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UNDER OECD GUIDELINES, ALBINO MICE ANIMAL STUDIES TO STANDARDISE PZ DRUG AGAINST THE REFRACTORY SPIKE PROTEIN INFECTION, HOMO SAPIENS SKIN DEPIGMENTARY DISORDER, CANCER (ALL) AND HENSEN PROBLEM

Dr. S. S. Sawhney*

Research and Development (R&D) Division, Department of Chemistry, Uttaranchal College of Science and Technology, Dehradun-248001 (Uttarakhand), India.

***Corresponding Author: Dr. S. S. Sawhney**

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ABSTRACT

Human system is a bio-automation and self- repairing. The four diseases in reference: spike protein infection, Homo sapien skin depigmentary disorder, cancer and Hensen problem which have varying root cause, are exceptional. Complementary characteristics of spike protein, human protein and PZ drug led to the development of Principles I whereas principles 2, is based upon the epidermal photosensitivity of PZ drug. Principle I fit the bill of treatment of Homo sapien skin depigmentary disorder, while Principle 2 applies for other diseases. Additionally Albino mice animal study is equally significant and promising. The cage side observations show no toxicity from 0.5 g and 1 g of drug treatment. The acute toxicity and sub toxicity study show that the body weight of each sex was significantly ($p<0.001$) increased in both groups. The organal histopathology (brain, heart, kidney, liver) at 0.5 g and 1.0 g treatment has resulted in normal histopathology status. The biochemistry of Albino mice showed no significant changes in any of the biochemical parameters when compared with the central group. The above data and discussion would lead us to the easy and safe, human trials at 0.5 and 1.0 g drug levels and treatments of the four diseases in reference with PZ drug.

INTRODUCTION

It is an age of scientific identification and treatment of the human diseases unknown to humanity. The medical systems so involved overtimes made the different underlying principles, having failed to meet out the human challenges completely. The human society has been benefitted to certain extent by each system medically. Each system continues to go deeper and deeper in understanding and treating different diseases unknown to the humanity since long.

Nature had taken million years to evolve human life upon earth, but could not perfect it overtimes as seen in the accompaniments of bacterial, viral diseases, cancer and Homo sapien skin depigmentary disorder, Hensen problem etc. to name a few. Human over the time could not identity the diseases, their causes and effects and could slowly identify the medicinal plants to treat or reduce the effects over the times. The human diseases grew and so the treatment. The survey shows that the disease which could not be treated are life threatening, and hard to treat inspite of the best researches and efforts thereon. The world situation is thereon negatively continues, demanding more research and the development of new techniques and concepts to contain them positively in the interests of humanity.

To treat the unpredictable viral and bacterial infections and other diseases like cancer, Hensen problem etc, Nature made available the plants as the sources of medicinal plants at the hands of humanity in the early million years ago since inception of humanity, called Ayurvedic system of medicine. The allopathic system of medicine is a recent development. Both systems are important in their scopes to treat the diseases. In recent times Ayurvedic system has played significant roles in

the treatment of spike protein infections, Homo sapien skin depigmentary disorder, cancer of all type and Hensen problem etc. in comparison of Allopathy, which has shown effectiveness in above infectious and diseases too.

The four diseases/infections: Spike protein infection, Homo sapien skin depigmentary disorder, cancer, Hensen problem are refractory and care and cure demanding: Scientists including Sawhney have invested heavily to innovate to conceptualize and treat them with plant based biomolecules with little advancement thereon. AstraZeneca CO-a UK based company, under the pressing demands of humanity in 1900-2000 developed spike protein infection without understanding the basics of this infection.

All these diseases as above are refractory and have grown care and cure demanding over the years. The human system is a bioautomation and self- repairing. Beyond this limit, the diseases, which inflict humans had/have to be dealt with to the point of cure with the human innovative and analytical brain through researches thereon, with the natural wealth: forests, vegetables, pure air, and water. In recent times the human dependencies upon junk food, have caused human diseases driven sufferings.

Sawhney which propounded the following two principles which fit the bills of treatments of the four diseases in reference.

Principle I

This underlying principle fits in the system where the drug acts as the photodynamics substance. When the UV rays at tropics, falling on the human body , penetrates the skin, meets the naturally defined photodynamic compound already present epidermally, provide by nature before birth in the epidermis, like Vitamin K an photo reactive, the vitamin K dimerising with the release of offspring photon energy (OPE), which on transduction to melanocytes triggers the dormant reaction between tyrosine and O2 enzymatically, forming melanin a polymer of indole-5,6-quinone, which conjugates the lipoprotein forming what is called melanolipoprotein (skin colour) which via skin layers (3) pigments stratum granulosum.

Underlying Principle II

The latest study by Sawhney has revealed that the spike protein with two functions groups are infection causing and its neutralizing is achieved where the drug with complemental functions, hydrogenbond the spike protein, neutralizing spike protein. (de-infections). The spike protein has the tendency to neutralize the protein, hydrogenbonding in the complementary groups. In the presence of the drug (with complementary functions) with the capacity of forming stronger hydrogenbonding, decouples hydrogenbonded protein and spike protein and thus hydrogenbond spike protein, leaving behind the protein (of body) (de-infection). The infection and de-infection is a continuous process in the treatment of spike protein infection.

SPIKE PROTEIN INFECTION

Spike protein infection struck planet earth, hitting hard the humanity in 2019-2020 followed by million deaths all over the world, except the humans dark black as described by Sawhney. Scientists had been confused about how to deal with a new injection. AstraZeneca CO (UK) in a hurry to monetize and deceive the world, marketed an injections based upon falsification: from concept, theory, experimental and applicability, causing human deaths beyond descriptions. Sawhney issued a note on the falsification of the research on SARS-CO-2 S protein and gave a new theory, concept etc. on the spike protein infections and its treatment with PZ drug, applying the principle II described by Sawhney.

HOMO SAPIEN SKIN DEPIGMENTARY DISORDER

Homo sapien skin depigmentary disorder is no disease per se, but a scientific challenge. Sawhney described it as a deficiency problem and blamed the epidermally absence of vitamin K, a photodynamic substance which photoreacts with photodynamic substance, releasing energy (OPE) which on transduction to melanocysts, triggers the biochemical bio environment and produces a conjugate of melanin and protein, coined as melanolipoprotein (skin colour). Sawhney used PZ drug as a photodynamic substance. The study has been based upon Principle I described by Sawhney.

CANCER

When the body focuses an infection the immune system responds by identifying and eliminating threat. Over time the medical science has learnt to harness the natural defence mechanism in the new ways. Immune theraphy applies this principle to cancer treating by helping the immune system recognize and act against cancer cells. The plants loaded with the naphthoquinone are the new approach to deal with cancer of all types the body suffers from. The treatment with synthetic compounds appears to be misfires. Principle II fits the bill.

HENSEN PROBLEM

This human problem is caused by Mycobacterium leprae an infection bacterium. The PZ drug has the capacity to neutralise the mycobacterium leprae, the root cause of Hensen problem which has grown with care and cure demanding over years. The way challenge is being met is another misfire demanding change of biostrategy. Both principles, apply here.

Sawhney[1-10] has understood and contributed to the causes and effects of the four diseases in reference.

METHODS AND MATERIALS

Under OECD/OCDE guidances, the Albino mice animal study with PZ drug on 0.5g-1g treatment has been done covering up.

Toxicity Study

- The cage side observations
- Acute toxicity study
- Sub – Acute toxicity (Male)
- Sub – Acute toxicity (Female)
- Brain Histopathology
- Heart Histopathology
- Kidney Histopathology
- Liver Histopathology

RESULTS

The Albino Mice study under OECD guidance has been done and the result so obtained on toxicity are very promising and fit to the treatment of four diseases in Reference.

Toxicity Study

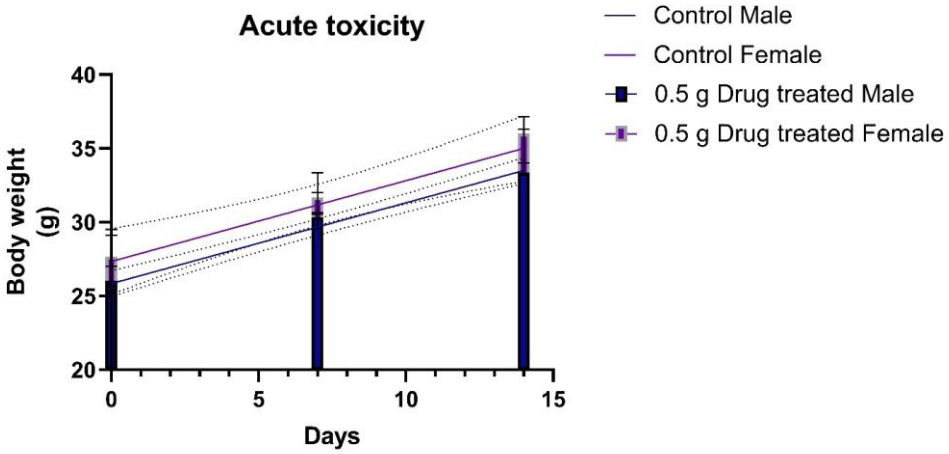
The cage-side observations show no toxicity from 0.5 g&1g of drug treatment.

S.No.	Cage-side observation:	Remark
1	Skin and fur changes	No
2	Eyes and mucous membranes	Normal
3	Respiratory	Normal
4	Somato-motor activity	Normal
5	Behavior patterns	Normal
6	Tremors	No
7	Convulsions	No
8	Salivation	No
9	Diarrhoea	No
10	Lethargy	No
11	Sleep	Normal circadian
12	Coma	No

Acute Toxicity Study

Observation

Sex	Days	Body weight	
		Control	0.5g drug treated
Male	0	26±1.732051	27±4.358899
	7	30.33333±0.57735	30.66667±2.309401
	14	33.33333±1.154701	34±4
Female	0	25.33333±0.57735	27.66667±2.516611
	7	29.66667±1.527525	31.66667±2.886751
	14	33.33333±1.154701	36±2

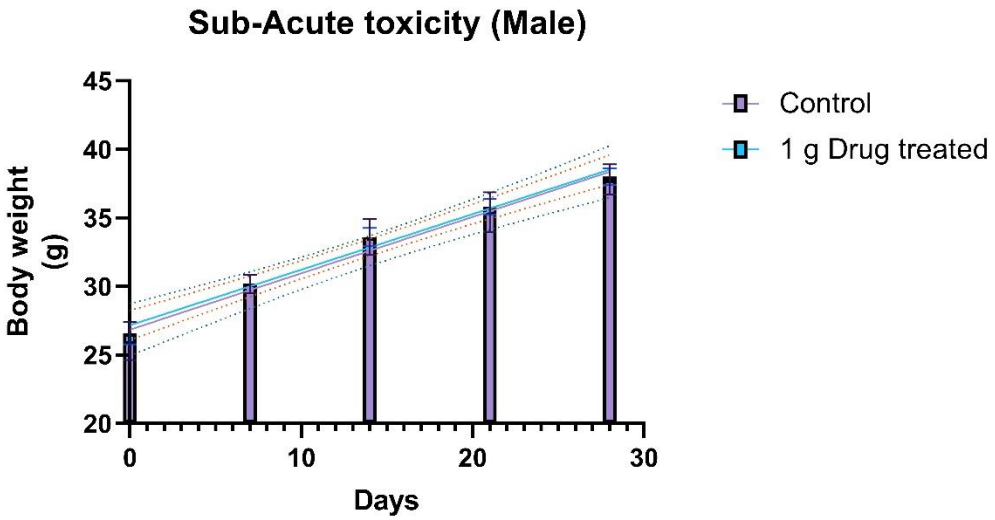


Result: The body weight of each sex was significantly ($p<0.001$) increased in both groups over 14 days.

Sub-Acute Toxicity Study

Observation: Male mice

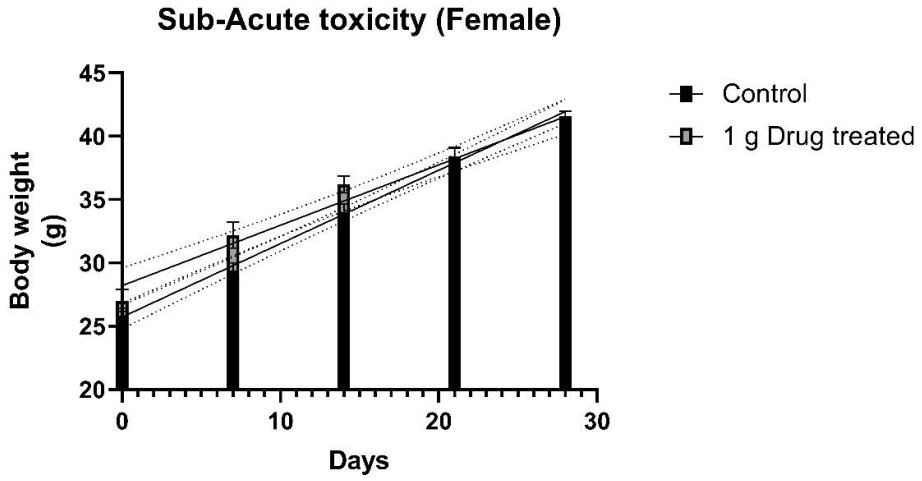
Days	Body weight	
	Control	1g drug treated
0	26±3.08	26.6±1.82
7	30.2±1.48	29.6±1.67
14	33.6±2.96	33.6±1.52
21	35.4±3.28	35.8±1.30
28	37.8±2.48	38±1.41



Result: The body weight of male mice was significantly($p<0.001$) increased in both groups over 28 days.

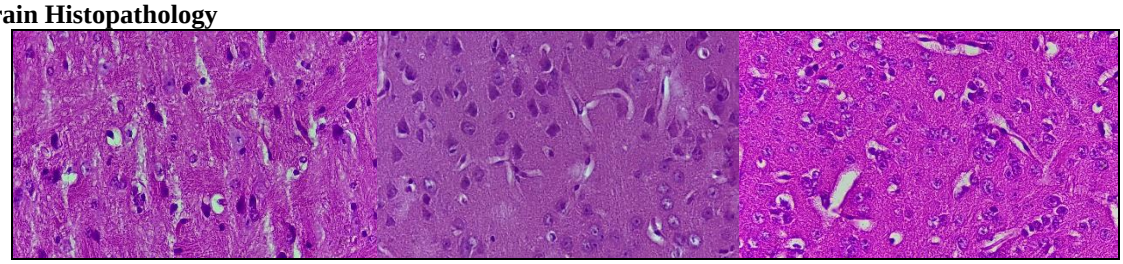
Observation: Female mice.

Days	Body weight	
	Control	1g drug treated
0	25.8±1.30	27±2
7	29.4±1.34	32.2±2.28
14	34±1.41	36.2±1.48
21	38.4±1.67	38.4±1.52
28	41.6±0.89	40.6±1.52



Result: The body weight of female mice was significantly($p<0.0001$) increased in both groups over 28 days.

❖ **Brain Histopathology**



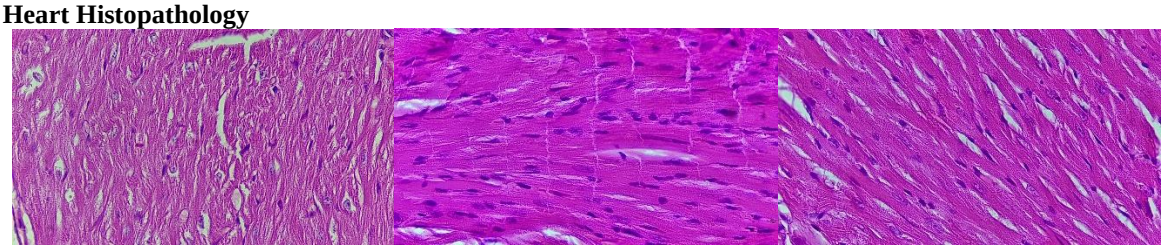
A **B** **C**

Comparative Summary

Image	Group	Neuronal degeneration	Vacuolization	Gliosis	HDI	Interpretation	Histological Status
A	Control	0	0	0	0	Preserved neuronal integrity	Normal
B	0.5 g treatment	1	1	1	3	Preserved neuronal integrity	Normal
C	1 g treatment	1-2	1-2	1	3-5	Partial neuronal damage	Partially abnormal

Conclusion: Histological analysis of cortical sections revealed preserved neuronal degeneration in both the control and 0.5g drug treatment group. Whereas the 1g drug treatment group should experience partial damage.

❖ **Heart Histopathology**



A **B** **C**

Image	Group	Major Cardiac Features	Interpretation	Status
A	Control	The fibres are intact, regularly arranged, and there is no sign of necrosis, inflammation, or fibrosis.	Bundles of branching cardiac muscle fibres with elongated, centrally placed nuclei. The striations characteristic of cardiac muscle are faintly visible.	Normal
B	0.5 g treatment	The presence of well-defined striations and intercalated discs indicates healthy myocytes, with no pathological changes such as cellular swelling or necrosis.	The striations and **intercalated discs** are very prominent here, clearly demonstrating the connection points between cardiac cells. The nuclei remain centrally located.	Normal
C	1 g treatment	The tissue appears well-organised, with consistent fibre structure and no signs of infiltration or degeneration.	Elongated fibers with central oval nuclei and faint cross-striations again confirm cardiac muscle. The cells are tightly packed and arranged in a parallel pattern.	Normal

Conclusion: All three are **normal cardiac muscle tissue** stained with **H&E**, showing normal morphology (striations, intercalated discs, and centrally located nuclei).

❖ **Kidney Histopathology**

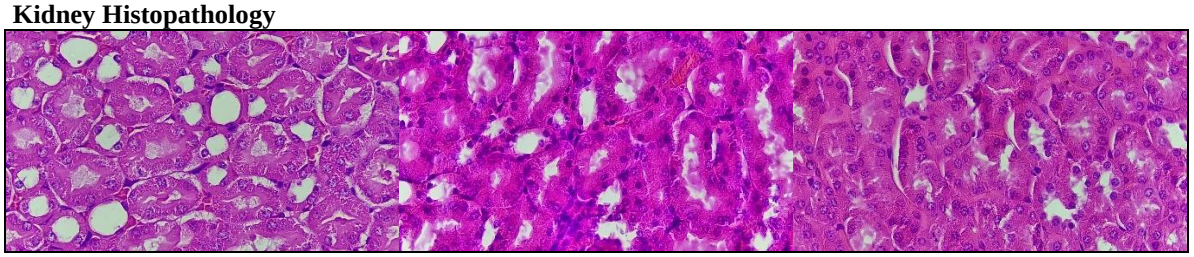
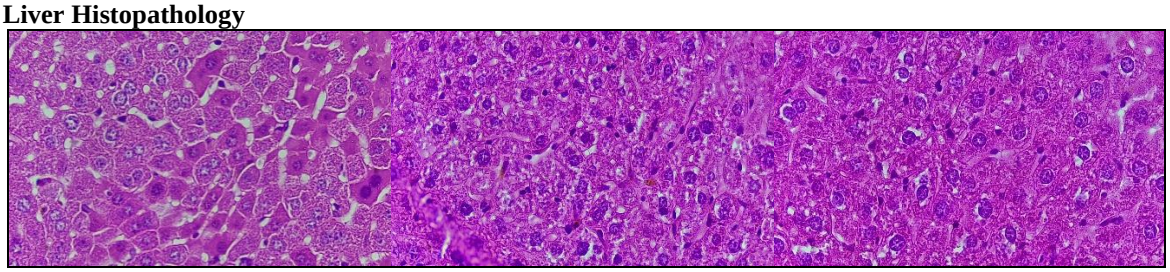


Image	Group	Major Renal Features	Interpretation	Status
A	Control	Intact tubules, normal nuclei	Healthy kidney	Normal
B	0.5 g treatment	Mild tubular damage, partial recovery	Renoprotective effect	Mildly abnormal
C	1 g treatment	Intact tubular structure and nuclear integrity	Healthy kidney	Normal

Conclusion: All groups represent**normal renal histology** with preserved structure and function.

❖ **Liver Histopathology**



A **B** **C**

Comparative Summary Table

Image	Group type	Interpretation	Histological status
A	**Control**	Normal hepatocyte morphology, normal sinusoids, inflammation and necrosis absent	Normal liver
B	**0.5 g treatment**	Normal hepatocyte morphology, but mild dilation of sinusoids and inflammation, withnecrosis absent.	Near-normal
C	**1 g Treatment**	Normal hepatocyte morphology, normal sinusoids, inflammation and necrosis absent	Near-normal

Conclusion: Liver section from thecontrol group was found normal, whereas the 0.5 g and 1g drug-treated groups demonstrated intact hepatic architecture with minimal cellular degeneration, indicating protective effects.

Biochemical Study

Biochemical parameter	**LABC Range**	**Control**	**0.5 g treated group**	**p-value**
AST (U/L)	64-258	72.667±2.5166	121.67±2.0817	0.503
ALT (U/L)	75-193	81.667±1.5275	99.333±2.0817	0.108
Urea (mg/dL)	22-51	24±1.7321	26±1	0.595
Creatinine (mg/dL)	0.2-0.6	0.2333±0.0577	0.3±0.1	>0.999
Biochemical parameter	**LABC Range**	**Control**	**1 g treated group**	**p-value**
AST (U/L)	64-258	72.667±2.5166	128.33±1.5275	0.87
ALT (U/L)	75-193	81.667±1.5275	118.67±1.5275	0.84
Urea (mg/dL)	22-51	24±1.7321	31.333±1.5275	>0.999
Creatinine (mg/dL)	0.2-0.6	0.2333±0.0577	0.4333±0.0577	0.994

Erythrogram & platelet count				
Biochemical parameter	**LABC Range**	**Control**	**0.5 g treated group**	**p-value**
RBC (10^6/mm3)	7.4-11.1	7.7±0.2646	8.2±0.2	0.996
Haemoglobin (g/dl)	34.3-51.3	34.867±0.8083	40.667±1.1547	0.619
Platelet (10^3/mm3)	635-1118	665.33±25.891	919.67±17.898	0.725
Biochemical parameter	**LABC Range**	**Control**	**1 g treated group**	**p-value**
RBC (10^6/mm3)	7.4-11.1	7.7±0.2646	8.4±0.1	0.992
Haemoglobin (g/dl)	34.3-51.3	34.867±0.8083	36.33±1.5275	0.967
Platelet (10^3/mm3)	635-1118	665.33±25.891	867±26.665	0.993

CONCLUSION

No significant changes were observed in any of the biochemical parameters when compared with the control group.

DISCUSSION

The inherent structure in PZ drug with the property of hydrogenbonding with the complementary functions of competitive molecules and photosensitivity due to the

presence of photodynamic napthoquinone which on photoreaction with the UV rays, at tropics, have been found significant, causing infection and deinfection. The spike protein hydrogenbonds the complementary functions groups of the body protein causing infection whereas the PZ drug presence in the human body decouples the spike protein and body protein coupling with strong hydrogenbonding and finally hydrogenbonding strongly with the spike protein, leaving behind the protin (de-infections).

Secondly the PZ drug presence epidermally photoreacts with UV rays, dimerization the drug with the release of energy coined as OPE by Sawhney. This OPE with transduction of OPE to melanocytes in skin where the dormant tyrosine and O2 molecules are triggered resulting in the formation of melanin-a polymer of indole-5,6- quinone, moving on to stratum granulosum layer via the skin layers.

Expression of skin whole discussion has been included into two principles 1, 2, the basis of the treatments of the said four diseases: spike protein infection, Homo sapiens skin depigmentary disorder, cancer and Hensen problem.

Albino mice animal study on toxicity has been promisingly fitting the bills of human trials, the basis of treatment of diseases with the non-toxic range of PZ drug: 0.5-1.0g both end of spectrum included.

The cage side observations show no toxicity from 0.5 and 1.0 g of drug treatment. The acute toxicity study shows that the body weight of each sex (male and female mice) was significantly (pe 0.005) increased in both groups over 14 days.

Sub-acute toxicity study shows that the body weight of male mice was significantly ($p<0.001$) increased in both groups over 28 days.

Organal Histopathology study

Brain histopathology study shows that the histopathology analysis of cortical sections reveal preserved neuronal degeneration in both the control and 0.5 g drug treatment group. Whereas the 1g drug treatment groups showed experience of partial damage.

In heart histopathology study all the three were normal cardiac muscle tissue strained with H and E, showing normal morphology (striation, intercalated discs and centrally located nuclei).

Kidney histopathology

All groups (0.5g and 1.0 g) represent normal renal histopathology with preserved structure and functions.

Liver histopathology

0.5 g and 1.0 g drug were tested. Liver section from central group was found normal, whereas 0.5 g and 1.0 g drug treated groups demonstrated intact hepatic architectun with minimal cellular degenrations indicative of protective effects.

Biochemistry

Biochemical parameters: AST(U/L), ALT (U/L), urea (mg/dl) and creatinine (mg/dl) had been determined of 0.5 g and 1.0 g drugged Abino mice. No significant changes were observed in any of the biochemical parameter when compared with the control groups.

Erythrogram and platelets count in reference to biochemical parameter: RBC (108 /mm3), Haemoglobin (g/u) and platelet (103 /mm3) with 0.5 g and 1 g treated groups, had been determined. No significant changes were observed in any of the biochemical parameter controlled with the central groups.

Seen the principles 1,2 together with the Albino mice animal study: toxicity, acute toxicity, sub acute toxicity, brain histopathology, heart histopathology, kidney histopathology, liver histopathology and biochemical study it had been made easy and safe the human trials, and treatment of four diseases in references.

On the horizon

Human trials and treatment of their diseases with the drug range : 0.5- 1.0 g both ends being inclusive.

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