterone	Test.	0.1 mg / An.	159.83	190.33
TESTOFEN	T.FEN	10 mg/ Kg	159.83	183.17
Testosterone	Test.	0.5 mg / An.	159.83	203.17
TESTOFEN	T.FEN	25 mg/ Kg	159.83	198.83

Comparision of Anabolic & Androgenic Activiry Increase in Musculus Levator ani

