ORGINAL ARTICLE

ScienZTech

INTERNATIONAL JOURNAL OF PHARMACEUTICAL RESEARCH AND LIFE SCIENCES

Published by ScienzTech Publication Journal Home Page: www.scienztech.org/ijprls

Pharmacological screening of polyherbal hepatoprotective -'Doctor's LIVAFIT'

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Article History:

Received on: 28 Jan 2020
Revised on: 26 Feb 2020
Accepted on: 24 Mar 2020
Published on: 05 Apr 2020

Volume: 8 Issue: 1

Keywords:

Herbal Formulations, Ayurvedic Treatment, Andrographis, Picorhiza, Livafit

ABSTRACT

Considering the importance of ayurvedic herbs, science behind their potential in treating diseases and advantages over synthetic medicines in limiting side effects, there is an urgent need to employ such sacred science to produce medicines that effectively cure diseases and to distribute them to the needy. Many herbs mentioned in ayurveda are used to treat dreadful hepatic diseases especially, cirrhosis which is caused by the liver damage due to toxins, chronic alcoholism, synthetic drugs etc. In the present study, poly herbal hepatoprotective formulation, LIVAFIT, had been prepared and standardized for determining its quality and safety. Methanol herbal extracts were formulated according to a formula with Phyllanthus neruri, Picorrhiza kurroa, Andrographis paniculata as active ingredients and various other herbs helpful for possible hepatic regeneration and preventing hepatotoxicity. Physico chemically, microscopically and chemically standardized extracts were used in the study. Following the results of acute toxicity studies and after confirming the safety of extracts, hepatoprotective activity of formulation was evaluated by CCL_4 induced hepatotoxicity method in albino wistar rats. It exhibited a dose dependent significant ($P<0.001$) reduction in hepatotoxicity when compared with that of standard, Silymarin and a pre-marketed ayurvedic product.

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DOI: https://doi.org/10.26452/ijprls.v8i1.1150

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INTRODUCTION

Ayurveda is an Indian traditional Indian health care system that had originated in 3000BC and was widely applied int eh world. Such effective herbs are being used to prepare medicinal products, nutraceuticals and cosmeceuticals. Understanding this demand many companies undertook the production and distribution of ayuredic medicines all over the world, thus drawing a great market benefits in competition with the synthetic drugs producers. The controversial issue which pulls back the herbal drugs in the competition with synthetic drugs is the concept of standardization of those medicines. Due to advancements in medical science and proximity of side effects that may occur due to medicines, ayurvedic medicines are also made to comply for standardization. This enables us to analyze theoretically the action and effect of medicines in the body, its duration, mode and dose regulation and all other drug related effects so as to maintain a common treatment and expected response everytime it is administered. But a shocking fact that these days ayurvedic medicines are being exploited by local companies and their active formulae are being duplicated as low quality medicines for finan-

cial benefit rather than human health. Many of the herbal formulations available in the market now are not properly standardized.

On the other hand, some herbalists feel that highly standardized and isolated herbal leads doesn't solely represent all the pharmacological qualities of herbs and can sometimes lead to safety and toxicity issues, especially when they are highly concentrated or purified. Sometimes, herbs are harvested at one place and shipped overseas to faraway places and are made into commercial products like capsules or tablets. Then it becomes very difficult to expect what happens to those herbs along the transport. When modern herbal medicines are shipped across countries, it is often necessary to find some way of ensuring the shipped medicines satisfy the label claim and presence of appropriate levels of active constituents, and that impurities are not present in the finished product even after down porting [1] .

Doctor's Herbal Solutions is a govt certified herbal medicine manufacturing company established to serve the people with good quality herbal products to treat almost all diseases. In present investigation, the quality assessment of Livafit, a product of Doctor's Herbal Solutions to treat liver diseases and disorders like Jaundice, Cirrhosis, alcohol induced liver damage, Drug induced toxicity etc. In this study Livafit was formulated and standardized in terms of physico-chemical parameters, microbiological content, toxicological and pharmacological effects with modern techniques [2] .

MATERIALS AND METHODS

Collection of Extracts

Herbal extracts used in the preparation of Livafit were bought from Plantex, Andhra Pradesh, Amines Bio-tech Ltd., Vadodara, India and Tulsi Amrit, Indore, India. They were properly processed and the standardization of the extracts was performed and they satisfy the analytical reports documented by the analytical departments of each of those companies. They were duly authentified by the heads of Quality Assurance departments [3] .

Animals

Wistar Albino rats of both the sexes (170-190g) were maitnained under ambient conditions like at 24 $\pm$ 5^0C and 45-50% of humidity under conditioned air and 12-12 hr light to dark cycle. The rats are fed and given water ad libitum.

Formulation of Livafit (LF)

Pharmacological Evaluation of Livafit

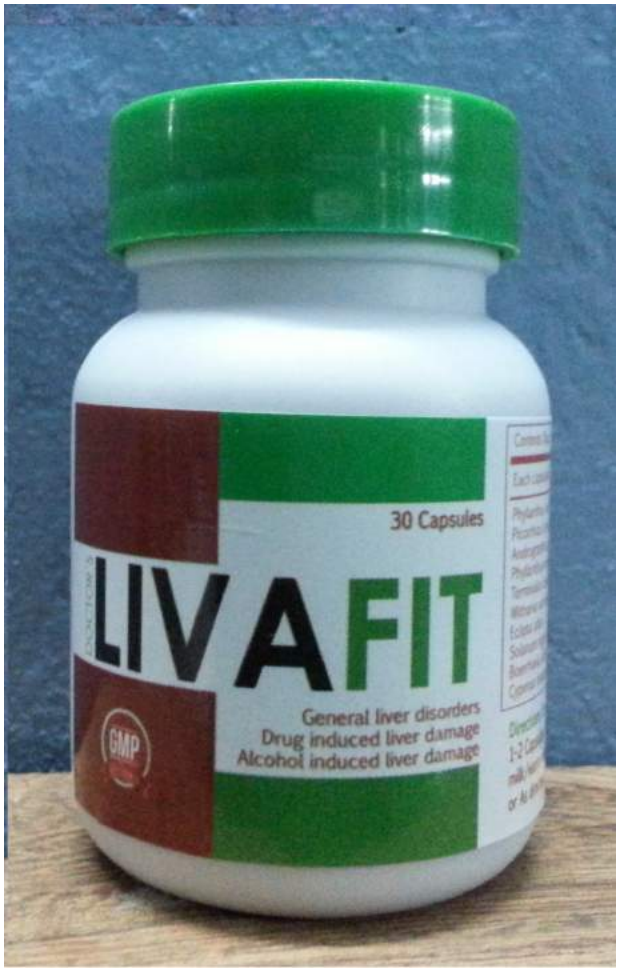

Figure 1: FinalProduct of LIVAFIT

ACUTE ORAL TOXICITY STUDIES

Albino wistar rats weigh about 100-120gm were selected for the study. The starting dose level of the formulation was 2000mg/kg body weight p.o as most of the crude extract posses LD 50 value more than 200mg/kg p.o. the dosage volume was given as 0.2ml per 100gm bodyweight to the rats. Food was withheld for a further 3-4 hours after administration of LF for 14 days and observed to find any signs for toxicity [4] .

HEPATOPROTECTIVE ACTIVITY

Hepatoprotective effect of Livafit was tested in CCl_4 induced hepatotoxicity in albino wistar rats. All the animals were divided into five groups with six animals in each viz, Group A-normal control (gum acacia 200mg/kg), Group B-negative control (CCL_4 2mg/kg), Group C-test control (Marketed polyherbal tablet 250mg/kg), Group D-standard test control (Silymarin 200mg/kg) and Group E-test group (Livafit 250mg/kg). They were administered orally along with olive oil in 1:1 ratio. The test was

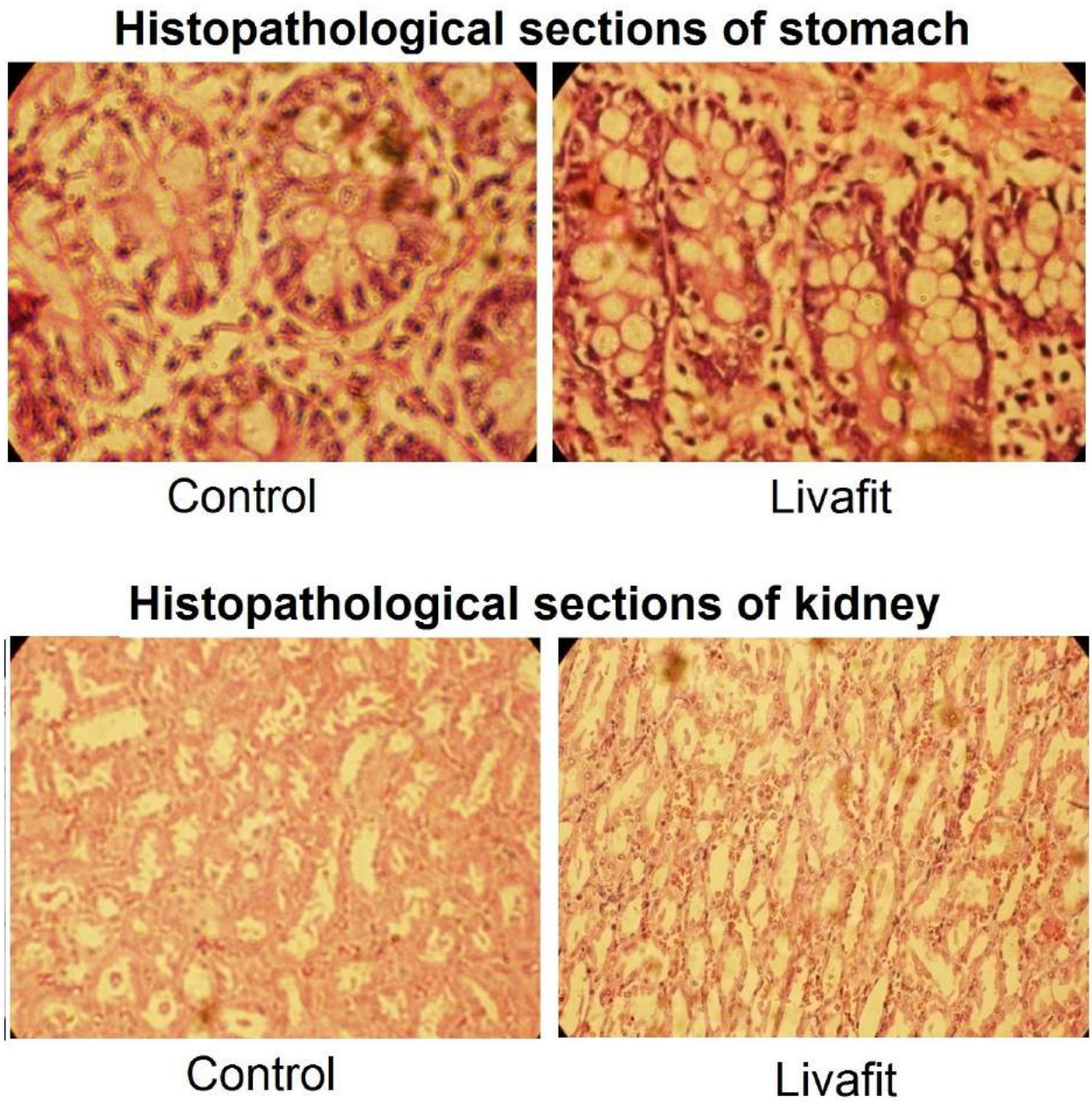

Figure 2: HistopathologicalSections of Stomach and Kidney

continued for 4 days and the blood was collected from retroorbital plexus on fourth day. The animals were sacrificed and liver was collected to estimate SGOT, Bilurubin, SGPT nad ALP levels. The liver tissue was also studies [5] . This includes histological changes in liver characters like arrangement of heaptic lobules, inflammatory cell infiltration, fat tissue changes [6].

Statistical studies

The mean and SEM were calculated by using one way ANOVA followed Dunnet's T-test.

RESULTS AND DISCUSSION

The Analytical Reports produced by the suppliers showed the moisture content in the extract under 9%w/w and Total ash values under 2%w/w which were satisfactory under pharmacopoeal standards. The microbial contents are under 200cpu. The reports concluded that the extracts are devoid of Staphylococcus, Salmonella, Bacillus, Aspergillus, Mycobacterium and E. coli. HPTLC fingerprinting reported the content of active principles as Kutkin >6%, Andrographolides>2.66%, Alkaloids 0.8%, Bitters >2.02% and tannins >5%.

Pharmacological Screening

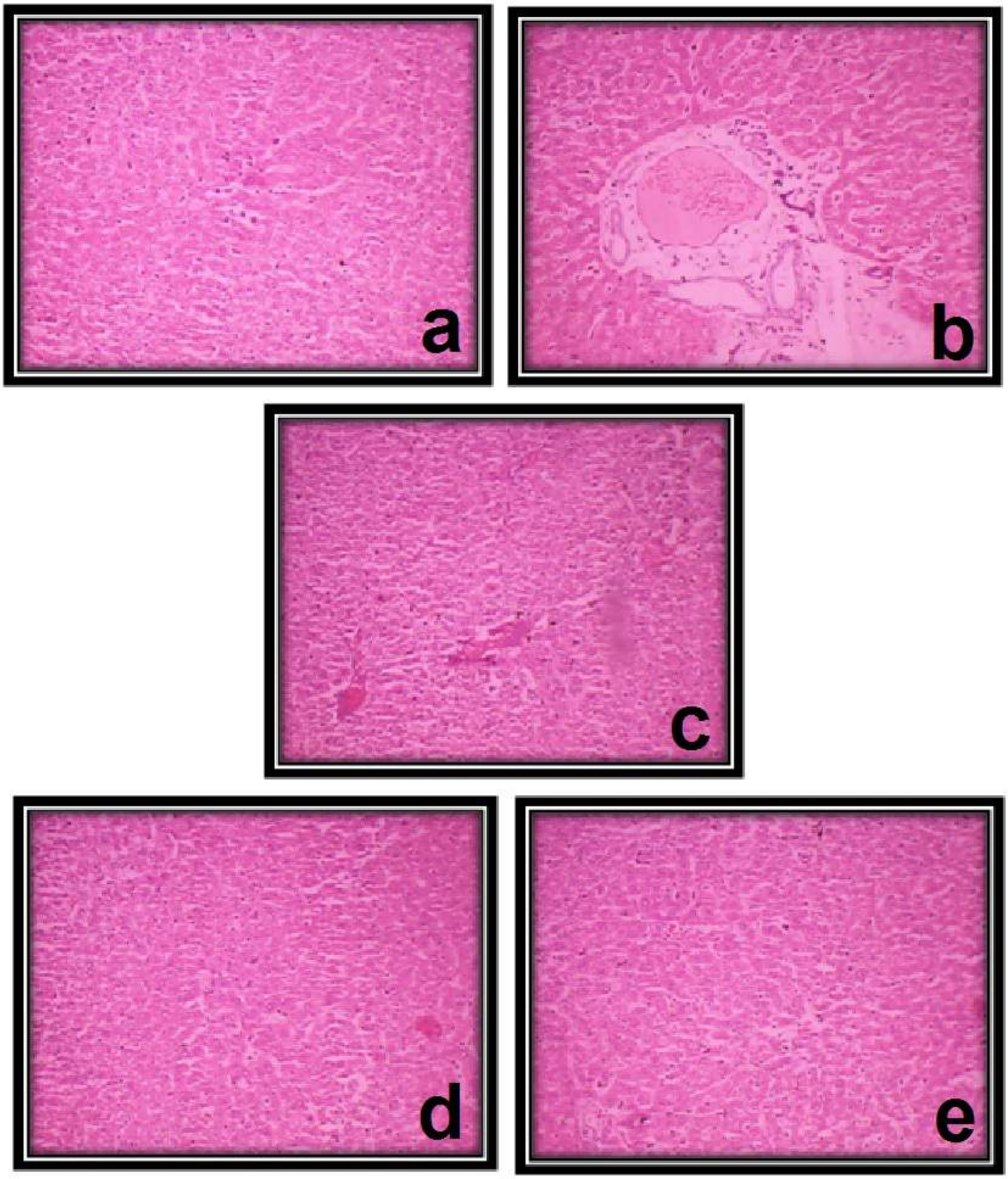

Figure 3: HepatocytesShowing the Effect of Livafit on CCl_4 Induced Hepatotoxicity inWistar Albino Rats. a. Normal Control, b. Negative Control (CCl_4),c. Marketed Formulation, d. Silymarin drug and e. Livafit

Table 1: Effectof Livafit on CCl_4-Induced Alteration of Hepatic Enzymes and SerumBilirubin in Rat Liver

Design of Treatment	Biochemical parameters				
	SGOT (U/ml)	SGPT (U/ml)	ALP (KA Units)	ϒ-GT (IU/L)	TP (gm/dl)	Bilirubin (mg/dl)
Group A-normal control (gum acacia 200mg/kg)	50.21 ± 1.16*	62.34 ± 0.06*	15.45 ± 0.92*	50.40±0.03*	7.45±0.04*	0.88 ± 0.03*
Group B-negative control (CCL4 2mg/kg),	162.93 ± 1.03	119.01 ± 1.41	48.33 ± 0.91	99.53±0.21	3.01±0.20	2.05 ± 0.04
Group C-test control (Marketed polyherbal tablet 250mg/kg)	55.15 ± 0.81*	63.43 ± 0.43*	15.98 ± 0.92*	60.06±0.03*	4.54±0.01*	0.85 ± 0.02*
Group D-standard test control (Silymarin 200mg/kg)	61.21 ± 0.91*	71.80 ± 0.62*	20.67± 0.64*	57.85±0.03*	6.6±0.07*	1.14 ± 0.02*
Group E-test group (Livafit 250mg/kg)	52.43 ± 1.24*	61.36 ± 0.04*	15.01 ± 0.02*	51.54±0.01*	7.53±0.02*	0.92 ± 0.01*

Livafit has not showed any signs of toxicity in any rat and the weights were remained as constant before and after the start of the test.

Livafit at tested dose (group E) has shown a reduction in carbon tetrachloride induced elevated levels of the enzymes and also total bilirubin when compared to the Positive control and standard group of animals (group -B, C & D) after 3days of treatment. After 3 days, the hepatic enzymes levels were balanced to the normal after treating with Livafit at the dose of 250mg/kg, p.o (Table 1). The hepatoprotective activity of Livafit is shown in Figure 2Figure 3 .

CONCLUSION

Traditional systems of medicine and the formulae are widely applied in india along with the western countries. The demand for their use and safety is always questionable due to the poor extent of standardization. So WHO gave some guidelines for safety, efficacy and wuality of herbs. The quest for newer formulae for treatment of diseases without side effects is never ending and in the present research, the potency of the formulated Livafit has been accessed. Overall, Livafit showed a remarkable activity in protecting liver against diseases and prevent its disorders. So it can be considered for further studies, licencing and active marketing.

CONFLICT OF INTEREST

Authors declared no conflict of interest.

FUNDING SUPPORT

None

ACKNOWLEDGEMENT

The authors are thankful to all who have extended their constant support for the completion of the work.

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Cite this article: G Avinash Kumar Reddy, S Jamal Basha. **Pharmacological screening of polyherbal hepatoprotective - 'Doctor's LIVAFIT'**. Int. J Pharm. Res. Life Sci. 2020; 8(1): 6-11.