"CLINICAL TRIALS OF *ECLIPTA PROSTRATA (L.)L* AS HEPATOPROTECTIVE AND THEIR MARKET FORMULATIONS"

By

Mr. Jitendra S. Patel [M. Pharm.]

Thesis Submitted to the

Saurashtra University, Rajkot, India

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of the requirements for the degree of

Doctor of Philosophy

in

Pharmaceutical Science

Under the guidance of

Dr. K. N. Patel [M. Pharm, Ph. D]

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Dept. of Pharmaceutical sciences,

Saurashtra University

Rajkot - 360005.

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Saurashtra University

Rajkot – 360 005

★ ★ ★ ★

DECLARATION BY THE CANDIDATE

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is a bonafide and genuine research work carried out by

Mr. Jitendra S. Patel [M. Pharm]

Under the guidance of

Dr. K. N. Patel [M. Pharm, Ph. D]

Date:

Place: **Mr. Jitendra S. Patel [M. Pharm]**

Saurashtra University

Rajkot – 360 005

★ ★ ★ ★

CERTIFICATE BY THE GUIDE

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Dr. K. N. Patel [M. Pharm, Ph. D]
Principal,
Arihant School of Pharmacy & BRI,
Adalaj, Gandhinagar – 382 421

Date:

Place:

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Dadicated

to

my Parents

and

my Family

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Mr. Jitendra S. Patel [M. Pharm]

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INTRODUCTION

1.1. Herbal Drugs

1.1.1 Introduction to Medicinal Plant:

Along with the disease nature has created their cure in the form of vegetables, minerals and animals. According to Ecclesiates “The Lord has created medicines out of the earth and a wise man will not abhor them.” (Siddiqui *et al.*, 1985)

As disease, decay and death have always co-existed with life the remedial measures for them have been one of the important needs of the man since the time immemorial. The earliest remedial measures were Plants (Gupta *et al*., 1981).

The relationship between man and plants has been close throughout the development of human culture. With the increase in the understanding of human diseases there has been continued interest in the drugs from the plant kingdom (Modi *et al*., 1984). Men’s existence on this earth has been made possible only because of vital role played by the plant kingdom is sustaining life (Sundaresh *et al*., 1978).

Medicinal plants were existing even before human being made their appearance on the earth (Shastri, 1993). So the story or history of drugs is as old as mankind (Shah *et al*., 1989).

This history of medicines and surgery dates back in the remote past. In India the earliest records referring to curative properties of certain herbs are continued in Rig-Veda (3500-1800 B.C.). Then came two important works of Indian system of medicine, the works of Charaka and Susruta (Kapur, 1991).

A new herbal 1551 by William Turner was the earliest English book, which gave a truly scientific account of plants (Wallis, 1982).

It has been estimated that from 25000 to 75000 species of higher plant exist on the earth. A reasonable estimate of about 10% has been used in traditional medicine. However perhaps only about 1% of these (250-750 species) are acknowledged through scientific studies to have real therapeutic value when used in extract form by human beings.(Farmworth, 1985).

Several approaches have been taken in the past to obtain as much biological activity data as possible following the administration of plant extract to rodent as a primary screen (Naik, 1989).

Natural products have been derived from higher plants, microbes or animals and those can be of either terrestrial or marine or aquatic origin. The medicinal preparations based on these raw materials were in the form of crude drug such as dried herbs, or an extract there of and are invariably derived from a mixture of several materials. With the advent of European scientific methods, many of these reputed medicinal plants came under chemical investigation leading to the isolations of active principles. Beginning with 1800 AD there was continuous activity in this area and many of the well known medicinal plants were chemically analyzed and their active principles characterized. Soon after their isolation and characterization these compounds, either in pure state or in the form of well characterized extracts, became part of Pharmacopoeias of several countries. This is where herbal medicine and modern medicine have a common link (Handa, 1991).

In modern medicine also, plants occupy a very significant place as raw materials for some important drugs, although synthetic drugs brought about a

revolution in controlling different diseases. But these synthetic drugs are out of reach to millions of people those who live in remote places depends on traditional healers, whom they know and trust. Judicious use of medicinal herbs can even cure deadly disease (Bhatacharjee, 1989).

1.1.2. The Indian System of Medicine (ISM)

These are traditional systems of medicine which encompasses 3 systems namely Ayurveda, Siddha and Unani, practiced by Vaidyas, Siddhars and Hakkims respectively. The medicines or formulations that come under Ayurveda, Siddha and Unani system of treatment are called as Indian System of Medicines. The Drug and Cosmetic Act defines the ISM as "Ayurvedic, Siddha and Unani drug includes all medicines, intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals"(Sampath, 2001).

1.1.3. Modern Drugs from Ayurveda

Ayurveda the traditional Indian system of medicine is as old as the Indian culture and civilization. Ayurveda has important classical texts of Charaka Samhita which deals with clinical diagnosis and Susruta Samhita which deals with surgery. Indian Ayurvedic system certainly has given birth to number of important modern drugs, viz. ajmalicine, reserpine, leurocristine, L-dopa, cardiac glycosides, sennosides etc (Naik, 1989).

The importance of plants as a source of useful antihypertensive drugs was supported by the isolation of reserpine from *Rauwolfia serpertina* by Muller *et al.,* 1952. Veratrum alkaloids were other antihypertensive agents from plant sources (Srimal and Shukla, 1987). Recently number of medicinal plants have been reported to have anti-platelet activity, notable among these

are *Allium cepa, Allium sativum, Coleus forskohli, Commiphora mukul, Cuminum cyminum, Curcuma longa, Zingiber officinale* etc. Many of these are also mentioned to be useful in cardiovascular ailments in classical text books of ancient medicine (Dvivedi and Amrita, 1993).

1.1.4. Herbal Wealth of India

Now a days natural products are an integral part of human health care system, because there is now popular concern over toxicity and side effects of modern drugs. There is also a realization that natural medicines are safer and allopathic drugs are often ineffective. India is one of the 12 leading bio-diversity centers with presence of over 45,000 different plant species, 15000 – 18000 flowering plants, 23,000 fungi, 16,000 lichens, 18000 bryophytes and 13 million marine organisms. From this flora 15,000 to 20,000 have good medicinal value. Among those only about 7,00 plants are used in Ayurveda, 600 in Siddha, 700 in Unani and 30 in modern medicines. (Wealth of India, 1952)

1.1.5. Herbal Drug Market

The global herbal products market is worth US $32 billion (Rs.1, 000,000 crores) and is growing at a rate of about 9-15%. The average turnover of Indian herbal medicine industry is about 2,300 crores against the pharmaceutical industry is about Rs.14,500 crores with a growth rate of 15%. However to achieve the goal of major exporter of herbal remedies several steps need to be taken:

A. Systematic study of world market demand and short listing of medicinal herbs with good potential.
B. Systematic cultivation of medicinal herbs on a large scale.

C. Encouragement for agro-based phytochemicals and pharmaceutical industries to manufacture value added herbal products.

D. Strict legislation to control quality and purity.

E. Upgradation of cultivation and collection process.

F. Documentation of research work and standardization for quality

The increasing demand for herbal medicines inevitably led to the issue of obtaining and maintaining their quality and purity based on internationally recognized guidelines. (Mukherjee *et al*., 1998).

1.1.6. A Brief Look into the History of Herbal Medicine:

We can certainly assume, however that the healing properties of some plants were discovered by primeval humans fairly early and they learned to use them. By collecting and using medicinal plants, people gained valuable experience good as well as bad and handed down their knowledge to future generations.

One of the first written records concerning curative drugs and narcotic substances was found on a clay tablet in Assyrian cuneiform script dating back to 2,700 BC. The tablet mentions a brown drug, daughter of the poppy, meaning opium. In ancient Egypt, medicinal science and the use of medicinal substances have an age-old tradition. The Egyptian Pharmacopoeia always had a supply of medications of plant and animal, as well as mineral origins. There were 25 types of medicinal plants, as basic nutritional and medicinal plants, onion, garlic, lettuce, lentils, olives and caraway were used (Gupta *et al*., 2000) The knowledge of Indian physicians is documented by the so-called Bower manuscript found in 1889 in the ruins of MINGSI in

central Asia. The document and its author praise the garlic as a panacea claiming it to prolong life to 100 years. In ancient Chinese pharmacology and herbal medicine the most extensive fields of medicine, they contained 8160 prescriptions for the use of various drugs, with instructions on how to use, how to collect and prepare various drugs from medicinal plants.

Ayurveda has well known treaties known as Charak Samhita and Susrut Sanhita, the oldest and very first written document of Ayurveda (900 BC). It describes 341 plants and plant products for use in medicine and more importantly classify these in terms of physiological activity. The traditional medicine used in India known popularly as the Indian system of medicine includes Ayurveda, Siddha, Unani and Naturopathy.

Herbal therapy provides rational means for the treatment of many internal diseases which are considered to be obstinate and incurable in other system of medicine. It lays a great deal of emphasis upon the maintenance of positive health of an individual. It thus aims at both the prevention and cure of diseases. Natural therapy also studies the basic human nature and natural things like hunger, thirst, sleep, sex etc. and provides measures for a disciplined, disease free life and will give a holistic approach to the therapy (Thaibinh, 1998).

1.1.7. What is a Herbal Medicine:

Herb has various meanings, but in the context of this it refers to "crude drugs of vegetable origin utilized for the treatment of disease states, often a chronic nature, or to attain or maintain a condition of

improved health". Herbal preparations called "phytopharmaceuticals", or "phytomedicine" are preparations made from different parts of plants. They come in different formulations and dosage forms including tablet, capsule, elixir, powder, extract, tincture, cream and parenteral preparations. Herbal products in the crude state are also used. A single isolated active principle derived from plants such as digoxin or reserpine tablets is not considered as Herbal medicine. Herbal remedies are not to be confused with homeopathic preparations. Homeopathic medicine, found in the 18th century by the German physician Samuel Hanemann also uses herbs and other natural products, but it is based upon the "Law of similar" and the "Law of dilution".

There is a wealth of non scientific herbal medicine information readily available to the health consumer. Access to scientific literature is crucial to the pharmacist for his or her role as a drug information provider. The pharmacist among all health care practitioners is in the best position to provide information about drug safety and effectiveness. If a herb is used as therapeutic agent it should be considered as a drug (Thaibinh, 1998).

1.1.8. Traditional Medicines:

There are several definitions and interpretations of this term, 'traditional medicine'. The most comprehensive is the one where the WHO has defined it as "The sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance relying exclusively

on practical experience and observations handed down from generation to generation, whether verbally or in writing (Thaibinh, 1998).

1.1.9. Popularity of Herbal Medicine:

The traditional medicine is largely gaining popularity over allopathic medicine because of the following reasons:

1. Rising costs of medical care.
2. As these are from natural origin, they are free from side effects.
3. Goes to root cause and removes it, so that the disease does not occur again.
4. Cure from many obstinate diseases.
5. Easy availability of drugs from natural sources.

1.1.10. Need and Scope of Herbal Therapy:

Today we are more concerned with life style diseases like depression, cancer and heart troubles caused by faulty nutrition and stress. Because these diseases have a mental or emotional component, there is a growing conviction that allopathy is largely unable to cure them, all of it offers is temporary relief from symptoms. There is a need of alternative therapy, to cover a good health for all. Herbal therapy will be one of the best practices to overcome the illness.

Traditional Indian practice held that certain drugs should be formulated through the addition of chosen substance that enhances bioavailability of the drug. Recent work, particularly in two Indian modern biology labs, has confirmed this bioavailability enhancer ability

of pepper and point to the active component as the molecule piperine. An anti-TB drug RIFAMPICIN has to be given at a higher dose than required, in order to compensate for losses on the way to the target site. Formulation of piperine with rifampicin will save the drug and counter effects.

Herbal oriented pharmaceutical companies like Dabur and the Himalaya Drug company are investing crores of rupees on research, development, and popularization of OTC remedies. Most of these address modern maladies such as stress, premenstrual syndrome, depression and obesity, based on adapted version of ancient vedic formulas (Thaibinh, 1998).

1.1.11. Side Effects of Herbs:

Little is known about safety of phytomedicine. There has been an increase in the number of side effects reported in the literature. Many cases, however, could have gone unreported because herbal medicine is usually self-prescribed and often ignored by health practitioners during the patients care. Identifying adverse effects is further hindered because it is not always possible to assess the quality of certain herbal medicinal products. (Calloway, 1997).

1.1.12. Herbal Medicine-Drug Interactions:

The potential risk of an herbal medicine interacting with a prescribed drug is also concern with the increased use of phytomedicine. Recently, several interactions have drawn the attention of the medical community.

A clinically significant interaction between warfarin and a herbal medicine containing ***Salvia miltiorrhiza*** roots causing clotting abnormalities was reported. A randomized, cross over study performed on eight healthy subjects reported no significant pharmacokinetic interactions between Levofloxacin and three selected traditional herbal medicines. No differences were found in Levofloxacin plasma concentration, area under the curve, terminal elimination half-life or renal clearance (Yu, 1987).

1.1.13. Adulteration in Herbal Medicine:

Standardized herbal preparations are becoming increasingly available. In some parts of the world where no government standards and quality control are enforced adulteration and contamination pose safety as well as efficacy problems. The presence of adulterants such as arsenic, mercury, lead in prescription drugs in herbal medications can cause significant toxicity. Having addressed this "public health concern" after finding that 23.70% of traditional Chinese medicines (total of 2.609 samples) collected over a year among eight hospitals in Taiwan were spiked with adulterants such as Caffeine, Acetaminophen, Indomethacin, Hydrochlorthiazide and other drugs.(Gupta *et al*., 2000)

1.1.14. Herbal Research:

The effectiveness, easy availability, low cost and comparatively being devoid of serious toxic effects (time tested) popularized, herbal remedies.

Natural products (crude drug extracts and pure compounds) have been derived from higher plants, microbes or animals and these can be of either terestrial or marine origin. Many of the reputed medicinal plants came under chemical scrutiny leading to the isolation of active principles. Beginning with 1800 A.D., the plants isolates and characterized extracts, became part of Pharmacopoeias of several countries. This is where herbal medicine and modern medicine have a common link.

Garlic *(Allium sativum)*, sometimes referred to as Nectar of the God is one of the most versatile medicinal plants. Numerous scientific studies have been conducted to evaluate its various potential therapeutic effects. Garlic's beneficial effect in hypercholesteroemic and coronary heart disease subjects is shown in a randomized study by Adler and double-blind, randomized cross over study by Steiner. A meta-analysis of five randomized, placebo-controlled trials reported a "significant reduction in total cholesterol levels" in persons with cholesterol level greater than 200mg/dl. Another meta-analysis of eighteen trials conducted that there is "inadequate justification for garlic and related allium" use to reduce cardiovascular risk. Its effect on platelet aggregation is well documented. Garlic's antibacterial, antifungal and antiviral properties have been studied *in vitro* (Dalaha and Garagusi, 1985) and *in vivo* (Davis *et al.*, 1990).

Maindenhair tree products are among the most popular herbal dietary supplements in the U.S., and in Germany, the extract from *Ginkgo biloba* leaves has been prescribed for circulatory system

disorders and its retail sales run around 719 million U.S dollars a year. A review (Kleijnen and Knispchiled, 1992) summarizes the possible mechanisms of action, clinical pharmacokinetics, side effects and efficacy of *Ginkgo biloba* extracts in the treatment of intermittent claudification and cerebral insufficiency, substantial scientific data about *Ginkgo biloba* is available in the German literature. Recently a placebo-controlled, double-blind, randomized trial, conducted in the United States found that *Ginkgo biloba* extract is "safe and appears capable of stabilizing and improving the cognitive performance and the social function" in Alzheimer's and multiinfarct dementia patients. (Le Bars, 1997) Alzheimer's disease is characterized by a subtle onset and progressive loss of immediate memory and other cognitive functions due to a degenerative process of the cerebral cortex nerve cells

1.1.15. Indian Herbal Market:

India can be a major player in the global market for herbal based medicines. Exports of herbal materials and medicines can jump from just Rs.456 crores now to Rs.3,000 crores by 2005 and exports can shoot to Rs.10,000 crores by 2010.

A 13 member task force on the conservation and sustainable use of medicinal plants has reported that there is a growing demand for plant based medicines, health products, pharmaceuticals, food supplements and cosmetics. The international market for such plants is more than 60 billion $ a year and growing at a rate of seven percent within the country, these could well provide affordable health care and conserve biodiversity.

According to the members of task force, India already has the expertise, medicinal plants are used in homes, there are 1.5 million practitioners of traditional medicine systems, and about 4.6 lakh registered pharmacies of Indian system of medicine and homeopathy. Nine tenths of the plants are collected from the wild, generating about 40 million man days of employment. (Tiwari, 2000)

Table 1.1. List of some of the Useful Medicinal Plants: (Tiwari, 2000)

Sr. no	**Latin Name**	**Sanskrit Name**	**Main indications in Ayurveda**
1.	*Acorous calamus*	Vacha	Nervine, antispasmodic, sedative, stomachic, laxative, diuretic.
2.	*Azadirachta indica*	Neem	Blood disease, antibacterial.
3.	*Bacopa monnieri*	Brahmi	Nervine tonic, diuretic, sedative.
4.	*Centella asiatica*	Mandukparni	Sedative, anxiolytic.
5.	*Curcuma longa*	Haridra	Arthritic pain, skin disease, antibacterial, anti-inflammatory.
6.	*Eclipta alba*	Bhringraj	Liver disease, tonic, emetic, purgative, antiviral.
7.	*Emblica officinalis*	Amalaki	Fruit: cooling, laxative, stomachic, tonic, diuretic.

8.	*Ocimum sanctum*	Tulsi	Demulcent, expectorant, anthelmintic, antispasmodic.
9.	*Picrorhiza kurroa*	Katuki	Hepatitis, asthma, anorexia.

1.2. Hepatotoxicity. (Rege *et al*., 1984; Doreswamy *et al*., 1995)

Liver plays a vital role in the metabolism and elimination of various exogenous and endogenous compounds. As a result of its continuous involvement, it is susceptible to toxic injuries caused by certain agents and any damage to hepatic cells disturbs body metabolism. In recent times lots of interest has been generated to find out a natural remedy for hepatic disorders caused by toxins like alcohol and hepatitis virus (Patel *et al*., 1998). The agent should protect against such damage, especially of one which facilitates regeneration by proliferation of parenchymal cells after damage and arrest growth of fibrous tissue

There is no remedy for liver diseases which are so prevalent in the population. The treatment is mainly symptomatic. (Rege *et al*., 1984) Scientists and some industrialists deliberated on various prospective plant remedies for ailments of liver disorder management. In the decade 70s, the world scientific community concentrated on a herbal plant *Vinca rosea*. Then in 80s the attention was focused on *Panax ginseng*. Now, the news of multifarious activities of the Neem tree indicates that it may become centre for research in 90s. Indian Council of Medical Research, New Delhi, in its revived research on traditional medicine, had adopted liver diseases as one among six thrust areas and for multidisciplinary study. Screening of active constituents from Kutki *(Picrorhiza kurroa),* Bhoomyamalaki *(Phyllanthus niruri)* have shown marked protection against jaundice. Hepatitis continues to be a major health problem in urban areas in India, and several studies in viral hepatitis were under investigation by the ICMR. For example, extracts of milk thistle *(Silybum marianum)* fruits under investigation for the treatment of

alcoholic hepatitis. According to Indian Society of Gastroenterology, Mulethi *(Glycyrrhiza glabra)* prevents multiplication of viruses inside liver cells. The disorder of liver may be acute or chronic hepatitis (inflammatory liver diseases), hepatosis (non-inflammatory liver diseases) and liver cirrhosis (fibrosis of the liver). Liver enzymes act as an index of sub-clinical hepatic damage. Serum glutamic pyruvic transaminase (SGPT), serum glutamicoxaloacetic pyruvic transaminase (SGOT), Serum lactic dehydrogenase (LDH) and Serum alkaline phosphatase are reported as an index of hepatic injury and cholestasis(Doreswamy *et al*., 1995).

1.2.1. Anatomy and histology of liver:

Anatomy: (Tortora and Grabouski, 2006**)**

The liver is a large, solid, gland situated in the right upper quadrant of the abdominal cavity. Liver is reddish brown in color, soft in consistency and very friable. It weighs about 1600 gm in males and about 1300 gm in females. The liver occupies the whole of the right hypochondrium, the greater part of the epigastrium and extends into the left hypochondrium reaching up to the left lateral line.

The liver is the largest gland in the body. It secretes bile and performs various other metabolic functions. The liver is also called the 'heaper' from which we have the adjective hepatic.

Histology of the Liver: (Tortora and Grabouski, 2006**)**

The liver is divided into two principle lobes – a large right lobe and smaller is left lobe. The lobes of the liver are made up of many functional units called lobules. A lobule is typically six sided structure (hexagon) that consists of specialized epithelial cells called hepatocytes (hepat=liver,

cytes=cells), arranged in irregular, branching interconnected plates around a central vein. Instead of capillaries, the liver has larger, endothelium-lined spaces called Sinusoids, through which blood passes. Also present in the sinusoids are fixed phagocyte called Stellate reticuloendothelial (Kupffer) cells, which destroy, worn-out white blood cells and red blood cells, bacteria and other foreign matter in the venous blood draining from the gastrointestinal tract.

Blood supply of the liver:

The liver receives blood from two sources, from hepatic artery it receives oxygenated blood and from the hepatic portal vein it receive deoxygenated blood containing newly absorbed nutrients, drugs and possibly microbes and toxins from gastrointestinal tract. Branches of both the hepatic artery and the hepatic portal vein carry blood into liver sinusoids, where oxygen, most of nutrients and certain toxic substances are taken up by the hepatocytes.

Functions of Liver:

- **Carbohydrate metabolism:**

The liver is especially important in maintaining a normal blood glucose level. When blood glucose is low, the liver can break down glycogen to glucose and release glucose into the bloodstream, when blood glucose is high it converts glucose to glycogen and triglycerides for storage. Liver can also convert certain amino acids and lactic acid to glucose.

- **Lipid Metabolism:**

Hepatocytes store some triglycerides, breakdown fatty acids to generate ATP, synthesize cholesterol and use cholesterol to make bile salts.

- **Protein Metabolism:**

Hepatocyte deaminate amino acids so that the amino acids can be used for ATP production or converted to carbohydrates or fats, resulting toxic ammonia is converted to less toxic urea, which is excreted in urine. Hepatocyte synthesizes most plasma proteins, such as alpha and beta globulin, albumin, prothrombin and fibrinogen.

- **Processing of drugs and hormones:**

The liver can detoxify substances such as alcohol or excrete drugs such as penicillin, erythromycin and sulfonamides into bile.

- ***Storage:***

In addition to glycogen, the liver is a prime storage site of certain vitamins (A, B_{12}, D, E and K) and minerals (iron and copper), which are released from liver.

1.2.2. Basic hepatic histsopathology (Kissane, 1990**):**

Hepatocellular changes:

Hydropic change is a descriptive term applied to the hepatocyte with pale, watery cytoplasm and a normal nucleus. A wide variety of conditions produce this relative lack of cytoplasmic staining. Increased eosinophilia may occur with drug-related hydroperplasia of the smooth endoplasmic reticulum. Active regeneration of hepatocytes after necrosis as in several viral hepatitis or recovery phase of fatty liver, produces a widespread hepatocellular hydropic change as well as a cobblestone pattern of the liver cords. Hydropic change is also an indicator of hepatocellular damage and is noted in acute viral hepatitis and drug induced hepatic injury including alcohol injury.

Hepatocellular fat accumulation may be either large cytoplasmic bodies of foamy fat. Fatty liver occurs because of 1) Sudden increase in mobilization of fat from the periphery to the liver, 2) Relative lack of protein necessary for hepatocellular fat release, 3) Increased hepatocellular fat formation by metabolic changes and 4) Decrease hepatocellular fat degradation. Fatty liver is common in alcohol ingestion, parenteral nutrition, tuberculosis, starvation, certain drugs, diabetes mellitus and obesity. Electron microscopy shows that the cytoplasmic fat is not membrane bound and lysosomes are greatly increased.

Hepatocellular Necrosis:

Necrosis may be classified in many ways, including location (zonal, periportal, perivenular and so on), mechanism (lytic, coagulative), amount (submassive versus focal), cellular type (lymphocytotoxic veruses hyline necrosis) and various patterns are associated with different etiologic factors. Zonal necrosis is a common pattern of injury after an acute hepatic injury. Sharply demarcated perivenular (zone 3) coagulation necrosis is typical of several anoxic injury or acetaminophen injury and may be explained by differences in oxygenation and activity of drug-metabolizing enzyme. Periportal necrosis (Zone 1) is not common and is noted in eclampsia. Midzonal injury is reported for yellow fever.

Hepatocellular necrosis (hepatocytolysis) of the lytic type, with the associated macrophage activity that is so complete and rapid that dead hepatocytes are rarely noted, such necrosis is common in viral hepatitis, alcoholic liver disease and many hepatotoxic reactions, and the type of inflammatory reactions varies in these conditions. Coagulative necrosis in the

liver is characterized by dying hepatocytes that retain some staining of the cytoplasm and the nuclei lose basophilia and gradually disappear. The cells become shrunken and slowly disappears because of the action of inflammatory cells.

Acidophilic injury usually occurs in an isolated hepatocyte and is similar to coagulative necrosis except that the cytoplasm becomes more eosinophilic and waxy and the nucleus may be retained and be a dark. These bodies are common in acute viral hepatitis, chronic active hepatitis, severe burns and other liver disorders. Confluent necrosis is attributable to fusion of focal or zonal necrosis and may result from intensive necrosis that bridge between different zones. Submassive hepatic necrosis is recognized by confluent necrosis that usually involves many perivenular areas and occur most commonly in severe acute viral hepatitis, drug injury etc. Massive hepatic necrosis is distinguished from submassive hepatic necrosis by the presence of a thin rim of viable-appearing hepatocytes around each portal tract.

Regeneration:

The liver has a remarkable capacity for regeneration and during recovery from submassive hepatic necrosis. In normal adult rat liver, the hepatocytes have an annual turnover of one mitosis per year; weight doubles 48 hours and has returned to normal weight at 3 to 6 days after partial hepatectomy. In man liver, regeneration also occurs rapidly and even in cirrhotic liver. After major hepatic resection for tumor, regeneration of normal hepatic volume occurs by 3 to 6 months, and liver function appears normal at 2 to 3 weeks after surgery.

Fibrosis:

Hepatic fibrosis is the most important feature of chronic liver disease and leads to cirrhosis and irreversible physiologic changes in the liver that account for many clinical manifestations of fatal liver disease. Fibrosis of the liver is a common response to chronic inflammatory conditions. Experimental cirrhosis in the carbon tetrachloride treated rat and mouse have served as models, but the adequacy of the morphological and biochemical lesions has been doubled compared to human cirrhosis.

Patterns of fibrosis:

Simple hepatocellular necrosis does not result in collagen formation, but in severe hepatic necrosis a collapsed stroma may form a framework for collagen retention. Repeated or continuous necrosis is associated with fibrosis, and the most striking fibrosis within the lobule is noted in chronic alcoholic liver disease. This fibrosis occurs even with a very mild inflammatory response. Another common pattern of fibrosis occurs in the portal areas in chronic active hepatitis, which tends to be more confirmed to the portal tracts and does not extend into the lobule as much as portal fibrosis does in alcoholic. Non-collagen matrix components have been investigated for a possible role in fibrosis. Fibronectin is a plasma protein and may produce a cellular form in injury.

Cirrhosis:

The currently accepted definition of cirrhosis may be applied to a liver with a diffuse fibrosis (that is the entire liver and not focal) and contain regenerative nodules, which are masses of hepatocytes lacking the normal blood flow because of the lack of terminal hepatic venules. Regenerative or

hyperplastic nodules are required for the identification of cirrhosis because altered blood flow and portal hypertension. In contrast hepatic fibrosis, which is usually a precursor to cirrhosis, is not associated as frequently with portal hypertension. The development of hepatocellular carcinoma is relatively common in cirrhosis with the required regenerative nodules and is not as frequent as it is in fibrosis.

Cirrhosis is classified as micronodular cirrhosis applies to the liver in which nearly all the nodules are less than 3 mm diameter though some have used 1.5 mm as the minimum diameter because that is the diameter of a normal lobule. Examples include – alcoholic cirrhosis, biliary tract obstruction and hepatic venous obstruction.

Macronodular cirrhosis applies if most of the nodules are greater than 3mm diameter, and it occur in two forms. The more common form has nodules divided by thin septa that are often incomplete and have linking to portal tracts. This pattern is common in so-called post-hepatitic cirrhosis. The median time interval for conversion of micronodular cirrhosis to macronodular type is 2.25 years and majority of patients have such progression. Alcoholic cirrhosis often contains fats within the hepatocytes and the parenchyma is increased in weight. Etiological factors related to cirrhosis include alcoholism, hepatitis B virus, various metabolic diseases such as hemochromatosis, Wilson's disease etc. Cirrhosis without recognizable cause is called as "Cryptogenic cirrhosis". The irreversibility of cirrhosis has been emphasized in several experimental and clinical studies. If cirrhosis is reversible, it must be very rare, though in the most convincing patients having biliary obstruction has been corrected surgically. Functionally more important than nodular size

in cirrhosis is the size of the entire hepatic mass, which can be estimated with radioisotope scans.

Steatosis (Derck *et al*, 1994**):**

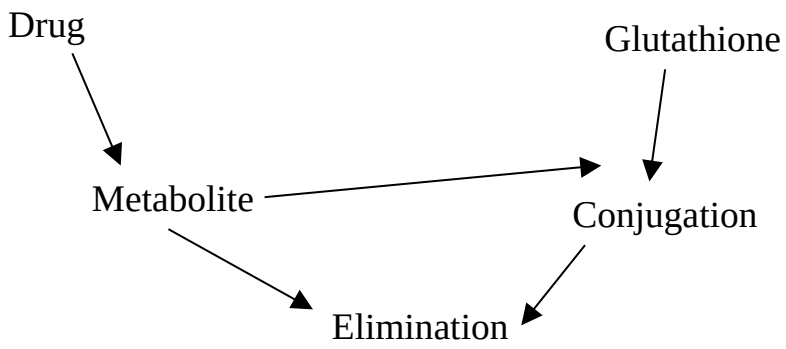
Steatosis may be produced by a wide variety of drugs and toxins, by far the commonest cause being alcohol. In most instances drug produce steatosis through inhibition of lipoprotein synthesis or secretion, or through interference with fatty acid oxidation.

Types of steatosis are, macrovesicular steatosis that takes the form of large vesicles due to coalescence of small lipid droplets within the cytosol and the eventual displacement and indentation of the nucleus. Corticosteroids may cause this type of steatosis. Agents which produce zonal liver necrosis, in particular industrial solvents such as carbon tetrachloride, phosphorous, toxins also show significant macrovesicular fatty infiltration. Chronic occupational exposure to organic solvents has been associated with steatosis.

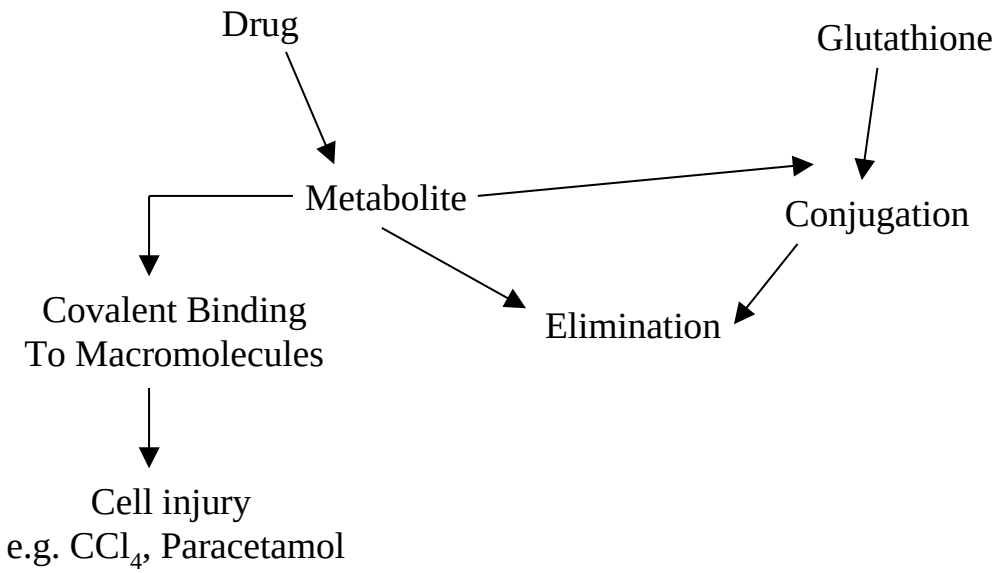
Microvesicular steatosis, in contrast mimics acute fatty liver of pregnancy and Reye's syndrome. In case of liver damage by tetracycline, hepatocytes are filled with finely divided fat droplets that do not displace the nuclei, initially the fat is confined to zone 3 but progressively become panacinar in distribution. There is no significant necrosis and little cholestasis. The liver damage probably results from inhibition of lipoprotein production, increased uptake of fatty acids, increased formation of triglycerides and/or impaired mitochondrial oxidation of fatty acids leading to severe intra hepatocytic lipid retention.

1.2. 3. Environmental injury – drug and toxins (Derck *et al*., 1994**):**

Water soluble drugs and chemical substances are polar molecules, they can be excreted by the kidneys, whereas those which are not water-soluble i.e. non-polar molecules are handled mainly by the liver. The main drug metabolizing enzymes increase the polarity of the molecule in one of the three ways :- a) oxido-reductase, of which the enzyme cytochrome P450 is important, b) hydrolase and transferase and c) conjugation reaction.



Traditionally, drug injury to the liver was classified into direct, where injury is predictable and dose-dependent, and indirect, where it is not dose-dependent and is unpredictable. It is now clear that this was a great oversimplification, and most drugs undergo metabolism within the liver cell before causing injury. Substances such as tannic acid, ethionine, ferrous sulphate, white phosphorus all cause liver damage, directly causing cell injury. In contrast, most of the traditional liver poisons such as carbon tetrachloride are in fact harmless in an animal such as Chicken which cannot metabolise them. Paracetamol in overdose and halothane probably operate generally in a similar way.



Alcoholic liver injury too may be the result of a reactive metabolite. Although both zonal necrosis and viral hepatitis-like liver cell necrosis caused by drugs and toxins usually have a mechanism similar to that outlined above, very occasionally reactive metabolite may create new cellular antigens which elicit an immunological response-free drug hypersensitivity e.g. Methyldopa.

Cell injury by CCl_4 (Zimmerman H.J., 1978**):**

Toxic injury of liver induced by carbon tetrachloride (CCl_4) is a model system of toxic injury. Toxic injury of liver by CCl_4 is the result of their metabolic conversion by a complex of enzymes bound to membranes of the smooth-surfaced endoplasmic reticulum. Action of these enzymes is a major mechanism by which toxic compounds are converted to less toxic ones. In some instance non-toxic substances are metabolized to toxic ones such as in case of CCl_4.

Carbon tetrachloride is converted by hemolytic cleavage to a highly reactive haloalkane free radical and a chlorine free radical in the following reaction:-

CCl_4 ----------> $CCl_3^+ + Cl^-$.

These in turn reacts with a variety of intracellular molecules, notably the unsaturated fatty acids.

Polyenolic fatty acids for example are converted to organic free radicals which in turn react with molecular oxygen to form organic peroxides. These compounds are highly unstable and decompose spontaneously to form aldehydes, ketones and other products.

CCl_4 reacts with sulfydryl groups which mediate the function of the many cell proteins including a number of important enzymes and this reaction leads to their alkylation and subsequent loss of function. The free radicals formed react rapidly with other molecules to form additional free radicals; such reactions are autocatalytic and tend to spread from a small focus to involve large areas of cytoplasm. The earliest change that has been detected in rat liver cells is a functional one that occurs 30 min after the I. P. administration of a single dose of 0.25 ml of CCl_4. It consists of rapid decrease in synthesis of protein albumin as well as the cytochromic. The diminution of protein synthesis after intoxication appears to be linked to disaggregation of the polysomes and probably represents a physical disruption of their association with messenger RNA.

Significantly in this early phase of carbon tetrachloride induced injury, mitochondria appear morphologically intact and are capable of normal oxidative phosphorylation and fatty acid oxidation among their many functions.

Within few hours after administration of CCl_4 neutral lipids (triglycerides) begin to accumulate in the cytoplasm making their first

appearance as osmiophilic droplets ultimately fill the entire cytoplasm. Approximately 10 to 12 hours after CCl_4 administration the liver is grossly enlarged and becomes pale because of accumulated fat. Lipid can also accumulate in the liver by mechanisms such as by increased mobilization of free fatty acids from depot fat.

Shortly after the ingestion of as little as 5 ml to as much as 100 ml of carbon tetrachloride, swelling and hydropic degeneration of the centrilobular hepatic cells develop. These changes progress to a diffuse fatty degeneration and necrosis in the centrilobular parenchyma with collapse of the reticulum network, followed shortly by haemorrhage and leukocytic infiltration.

Autoradiographic studies have shown a rapid uptake of carbon tetrachloride by the cytoplasm and nuclei of the cells of centrilobular areas. Autoradiographic avoidance shows that radioactive ^{14}C and carbon tetrachloride remain in the centrilobular areas as long as 2 days after ingestion.

Endoplasmic reticulum is damaged within 30 minutes of the administration of carbon tetrachloride, whereas the mitochondria survive unaltered for several hours. Protein synthesis is reduced within 2 hours of poisoning. Fatty acids are mobilized from peripheral fat depots to the liver. In the liver cell they are oxidized to triglycerides.

Experimentally, CCl_4 has been widely used to study toxic hepatic necrosis and it is still a favoured model of cirrhosis, which regularly develops after repeated injection of CCl_4 into rats. (Kissane, 1990)

1.2.4. Enzyme that detect hepatocellular necrosis (Schiff *et al*., 1993**):**

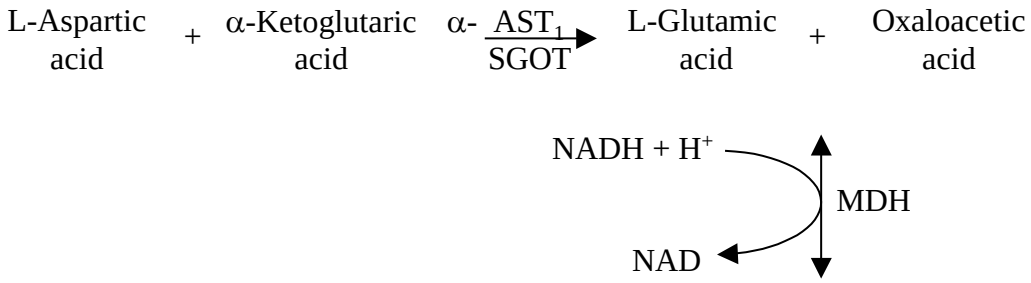
The liver contains thousands of enzymes, some of which are also present in serum in very low concentrations. These enzymes have no known function in serum and behave like other serum proteins. They are distributed in plasma and intestinal fluid and have characteristic half-lives of disappearance, usually measured in days. The elevation of a given enzyme activity in serum is thought to primarily reflect its increased rate of entrance into serum from damaged liver cells. Serum enzyme tests can be grouped into two categories:- 1) enzymes whose elevation in serum reflects generalized damage to hepatocytes and, 2) enzymes whose elevation in serum primarily reflects cholestasis.

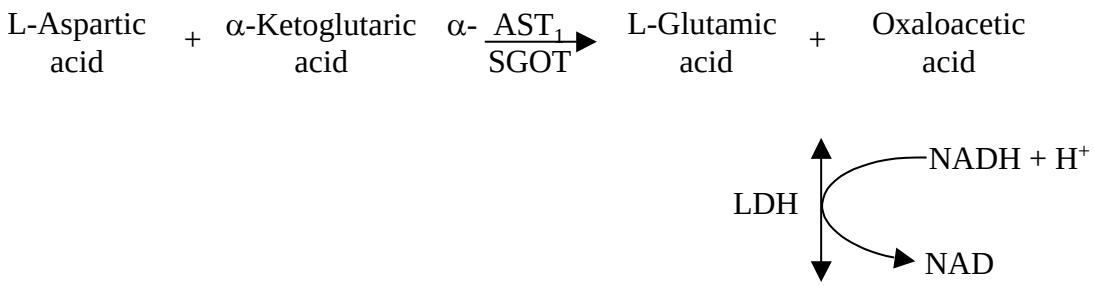
Aminotransferase:

The serum aminotransferases (formerly called transaminases) are sensitive indicator of liver cell injury, and most helpful in recognizing acute hepatocellular diseases such as hepatitis. Alanine aminotransferase [(ALT, serum glutamic-pyruvic traqnsaminase (SGPT)] and Aspartate aminotransferase [(AST, serum glutamic-oxaloacetic transaminase (SGOT)], activities in serum are the most frequently measured indicator of liver disease. These enzymes catalyze the transfer of the α-amino groups of alanine and aspartic acid respectively to the α-keto group of ketoglutaric acid. This results in the formation of pyruvic acid and oxaloacetic acid. Of the numerous methods developed for measuring ALT and AST activity in serum, the most specific method couples the formation of pyruvate and oxaloacetate, the products of the aminotransferase reactions. The reduced form of nicotinamide-adenine dinucleotide (NADH), the cofactor in this reduction is

oxidized to NAD. Because NADH, but not NAD, absorbs light at 340 nm, the event can be followed spectrophotometrically by the loss of absorptivity at 340nm. Both aminotransferase normally are present in serum in low concentrations, less than 30 to 40 IU/ml.

AST is found in the liver, cardiac muscle, skeletal muscle, the kidneys, the brain, the pancreas, the lungs, leucocytes and erythrocytes, in decreasing order of concentration, whereas ALT is present in highest concentration in the liver. The increase in ALT and AST serum values is related to damage to or destruction of tissue rich in the aminotransferases or to changes in cell membrane permeability that allow ALT and AST to leak into serum.





Aminotransferases are typically elevated in all liver disorders. These include all types of acute and chronic hepatitis, cirrhosis, infectious mononucleosis, alcoholic liver diseases etc. Elevations up to eight times the upper limit of normal are non-specific and may be found in any of the mentioned disorders. The highest elevations occur in disorders associated

with extensive hepatocellular injury, such as drug and viral hepatitis, exposure to hepatotoxins such as carbon tetrachloride and phalloidi. ALT is somewhat higher than AST.

The aminotransferases may be falsely elevated or diminished under certain circumstances. Aminotransferase values falsely increase, if older colorimetric tests are used. Conversely low values of AST may be seen in uremia. These values increase after dialysis.

1.3 Clinical trials.

1.3.1. What is a clinical trial? (http://www.biotechmedia.com/definitions-c.html)

A clinical trial is a research study in which a treatment or therapy is tested in people to see whether it is safe and effective. The information learned from clinical trials helps to improve health care and to keep people healthier. Researchers also conduct clinical trials to find out which treatments are more effective than others. The results from trials can also contribute to our understanding of diseases and conditions—for example, how a disease progresses or how it affects different systems in the body. Clinical trials are also called medical research, research studies, or clinical studies. Each trial follows a protocol—a written, detailed plan that explains why there is a need for the study, what it is intended to do, and how it will be conducted. The protocol is written by the trial's principal investigator (the person who is in charge of the trial).

1.3.2. What are the major types of clinical trials? (http://www.biotechmedia.com/definitions-c.html)

Clinical trials are used to study many aspects of medical care:

- Treatment trials tests for a specific disease or condition.
- Supportive care trials, also called quality-of-life trials, study ways of making sick people more comfortable and giving them a better quality of life.
- Prevention trials study ways, to reduce the chance of the disease to people who are healthy, but may be at the risk for a disease, will develop the disease.

- Early detection or screening trials, study new ways of finding diseases or conditions in people who are at risk, before they have any signs or symptoms.
- Diagnostic trials, test new ways to identify, more accurately and earlier, whether people have diseases and conditions.

Clinical trials have sometimes been thought of as a last resort for those who have a disease and have tried all other treatment options. This is not true. There are trials for healthy people (for example, to study disease prevention) and trials for all different types and stages of diseases.

1.3.3. What are the different phases of Clinical trials?

(http://www.biotechmedia.com/definitions-c.html**)**

Because the therapy will be tested in people, before a clinical trial can start, there needs to be some evidence that it is likely to work. This evidence can come either from previous research studies in animals or from reported information on its use by people. Clinical trials take place in phases. In each phase, different research questions are answered.

Phase 1: (http://www.nccam.nih.gov)

Initial safety trials on a new medicine in which investigators attempt to establish the dose range tolerated by about 20-30 healthy volunteers for single or multiple doses. Although usually conducted with healthy volunteers, Phase 1 trials are sometimes conducted with severely ill patients, for example those with cancer or AIDS. When pharmacokinetic issues are being addressed (for example, metabolism of a new antiepileptic medicine on stable epileptic patients whose microsomal liver enzymes have been induced by other antiepileptic medicines), trials may be conducted in less ill patients.

Pharmacokinetic trials are usually considered Phase 1 trials regardless of when they are conducted during a medicine's development.

Phase 2a: (http://www.nccam.nih.gov)

Pilot clinical trials to evaluate efficacy and safety in selected populations of about 100 to 300 patients who have the disease or condition to be treated, diagnosed or prevented. Often involve hospitalized patients who can be closely monitored. Objectives may focus on dose-response, type of patient, frequency of dosing, or any of a number of other issues involved in safety and efficacy.

Phase 2b: (http://www.nccam.nih.gov)

Well controlled trials to evaluate safety and efficacy in patients who have the disease or condition to be treated, diagnosed or prevented. These trials usually represent the most rigorous demonstration of efficacy of the medicine. Synonym: pivotal trials.

Phase 3a: (http://www.nccam.nih.gov)

Multicenter studies in populations of 1000 to 3000 patients (or more) for whom the medicine is eventually intended. Phase 3 trials generate additional safety and efficacy data from relatively large numbers of patients in both controlled and uncontrolled designs and are used to support a PLA (Product License Application). Trials are also conducted in special groups of patients or under special conditions dictated by the nature of the particular medicine and/or disease. Phase 3 trials are often providing much of the information needed for package insert and labeling of the medicine.

Phase 3b: (http://www.nccam.nih.gov)

Trials are conducted after submission of a new drug application (NDA), but before the product's approval for market launch. Phase 3b trials may supplement or complete earlier trials, or they may seek different kinds of information (for example, quality of life or marketing). Phase 3b is the period between submission for approval and receipt of marketing authorization.

Phase 4: (http://www.nccam.nih.gov)

After a medicine is marketed, Phase 4 trials provide additional details about the product's safety and efficacy. They may be used to evaluate formulations, dosages, and duration of treatment, medicine interactions, and other factors. Patients from various demographic groups may be studied. An important part of many Phase 4 studies is detecting and defining previously unknown or inadequately quantified adverse reactions and related risk factors. Phase 4 studies that are primarily observational or non experimental are frequently called post marketing surveillance.

1.3.4. What are some common elements of Clinical trials?

(http://www.biotechmedia.com/definitions-c.html**)**

Trials can be randomized. Each participant in a randomized trial is assigned by chance (through a computer or a table of random numbers) to one of two groups:

- The investigational group, made up of people who will receive the therapy, also called the active treatment
- The control group, made up of people who will receive either the standard treatment (if there is one) for their disease or condition, or a placebo

Each participant has an equal chance of being assigned to either group. In some complex trials, there are more than two groups. Randomization is used in all phase III studies and in some phase II studies. It gives the best chance of knowing that the study results are caused by the treatment and not some other factor, such as people's choices or beliefs. Trials can be double-blind. This means that neither the researchers nor the participants know who has been assigned to which group. Blinding is another way to help minimize the chance of bias influencing the trial results. The information is kept on file at a central office, so if there is an urgent need for the research team to find out who was assigned the active treatment, they can.

Researchers design clinical trials to have one or more endpoints. An endpoint is a measure that determines whether the treatment under study has an effect. An example of an endpoint is whether a person's tumor shrinks after receiving chemotherapy.

1.3.5. What is a placebo? (http://www.biotechmedia.com/definitions-c.html**)**

A placebo is designed to resemble as much as possible the treatment being studied in a clinical trial, except that the placebo is inactive. An example of a placebo is a pill containing sugar instead of the drug being studied. By giving one group of participants a placebo and the other group the active treatment, the researchers can compare how the two groups respond and get a true picture of the effect of active treatment.

Another type of placebo is called a "sham" procedure. When the treatment under study is a procedure (not a drug or other substance), a sham procedure may be designed that resembles the active treatment but does not have any active treatment qualities. For example, in a clinical trial of

acupuncture, the sham procedure might consist of placing acupuncture needles in areas of the body that are not expected (from previous knowledge) to have any therapeutic response.

In recent years, the definition of placebo has been expanded to include other things that could have an effect on the results of health care. Examples include how a patient and a health care provider interact, how a patient feels about receiving the care, and what he or she expects to happen from the care. Therefore, when a treatment is compared to a placebo in clinical trials, the patients should differ only in whether they receive treatment, and not in other aspects. Not all clinical trials compare an active treatment to a placebo. No patient is denied treatment in a clinical trial if there is a standard therapy available that could improve the comfort and survival of the patient.

1.3.6 Who can participate in a clinical trial?

(http://www.biotechmedia.com/definitions-c.html**)**

Clinical trials include people of various ages and ethnic groups and both genders as much as possible, so that the results can apply to the general population. Each clinical trial, however, is unique in its eligibility criteria (rules for who can and cannot participate). Examples of criteria include sex, age, type of disease, severity of disease, and history of prior treatment. If a disease is being studied in a trial, participants must have a similar degree of illness, so that there is a good chance they will respond in similar ways to the treatment being studied.

1.3.7. Are there protections for people who participate in clinical trials?

(http://www.biotechmedia.com/definitions-c.html**)**

Yes, the Federal Government requires many protections for people who participate in federally funded clinical trials. Before a clinical trial can start, the written protocol must be approved and monitored by an Institutional Review Board (IRB). An IRB is an independent group of health care providers, other experts, and lay people from the community who make sure that the study is set up and run safely and fairly. IRBs review protocols and the consent documents that people must sign in order to participate in a clinical trial.

Participants are also protected by a process called informed consent. If you are considering taking part in a clinical trial, during this process you will meet with a member of the research team. He or she will provide you with key facts about the study, such as:

- Who is sponsoring and conducting the research?
- Who has reviewed and approved the study?
- What the researchers want to learn?
- How the research team will monitor your health and safety?
- What participants will be required to do during the trial, and for how long?
- Possible benefits and risks of participating.
- Other treatments that are available for your disease or condition.
- How the privacy of your medical records will be protected?

You have a right to have all your questions answered. If you do not understand an answer you receive, ask again. It can be helpful to make a list of questions and concerns before you talk to the study team.

The staff will also give you a consent form, an agreement that you will sign if you decide to join the trial. Consent forms can be long, and they contain a lot of information. It is a good idea to take the consent form home, so that you can think about it and review it with family members or friends. If you have an interest in joining a study, it is also very helpful to discuss it with your health care practitioner and others whose advice you trust.

Participating in a clinical trial is completely voluntary. You can leave the trial at any time, for any reason even after you have signed the consent form.

1.3.8. What happens once a clinical trial starts?

(http://www.biotechmedia.com/definitions-c.html**)**

The research team will check the participant's health at the beginning of the trial, give specific instructions for participating, and monitor their health carefully during the trial. Participants may be required to do some things between appointments, such as take medication according to a schedule or make a phone call to report their experiences.

Clinical trials take place in a variety of settings, depending on the type of trial and what is being studied. For example, participants in a trial of an herb might follow the protocol at home, while a trial that involves specialized equipment (such as acupuncture) might be carried out in a clinic or other health care setting. Still other trials may require participants to be in a hospital, clinic, or research center while the therapy is given.

1.3.9. What happens after a clinical trial ends?

(http://www.biotechmedia.com/definitions-c.html**)**

The researchers carefully analyze the data from the trial. Then they conclude about their findings and decide whether further testing is required or not. If the trial is completed, the results have medical importance, they usually report the results first in a peer-reviewed medical journal ("peer reviewed" means that each report is reviewed before publication by a group of experts in the same field). A new treatment which is found safe and effective in a carefully conducted clinical trial become new standard practice. The results of clinical trials are given to the participants after its completion.

1.3.10. What are the possible benefits of being in a clinical trial?

(http://www.biotechmedia.com/definitions-c.html**)**

- You will receive expert medical care.
- Your health will be closely watched throughout the study.
- Clinical trials can be one treatment or prevention option for a disease or condition.
- In some types of trials, you may be among the first to get benefit from a new treatment or get new knowledge about a current treatment.
- You can motivate others to take part in the clinical trial or to be treated in the clinical trial.

1.3.11. What are the possible risks in a clinical trial?

(http://www.biotechmedia.com/definitions-c.html**)**

There are some risks for being in a clinical trial, as they are treatment with any other illness in a clinical trial:

- The treatment under study does not always turn out to be better than, or even as good as, standard treatment.
- The treatment may have side effects which are not known to the researchers.
- If you are in a randomized trial, you may be assigned to the control group, where you may not receive the drug but you may receive placebo treatment.
- Participation may require more tests and more visits or treatments than regular care.

Objective

OBJECTIVE

2.1 Aim of the present work:

- To study different effects of *Eclipta prostrata* in the patients of jaundice. The plant is described in Ayurveda and is proven pharmacologically for the hepatoprotective activity.
- To study different effects of treatment of the marketed polyherbal formulation containing *Eclipta prostrata* in patients with jaundice.
- Compare the effects of *Eclipta prostrata* and its market formulation in the patients of jaundice.

2.2 Plan of the work:

- Collect the plant *Eclipta prostrata.* Confirmation of its identity by the government authority and comparing its morphological and microscopical characters with the published literature.
- Drying, powdering and storage of the collected drug.
- Determination of quality of the powder drug by determining its water soluble extractive value, alcohol soluble extractive value, ash value, acid insoluble ash value and water soluble ash value.
- TLC study of the powdered drug and comparison with the published literature to determine the quality.
- To form ethical committee to surprise protocol and condition of patients etc. To explain importance of this medicine, regarding different tests and importance of this study to the patients.
- Confirming the hepatoprotective activity (Ayurvedic claim) of the powder of *Eclipta prostrata* by giving it to the patients with jaundice and determining their biochemical markers like SGPT, bilirubin at different

time interval. Also to study effect of this herb on other biochemical parameters like Haemoglobin, Hair growth, Urine sugar, Creatinine, etc.

- To study effects of different marketed polyherbal formulations containing *Eclipta prostrata* on the patients having jaundice by determining different biochemical markers like SGPT, bilirubin, haemoglobin etc.
- Comparison of the activity of *Eclipta prostrata* and its marketed formulations.

Review of Literature

REVIEW OF LITERATURE

3. 1. *Eclipta prostrata* (L.) L

Introduction to the herb and review of literature: -

Drug consistes of whole plant of *Eclipta prostrata* (L.)L (Kirtikar and Basu, 1933: Thakur *et al*., 1989; Indian Herbal Pharmacopoeia, 2002)

Synonyms: *Eclipta alba* Linn. Hassk, *Eclipta erecta* Linn*., E. appressa* Moerich, *Cotula alba* Linn*, Micrelium asteroides* Forsk*, Verbensina prostrata* Linn, *Verbensina alba* Linn.

Fig. 3.1 Plant of *Eclipta prostrata*

3. 1. 1. Introduction

Common Name (Ayur. Pharm., 1999)

Sanskrit : Kesaraja, Tekaraja, Bhringa, Markava, Bhrngaja

Assam : Bhrngaraja

Gujarati : Bhangro, Bhangaro

Hindi : Babri, Bhangra, Mochkand.

Kannad : Garagadasoppu

Malayalam : Kayyonni, Knnunni

Tamil : Kayanthakoru, Kaikeshi

Telugu : Guntagalagara.

Urdu : Bhangra

Uriya : Kesarda

Biological Source: (Ayur. Pharm., 1999) Drug consists of whole plants of *Eclipta alba* Hassk (Fam. Asteraceae).

Scientific Classification: (Chopra *et al*., 1965)

Kingdom : Plantae

Division : Magnoliophyta

Class : Magnoliopsida

Family : Asteraceae (Compositae)

Order : Asterales

Genus *: Eclipta*

Part Used : Leaves, Flowers, Whole plants

Geographical Source: It is one of the common herbs found in Bengal, Central India, Rajasthan, Gujarat, South India, Burma, Srilanka etc.

3.2. Macroscopic: - (Ayur. Pharm., 1999; Indian Herbal Pharmacopoeia, 2002)

It is an erect or prostrate annual herb with rooted nodes. Stem cylindrical, with longitudinal ridges, 2-5 mm in diameter, dark green in color. Leaves opposite, sessile, usually oblong lanceolate with appressed hairs on both sides; flowers white in heads, ray compressed.

Root: Well developed, a number of secondary branches arise from main root, upto about 7mm in diameter, cylindrical, grayish.

Stem: Herbaceous branched, occasionally rooting at nodes, cylindrical or flat, rough due to appressed white hairs, node distinct, greenish, and occasionally brownish.

Leaf: Opposite, sessile to sub sessile, 2.2-8.5 cm long, 1.2-2.3 cm wide, usually oblong, lanceolate, sub-entire, sub-acute, strigose with appressed hairs on both surfaces.

Flower: Solitary or together on unequal axillaries peduncles; involucres bracts about 8 ovate, obtuse or acute, herbaceous, strigose with appressed hairs; ray flowers ligulate, ligule small spreading, scarcely as long as bracts, not toothed white; disc flowers tubular, corolla often 4 toothed; Pappus absent except occasionally very minute teeth on the top of achene; stamen 5, filaments epipetalous free, anthers united into a tube with base obtuse; pistil bicarpellary; ovary inferior, unicellular with one basal ovule.

Fruits: Achenial cypsela, one seeded, cuneate, with a narrow wing, covered with warty excrescences and brown in colour.

Seed: 0.2-0.25 cm long, 0.1 cm wide, dark brown, hairy and non endospermic.

3.3. Microscopy (Ayur. Pharm., 1999; Indian Herbal Pharmacopoeia, 2002; Patel 2000**)**

3.3.1. Lamina in surface view (Lower surface)

Cells of both upper and lower epidermis are polygonal and wavy in outline and are traversed by anisocytic and anomocytic types of stomata- which are more in number on lower side. The cells of lower epidermis are more wavy in outline. The epidermal trichomes of both the surfaces are very characteristic. They are simple, covering, thick-walled, wavy, conical,

tricellular with very long central cell and contain the cystoliths. In the middle cell it is spindle shaped and in lower and apical cell they are oval to conical in shape. There are also few covering multicellular trichomes which are smaller than the previously described trichomes. It also shows small glandular trichomes with uni or bicellular head and uni to multicellular small stalk. Prisms of Ca-oxalate crystals are seen in the mesophyll cells. The average stomatal index of the lower surface is 30, palisade ratio is 4 and vein islet number is 3.

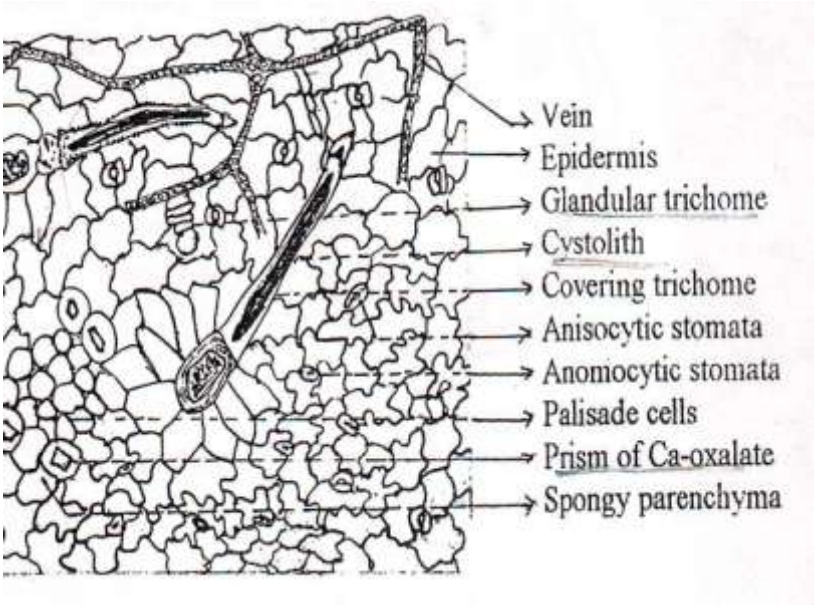


Fig: 3.2 Lamina of *E. prostrata* in surface view (Lower surface)

3.3.2. Transverse section of the leaf passing through midrib (Patel 2000)

The leaf is dorsiventral with single layer of palisade cells below the upper epidermis; it is discontinuous in the midrib region. Both the epidermis are covered with thin cuticle and the trichomes.

The spongy parenchyma contains Ca-oxalate prisms and few cystoliths and is traversed by obliquely cut vascular bundles. Mesophyll cells also contain oil globule. In center of the midrib lie 3-5 collateral vascular bundles

and collenchymatous cells below the epidermis. Trichomes are covering as well as glandular on both the surfaces.

The characters of the leaf tallies with the microscopical characters reported earlier (Indian Herbal Pharmacopoeia, 1998: Gopalkrishnan *et al*., 1992), except presence of prisms of Ca-oxalate crystals and few cystoliths in parenchymatous cells of the mesophyll and midrib region; presence of spindle shaped cystoliths in the middle cells of the covering trichomes and oval and triangular shapes in the lower and apical cells respectively. It also shows glandular trichomes with either unicellular head without stalk or unicellular or bicellular head with multicellular stalk. Occasionally, unicellular covering trichomes are also found.

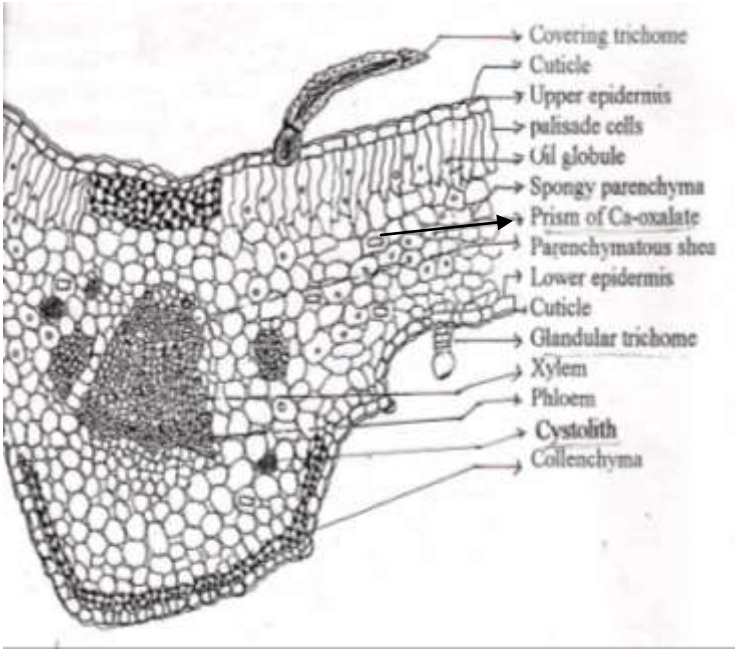


Fig: 3.3 T. S. of *E. prostrata* leaf through midrib

3.3.3. Transverse section of stem (Patel 2000)

The transverse section of the stem is circular in outline with a narrow ring of collateral vascular bundles surrounding the central parenchymatous pith containing prisms of Ca-oxalate crystals. Groups of pericyclic fibers are

seen at the periphery of the vascular ring. Endodermis is distinct. The trichomes of the epidermis are similar to that of the leaf. Hypodermis is composed of 2-3 layers of collenchymatous tissue; cortex is parenchymatous and is transversed by many small air chambers.

Some of the reports do not mention anything about the presence or absence of Ca-oxalate crystals (Indian Herbal Pharmacopoeia, 2002) while some other has mentioned the presence of acicular crystals (Gopalkrishnan *et al*., 1992). These findings differ from the one which is noticed here.

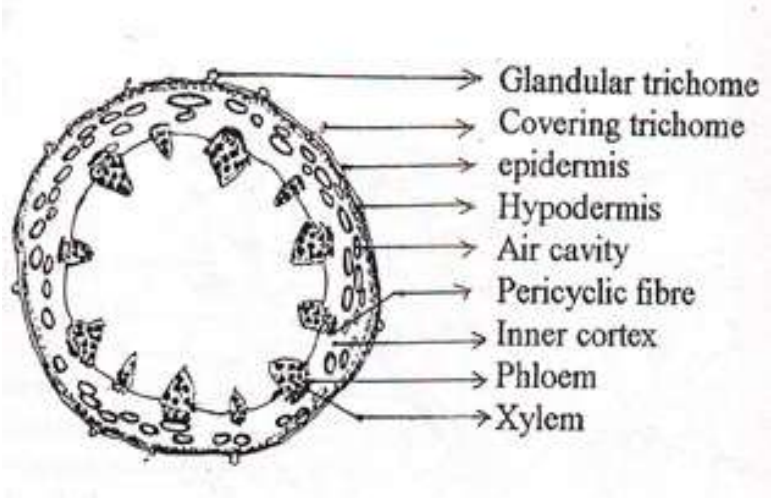


Fig: 3.4 Diagrammatic T.S. of stem of *E. prostrata*

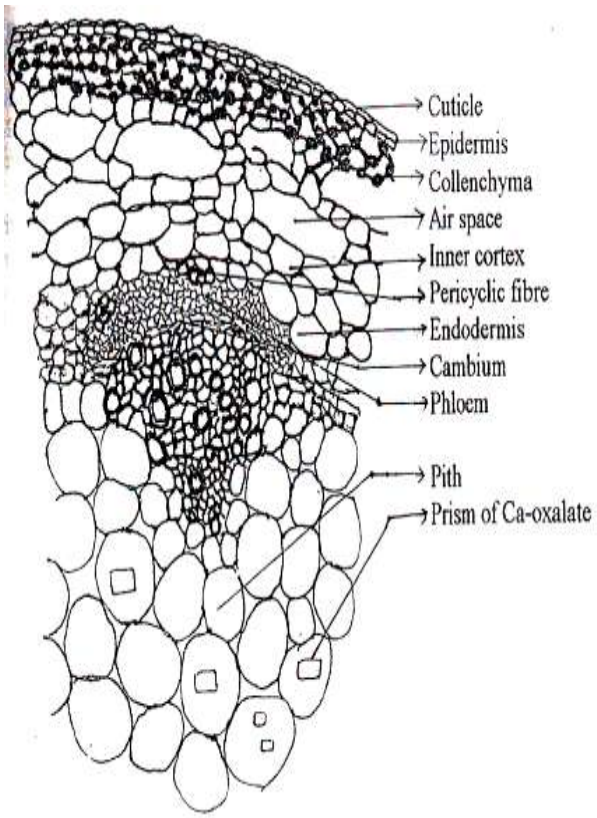


Fig: 3.5 Detail T. S. of stem of *E. prostrata*

3.3.4. Transverse section of the root: (Patel 2000)

It is circular in outline with a central narrow xylem surrounded by a layer of cambium, phloem and a wide zone of cortex interspersed by the circles of giant air spaces. The outermost tissue is composed of ill developed 1-2 layered brownish cork cells, which often gets exfoliated leaving behind the inner secondary cortical zone. Cortex is parenchymatous transversed by large air spaces in the outer zone. The inner cortical parenchyma contains Ca-oxalate prisms and scattered isolated pitted stone cells. Xylem is composed of radially arranged annular and reticulated xylem vessels associated with xylem parenchyma and fibers.

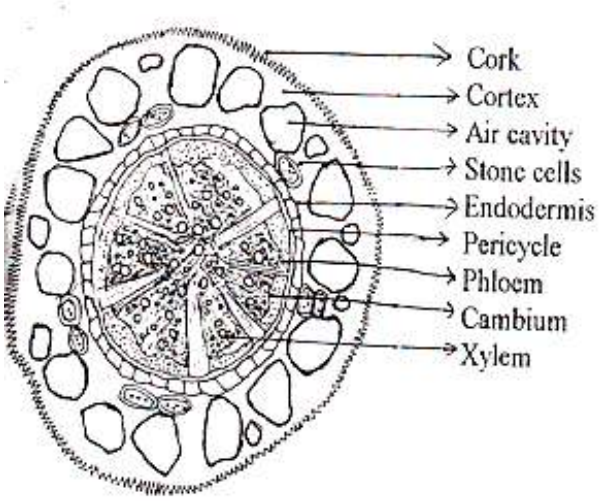


Fig: 3.6 Diagrammatic T. S. of root of *E. prostrata*

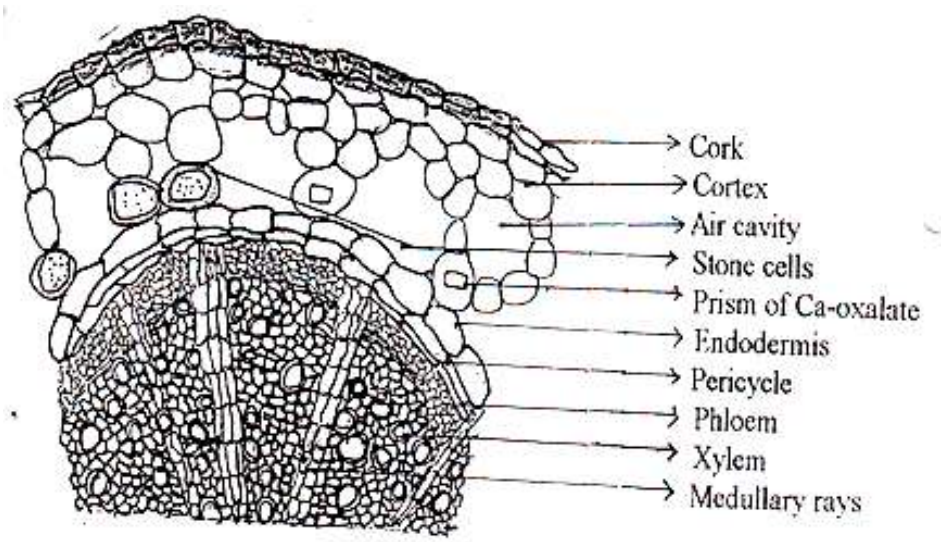


Fig: 3.7. Detail T. S. of root of *E. prostrata*

3.3.5. Powder study of *E. prostrata* herb: (Patel 2000)

It shows the characters of the leaf, stem, root and flower. The diagnostically important characters are as mentioned in fig 3.2 to fig 3.7.

Leaf: Many greenish pieces of lamina in surface view are seen as shown in fig 3.2. The tricellular covering trichomes are characteristic of *E. prostrata*, they are described in 3.3.1. along with other characters of the lamina like polygonal wavy walled epidermal cells with anisocytic and anomocytic stomata, prisms

of Ca-oxalate, crystals etc. Transversely cut lamina (3.8a) along with single layer of palisade cells, oil globules and prisms of Ca-oxalate crystals are seen.

Stem: It shows group of pericyclic fibres along with phloem parenchyma (3.8b). It also shows bifurcate xylem fibres (3.8c).

Root: It shows brownish polygonal cork cells in surface view (3.8d); oval to elongated, pitted stone cells (3.8e) and annular to reticulate thickened xylem vessels (3.8f).

Flower: It shows round pollen grains with spines (3.8g).

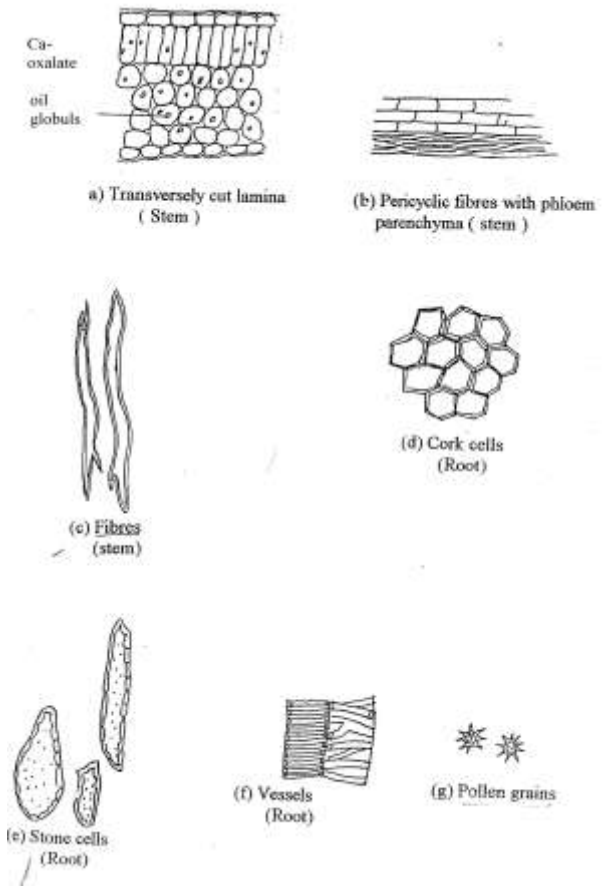


Fig: 3.8. Powder of *E. prostrata* herb.

3.4. Medicinal value: (Kirtikar and Basu, 1933; Thakur *et al*., 1989).

The herb popularly known as Bhringraj or Bhangra is reputed in many indigenous systems of medicine. The plant has a bitter, hot and sharp taste

and is used in Ayurveda for the treatment of *'*Kapha*'* and *'*Vata'. It is found to possess antihepatotoxic (Wagner *et al*., 1986: Chandra *et al*., 1987: Singh *et al*., 1985: Dixit *et al*., 1981: Dule *et al*., 1982: Sankarm *et al*., 1984), anti-inflammatory (Singh *et al*., 1985), antiulcerogenic (Dhar *et al*., 1967: Reddy *et al*., 1990), antibiotic (Al-Sharma *et al*., 1979: Phadke *et al*., 1989: Farouk *et al*., 1983: Sushil *et al*., 1985) properties. In traditional medicine the decoction of the herb is much valued as a tonic and is also used in liver and spleen enlargement (Kirtikar and Basu, 1933). An Ayurveda alcoholic preparation *"*Bhringraj Asawa*"* is highly reputed for general itching, elephantiasis and for curing sores on shoulders caused by carrying heavy loads (Kirtikar and Basu, 1933). An Ayurvedic herbomineral preparation 'Gandhak Rasayanis' is highly valued in all types of skin diseases.

It is astringent and is used in cases of stomatitis, toothache and for strengthening the gums. In China the plant is rubbed on gums for toothache and pounded leaves are prescribed in cases of haemorrhages and fluxes (Kirtikar and Basu, 1933).

It is used as anthelmintic, antiseptic, alexipharmic, expectorant, antipyretic, stomachic, and antiabortificient, uterine pain reliever after delivery, antiasthmatic and antibronchitis (Kirtikar and Basu, 1933).

The root is emetic and purgative. It is used in veternary practice. It is applied externally as an antiseptic to ulcer and wounds of the cattles. The root is applied in conjunctivitis and galled necks of the cattle. In Chota Nagpur, the roots are merely tied to the belly of the cattle to remove its diseased condition. The root is also used for relieving scalding urine (Kirtikar and Basu, 1933).

It is highly valued in cosmetics. The paste of the herb is rubbed on the discolored skin for improving its complexion. The extract of the herb is used internally and externally to give the natural black color to the hair. The fresh juice or the “Bhringaraj hair oil” is rubbed on the shaven scalp to promote the growth of the hair. Due to these properties the herb is commonly named as hair promoting herb or “Keshraj “.

3.5. Ethnomedical uses

As per the disease its ethno medical uses are listed below, along with name of the country and part of plant used in the bracket.

3.5.1. Antiasthamatic: Dry (Ar- Thailand) powder is taken (Gupta *et al*., 1977).

3.5.2. Anticancer: Decoction (Lf-Indonesia) is used orally in stomach and matrix cancer (Lin *et al*., 1986).

3.5.3. Antidiarrhoeal: Decoction (Ar-India; Srivastava *et al*., 1990); Lf-Nigeria (Gopalkrishanan *et al*., 1992) are used orally

3.5.4. Antidiabetic: Decoction (Hb-Taiwan) is used orally (Linn *et al*., 1992).

3.5.5. Antiepileptic: Leaf pounded with garlic and pepper is taken orally (Anantapur, A.P., and India) in conscious epileptic patient. Its extract is dropped in the nostrils of the unconscious patient (Reddy *et al*., 1989).

3.5.6. Anti-inflammatory: Decoction (Hb-Bihar, India) along with black pepper and raw sugar is taken orally as an anti-inflammatory drug (Jain *et al*., 1994).

3.5.7. Antileprotic: Decoction (Hb-India) is used alone orally as antileprotic (Kosuge *et al*., 1981) while in other parts (Bundelkhand, India) hot water extract with other four herbs is used orally (Saxena *et al*., 1981). In Somalia

they crush the entire plant, mix it with oil and apply externally (Samuelsson *et al*., 1992).

3.5.8. Antileucodermal: In Bundelkhand (A.P, India) they use the plant along with four other herbs orally (Saxena *et al*., 1981).

3.5.9. Antimalarial: Chenchu tribal people (A.P, India) use plant with pepper orally (Reddy *et al*., 1988).

3.5.10. Antioedemic: Leaf paste along with salt is applied externally by the people of Anantpur (A.P, India) on edema of the legs (Reddy *et al*., 1989).

3.5.11. Antipyretic: Decoction (Hb- India; Sahu *et al*., 1984) and paste (Lf – Chittoor, India; Reddy *et al*., 1989) are used orally.

3.5.12. Antirabbies: Tribal people of Bihar (India) use 2-3 pills of root paste with sugar candy orally in dog bite (Jain *et al*., 1994).

3.5. 13. Antitubercular: Decoction (Hb-China) is taken orally (Duke *et al*., 1985).

3.5.14. Antivenin: Decoction (Hb-China) is taken orally in snake bite (Mors *et al*., 1989) while they use fresh herb in Brazil (Martz, 1992). Yanadi tribal people (S. India) use leaf juice with butter milk orally (Sudarshanam *et al*., 1995), while in N. Gujarat they use orally, leaf juice as an antidote for snake bite (Shah *et al*., 1985).

3.5.15. Bronchitis: Decoction (Hb-India) is used orally by tribal people of Ujjain (Singh *et al*., 1980).

3.5.16. Cholagogue: Decoction (Ar-Arab countries) is used orally (Schmucker *et al*., 1969).

3.5.17. Emetic: Decoction (Ar-Arab countries; Schmucker *et al*., 1969); Lf-Nigeria (Akah *et al*., 1995) is used orally.

3.5.18. Eye disease: Decoction (Hb-Ujjain, India) is used externally in eye diseases (Singh *et al*., 1980). Leaf juice with honey is used orally by tribal people of Katra (J& K, India) in catarrhal disorders (Kapur *et al*., 1984).

3.5.19. Haemostatic: Decoction (Hb-China) is used orally (Kosuge *et al*., 1981).

3.5.20. Headache: Tribal people of Rayalseema (Nagarajun *et al*., 1990) (A.P., India) and others (Sahu *et al*., 1984) apply extract of the bud and the herb respectively in sesame oil externally on forehead.

3.5.21. Hair care: Tribal people of Katra (J & K India) apply leaf juice with Neem oil for the growth of hair (Sahu *et al*., 1984) while people (Japan) apply water extract of the herb externally for this purpose (Tanaka *et al*., 1980). Chenchu tribe (AP., India) uses juice of plant with coconuts oil externally as hair tonic (Reddy *et al*., 1988). People in Tamilnadu (India) use fresh unripe fruit juice with other herbs in olive oil externally to prevent premature graying of hair (Kumar *et al*., 1987). Kani tribal people (Kerala, India) use leaf extract boiled with coconut oil to deepen black color of the hair and to promote their growth (John, 1984).

3.5.22. Heart diseases: Hot water extract of the herb with other herbs and minerals is used orally in India (Kumar *et al*., 1987).

3.5.23. Hepatitis: Decoction (Hb-Bangladesh; Atahara *et al*., 1990) and Taiwan (Linn *et al*., 1990)) is used orally. Hot water extract with other three herbs is used orally in Tirupati (AP., India), 4g thrice a day in divided doses for infective hepatitis in children (Vedavathyk *et al*., 1995).

3.5.24. Insanity: People in Bihar (India) use pills prepared from the root paste in insanity (orally), 4 to 5 pills twice a day for 7 days (Jain *et al*., 1994).

3.5.25. Jaundice: In Arab countries leaf juice is used orally as hepatic tonic (Schmucker *et al*., 1969). In Tamilnadu people use fresh leaves, in Dandakaranya (Saxena *et al*., 1981) (India) they use herb orally in case of Jaundice. People in India also apply paste of root and seeds of *Ricinus communis* near eyes in case of jaundice (Hemadri *et al*., 1984). They use root juice orally in liver complains in N. Gujarat (Shah *et al*., 1985) (India). People in Cannanore (Kerala, India) use leaf with other herbs orally in case of jaundice (Ramachandran, 1987). Tribal people of Chittoor (AP., India) use dry powder of the herb orally, 4gm for a week to cure jaundice along with *P. amarus* to rejuvenate the liver (Reddy, 1988). In Rayalseema (AP., India) they use juice of the herb with butter milk and curd twice a day orally, but no salt in case of jaundice (Nagaraju *et al*., 1990).

3.5.26. Male sterility: Tribal people of Gorakpur (UP., India) use juice of the plant with *Terminalia chebula* fruit powder to treat male sterility.

3.5.27. Purgative: Decoction (Ar-Arab countries, Schmucker *et al*., 1969) and Lf-Nigeria (Akah *et al*., 1995) are used orally as purgative and laxative respectively.

3.5.28. Safe delivery (Prevention of miscarriage):10 to 15 ml juice of herb with cow's milk per day are taken orally from early days of pregnancy to prevent miscarriage and to have safe delivery (Bhattarai, 1994).

3.5.29. Skin diseases: The roots of the plant with other herbs are used externally for cow as an antiseptic in Ujjain (MP. India) (Singh *et al*., 1980). Decoction (Hb-India) in combination with other plants is taken orally in elephantiasis (Upadyay *et al*., 1988). A paste of the herb (India) with other plants in sesame oil is applied externally in case of ringworm lesions (Girach,

1994). People of Rayalseema (AP., India) use fresh juice of the plant externally in skin diseases (Jain *et al*., 1981). People use decoction (Hb-Somalia) externally in skin infection and vesicles in the skin (Samuelsson *et al*., 1992). They use juice (Lf-Nepal) externally in wound healing (Bhattari *et al*, 1997).

3.5.30. Spleen disorder: People in Katra (J & K., India) use leaf juice with honey orally (Nagaraju *et al*., 1990).

3.5.31. Tonic: Decoction (Hb-Arab countries (Schmucker *et al*., 1969)) is taken orally.

3.5.32. Toothache: Paste of the plant (India) in sesame oil is applied externally (Sahu *et al*., 1984).

Abbreviations: Ar = aerial parts; Hb = Herb; Lf = Leaf; Rt = Root.

3.6 Pharmacognostical review:

Satyavati *et al*., (1976) have mentioned morphological and microscopical characters of *E. alba.*

Mehra *et al*., (1968) have compared the morphological and microscopical character of *Eclipta alba* with its Ayurvedic substitute, *Wedelia calendulacea*, commonly known as peeta (yellow flowered) Bhringraj.

Gupta, (1977) has reported two forms of *E. prostrata, erect* and *prostrate*. Erect forms grow luxuriantly in shady and moist habitat where as *prostrate* forms flourish in open sunlight, dry and disturbed areas irrespective of seasons. There is difference in size of roots, internodes, flower head etc. but no major difference in extractive values.

Linn *et al*. (1986) have described the Pharmacognostical characters of a Chinese drug ‘Han-lian-cao’ i.e. *E. alba*.

Patel, (1989) has described diagnostic microscopic characters of the powder of *E. alba.*

Indian Herbal Pharmacopoeia, (1998) has mentioned the morphological and microscopical characters of leaf, stem and root of *E. alba* and it's certain constants like foreign matter, ash values and extractive values.

Shrivastava *et al*., (1990) have discussed the morphological characters of three commercial adulterants of Bhringraja namely, *Ageratum conyzoids* (Asteraceae), *Caesulia axillaris* (Asteraceae) and *Alternantera sessilis* (Amaranthaceae) and compared the diagnostic microscopical characters of their powdered drugs of leaf, stem and root with that of *E. alba*.

Gopalkrishnan & Johnson *et al*., (1992) have compared the microscopical characters of leaves & stems of *E. alba* with its substitute *W. calendulacea*. Their certain physical constants (ash value, extractive values, loss of wt on drying etc.) and other observations (fluorescence and chemical analysis) are also compared.

Shrotiya *et al*., (1986) have reported growth performance study of *E. alba* in relation to Cadmium treatment. Cadmium, a heavy metal was found to be toxic to the growth of the plant at all the concentration tested. Tolerance of the plant to some degree was also noticed.

Saeed *et al*., (1996) have carried out comparative cytomorphological studies of T.S of fresh herb and dried powder of various parts of *Conyza ambigua, Eclipta alba & Sonchus asper.* Chloroform &Menthol extracts of the leaves, roots and flowers of all the herbs exhibited prominent erythema on mice's skin. Extracts of Sonchus as per flowers were more potent than the other extracts of the same species and also the other herbs. The possible

relationship of anatomical structures with photochemistry and irritancy of these species has been discussed.

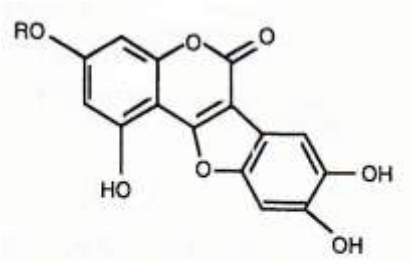
Subha Rao *et al*., (1983) have studied the effect of heavy oil effluent on morphological characters and pigment concentration of *E. alba*. Decrease in pigment concentration and increase in the number of branches, leaves, flower buds, fruits and leaf area of *E. alba* growing in polluted places have been reported.

Siddiqui *et al*., (1987) have studied the salinity effect of sodium sulphate (S.S) on seed germination of *E. alba*. Seeds of two population (saline & non saline) of *E. alba* were germinated in various concentrations of sodium sulphate containing ethrel. Exogenous application of ethrel inhibited the seed germination in both population and germination continued up to 6 atm. Only in saline population. Increasing concentration of S. S. also lowered % germination of seeds in both the population. Higher concentration of ethrel reduced % of germination of seed in non saline population.

3.7 Chemical constituents:

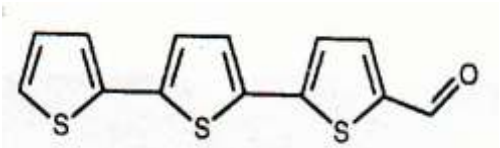
Different types of chemical constituent like alkaloids, alkenynes, cardiac glycosides, coumarins, flavonoids, lipids, polyacetylene compounds, triterpenes, steroids, saponins, steroidal alkaloids etc. have been reported by various workers in different parts of *E. prostrata* from different countries. Genetic environment or other factors like geographical sources, season and time of collection may also cause the variability in these constituents where by contradictory reports regarding presence or absence of certain constituents are found to exist. The reported compounds are mentioned below. The place

from where these reports are published and parts of plant are mentioned in the bracket.



R=CH_3 wedelolactone

R=H demethylwedelolactone



ecliptal

Entire plant (India) is reported to contain an alkaloid nicotine (Pal *et al*., 1943) but other reports (Gopalkrishanan *et al*., 1992, : Debelmas *et al*., 1973,: Al-Sharma *et al*., 1979,: Aynehchi *et al*., 1985,: Abu-Mustafa *et al*., 1977,: Sinha *et al*., 1985) have shown its absence in the different parts of the plant .It is also reported to contain **Alkanes-**hentriacontan-1-ol (Sikroria *et al*., 1982) (Rt-India), heptacosan-14-ol (Sikroria *et al*., 1982) (Rt-India) and heptacosane-n (Ali *et al*., 1997) (Ar-India); **Alkyne-**tetradeca-4-6-diene-8-10-12 triyne (Rt),trideca-1-ene-3-5-7-9-11-pentayne (Rt), trideca-cis-1-7-diene-3-5-9-11-tetrayne-8-methyl sulfonate (Rt), trideca-trans-1-7-diene-3-5-9-11-tetrayne-5-methyl sulfonate (Bohlmann *et al*., 1990) (Rt) and cardiac glycosides (Debelmas *et al*., 1973) (Ent-Nepal). **Coumarins-** Wedelolactone (Wagner *et al*., 1986: Govindachari *et al*, 1956,: Mors *et al*., 1991: Franca *et al*, 1995: Wagner *et al*., 1987: Melo *et al*, 1994: Mors *et al*., 1989: Zou *et al*., 1993: Sarg *et al*., 1981) and demethylwadelolactone (Wagner *et al*., 1986).

Flavonoids- cynaroside (Sarg *et al*., 1981) (Ar-Egypt), apigenin (Wagner *et al*., 1986) (Ar-India) and unspecified (Aynehchi *et al*., 1985) type (Ar-Iran) **Lipids-**heptacosan-5-one-1-ol-myristate (Ali *et al*., 1997) (Ar-India) and pentadeca-1ol-palmitate-11-hydroxy (Ali *et al*., 1997) (Ar-India) are also reported to be present. Roots and aerial parts are reported to contain various types of number of (more than 26 number) **Polyacetylene Sulphur compounds** like bithienyl derivatives (Bohlmann *et al*., 1990), dithiophene derivatives (Singh, 1988,: Sihgh *et al*., 1985,: Singh *et al*., 1992), terthienyl derivatives (Bohlmann *et al*., 1990,: Jain *et al*., 1988), thiophene derivatives (Bohlmann *et al*., 1990,: Singh, 1988,: Jain *et al*., 1988). **Triterpenes-**B-amyrin (Sarg *et al*., 1981) (Ar-Egypt), Enchinocystic acid (Zhang *et al*., 1996) (Ent-China), Eclalbasaponins (Yahara *et al*., 1994,: Yahara *et al*., 1997) triterpene acid glycoside (Sarg *et al*., 1981), Ecliptasaponin A (Zhang *et al*., 1996), Ecliptasaponin B (Zhang *et al*., 1996) and Ecliptasaponin D (Zhang *et al*., 1997); oleanolic acid (Zhang *et al*., 1996); **Steroids-**B-sitosterol (Mors *et al*., 1989) (Ar-Brazil) and stigmasterol (Mors. *et al*., 1991) (Ar -India (Singh, 1988), Ar-Brazil (Melo *et al*, 1994), Ent-China (Zou *et al*.,1993), Rt-India (Sikroria *et al*., 1982); **haemolytic saponins** (Debelmas *et al*., 1973,: Aynehchi *et al*., 1985,:Abu-Mustafa *et al*., 1977,: Sinha *et al*., 1985), **Steroidal alkaloids-**Ecliptalbine (Abdel- Kader *et al*., 1998) (Lf-Suriname), Verazine and its derivatives (Abdel- Kader *et al*., 1998) (Lf-Suriname) are reported to be present in *E. prostrata.*

3.8. Pharmacological Review:

Eclipta prostrata is reported to have different types of biological activities on different animals and tissues at different dose levels. These

activities are produced by various types of extracts obtained from different parts of the plant and are reported by different countries. It has antibacterial, antifungal, antiviral, antiyeast, mollucidal, nematocidal, ovicidal, antidiarrhoeal, antihepatotoxic, antihepatitisB, analgesic(weak), anticonvulsant(weak), anti-inflammatory, antipyretic, antispasmodic, antihistaminic, antivenin, hypolipidemic, hypotensive, cytotoxic, weak uterine stimulant (pregnant rat) etc. activities. Clinical trials have proved its antihepatotoxic activities. All these activities have been elaborated below. The name of the country where these activities have been reported and part of plant used are mentioned in the bracket.

3.8.1. Antibacterial;

- 80% alcohol extract (Ar-Iraq) is active against *Mycobacterium smegmatis* at 1mg/ml (Al-Shamma *et al*., 1979).
- Chloroform and methanolic extracts of the plant (Sudan) are active against *Bacillus subtilis, Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus* at 1.0 gm/ml (Farouk *et al*., 1983).
- The ethanol extract (Hb-Suriname) is inactive at 50mg/ml, versus *B. subtilis, E. coli, P. aeruginosa and S. aureus* (Verpoorte *et al*., 1987).
- Ethanol extract (Hb-India) is active against *Staphylococcus albus, E .coli, Shigella flexheri, Staphylococcus aureus* but it is inactive against *Proteus vulgaris* and other *bacteria, Klebsiella pneumonia, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella parathyphi* A*, S. paratyphi* B*, S. paratyphi* C*, S. typhi, Staphylococcus citreus* at 500 mcg/disc concentration. It has weak activity on *Shigella boydii, Sh.*

dysenterica, Sh. schmitzi and Sh. sonnei at 500 mcg/disc concentration (Phadke *et al*., 1989).

- Ethanol extract (Lf-India) is inactive at 10 mg/ml against *Corynobacterium diphtheriae, Diplococcus pneumonia, S. aureus, Streptococcus pyogens, Streptococcus viridans* (Naovi *et al*., 1991).
- Seeds of the herb when placed on nutrient media have activity against *B. subtilis, E. coli, Pseudomonas cichorri*, but inactive against *Salmonella typhimurium* (Sushil *et al*., 1985).

3.8.2. Antifungal activities

- Ethanol extract (Ar-India) is active against *Helminthosporium turcicum* (Nene *et al*., 1968).
- Ethanol extract (Hb-Suriname) is inactive against *Aspergillus niger* at 50 mg/ml concentration (Verpoorte *et al*., 1987).
- Ethanol extract (Hb-India) is inactive against *Microsporium canis, Phylophora jeanselmei, Piedaria hortae, Trichophyton mentagrophytes* and *Microsporus gypseum* at 10 mg/ml concentration (Naovi *et al*., 1991).

3.8.3. Antiviral activities:

- Ethanol: water (1:1) extract (Hb-India) has antiviral activities against Ranikhet virus at 50 mcg/ml concentration (Dhar *et al*., 1967).
- Juice (undiluted) of the leaf (India) has activities against *Bean mosaic* virus (Tripathi *et al*., 1982).
- Decoction (Hb-China) has weak activities against *Herpes simplex* type 1 at conc. of 100 mg/ml by cell culture method (Zheng, 1988).

- Alcohol extract (Hb-China) has weak activities against *Herpes simplex* at 10 mg/ml concentration (Minshi, 1989).
- Ethyl acetate extract of the plant is inactive at 100 mcg/ml while water extract has weak activities against *Herpes simplex virus-1* at the same concentration (Hattori *et al*., 1995).
- Water extract of the plant is inactive against HIV type 1 (Protease inhibition) at 200 mcg/ml concentration (Kusumoto *et al*., 1995).

3.8.4. Antiyeast activities:

- 80% ethanol extract (Ar-Iraq) is inactive against *Candida albicans* at 1 mg/ml)
- Ethanol extract (Hb- Surinam) is also inactive even at higher concentration (50 mg/ ml) against *Candida albicans* (Verpoorte *et al*., 1987).
- Ethanol, water and hexane extracts (Hb-India) are inactive against *Candida albicans* and *Candida tropicalis* at 10 mg/ml concentration (Naovi *et al*., 1991).
- Methanol extract (Hb-Surinam) is active against *Saccharomyces cervisiae* strain 1138, S. *cervisiae strain* 1140 and *S. cervisiae* strain 1353 at the conc. 16 mcg, 26 mcg and 9 mcg per ml respectively (Abdel- Kader *et al*., 1998)

3.8.5. Mollucidal activities:

- Ethanol extracts (Lf & St, Brazil) are active against *Biomphalaria glabrata* at 100 ppm conc. but the hexane extract is inactive at 100 ppm concentration (Mendes *et al*., 1984).

3.8.6. Anthelmintic activities:

- Ethanol, water and n-hexane extracts (Lf-India) have no anthelmintic activity at 10 mg/kg (Naovi *et al*., 1991).

3.8.7. Antinematodal (Nematocidal) activity:

- Water extract (Hb-India) has strong activity against *Meloidogyne incognita* (Vijayalakshmi *et al*., 1979).

3.8.8. Ovicidal activity:

- Water extract (St & Rt-India) is active against ova of *Sitostroga cerealella*, ED_{50} is 25% extract (Prakash *et al*., 1979).

3.8.9. Antidiarrhoeal activities:

- Hot and cold water extracts (Hb-India) are active against *E. coli* enterotoxin induced secretion at 300 mg dose ,on rabbit and guinea pig ileal loop (Gupta *et al*., 1993)

3.8.10. Antihepatotoxic activity:

- Leaf juice (Burma) is hepatoprotective to female guinea pig by oral route if given four days prior to CCl_4 treatment (Khin Ma-Ma, *et al*., 1978).
- Chloroform and water extracts (Hb-India) are active against Hepatitis B surface antigen at 2% concentration (Thyagarajan *et al*., 1982).
- Ethyl acetate fraction of the methanol extract (Hb-India) is active at 0.1 mg/ml conc. against rat hepatocytes intoxicated with CCl_4 and galactosamine; $P < 0.01$ and $P < 0.001$ respectively (Wagner *et al*., 1986).
- Aerial powder of the herb 500 mg/kg for 9 days, by gastric incubation has hepatoprotective activity in male rats intoxicated with CCl_4; inhibit

AAT, GTP, and AP. Ethanol extracts 1mg/ml stabilized human RBC membrane (Chandra *et al* 1987).

- Ethanol extract (Hb-India) 50 mg/kg oral, increase the bile flow and liver weight in the rats (Kumar *et al*., 1987).
- Extracts of aerial parts and roots are reported to have antihepatitis B surface antigen activity *in vitro* studies. Red pigment was the active constituent (Khin Ma-Ma, *et al*., 1978).
- Red pigment of the herb inactivates hepatitis B surface antigen *in vitro* (Jayaram *et al*., 1989).
- Total aqueous and successive aqueous extracts (Hb-India) have hepatoprotective activity (20% and 12 % activity respectively) versus CCl_4 toxicity in rats at 500 mg/kg/i.p.; chloroform, methanol and petrol extracts are inactive (Sharma *et al*., 1991). Ethanol extract (Ar-India) 62.5 mg/kg/intragastric to mouse inhibit zoxazolamine induced paralysis.ED_{50}, 175.9 mg/kg/intragastric to mouse decrease bromosulphalein clearance time, ED_{50}, 156.7 mg/kg/intragastric to mouse reduces barbiturate sleeping time in CCl_4 treated animals (Chandra *et al*., 1987).
- Ethanol extract (Hb-India) is hepatoprotective to rat and mouse (Pandey *et al*., 1993).
- Ethanol extract (Hb-India) is active against CCl_4 toxicity in rabbit at 100 mg/kg/intragastric dose (Murthy *et al*., 1993).
- 60% ethanol extract is active against Hepatitis B-virus (DNA polymerase inhibitor) at 10 mg/ml in the cell culture (Ghisalberti *et al*., 1995).

3.8.11. Polyherbal formulations:

- Eclinol-a polyherbal formulation (PHF-India) reduces liver and serum lipids in rats by oral route, which are induced by CCl_4 (Vaishwanar *et al*., 1967).
- PHF (four herbs - India) is active versus CCl_4 toxicity in rats (Chandra *et al*., 1987).
- A herbomineral preparation is also active in rats versus hepatocellular Jaundice (Patki *et al*., 1990).
- Hepatogard, a PHF (India) is active versus CCl_4 toxicity in rats (Saraf *et al*., 1981).
- Hepatomed, a PHF (India) 3ml/100gm for 15 days is active versus cumene hydroperoxide toxicity (Sharma *et al*., 1995).

3.8.12. Analgesic activity:

- Hot water extract (Hb-Nepal) at 500 mg/kg/intragastrically has a weak analgesic activity in mouse versus acetic acid injury but was inactive against hot plate (Debelmas *et al*., 1976).

3.8.13. Anticonvulsant activity:

- Hot water extract (Hb-Nepal) at 500 mg/kg/intragastric has a weak anticonvulsant activity versus superamaxial electroshock induced convulsions in male mouse but inactive versus strychnine induced convulsions (Debelmas *et al*., 1976).

3.8.14. Anti-inflammatory activity;

- Powder of aerial parts, 1.5 g/kg/intragastric, is active against carrageenin induced pedal edema in male rats (Chandra *et al*., 1987).

- Decoction (Hb-India), 1.0 g/kg/intragastric is active versus chronic inflammation in rats but weak activity versus carrageenin induced pedal edema and adjuvant induced arthritis (Reddy *et al*., 1990).

3.8.15. Antimalarial activity:

- Ethanol: water (1:1) extract (Hb-India) is inactive against *Plasmodium berghei* at 100 mcg/ml concentration in vitro and 1 g/kg/intragastric in mouse (Jayaram *et al*., 1987).

3.8.16. Antioxidant activity:

- Herb (India), (EC_{50} 2.28 mg/ml) inhibit lipid peroxide formation and scavenges hydroxyl radical (Joy *et al*., 1995).

3.8.17. Antipyretic activity;

- Hot water extract (Hb-Nepal) has antipyretic activity at 500 mg/kg/gastric incubation in male mouse (Debelmas *et al*., 1976).

3.8.18. Antispasmodic activity:

- Alcohol: water (1:1) extract (Hb-India) has antispasmodic activity versus acetylcholine and histamine induced spasms on guinea pig ileum (Dhar *et al*., 1967).
- Hot water extract (Hb-Nepal) has no anticholinergic activity in male mouse at 500 mg/kg/gastric incubation (Debelmas *et al*., 1976).
- Decoction (Hb-India) has antihistaminic activity at 1.0 g/kg/gastric incubation in rats (Reddy *et al*., 1990).

3.8.19. Antiulcerogenic activity:

- Cauvery 100, PHF (India) has antiulcerogenic activity in rats through oral route versus indomethacin induced ulcer (Manonmani *et al*., 1994).

3.8.20. Antivenin (Antisnake venom) activity:

- Ether, ethanol (40%) and ethanol (95%) extracts (Brazil) have antivenin activity at 0.5 mg, 2.5 mg and 1.8 mg per animal respectively. Hexane extract is inactive (2-3mg/animal)
- Water extract has kinase inhibition (skeletal muscle of mouse) and creatinine kinase inhibition (in mouse) activity at 8.5 mcg/ml and 250 mcg/kg respectively (Mors *et al*., 1989).
- The plant (Brazil) extract through i.v route to mouse, protect against snake venom injection (Mors *et al*., 1991).

3.8.21. Activity on blood:

- Water extracts of the plant, 1.0 g/kg/i.p. has a haemostatic activity in mouse (Kosuge *et al*., 1981).
- Methanol extract (IC50 2.0 mcg/ml) and Wedelolactone (IC50 2.5 µmol) have lipoxygenase-5-inhibitory activity on leucocytes of pig (Wagner *et al*., 1986).
- Hexane extracts (Lf & St-Thailand) has no coagulant, fibrinolytic or platelet aggregation stimulation activity (Triratana e*t al*., 1988).
- PHF, Abana (India), 50mg/kg/intragastric has hypolipidemic activity in rat (Khanna *et al*., 1991).

3.8.22. Blood pressure:

- Ethanol: water (1:1) extract (Hb-India) has hypotensive activity on dog at 50mg/kg/i.v. (Dhar *et al*., 1967).
- Ethanol extract and columbin (the active compound) have hypotensive activity on anaesthetized cat (Rashid *et al*., 1992).

3.8.23. Cytotoxic activity:

- Methanol extract of the herb is active against CA-Ehrlich Ascites cell culture at 1.25 mg/ml (Koshuget *et al*., 1985).
- Water extract (Ar-China) is inactive at 500 mcg/ml versus CA-mammary micro alveolar cell culture (Sato *et al*., 1989).
- Ethanol: water (1:1) extract (Hb-India) is inactive at ED_{50} > 20.0 mcg/ml versus CA-9KB cell culture (Dhar *et al*., 1967).
- Water and ethyl acetate extracts of the herb are inactive at 100 mcg/ml in cellvero (Hattori *et al*., 1995).

3.8.24. Tranquilizing activity:

- Hot water extract (Hb-Nepal) is neither having tranquilizing activity nor spontaneous activity at 500 mg/kg/gastric intubation to male mouse (Debelmas *et al*., 1976).

3.8.25. Uterine activity:

- Water extract (Lf-India) has no stimulant activity on the uterus of non pregnant guinea pig (Kapur, 1948).
- Water extract (Rt-India) is having no simulative activity on the uterus of rat (Dhawan *et al*., 1958).
- Hot water extract of the herb has no stimulant activity on the uterus of non pregnant rat but has a weak activity on the uterus of pregnant rat (Gupta *et al*., 1993).
- Ethanol: water (1:1) extract (Ar), 100mg/kg/oral has no anti-implantation activity on the female rat (Mishra *et al*., 1979,: Kamboj, 1988).

3.9. Clinical trials- *E. prostrata* alone:

3.9.1. Antihepatotoxic activity:

- Powder (Hb-India), 50 mg/kg/oral has antihepatotoxicity activity, 40 children recovered from jaundice out of 50 (Dixit *et al*., 1981).
- Powder (Hb-India), 500 mg/person, three times a day for 3-4 weeks cured 55% of hepatic patients and for 8 weeks treatment cured 75 % patients (Dule *et al*., 1982).

3.9.2. Dyspepsia:

- 20gm powder (Hb-India) in a syrup base in three divided doses (oral) for six weeks, cured 90 % of patients (out of 30) from non ulcerative and peptic ulcer dyspepsia by reducing the gastric activity (Singh *et al*., 1990).

3.9.3. Gastritis:

- 12 gm of the herb powder (India) in three divided doses (oral) for 45 days has excellent response in 52% patients (out of 25) of gastritis by reducing the gastric acidity (Das, 1992).

3.10. Clinical Trials with polyherbal formulations (PHF)

- Shen Mari Yin (China) has well anti Aids activity if taken for 8 months orally (Yu, 1987).
- Tefroli (India) is active against hepatitis virus, orally (Sankarm *et al*., 1984).
- Pilex tablet and ointment (India) orally and externally respectively have anti-inflammatory activities (Vijayasarathy *et al*., 1981: Agrawal *et al*., 1982).

- A polyherbal capsule (1 cap. twice a day for 3, 6, 9, 12, months, orally) and the cream (externally, twice a day) cured 40 to 66 % patients of leucoderma out of 40 patients (Karnick *et al*., 1990).
- A polyherbal (six herbs) capsule (450 mg/oral) for 15 days was active against renal calculi (Karnick, 1992).
- A polyherbal preparation (including fruit of *E .alba*) containing vitamins is active externally in controlling grey hair (China; Zhang, 1990).

3.11. Toxicity:

- Alcohol extract (India), 2 g/kg/mouse/intragastric has no toxicity in mouse (Singh *et al*., 1993).
- 0.2 mg extract/day/oral in mouse for 90 days has no mortality or weight loss (Jayaram *et al*., 1987).
- Ethanol: water (1:1) extract (India) 1mg/kg/i.p.in mouse is the maximum tolerated dose (Dhar *et al*., 1967).

Methodology

METHODOLOGY

4.1. Material and method:

4.1.1 Plant material

The plant of *Eclipta prostrata* was collected in the month of August 2006 from the fields of a village Dugarwada in Modasa Taluka in Sabarkatha (S.K.) District (Gujarat) where it is growing wild. The herb was authenticated by Dr. H.B. Singh, Scientist F & Head, Raw Materials Herbarium & Museum, Council of Scientific and Industrial Research (CSIR), NISCAIR, New Delhi. (Date: 04-08-08, Ref. 1031/62). After authentication, the herbs were subjected to study physicochemical parameters. Livercare Churna manufactured by Rajsha pharmaceuticals, Ahmadabad and Hepatogard forte tablet manufactured by Surajmani Enterprises, Daman were purchased from local market.

4.1.2 Study protocol

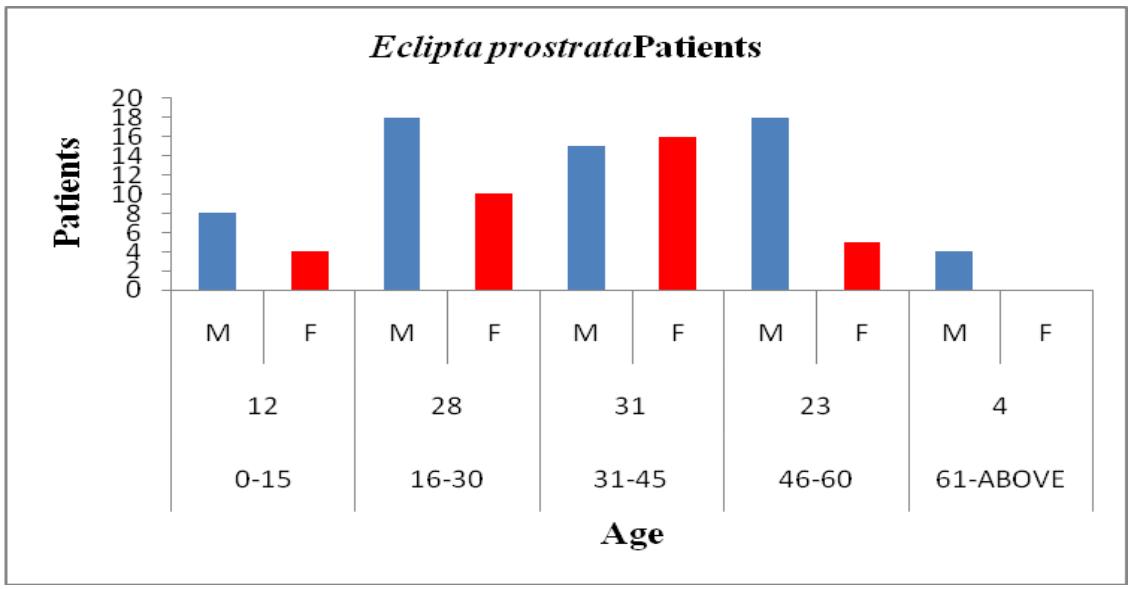
The ability of whole dried drug powder of *Eclipta prostrata* was tested at Sapan Hospital, Bayad, Dist-S.K., Gujarat, for hepatoprotective activity on patients who were suffering from liver disease. Before starting this study on the patients an ethical committee was formed (consisting of an ayurvedic physician, modern physician MD, social worker, advocate, scientist etc. Annexure II). The strategy of work was planned and before starting the work with patients. Their written consent was taken, after explaining the details regarding the effect of the drug and the analysis of blood sample at different time interval. The powder of *Eclipta prostrata* was given thrice a day (morning, noon and night, 3 gm each time) orally with glucose to the first group of liver damage 98 patients of different age groups and sex for one, two, three, four

and six weeks as per severity of the patients and treatment was continued until the recovery. The marketed formulation Livercare Churna was given thrice a day (morning, noon and night, 3 gm each time) orally with honey to the second group of liver damage 93 patients of different age groups and sex for one, two, three, four and six weeks as per severity of the patients and treatment was continued until the recovery. Hepatogard forte tablet was given thrice a day (morning, noon and night, 1 tablet each time) orally to the third group of liver damage 95 patients of different age groups and sex for one, two, three, four and six weeks as per severity of the patients and treatment was continued until the recovery. Biological parameter like SGPT, Bilirubin, Haemoglobin, Creatinine, HBsAg, urine sugar, blood pressure, etc were measured and monitored during the treatment.

The reagents used in clinical investigations were collected from Span Diagnostic Ltd, Shivam Surgical, Ahmadabad, for estimation of SGPT, Bilirubin and Haemoglobin.

Table 4.1: Different age of patients who were treated with *Eclipta prostrata* as hepatoprotective drug.

ECLIPTA PROSTRATA			
Age	**Male**	**Female**	**Total Patients**
0-15	8	4	12
16-30	18	10	28
31-45	15	16	31
46-60	18	5	23
61-Above	4	0	4
Total	63	35	98

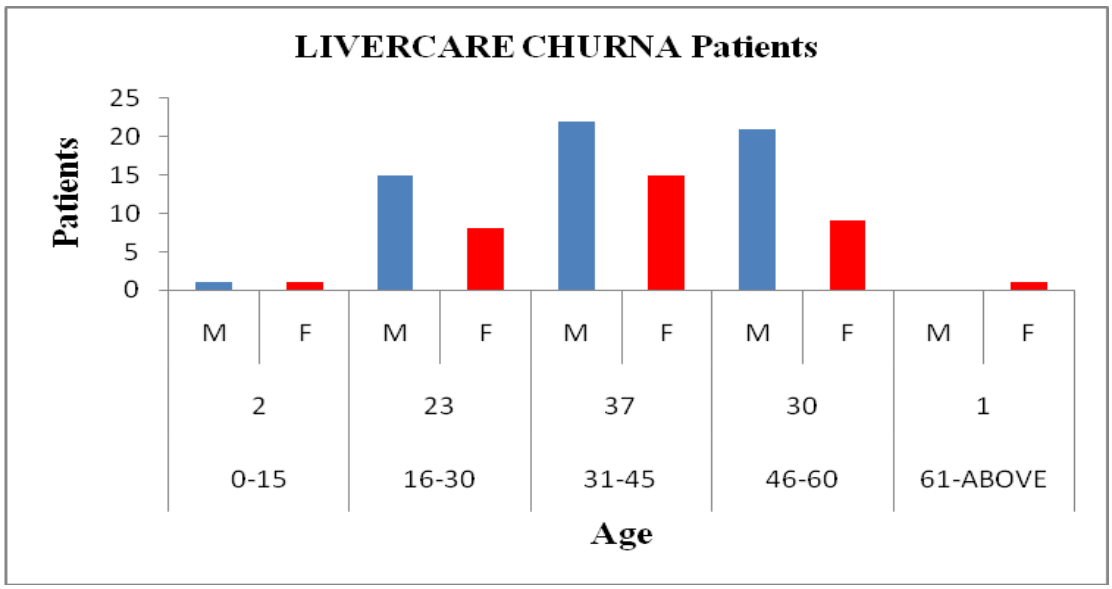


M = Male, F = Female

Figure 4.1: Patients v/s Age. Column graph showing patients of *Eclipta prostrata* with different age.

Table 4.2: Different age of patients who were treated with Livercare Churna as hepatoprotective drug.

LIVERCARE CHURNA			
Age	**Male**	**Female**	**Total Patients**
0-15	1	1	2
16-30	15	8	23
31-45	22	15	37
46-60	21	9	30
61-Above	0	1	1
Total	59	34	93

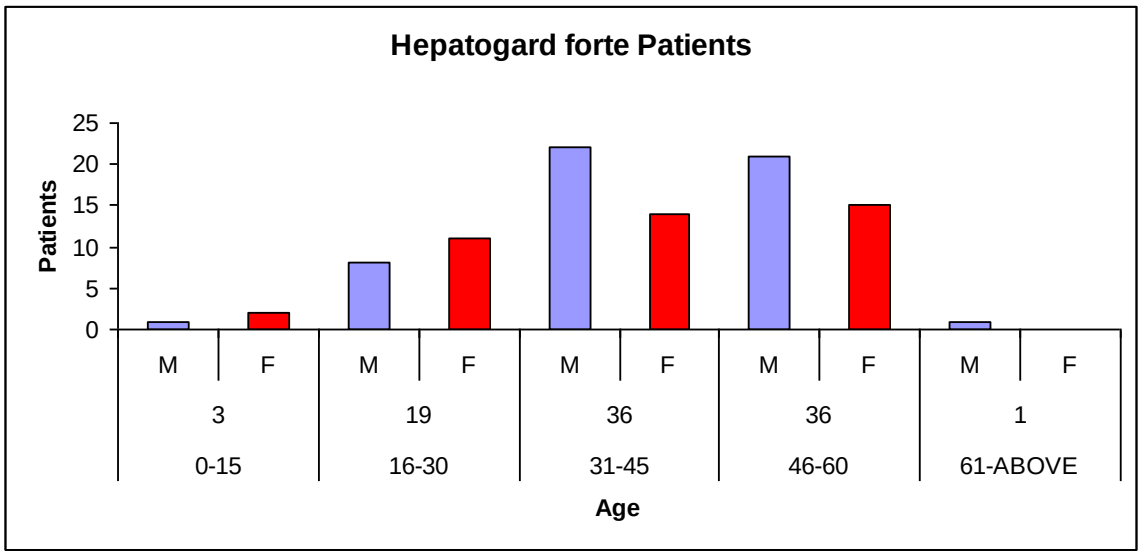


M = Male, F = Female

Figure 4.2: Patients v/s Age. Column graph showing Patients of Livercare Churna with different age.

Table 4. 3: Different age of patients who were treated with Hepatogard Forte Tablet as hepatoprotective drug.

HEPATOGARD FORTE TABLET			
Age	**Male**	**Female**	**Total Patients**
0-15	1	2	3
16-30	8	11	19
31-45	22	14	36
46-60	21	15	36
61-Above	1	0	1
Total	53	42	95



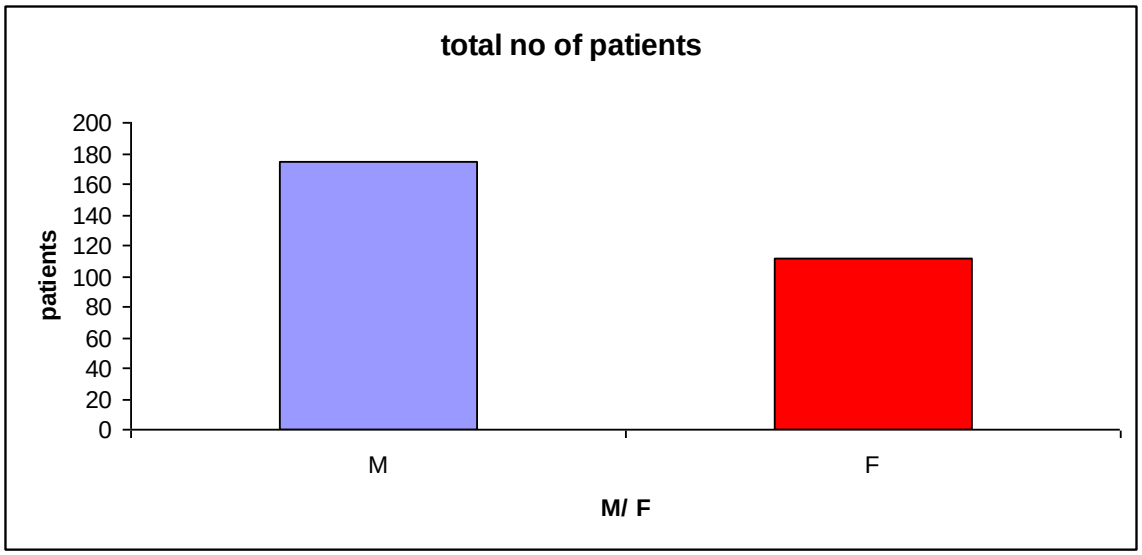
M = Male, F = Female

Figure 4. 3: Patients v/s Age. Column graph showing patients of Hepatogard Forte Tablet with different age

Table 4.4: Total number of patients for *Eclipta prostrata*, Livercare Churna, and Hepatogard Forte Tablet.

M/F	*Eclipta prostrata*	Livercare Churna	Hepatogard Forte Tablet	Total
M	63	59	53	175
F	35	34	42	111
Total	98	93	95	286

M = Male, F = Female



M = Male, F = Female

Figure 4.4 : Patients V/S Total number of patients M/F. Column graph showing total number of Patients for *Eclipta prostrata*, Livercare Churna, and Hepatogard Forte tablet.

4.2. TLC studies of the herbs (Patel, 2000)

TLC studies of the extracts of fresh herb as well as their market formulations were carried out to know their TLC finger prints and to compare them and also to identify the presence of the active hepatoprotective compound present in them.

Eclipta prostrata

Extraction: 50 mg of the dry herb *Eclipta prostrata* (EE) and marketed formulations containing 50 mg equivalent amount *Eclipta prostrata* of Livercare Churna (EL) and Hepatogard forte tablet (EH) containing 50 mg equivalent amount *Eclipta prostrata* were separately extracted with 10 ml of methanol by heating on water bath for 10 min. To ensure the complete extraction the marc was again extracted similarly twice by using 5 ml methanol each time. The combined filtrate was concentrated to 0.5 ml and used for spotting on the TLC plate.

TLC:

Extract of each of the above fresh herb of *Eclipta prostrata* (EE), and marketed formulations Livercare Churna (EL) and tablet Hepatogaurd Forte tablet (EH) were spotted on silica gel G plate. It was developed using Toluene: Acetone: Formic acid (11: 6: 1) as a mobile phase; dried and observed in day light, UV light and after spraying with 5 % aqueous $FeCl_3$ solution.

Detection:

1. 5% aqueous $FeCl_3$ (day light)
2. UV light(254 nm)

Extracts: Alcoholic extracts of dry fresh herb *Eclipta prostrata* (EE), and marketed formulation containing Livercare Churna (EL) and Hepatogaurd Forte tablet (EH).

4.3. Physicochemical parameter

4.3.1. Ash values. (Harbone, 1998; WHO/QCMMPM guidelines, 1992)

Ash content of the crude drug is generally taken to be the residue remaining after incineration. It represents the inorganic salts naturally occurring in the drug and adhering to it, but it may also include inorganic matter added for the purpose of adulteration.

Total ash is the residue remaining after incineration. Acid insoluble ash is the part of the total ash, which is insoluble in dilute hydrochloric acid. Water-soluble ash is the part of total ash, which is soluble in hot water.

4.3.1.1. Determination of Total Ash.

About 2g of the powdered drug was accurately weighed (W) in a tarred silica crucible. The powdered drug was spread as a fine layer at the bottom of the crucible. The crucible was incinerated at a temperature not exceeding 450°C until free from carbon. The crucible was cooled and weighed.

The procedure was repeated till a constant weight was observed. The percentage of the total ash was calculated with reference to the air-dried drug.

4.3.1.2. Determination of Acid Insoluble Ash

The ash obtained as described in the determination of total ash was boiled with 25 ml of hydrochloric acid for 5 min. The insoluble ash was collected on an ashless filter paper and washed with hot water. The insoluble ash was transferred into a tarred silica crucible along with filter paper, ignited, cooled

and weighed. The procedure was repeated till a constant weight was observed. The percentage of acid insoluble ash was calculated with reference to the air-dried drug.

4.3.1.3. Determination of Alcohol-Soluble Extractive:

Macerate 5 gm of the air dried coarsely powdered drug with 100 ml of alcohol in a 250 ml volumetric flask for 24 hours, shake frequently during six hours and allow to stand for 18 hours. Filter rapidly taking precaution against loss of alcohol, evaporate 25% of the filtrate to dryness in a tarred shallow dish dried at 105^0C and weighed. Calculate the percentage of alcohol soluble extractive with reference to the air dried drug.

4.3.1.4. Determination of Water-Soluble Extractive:

Macerate 5 gm of the air dried coarsely powdered drug with 100 ml of chloroform water in a 250 ml volumetric flask for 24 hours, shake frequently during six hours and allow to stand for 18 hours. Filter rapidly, evaporate 25% of the filtrate to dryness in a tarred shallow dish dried at 105 ^{0}C and weighed. Calculated the percentage of water soluble extractive with reference to the air dried drug.

4.4. Estimation of SGPT (Reitman *et al*., 1957: Nobert, 1970, Godkar *et al*, 2006)

4.4.1. Intended Use:

This reagent kit is intended for *in-vitro* quantitative determination of SGPT (ALT) activity in serum/plasma.

4.4.2. Principle:

Glutamate pyruvate transaminase (GPT) or Alanine aminotransferase (ALT) catalyses alphaketoglutarate and L-Alanine. Pyruvate formed by this catalysis

reacts with 2, 4 dinitrophenylhydrazine (2, 4 DNPH) to give a brown-red colored hydrazone complex in an alkaline medium. The concentration of brown red colored complex is directly proportional to the activity of SGPT present in sample and it is measured colorimetrically at 505nm or with green filter.

4.4.3. Reaction:

i. Alpha-ketoglutarate + L-Alanine $\xleftrightarrow{GPT}$ L-Glutamate + Pyruvate.

ii. Pyruvate + 2, 4 DNPH $\xleftrightarrow{Alk\ medium}$ Brown-Red Hydrazone Complex

4.4.4. Clinical Significance:

Even though glutamate pyruvate transaminase is widely distributed in various tissues of the body; it is a useful parameter in evaluating liver function. The elevated serum levels are found in case of hepatitis, obstructive jaundice, metastatic carcinoma, hepatic congestion and myocardial infarction or in kidney diseases.

4.4.5. Reagent Preparation:

Reagent 1: Buffered alanine α-KG substrate.

Reagent 2: DNPH color reagent.

Reagent 3: sodium hydroxide, 4N.

Reagent 4: Working pyruvate standard, 2mM.

Solution 1: One ml of Reagent No.3 was diluted to 10 ml with distilled water. Reagent 1, 2 & 4 are ready for use as such.

4.4.6. Test Procedure:

Reagent 1(Buffered alanine α-KG substrate) 0.5 ml is taken in a test tube. It is incubated at 37^{o}C for 5 min, fasted serum 0.1 ml is added to the test tube. It is

mixed well and incubate at 37^{o}C for 30 min. Reagent 2, (DNPH color reagent) 0.5 ml is added to the above test tube. It is allowed to stand at room temperature for 20 min. Solution 1; 5 ml is added to the solution of the test tube. It is mixed well and allow to stand for 10 min. The absorbance of the solution is measured 505 nm using water as blank.

4.4.7. Test Results:

The calibration graph is used to obtain test results in U/ml.

4.4.8. Linearity:

This method is linear up to 150 U/ml of SGPT in serum. Samples having higher values are diluted with 0.9% saline and assay results were multiplied with dilution factor.

4.5. Estimation of Bilirubin (Malloy *et al*., 1937, Godkar and Godkar, 2006**)**

4.5.1. Intended Use:

This diagnostic reagent kit is intended for *in-vitro* quantitative estimation of direct and indirect bilirubin from serum/plasma.

4.5.2. Principle:

The direct or conjugated bilirubin reacts with diazotized sulphanilic acid to form purple colored complex, whereas indirect or unconjugated Bilirubin reacts only in presence of DMSO reagent to give purple colored complex. The intensity of the purple color developed is proportional to the amount of either total or direct bilirubin present in sample and it is measured colorimetrically at 540 nm or with yellow-green filter.

4.5.3. Reaction:

Direct/ conjugated Bilirubin + Diazotized Sulphanilic acid → Purple colored azo bilirubin complex

Indirect / unconjugated bilirubin + Diazotized sulphanilic acid $\xrightarrow{\text{DMSO}}$ Purple colored azo bilirubin complex.

4.5.4. Clinical Significance:

Bilirubin is produced from haemoglobin in reticulo endothelial system and circulates in normal concentration in blood. It is conjugated with glucuronic acid in liver and excreted through bile. The estimation of total and direct bilirubin is of importance for diagnosis, differentiation and follows up of jaundice. The serum levels of unconjugated Bilirubin rises in the cases of hemolytic jaundice. Whereas conjugated serum bilirubin levels rises in the cases of obstructive jaundice. Hepatic jaundice is characterized by simultaneous rise in both, conjugated and unconjugated serum bilirubin levels.

4.5.5. Reagent Preparation:

Reagent A: Total bilirubin reagent.

Reagent B: Direct bilirubin reagent.

Reagent C: Sodium nitrite reagent.

Reagent D: standard bilirubin = 10mg% bilirubin.

All reagents in the kit are ready to use as such.

4.5.6. Procedure for Colorimetric estimation of Bilirubin:

For total bilirubin estimation 3 ml of reagent A and 0.1 ml of reagent C are mixed by inversion of test tube No T and waited for 30 seconds. For total bilirubin blank 3 ml of reagent A is taken in test tube No TB. Fasted serum 0.15 ml is added in each test tube No T and TB. The content of both the test tubes are mixed well and incubated at 37^{o}C for 5 min and absorbance is read at 540 nm using water as blank.

For direct bilirubin estimation 3 ml of reagent B and 0.1 ml of reagent C are mixed by inversion of test tube No D and waited for 30 seconds. For direct bilirubin blank 3 ml of reagent B is taken in test tube No DB. Fasted serum 0.15 ml is added in each test tube No D and DB. The content of both the test tubes are mixed well and incubated for 37^{o}C for 5 min and absorbance is read at 540 nm using water as blank.

The absorbance of the reagent D (standard bilirubin) is read directly against distilled water. The standard once used is discarded. Serum Bilirubin in mg% calculated as below.

4.5.7. Test Results:

$$\text{Total bilirubin mg\% (A)} = \frac{\text{Absorbance of T - Absorbance of TB}}{\text{Absorbance of standard bilirubin}} * 10$$

$$\text{Direct bilirubin mg\% (B)} = \frac{\text{Absorbance of D - Absorbance of DB}}{\text{Absorbance of standard bilirubin}} * 10$$

Where T= Total bilirubin, TB= Total bilirubin blank, D= Direct bilirubin, DB= Direct bilirubin blank.

4.5.8. Linearity:

This method is linear up to bilirubin concentration of 15 mg%, for sample having higher values of bilirubin are diluted with 0.9% normal saline and multiplied with dilution factor.

4.6. Estimation of Creatinine (Tora and Ackermann, 1975: Bonses and Taussky, 1945; Godkar and Godkar, 2006**)**

4.6.1. Method: Alkaline Picrate Method

4.6.2. Principle: Creatinine in a protein free solution reacts, with Alkaline Picrates and produces a red colored complex, which is measured colorimetrically.

4.6.3. Advantages:

- Very popular method
- Simple, convenient and highly reproducible.
- One minute deprotenization step with a single deprotenization reagent.
- Result within half an hour.
- Economic.

Sample: 24hrs urine is preferred. Dilute 1ml of urine to 250 ml with purified water.

4.6.4. Reagent:

Reagent 1: Picric acid

Reagent 2: Sodium Hydroxide, 0.75N

Reagent 3: Stock Creatinine Standard, 150 mg%

Preparation of working solution: Dilute 0.1 ml of reagent 3 to 10 ml with purified water and mix well. All other reagents are ready for use.

Storage and stability: All reagents are stable at room temperature till the expiry date mentioned on the individual label. Once opened Reagent 3 is stable at 2-8 ^{0}C. Working standard has to be prepared fresh everyday.

4.6.5. Precautions:

1) Use clean and dry glassware.
2) Bring all solution to room temperature before use.
3) Prepare one blank and one standard for each series of estimations.

4) Mark the test tube properly as blank (B), standard (S), and test (T) before proceeding for the estimation, because markings may come off when the tubes are placed in the boiling water bath during deprotenization (step A).

5) Do not fail to dilute the urine during creatinine estimation from urine.

4.6.6. Procedure

A. For colorimetry

Step A. Deprotenization of test sample:

Dilute urine	0.5 ml
Purified water	0.5 ml
Reagent 1: Picric acid	3.0 ml

Mix well; keep in a boiling water bath exactly for one minute. Cool immediately under running tap water and centrifuge or filter

Step B. Color Development:	Blank	Standard	Test
Filtrate/Supernant (From Step A.)	-	-	2.0 ml
Working Standard	-	0.5 ml	-
Purified water	0.5 ml	-	-
Reagent 1: Picric acid	1.5 ml	1.5 ml	-
Reagent 2: NaOH (0.75N)	0.5 ml	0.5 ml	0.5 ml

Mix well and allow to stand at room temperature exactly for 20 minutes and measure immediately the optical density of Blank (B), Standard(S) and Test (T) against Purified water on a colorimeter with a green filter.

B. For Spectrophotometer: All the volumes mentioned under colorimetric procedure can be adjusted proportionately depending on flow

cell/cuvette capacity. Rest of the procedure remains unchanged. Measure the O.D. at 520nm.

4.6.7. Calculation:

Urine Creatinine in mg/ 100ml = $\frac{\text{O.D. test – O.D. blank}}{\text{O.D. std – O.D. blank}}$

Normal values of Urine Creatinine: Men: 1.1- 2.8 g/ 24hrs

Women: 0.9- 1.6 g/24 hrs

4.6.8. Note:

1) If the O.D. of test exceeds 0.8 repeat the test after diluting the urine 1 → 50 or more if necessary and multiply the final result so obtained with 2.0 or an appropriate factor.
2) Optical density should be measured exactly after 20 minutes after the addition of sodium hydroxide.
3) The filtrate/ supplement obtained during deprotenization should be crystal clear.

4.6.9. Clinical significance

In renal disease, creatinine determinations have one advantage over urea determinations that they are not affected by a high protein diet as is the case for urea determinations. In addition to renal disease, elevated levels of Serum Creatinine and Creatinuria may be observed in extensive muscle destruction.

4.7. Estimation of HBsAg test. (Godkar and Godkar, 2006**)**

4.7.1. Intended use:

The Advanced quality one step HBsAg test is a rapid, one step, immunochromatographic assay for the detection of Hepatitis B surface

antigen (HBsAg) in human serum or plasma. The presence of 5ng /ml HBsAg can be detected within 10 minutes and 1ng/ml HBsAg in 30 minutes. The test provides a visual, qualitative result, and is intended for professional use.

4.7.2. Principle of the assay

Solid phase “Sandwich” immunoassay for the detection of HBsAg was described by Wisdom (Wisdom, 1976, Wolters *et al.,* Wei *et al*., 1977). The production, characterization and application of monoclonal antibodies for the detection of HBsAg have previously been reported (David, 1981: Goodall, *et al*., 1981: Kennedy. e*t al*., 1983: Shih, *et al*., 1980: Wands *et al*., 1981).

The advanced quality one step HBsAg test is a colloidal gold enhanced immunoassay that detects Hepatitis B surface antigen in human serum or plasma. The sample initially reacts with the monoclonal antibody-colloidal conjugate on the sample pad. This mixture migrates across the membrane by capillary action and reacts with the anti-HBsAg in the test region. If the sample contains HBsAg a line will form on the membrane at this point. If the antigen is not present in the sample no line is formed, indicating a negative result. The mixture continues to flow to the control area of the membrane, where it forms a line indicating the test result valid.

4.7.3. Storage conditions

The kit must be stored at 2-30C.

4.7.4. Precautions

It is recommended that all specimens be handled in accordance with biosafety level 2 practices as described in the CDC NIH publication, Biosafety on microbiological and biomedical laboratories (USDHHS, 1988) or other equivalent guidelines (WHO, 1983: NCCLS, 1989)

1. For *in vitro* diagnostic use only.
2. Wear gloves to perform this procedure and treat all specimens and used devices as potentially infectious.
3. Clean and disinfect all spills of specimens and reagents using a suitable disinfectant, such as 1% sodium hydrochlorite12.
4. Sterilize all devices used in this assay prior to disposal.
5. Do not use test beyond the expiration date

4.7.5. Specimen collection

1. **S**erum or plasma may be used in this test .Anticoagulants typically used for blood collection do not interfere with this test.
2. Remove the serum or plasma from the clot or red cells as soon as possible to avoid hemolysis.
3. Haemolyzed extremely thickened or fatty specimens are not suitable for this assay. Specimens containing particulate matter may give inconsistent results and should be clarified prior to testing.
4. Serum or plasma specimens should be refrigerated at 2 to 8 ^{o}C up to 3 days and frozen at -20 ^{o}C for longer periods.
5. Shipped specimens should be packed in compliance with federal and international regulations covering the transportation of etiologic agents.
6. Avoid frequent (more than 3 times) thaw- and freeze of specimens.
7. 0.1% sodium azide can be added to the specimen as a preservative without affecting results of the assay.

4.7.6. Materials provided

- 10 or 40 test cards individually foil pouched with a desiccant.
- Instruction for use.

- Sample dispensing plastic dropper with each test pouch.

4.7.7. Assay procedure

Do not open pouch until you are ready to the sample.

1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Dispense 2-3 drops of the specimen or control into the sample well on the card by provided plastic sample dropper. Caution: Use only provided sample dropper for every sample to avoid cross-contamination.
5. Read the result between 5 to 10 minutes for 5ng/ml, and 30 minutes for 1ng/ml. A positive result may be interpreted early, however read any negative at 30 minutes to ensure sample is negative and not a low concentration of the HBsAg, requiring more time to develop. Do not interpret the result after 30 minutes.

It is recommended to run a known positive and negative control in each performance to ensure the assay procedure.

4.7.8. Interpretation of Results

Negative: Only one purplish red colored band appears in the control region.

Positive: In addition to the purplish red control band, a distinct purplish red colored band also appears in the test region.

Invalid: Neither test band nor control band appears. The specimen should be tested again using a new test card.

4.7.9. Limitations:

Although the association between the presence of HBsAg and infection is strong, available methods for HBsAg detection are not sensitive enough to detect all potentially infectious units of blood or possible hepatitis infections.

4.7.10. Performance characteristics

Serum or plasma concentration as low as 1ng/ml is detected by this assay. The advanced quality one step HBsAg test has been compared to an equivalent EIA system. A result of 99.5% correction to EIA test was demonstrated by a clinical study of 1208 patient's specimens.

4.8. Estimation of Urine Sugar (Godkar and Godkar, 2006, Goyal *et al*., 2006)

4.8.1. Principle:

Benedict's quantitative reagent consists of copper sulphate, potassium thiocyanate and other chemicals in alkaline media. Copper sulphate is reduced to cuprous oxide by glucose. Potassium thiocyanate reacts with cuprous oxide and form white precipitates of cuprous thiocyanate instead of usual precipitates of cuprous oxide. Disappearance of blue tint from solution, indicate complete reaction of copper sulphate.

4.8.2. Reaction

$$2\ Cu(OH)_2 \ \text{(reduction)} \rightarrow Cu_2O + 2\ H_2O$$

4.8.3. Reagents:

1) Benedict's quantitative reagent:

(A) Dissolve with the aid of heat, 100 gm of anhydrous sodium carbonate, 200 gm of sodium or potassium citrate and 125 gm of dry potassium thiocyanate in 800 ml water and filter if necessary.

(B) Dissolve 18gm of copper sulphate in 100ml of water. Cool the solution. Add 'B' to 'A' with constant stirring. Add 5 ml of 5% potassium ferricyanide solution. Add water to make 1000 ml. 25ml of the reagent is reduced by 50 mg of glucose. Check the strength by titrating with standard solution of glucose; 1ml of reagent = 2mg of glucose.

2) Anhydrous sodium carbonate:

Dilution: The urine is diluted in such a way that the burrate reading is between 5 to 15 ml for 10 ml of the reagent. For this, take 5 ml of Benedict's qualitative reagent. Add 8 drops of urine, boil and cool.

Green ppts: Dilute urine 1 in 2 or 3

Yellow ppts: Dilute urine 1in 5 or 8

Brick red ppts: Dilute urine 1 in 10 or more

End point: Complete disappearance of the blue color.

4.8.4. Procedure:

(A) Pipette out 10 ml of Benedict's qualitative reagent solution in a 100 ml conical flask. Add 20 ml of water, 5gm of anhydrous sodium carbonate and few pieces of porcelain to prevent bumping. Heat the flask on a flame to boiling. Keeping the mixture just boiling, add this urine in a flask rapidly, until white precipitates begin to form. After this add urine, drop by drop at the interval of 10 seconds until the blue color just disappear. The solution must be kept vigorously boiling and be stirred continuously throughout the entire titration.

(B) Add 5ml of the Benedict's qualitative reagent and mix with 0.5 ml of urine, Boil for 2 minute and cool

Green precipitates	Glucose up to 1%
Yellow precipitates	Glucose up to 2%
Red precipitates	Greater than 2%

4.8.5. Calculation:

If n ml of urine, dilution 1 in D (if not diluted D=1) required, then the glucose contents of urine are,

$$\frac{0.02 \times 100}{N} \times D = \frac{2D}{n} \text{ gm\%}$$

Note: In Benedict's qualitative reagent, small amount of potassium ferricyanide assists in maintaining the cuprous oxide in solution. The use of sodium carbonate as alkali instead of sodium hydroxide, prevent the destruction of the small amount of sugar.

4.8.6. Interpretation; Normal value of glucose excretion is 2 to 10 mg glucose/100 ml or 78.5 mg/day, which is not detected by common qualitative test. Determination of sugar concentration in urine is important for the management of diabetics. Presence of sugar in urine is known as glucosuria and the persistent presence indicate diabetes mellitus.

4.9. Determination of Haemoglobin. (Godkar and Godkar, 2006, Goyal *et al*., 2006**)**

4.9.1. Reagent and Glassware:

Sahil haemoglobinometer or hemometer which consists of two sealed comparison tubes fixed in rack, a specially graduated diluting tube, a thin

glass rod and micropipette of 20 cubic millimeter capacity, pricking needle, N/10 HCl, distilled water, 70% alcohol and absorbent cotton.

4.9.2. Principle:

When blood is mixed with N/10 HCl, RBCs are haemolyzed and Hb is librated. This Hb is converted into acid hematin which is reddish brown in color. The solution is diluted with distilled water till it matches with the standard glass (Comparison) tubes. The Hb% can directly be read from the graduated tube.

4.9.3. Procedure: The graduated diluting tube and the micropipette are cleaned thoroughly and dried. The graduated diluting tube is filled with N/10 HCl up to the mark 2 gm or till the micropipette touches the level of acid in the tube. The finger is cleaned with 70% alcohol and it is pricked to obtain a drop of blood. First drop is wiped out. Second drop is sucked in the micropipette upto the mark 20cmm. The blood is immediately deposited at the bottom of the graduated tube. The pipette is rinsed two to three times in HCl. The blood is mixed with the help of stirrer and then solution is allowed to stand for 10-15 minutes so that all Hb is converted into acid haematin. Then mixture is diluted with distilled water. Distilled water is added drop by drop and every time it is stirred till the exact match with standard glass tubes is obtain and the scale is read on the side of tube.

4.9.4. Observation and Calculation

Observed Hb gm % = --------- gm %

Observed Hb % = ---------- %

International value of Hb is 14.5 gm% = 100 %

Calculation Hb% = $\frac{\text{gm \%}}{14.5} \times 100$

4.9.5. Normal value

Normally 14.5 gm of Hb in 100 cc of blood is considered to be 100 % Hb according to British Standards. The value may vary according to sex, age and altitude. In female adults it may vary from 12 to 15 gm (average 13.7 gm %) and in adult males it ranges from 13 gm to 16 gm (average 14.8 gm %). New born child has an average of 23 gm% by the end of third month it falls below the normal. After this it gradually recovers within a year to 12.5 gm. People at higher altitude have higher value, because oxygen of air is less at that level.

4.9.6. Precautions;

- While filling the micropipette, entry of air bubbles should be avoided. It is advisable to fill up the micropipette more than 20 cmm marks. The excess of blood in the micropipette may be removed by touching the tip of the pipette on palm.
- While depositing blood into graduated tube, one should not blow it forcibly so that blood sticks to the side of pipette. Rinsing should also be done slowly.
- Never take less quantity of N/10 HCl.
- While observing for color match, stirrer should be kept out of solution, and the calibrated side should not come in view. The observation must be done while facing it against uniform intensity of light.

4.10. Estimation of Blood Pressure (Godkar and Godkar, 2006; Goyal *et al*., 2006**)**

Blood pressure (B.P.) is defined as the lateral pressure exerted on the walls of the vessels by the contained blood. This is due to muscularity and elasticity of the walls of blood vessels. The B.P. also depends on the force with which heart pumps the blood. The maximum pressure during systole is defined as systolic B.P whereas the minimum pressure during diastole is defined as the diastolic B.P. The difference between systolic and diastolic B.P is described as the pulse pressure.

4.10.1. Principle:

The blood flow through a large sized artery is obstructed by means of air pressure exerted through a rubber bag wrapped around the limb. The pressure is slowly released and the entry of blood through the obstruction is studied by

- Feeling of the pulse(Palpatory method)
- Observation of oscillation of the mercury level (oscillatory method)
- Hearing with the stethoscope the sounds produced in the segment of the artery distal to obstruction (Auscultatory method)

The blood flow stops when the pressure transmitted to the artery through the rubber bag is equal to or more than the blood pressure. The first entry of blood through an obstruction indicates the blood pressure. Usually the arm or thigh is used because there is only one big vessel which runs superficially in each of these parts of the extremities.

4.10.2. Procedure:

1. The cuff is tied around the arm. It should be neither too tight to cause any discomfort to the subject, nor too loose to allow its movement round the arm.
2. The artery is felt and its course is marked in the cubital fossa. Also the radial pulse is felt and marked at the place where it is felt well.
3. The manometer is placed by the side of the subject, between his arm and the body. The screw of the rubber pump is tightened and the pump is pressed to inflate the bag. It is inflated to raise the mercury to 200 mm level or 20-25 mm hg higher after the disappearance of pulse.
4. Keeping the eyes fixed at mercury level and the finger at the pulse, pressure is slowly released by unscrewing the valve of the rubber pump. The reading of the level of mercury when the pulse reappears gives systolic pressure. This is Palpatory method. This method does not give idea of diastolic pressure. The systolic pressure recorded by this method is about 5-10 mm lower than the actual systolic pressure.

When the pulse appears, it is also noted that mercury starts oscillation. The first oscillation starts increasing in magnitude and then slowly diminishes. The level at which the oscillation are maximum is taken as the diastolic pressure. This is oscillatory method. In this method the deflation has to be carried out slowly the systolic pressure should be read within fifteen seconds and the diastolic pressure within thirty second.

In the Auscultatory method after as usual the chest piece of stethoscope is placed over the brachial artery in the cubital fossa and deflation is started by slowly releasing the pressure. The level at which a sudden tap is heared is the systolic blood pressure. The sound suddenly gets muffled and disappears. The level at which the sinus muffles is the diastolic pressure, the sounds heared are korokorr's sounds. These are due to interrupted flow of blood.

In many instances when the systolic blood pressure is very high, the first sound is a faint tap and is then missed. As the pressure in the bag is reduced the sound produced become louder and audible at a much lower level. This reading is then erroneously taken as the systolic blood pressure reading. The difference between this reading and the true systolic reading is described as the 'Auscultatory gap'.

4.11 Statistical Analysis

Results of biochemical estimation were reported as Mean, S.D, SEM and Median for determination of significant inter group difference each parameter was analyzed separately and one way analysis of variance P value was carried out Graph Pad statistics software.

Results of biochemical estimation were reported as Mean, S.D, and SEM for determination Student T Test of significant inter group difference each parameter was analyzed separately and one way analysis of variance t value and P value was carried out by SPSS 12.0 statistics software.

Results & Discussion

RESULT AND DISCUSSION

Result and Discussion

5.1 Physicochemical parameter

The herb of *Eclipta prostrata* collected from the field of village Dugarwada in Modasa was identified as *Eclipta prostrata* by scientist of NISCAIR, New Delhi (4/8/08; Ref: 1031/62).

The physicochemical parameters of the powder of the herb were determined which are shown in Table no. 5.1

Table 5.1: Physicochemical parameter for *Eclipta prostrata*

Sr. no	Name of parameter	Experimental Value	Indian Herbal Pharmacopoeia	Ayurvedic Pharmacopoeia of India
1	Water soluble extractive value	17.0 %	NLT 20 %	NLT 15 %
2	Alcoholic soluble extractive value	7.0 %	NLT 5 %	NLT 5 %
3	Total ash	14.5	NMT 19 %	NMT 22 %
4	Acid insoluble ash value	8.0 %	NMT 8 %	NMT 11 %

Water soluble extractive value, Alcoholic soluble extractive value, Total ash and Acid insoluble ash value of the *Eclipta prostrata* herb collected for the use comply with the Ayurvedic Pharmacopoeia of India

as well as Indian Herbal Pharmacopoeia. Only Water soluble extractive value is 3% less than the value mentioned by Indian Herbal Pharmacopoeia.

5.2 TLC of *Eclipta prostrata* and its market formulations

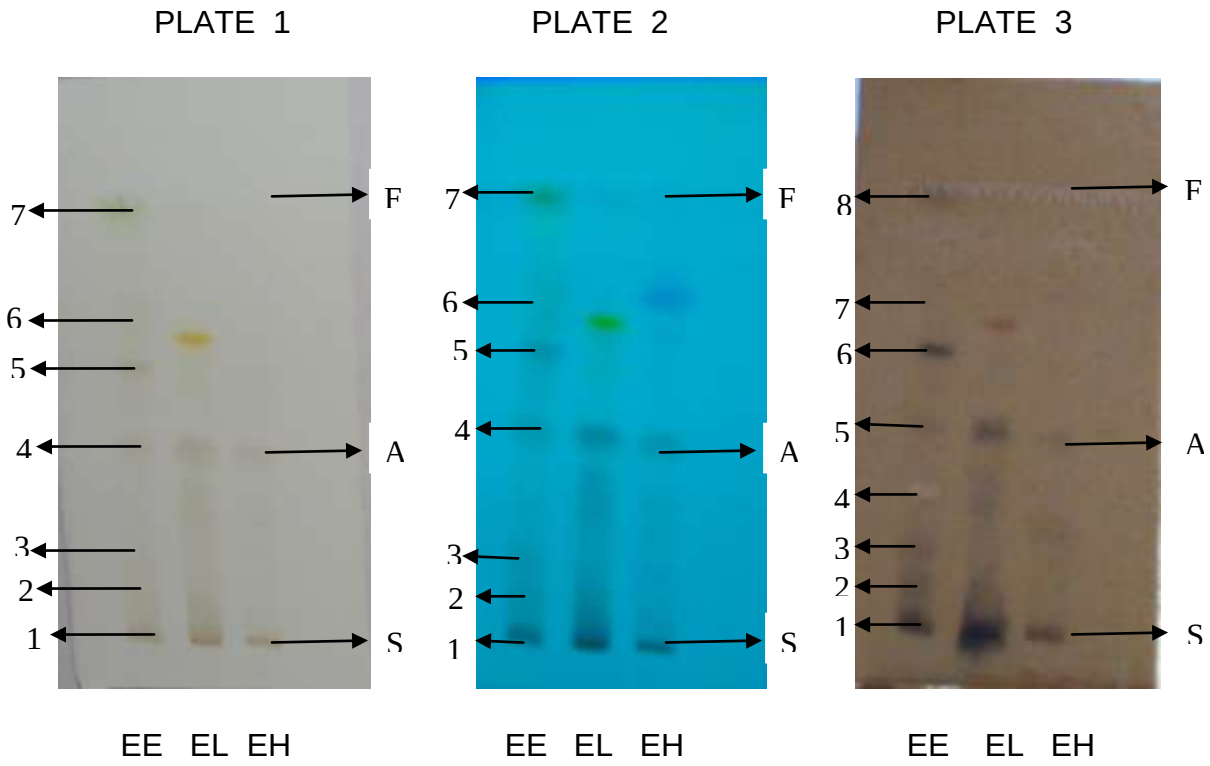


Figure 5.1: **TLC study of *Eclipta prostrata* and their formulations.**

Where A= Spot of wedelolactone (Rf=0.43, Identified through literature as Wedelolactone), S = Place of spotting, F = Solvent front.

Stationary phase: Silica gel G.

Mobile phase: Toluene: Acetone: Formic acid (11: 6: 1).

Detection: Plate 1 – As seen in day light.

Plate 2 – As seen in U. V. light (254nm)

Plate 3 - After spraying with 5% aqueous $FeCl_3$ as seen in day light

EH; Alcoholic extract of Hepatogard forte Tablet

EL; Alcoholic extract of Livercare Churna

EE; Alcoholic extract of *Eclipta prostrata*

TLC was observed in day light, UV light (254nm) and after spraying with 5% aq. $FeCl_3$ solution as seen in day light.

In day light, UV and after spraying with 5% $FeCl_3$ reagent spot at Rf= 0.43 is prominent. It turns dark blue after spraying with $FeCl_3$ reagent. As per the literature description this spot at Rf= 0.43 is Wedelolactone which is present in the collected herb sample, Livercare Churna and Hepatogard forte Tablet. However the intensity of the spot (Rf = 0.43) and diameter was bigger in the sample of Livercare Churna than in collected herb and Hepatogard forte Tablet.

Total 7 spots were seen in Eclipta herb in day light, but they were less in number in Livercare Churna and Hepatogard forte Tablet.

About 8 spots were seen in Eclipta herb chromatogram after spraying with $FeCl_3$ reagent. All the spots were blue to dark blue in colour. The number of spots were less in Livercare Churna and Hepatogard forte Tablet after spraying with $FeCl_3$ reagent.

5.3 Clinical data

Table 5.2: SGPT values of the patients after treatment with *Eclipta prostrata*

Sr. no of patients	Age	SGPT values after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	248	210	35	-	-	-
2	30	1500	900	380	-	40	-
3	38	154	90	35	-	-	-
4	38	420	140	45	-	-	-
5	35	255	110	55	-	-	-
6	40	570	430	310	60	40	-
7	60	1300	710	430	180	55	-
8	4.5	621	390	120	39	-	-
9	50	74	60	50	35	-	-
10	50	738	380	110	-	-	-
11	25	520	210	60	30	-	-
12	45	840	320	58	-	-	-
13	30	318	45	-	-	-	-
14	24	680	270	45	-	-	-
15	40	1200	840	480	55	-	-
16	16	540	370	55	-	-	-
17	50	380	110	65	-	-	-

18	41	135	48	-	-	-	-
19	35	750	520	340	240	65	-
20	49	1050	530	170	45	-	-
21	9	1100	670	250	65	-	-
22	32	2043	1180	650	90	-	-
23	9	2020	1980	1250	720	450	90
24	47	160	85	65	-	-	-
25	20	2100	1200	950	680	430	85
26	40	110	80	65	35	-	-
27	29	1890	1340	750	430	250	45
28	42	680	410	240	65	-	-
29	60	2500	1870	1110	940	450	70
30	47	2000	1640	1020	450	65	-
31	9	1520	1080	830	320	45	-
32	40	330	240	65	-	-	-
33	17	116	70	-	-	-	-
34	27	1740	1090	550	70	-	-
35	50	600	540	380	85	-	-
36	53	920	540	210	90	-	-
37	25	270	60	-	-	-	-
38	19	1550	1270	650	280	65	-
39	18	2200	940	430	170	95	-
40	38	130	47	-	-	-	-
41	37	110	75	-	-	-	-

42	52	3600	2200	1100	620	450	65
43	50	370	280	140	65	35	-
44	60	1500	880	320	80	-	-
45	22	1500	1200	650	120	-	-
46	9	1600	1140	740	470	110	-
47	10	3100	2800	1200	440	220	45
48	40	540	290	140	45	-	-
49	19	1900	940	530	110	-	-
50	38	2400	1840	1100	325	85	-
51	50	590	310	230	170	51	-
52	39	400	150	45	-	-	-
53	45	720	430	290	110	-	-
54	47	125	45	-	-	-	-
55	50	220	95	45	-	-	-
56	57	1640	1070	650	290	120	65
57	32	1420	1210	730	380	90	-
58	50	4500	2700	1300	820	370	85
59	53	2220	1480	890	680	380	55
60	40	450	310	150	70	65	45
61	48	750	490	270	85	-	-
62	29	2450	1460	650	130	-	-
63	28	1050	780	370	85	-	-
64	42	600	540	430	190	45	-
65	29	2340	1790	730	290	45	-

66	42	55	50	45	-	-	-
67	37	1850	720	390	45	-	-
68	21	1100	790	290	55	-	-
69	37	950	640	250	130	65	-
70	22	262	135	85	-	-	-
71	22	880	610	220	75	-	-
72	40	145	75	-	-	-	-
73	24	1700	1470	525	220	75	-
74	10	1620	1340	540	320	85	-
75	48	3250	2800	1800	830	410	65
76	27	750	390	180	85	-	-
77	16	440	290	75	35	-	-
78	12	1290	780	540	220	65	35
79	48	258	140	65	-	-	-
80	28	190	65	-	-	-	-
81	46	160	70	-	-	-	-
82	65	290	120	50	-	-	-
83	38	380	190	60	35	-	-
84	12	435	280	180	90	60	-
85	8	480	310	220	110	55	-
86	56	300	160	85	-	-	-
87	42	2190	1790	730	490	230	60
88	38	230	120	90	50	-	-
89	42	1100	670	390	110	35	-

90	28	850	480	210	85	-	-
91	23	380	210	65	-	-	-
92	35	280	140	60	-	-	-
93	18	580	240	80	-	-	-
94	11	460	210	90	-	-	-
95	18	910	420	180	60	-	-
96	45	190	85	-	-	-	-
97	12	430	190	65	-	-	-
98	20	50	-	-	-	-	-
Average		**987.775**	**654.639**	**378.697**	**222.483**	**152.823**	**62.3076**

Table 5.3. a: P value of SGPT after treatment with *Eclipta prostrata*

Group (week)	**Mean**	**Standard Deviation**	**Standard Error of Mean**	**Median**
Initial	987.77	869.90	84.894	621.00
First	654.63	648.86	64.247	390.00
Second	378.69	367.28	38.715	235.00
Third	222.48	227.91	28.489	110.00
Fourth	152.82	145.98	24.675	75.000
Sixth	62.308	16.596	4.436	63.654

Table 5.3.b: Paired samples test of SGPT after treatment with *Eclipta prostrata*

Pair	Paired Differences					t test	df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
A	313.685	313.245	30.425	253.358	374.013	10.31	105	0.000*
B	677.106	577.708	60.230	557.466	796.746	11.24	91	0.000*
C	1074.36	761.960	93.790	887.048	1261.67	11.45	65	0.000*
D	1459.67	918.343	153.05	1148.95	1770.40	9.537	35	0.000*
E	2303.07	1042.80	289.22	1672.91	2933.24	7.963	12	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week , D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.4: SGPT values of the patients after treatment with Livercare Churna

Sr. no of patients	Age	SGPT values after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	17	210	130	70	-	-	-
2	47	1050	630	290	80	-	-
3	49	490	270	85	-	-	-

4	51	2450	1760	1030	540	230	40
5	31	610	310	110	-	-	-
6	53	890	470	190	45	-	-
7	47	298	170	110	45	-	-
8	40	3200	2350	1430	770	310	35
9	47	2250	1770	1090	440	130	-
10	50	1450	730	470	180	90	-
11	44	790	410	100	-	-	-
12	46	3480	2570	1720	1070	645	95
13	35	780	590	310	80	-	-
14	55	450	195	60	-	-	-
15	50	1270	1040	770	490	110	
16	60	3610	2140	1950	1170	640	80
17	43	270	110	-	-	-	-
18	45	320	185	65	-	-	-
19	40	3200	1530	890	540	360	40
20	29	492	240	80		-	-
21	44	2015	1310	430	190	28	-
22	25	2540	1070	610	310	35	-
23	17	2215	1130	680	210	42	-
24	40	195	45	-	-	-	-
25	35	2250	1240	700	240	60	-
26	25	2600	1330	790	320	75	-
27	21	1810	1020	570	270	40	-

28	52	285	70	25	-	-	-
29	45	1420	830	440	180	65	-
30	62	2470	1820	1180	830	540	90
31	50	430	110	55	-	-	-
32	45	1350	760	320	85	-	-
33	50	1845	1130	680	210	80	-
34	30	1530	890	570	390	100	-
35	19	1745	1090	630	210	55	-
36	45	515	270	65	-	-	-
37	25	1420	690	120	60	-	-
38	25	1240	640	210	90	-	-
39	27	1420	890	480	110	75	-
40	17	945	540	320	90	-	-
41	57	1200	580	270	85	-	-
42	45	260	190	65	-	-	-
43	60	380	210	100	-	-	-
44	49	360	170	65	-	-	-
45	36	200	120	65	-	-	-
46	49	2200	1870	1170	775	390	50
47	50	1240	730	370	85	-	-
48	40	3290	2500	1390	820	380	75
49	40	2100	1870	1070	390	90	-
50	39	245	95	-	-	-	-
51	41	2700	2250	1785	1190	540	95

52	45	480	170	80	-	-	-
53	29	1210	650	320	65	-	-
54	52	560	270	62	-	-	-
55	50	1265	775	390	100	-	-
56	49	1750	1080	680	310	45	-
57	39	340	110	-	-	-	-
58	11	680	240	60	-	-	-
59	19	715	210	45	-	-	-
60	52	550	430	240	90	-	-
61	21	1320	940	690	360	120	-
62	29	750	580	310	180	55	-
63	40	140	80	45	-	-	-
64	55	180	40	-	-	-	-
65	50	750	480	370	210	70	-
66	39	310	110	54	-	-	-
67	38	380	160	45	-	-	-
68	19	1075	490	210	85	-	-
69	35	2650	1280	630	290	80	-
70	45	340	190	75	-	-	-
71	31	1625	745	320	65	-	-
72	49	190	60	-	-	-	-
73	45	130	65	-	-	-	-
74	53	470	190	75	-	-	-
75	48	230	40	-	-	-	-

76	20	160	45	-	-	-	-
77	17	750	370	60	-	-	-
78	27	3010	1830	1110	830	460	80
79	31	800	380	45	-	-	-
80	50	180	50	-	-	-	-
81	35	2190	1745	1070	470	90	
82	39	130	50	-	-	-	-
83	29	380	85	-	-	-	-
84	41	118	45	-	-	-	-
85	22	120	85	-	-	-	-
86	31	1060	470	270	95	-	-
87	47	260	75	-	-	-	-
88	28	425	190	40	-	-	-
89	12	390	90	-	-	-	-
90	41	140	50	-	-	-	-
91	36	410	85	-	-	-	-
92	44	460	180	65	-	-	-
93	39	540	280	65	-	-	-
Average		**1092.344**	**651.075**	**446.28**	**334.893**	**194.516**	**68**

Table 5.5.a: P value of SGPT after treatment with Livercare Churna

Group (week)	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	1092.3	933.22	96.254	750.00
First	651.08	658.63	67.932	420.00
Second	446.28	463.63	53.182	310.00
Third	334.89	309.64	44.692	210.00
Fourth	194.52	192.65	34.056	90.00
Sixth	68.000	22.935	6.915	75.00

Table 5.5.b: Paired samples test of SGPT after treatment with Livercare Churna

Pair	Paired Differences					t test	df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
A	397.374	354.245	34.407	329.151	465.597	11.549	105	0.000*
B	779.914	558.323	60.918	658.750	901.077	12.803	83	0.000*
C	1342.05	698.744	96.898	1147.52	1536.58	13.850	51	0.000*
D	1862.10	777.905	135.415	1586.26	2137.93	13.751	32	0.000*
E	2893.00	474.881	150.170	2553.29	3232.70	19.265	9	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week, D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.6: SGPT values of the patients after treatment with Hepatogard forte Tablet.

Sr. no of patients	Age	SGPT values after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	370	190	45	-	-	-
2	34	700	390	210	85	-	-
3	50	2250	1890	1200	970	535	110
4	39	3690	2980	2110	1340	650	210
5	39	2700	2260	1390	810	390	110
6	60	3250	2790	1770	1090	435	110
7	32	1250	810	645	290	85	-
8	49	780	610	370	230	65	-
9	55	260	170	90	-	-	-
10	60	380	210	85	-	-	-
11	35	520	310	140	65	-	-
12	36	290	130	90	-	-	-
13	58	680	490	330	290	170	65
14	40	300	130	60	-	-	-
15	50	340	170	65	-	-	-
16	29	235	165	90	-	-	-
17	38	180	112	65	-	-	-
18	42	210	150	75	-	-	-

19	59	205	130	65	-	-	-
20	11	340	190	70	-	-	-
21	32	1150	740	390	190	45	-
22	60	1800	845	340	190	65	-
23	35	470	190	75	-	-	-
24	59	1100	590	240	85	-	-
25	49	680	390	110	55	-	-
26	21	1260	740	320	110	-	-
27	60	260	180	80	-	-	-
28	45	220	170	110	45	-	-
29	50	1490	970	530	320	110	-
30	55	250	120	85	45	-	-
31	51	940	430	190	110	-	-
32	23	1110	820	520	310	90	-
33	20	210	120	50	-	-	-
34	22	115	50	-	-	-	-
35	48	220	130	60	-	-	-
36	47	1500	980	590	310	95	-
37	41	940	470	230	110	-	-
38	32	1040	725	410	210	110	-
39	21	740	360	95	-	-	-
40	21	810	430	220	65	-	-
41	22	140	60	-	-	-	-
42	50	180	70	-	-	-	-

43	42	120	55	-	-	-	-
44	30	375	110	55	-	-	-
45	18	425	340	210	63	-	-
46	30	150	45	-	-	-	-
47	40	410	180	120	58	-	-
48	35	180	50	-	-	-	-
49	28	430	370	290	180	70	-
50	37	895	710	410	310	170	60
51	49	130	100	45	-	-	-
52	30	125	110	65	-	-	-
53	29	190	70	-	-	-	-
54	41	470	310	190	85	-	-
55	42	450	300	95	-	-	-
56	37	130	55	-	-	-	-
57	18	650	430	280	160	60	-
58	13	145	65	-	-	-	-
59	23	485	240	180	150	100	45
60	28	110	53	-	-	-	-
61	45	635	540	320	120	80	-
62	15	670	480	370	80	-	-
63	50	1310	840	530	210	80	-
64	32	380	90	-	-	-	-
65	43	2100	1400	790	460	320	80
66	36	2020	970	470	310	70	-

67	38	390	90	-	-	-	-
68	35	648	320	110	-	-	-
69	51	290	180	80	-	-	-
70	55	550	430	220	110	50	-
71	43	270	120	60	-	-	-
72	46	390	190	70	-	-	-
73	59	270	90	-	-	-	-
74	39	320	280	170	110	70	-
75	55	1060	630	480	210	90	-
76	35	1100	620	310	80	-	-
77	51	155	60	-	-	-	-
78	45	980	610	290	85	-	-
79	40	600	310	90	-	-	-
80	17	1920	1010	640	380	200	49
81	50	825	580	320	75	-	-
82	50	280	95	-	-	-	-
83	20	700	350	85	-	-	-
84	51	430	220	75	-	-	-
85	55	320	120	60	-	-	-
86	50	1250	570	310	45	-	-
87	39	250	150	55	-	-	-
88	47	2190	1540	630	310	45	-
89	37	538	230	110	-	-	-
90	40	280	130	45	-	-	-

91	51	1750	880	320	75	-	-
92	47	2380	1790	1430	910	425	90
93	49	1390	870	530	290	95	-
94	39	300	140	55	-	-	-
95	35	550	290	130	45	-	-
Average		**746.484**	**470.157**	**308.812**	**254.916**	**170.357**	**92.9**

Table 5.7.a: P value of SGPT after treatment with Hepatogard forte Tablet

Group (week)	**Mean**	**Standard Deviation**	**Standard Error of Mean**	**Median**
Initial	746.48	690.95	66.486	430.00
First	470.15	533.54	52.318	285.00
Second	308.81	370.96	39.771	180.00
Third	254.91	280.11	38.477	120.00
Fourth	170.35	159.93	28.725	90.000
Sixth	92.900	45.658	13.767	90.000

Table 5.7.b: Paired samples test of SGPT after treatment with Hepatogard forte Tablet

Pair	Paired Differences					t test	df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
A	271.822	218.012	21.076	230.037	313.607	12.897	106	0.000*
B	536.329	395.935	42.206	452.438	620.220	12.707	87	0.000*
C	907.944	528.325	71.895	763.739	1052.14	12.629	53	0.000*
D	1255.64	728.786	130.893	988.324	1522.96	9.593	30	0.000*
E	1804.18	1082.899	326.506	1076.67	2531.68	5.526	10	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week, D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.8: Comparative average SGPT values for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Week	*Eclipta prostrata*	Livercare Churna	Hepatogard forte Tablet
Initial	987.7755	1092.344	746.4842
First	654.6392	651.0753	470.1579
Second	378.6977	446.28	308.8125
Third	222.4839	334.8936	254.9167
Fourth	152.8235	194.5161	170.3571
Sixth	62.30769	68	92.9

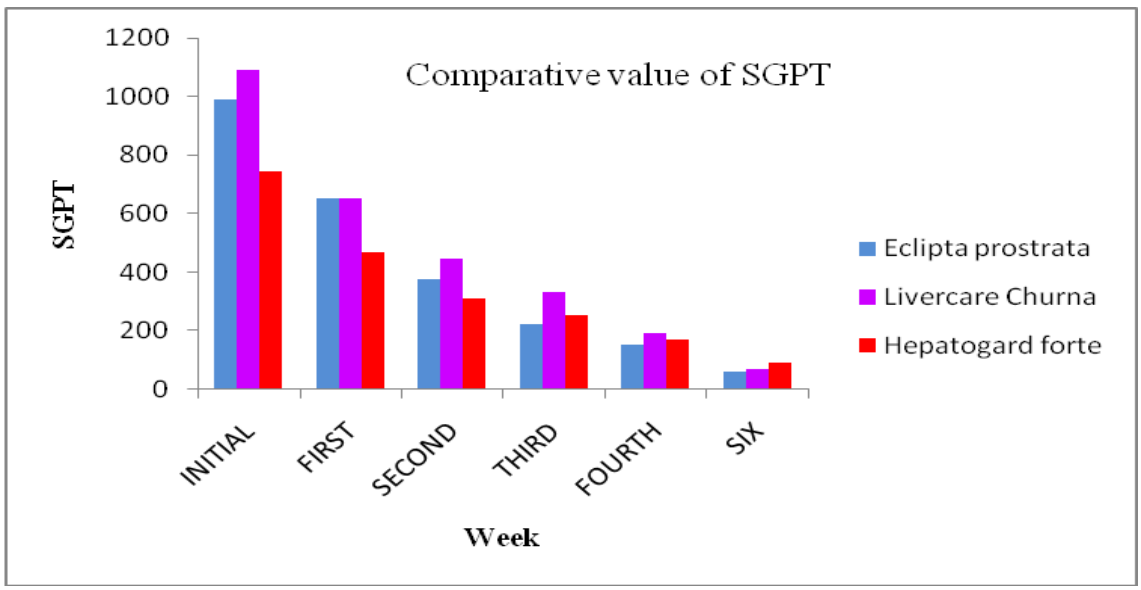


Figure 5.2: SGPT v/s Week of treatment. Column graph showing comparative value of SGPT for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet as hepatoprotective drugs.

For *Eclipta prostrata* the mean SGPT value of the group on zero day is considered as 100%. In comparison with zero week, SGPT level are recovered on first week 33.73%, on second week 61.67%, on third week 77.48%, on fourth week 84.53% and sixth weeks 93.70% respectively. The P value is < 0.0001.

For Livercare Churna the mean SGPT value of the group on zero day is considered as 100%. In comparison with zero week, SGPT level are recovered on first week 40.38%, on second week 59.15%, on third week 69.41%, on fourth week 82.23% and sixth weeks 93.77% respectively. The P value is < 0.0001.

For Hepatogard forte Tablet the mean SGPT value of the group on zero day is considered as 100%. In comparison with zero week, SGPT level are recovered on first week 36.99%, on second week 58.71%, on third week 65.95%, on fourth week 77.21% and sixth weeks 87.66% respectively. The P value is < 0.0001.

Table 5. 9: Percentage recovery of SGPT with different formulations

Treatment	%Recovery				
Formulation	First week	Second week	Third week	Fourth week	Sixth week
Eclipta prostrata	33.73	61.67	77.48	84.53	93.70
Livercare Churna	40.38	59.15	69.41	82.23	93.77
Hepatogard forte Tablet	36.99	58.71	65.95	77.21	87.66

Table 5.10: Bilirubin values of the patients after treatment with *Eclipta prostrata.*

Sr. no of patients	Age	Bilirubin value mg % after different week treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	3	2.1	0.8	-	-	-
2	30	4	3.2	1.9	-	0.8	-
3	38	2.4	1.8	1.1	-	-	-
4	38	7.1	4.1	1.2	-	-	-
5	35	4.8	2.1	1.3	-	-	-
6	40	30	22	14	6.3	2.3	-
7	60	9	7.2	5.4	3.1	1.2	-
8	4.5	8	5.1	2.9	1.1	-	-
9	50	17	11.2	5.1	1.3	-	-
10	50	9	5.3	3.2	-	-	-
11	25	7	3.2	1.8	0.8	-	-
12	45	4.3	2	0.8	-	-	-
13	30	6.9	1.4	-	-	-	-
14	24	10.2	4.8	1.6	-	-	-
15	40	10.8	8.3	6.2	1.8	-	-
16	16	9.1	5.1	2	-	-	-
17	50	11.2	6	1.3	-	-	-
18	41	1.9	1.1	-	-	-	-

19	35	11.3	7.1	5.2	4.9	1.3	-
20	49	3.2	3	2.1	0.8	-	-
21	9	7.8	5.8	2.2	1	-	-
22	32	8.9	6.2	3.2	0.9	-	-
23	9	6.2	6.8	4.2	3.9	2.2	1
24	47	2.4	2.2	0.9	-	-	-
25	20	3.9	3.9	2.1	1.8	1.8	1.2
26	40	12	8	4.3	1.8	-	-
27	29	23	17	11.2	7.3	2.8	1.1
28	42	4.2	3.8	1.8	0.9	-	-
29	60	10.4	8.2	6.2	4.8	3.2	1.1
30	47	3.9	3.1	2.7	2.1	1.2	-
31	9	5.9	4.2	3.6	2.2	0.9	-
32	40	2.2	1.8	0.9	-	-	-
33	17	1.8	1.1	-	-	-	-
34	27	4.2	3.8	2.2	0.9	-	-
35	50	10.5	6.2	3.2	1.3	-	-
36	53	5.1	3.4	2.2	1.2	-	-
37	25	3	1.2	-	-	-	-
38	19	1.2	1.1	1.1	1	0.9	-
39	18	1.8	1.1	0.9	0.9	0.9	-
40	38	1.1	0.9	-	-	-	-
41	37	2.9	1	-	-	-	-
42	52	9.2	6.2	4.3	2.2	1.8	1.1

43	50	12.9	8.4	4.2	2.2	1	-
44	60	4.2	3.2	2.2	1.1	-	-
45	22	4.2	2.8	2.1	1.1	-	-
46	9	2.8	2.5	1.7	1.6	1.1	-
47	10	5.4	4.9	3.2	2.2	2.1	1.3
48	40	7.4	4.3	2.2	0.9	-	-
49	19	1.8	1.7	1.4	0.8	-	-
50	38	10.6	8.2	7.2	3.2	1.3	-
51	50	10.8	8.3	5.9	2.9	1.1	-
52	39	4.3	2.2	1.1	-	-	-
53	45	1.8	1.6	1.2	1	-	-
54	47	1.2	0.9	-	-	-	-
55	50	2.4	1.8	1.2	-	-	-
56	57	18	13.8	12.2	6.9	3.1	1
57	32	2.3	2	1.9	1.5	0.8	-
58	50	3.4	2.7	2.2	1.8	1.2	0.9
59	53	11.1	7.9	6.1	5.1	4.2	1.3
60	40	22.4	16.2	9.4	6.2	4.3	1.2
61	48	4.6	2.3	1.2	0.9	-	-
62	29	1.8	1.6	1.4	1.2	-	-
63	28	4.9	3.1	2.4	1.2	-	-
64	42	13.1	12.1	6.2	2.8	1.2	-
65	29	10.9	8.2	3.4	3.4	1.2	-
66	42	8.2	4.8	2.1	-	-	-

67	37	2	1.6	1.2	0.9	-	-
68	21	1.4	1.1	1	0.9	-	-
69	37	10.2	6.4	3.9	2.3	1.1	-
70	22	3.2	2.1	1		-	-
71	22	4.3	3.5	2.2	0.9	-	-
72	40	1.3	0.9	-	-	-	-
73	24	6	4.2	2.2	1.2	0.9	-
74	10	2.8	2.3	1.8	1.4	1	-
75	48	11.3	8.4	6.3	4.2	3.2	1.1
76	27	6.3	4.1	2.2	1.2	-	-
77	16	3.1	2.8	1.7	1	-	-
78	12	12.1	8.3	6.8	4.2	2.2	1.1
79	48	2.2	1.4	1.1	-	-	-
80	28	2.2	1.2	-	-	-	-
81	46	2.1	1.1	-	-	-	-
82	65	4.3	2.2	1	-	-	-
83	38	3.9	3	1.6	1	-	-
84	12	6.8	4.8	2.7	1.4	1	-
85	8	11	9.3	6.1	3.6	1.3	-
86	56	1.1	1	0.9	-	-	-
87	42	12.2	10.1	6.2	4.1	3	1
88	38	3.9	2.8	1.4	1.1	-	-
89	42	6.8	3.2	2.8	1.2	0.9	-
90	28	3.2	2.9	1.3	1	-	-

91	23	2.1	1.6	0.9	-	-	-
92	35	4.1	2.3	1.1	-	-	-
93	18	4.8	2.9	1.2	-	-	-
94	11	3.6	1.8	0.9	-	-	-
95	18	2.8	1.9	1.1	0.9	-	-
96	45	2.1	1	-	-	-	-
97	12	3.9	2.1	1	-	-	-
98	20	1.8	1	-	-	-	-
Average		6.3387	4.4071	3.0093	2.1741	1.6787	1.1076

Table 5.11.a : P value of bilirubin after treatment with *Eclipta prostrata*

Group (week)	**Mean**	**Standard Deviation**	**Standard Error of Mean**	**Median**
Initial	6.3387	3.782	0.3745	4.9
First	4.4071	2.917	0.2917	2.8
Second	3.0093	2.112	0.2326	2.05
Third	2.1741	1.354	0.1934	2.1
Fourth	1.6787	0.8531	0.1485	1.1
Sixth	1.1076	0.1020	0.03075	0.9

Table 5.11.b: Paired samples test of bilirubin after treatment with *Eclipta prostrata*

Pair	Paired Differences					t test	df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
A	1.931	1.6868	0.170	1.5934	2.269	11.336	97	0.000*
B	3.884	3.0642	0.330	3.2279	4.541	11.757	85	0.000*
C	5.551	4.4478	0.564	4.4220	6.681	9.828	61	0.000*
D	7.554	5.8632	1.020	5.4755	9.633	7.402	32	0.000*
E	10.323	6.3816	1.769	6.4666	14.179	5.832	12	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week , D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.12: Bilirubin values of the patients after treatment with Livercare Churna.

Sr. no of patients	Age	Bilirubin value mg % after different week treatment					
		Initial(zero week)	First	Second	Third	Fourth	Sixth
1	17	4.1	2.2	1	-	-	-
2	47	3.9	2.9	1.8	1	-	-
3	49	5.7	2.1	1.2	-	-	-
4	51	6.9	4.6	3.1	2.3	1.7	0.8

5	31	4.9	2.6	1	-	-	-
6	53	8	4.4	2.1	0.9	-	-
7	47	8.9	5.4	3.1	1	-	-
8	40	7.9	6.3	5.3	3.1	2.7	0.9
9	47	9.7	4.3	3.1	2	1	-
10	50	6.8	4.2	3.4	2.1	1	-
11	44	3.2	1.7	0.9	-	-	-
12	46	9.9	7.8	5.4	4.3	2.1	0.9
13	35	5.5	3.3	2	0.9	-	-
14	55	3.7	2.1	0.9	-	-	-
15	50	11.5	8.9	6.5	3.1	1	-
16	60	7.7	4.3	3.2	2.1	1.3	0.9
17	43	3.9	1.1	-	-	-	-
18	45	4.5	2.9	0.9	-	-	-
19	40	7.6	6.2	4.9	2.4	1.4	1
20	29	2.4	1.7	0.9	-	-	-
21	44	9.5	6.3	4.3	2.1	1	-
22	25	4.1	3.2	2.5	1.8	0.9	-
23	17	6.7	4.3	3.2	1.8	1.1	-
24	40	2.9	1.2	-	-	-	-
25	35	8	6.1	4.3	3.1	1	-
26	25	5.3	5.2	4.6	2.8	1.2	-
27	21	6.5	4.3	3.2	1.8	1	-
28	52	4	1.8	1	-	-	-

29	45	4.8	3.2	2	1.3	0.9	-
30	62	30	21.2	12.6	7.3	4.9	1.2
31	50	2	1.4	1	-	-	-
32	45	5.7	4.5	2.2	1	-	-
33	50	7.3	4.3	3.2	1.8	1	-
34	30	6	4.9	4	2.1	1.1	-
35	19	6.2	4.8	3.2	2.2	0.9	-
36	45	4	2.3	1	-	-	-
37	25	3.2	1.9	1.4	0.9	-	-
38	25	4	2.4	1.6	1	-	-
39	27	6.6	5.1	3.8	2.1	1.1	-
40	17	2.4	2	1.5	1	-	-
41	57	5.3	2.9	1.6	1	-	-
42	45	4.7	2.1	1.1	-	-	-
43	60	5.1	2.6	1.2	-	-	-
44	49	5.5	2.6	1.1	-	-	-
45	36	4.7	1.9	0.9	-	-	-
46	49	6.9	6.2	4.4	3.2	2.1	0.9
47	50	4.3	3.2	2.1	1	-	-
48	40	7.4	5.9	3.6	2.2	1.7	0.9
49	40	6.7	5.8	3.2	1.8	0.9	-
50	39	3.9	1.2	-	-	-	-
51	41	13.2	11.2	8.9	6.4	2.8	1
52	45	5.6	2.8	0.9	-	-	-

53	29	5.3	2.4	1.8	0.9	-	-
54	52	3.5	1.3	0.9	-	-	-
55	50	7.8	4.7	3.8	1.1	-	-
56	49	6.8	5.3	4.3	2.1	1	-
57	39	3.8	1	-	-	-	-
58	11	7	3.2	1.1	-	-	-
59	19	5.5	2.2	1.1	-	-	-
60	52	4.5	3.9	2.3	1	-	-
61	21	12.2	8.4	5.9	3.4	1	-
62	29	10.3	8	4.7	2.1	0.9	-
63	40	6.9	3.1	1.2	-	-	-
64	55	1.9	1.1	-	-	-	-
65	50	14.9	8.4	5.3	2.9	1.1	-
66	39	4.3	1.8	0.9	-	-	-
67	38	4	2.1	1	-	-	-
68	19	3.2	2.3	1.2	0.9	-	-
69	35	6.2	5.4	3.8	2.4	1.1	-
70	45	5.5	3.2	1.2	-	-	-
71	31	5.6	3.1	2.4	1.1	-	-
72	49	2.6	0.9	-	-	-	-
73	45	2.4	1	-	-	-	-
74	53	3.4	1.8	0.9	-	-	-
75	48	1.9	0.9	-	-	-	-
76	20	2.1	1	-	-	-	-

77	17	3.6	1.9	1	-	-	-
78	27	16	10.3	7.6	5	3.1	0.9
79	31	3.9	1.8	0.9	-	-	-
80	50	1.3	1	-	-	-	-
81	35	12	9.7	6.4	3	1	-
82	39	3.9	1	-	-	-	-
83	29	3.4	1	-	-	-	-
84	41	2.1	1	-	-	-	-
85	22	2.9	1	-	-	-	-
86	31	6.7	4.1	2.3	1	-	-
87	47	3.4	1	-	-	-	-
88	28	5.1	2.3	1	-	-	-
89	12	4.4	1	-	-	-	-
90	41	1.4	1	-	-	-	-
91	36	3.2	1	-	-	-	-
92	44	5.2	3.1	0.9	-	-	-
93	39	4.9	2.8	1.1	-	-	-
Average		**5.8516**	**3.6483**	**2.7373**	**2.1659**	**1.4516**	**0.94**

Table 5.13.a : P value of bilirubin after Livercare Churna treatment

Group (week)	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	5.851	3.758	0.3614	4.85
First	3.648	2.996	0.2938	2.9
Second	2.737	2.105	0.2297	2.0
Third	2.165	1.347	0.1869	2.05
Fourth	1.451	0.8450	0.1449	1.075
Sixth	0.940	0.1020	0.03075	0.9

Table 5.13.b: Paired samples test of bilirubin after treatment with Livercare Churna

	Paired Differences							
				95% Confidence Interval of the Difference				
Pair	Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t test	df	P Value Significant. (2 tailed)
A	2.1561	1.3007	.1314	1.8953	2.4169	16.409	97	0.000*
B	3.7794	2.1930	.2483	3.2850	4.2739	15.221	77	0.000*
C	5.5416	3.4018	.4910	4.5538	6.5294	11.286	47	0.000*
D	7.6322	4.2186	.7576	6.0848	9.1796	10.073	30	0.000*
E	10.4100	7.1326	2.2555	5.3076	15.5123	4.615	9	0.001*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week , D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table5.14: Bilirubin values of the patients after treatment with Hepatogard forte Tablet.

Sr. no of patients	Age	Bilirubin value mg % after different week treatment					
		Initial(zero week)	First	Second	Third	Fourth	Sixth
1	32	4.2	2.1	1	-	-	-
2	34	6.9	4.2	2.2	1.1	-	-
3	50	13.4	8.9	6.3	4.8	3.1	1
4	39	6.9	5.4	4.9	4	3.1	1.7
5	39	22.1	18.3	12.2	9.4	6.3	2.1
6	60	14	12.1	8.3	6.9	3.4	1.2
7	32	7.4	4.3	3.1	2.7	1	-
8	49	11	8.4	5.9	3.7	1.2	-
9	55	6.2	3.9	1.3	-	-	-
10	60	4.3	2.4	0.9	-	-	-
11	35	6.9	3.6	1.7	0.9	-	-
12	36	4.9	2.4	1	-	-	-
13	58	13.7	8.9	6.2	3.4	2.1	0.9
14	40	7.4	3.2	1.2	-	-	-
15	50	2.9	1.4	0.9	-	-	-
16	29	3.7	2.1	1	-	-	-
17	38	4	1.9	1	-	-	-
18	42	5.1	2.9	1	-	-	-
19	59	3.4	2.1	0.9	-	-	-

20	11	4.3	2.1	1	-	-	-
21	32	6.4	3.2	2.4	1.3	0.9	-
22	60	7	4.3	2.1	1.7	0.9	-
23	35	3.9	1.6	1	-	-	-
24	59	7	3.2	2.1	1	-	-
25	49	4.4	2.1	1.7	0.9	-	-
26	21	3.9	2.1	1.4	1	-	-
27	60	2.9	1.4	0.9	-	-	-
28	45	6.4	3.9	2.1	1	-	-
29	50	8.2	6.8	4.6	2.8	1.2	-
30	55	6.3	4.2	2.4	1.1	-	-
31	51	6.4	4.2	1.9	1	-	-
32	23	4.2	2.2	1.2	1	0.9	-
33	20	5.7	2.6	1.2	-	-	-
34	22	3.2	1.2	-	-	-	-
35	48	5.3	2.9	1.1	-	-	-
36	47	4.3	3.2	2.8	1.9	1	-
37	41	5.9	4	2.2	1	-	-
38	32	7.4	5.4	3.2	2.8	1.1	-
39	21	4.4	2.2	0.9	-	-	-
40	21	4.3	2.3	1.4	0.9	-	-
41	22	1.3	0.9	-	-	-	-
42	50	3.3	1.1	-	-	-	-
43	42	1.4	1	-	-	-	-

44	30	5.6	3.2	1	-	-	-
45	18	10	8.3	5.8	1.2	-	-
46	30	1.3	1	-	-	-	-
47	40	7.1	4.3	2.3	1	-	-
48	35	2.7	1	-	-	-	-
49	28	8.3	6.3	3.9	2	1	-
50	37	12.1	9.1	8.4	6.1	2.3	1
51	49	3	1.8	0.9	-	-	-
52	30	5.9	3	1.2	-	-	-
53	29	3.8	1.4	-	-	-	-
54	41	6.1	4.8	1.9	1	-	-
55	42	5.9	3.2	1.1	-	-	-
56	37	1.6	0.9	-	-	-	-
57	18	11.2	9.3	6.1	4.1	1.2	-
58	13	3.2	1.1	-	-	-	-
59	23	19	12.7	9.5	6.1	3.1	1
60	28	2.9	1.1	-	-	-	-
61	45	13.25	10.8	9.7	3.2	1.2	-
62	15	5.7	5	3.8	1.2		-
63	50	7.4	6.2	4.1	1.8	0.9	-
64	32	2.1	1	-	-	-	-
65	43	8.3	6.8	4.9	3.2	1.8	0.9
66	36	10.1	8	5.8	3.2	1.1	-
67	38	1.2	0.9	-	-	-	-

68	35	3.2	2.2	1.1	-	-	-
69	51	3.1	2.1	1.1	-	-	-
70	55	6.2	4.8	2.9	1.8	0.9	-
71	43	3.1	1.4	0.9	-	-	-
72	46	4.1	2	1	-	-	-
73	59	1.6	1	-	-	-	-
74	39	7.6	6.4	4.3	2.6	1.1	-
75	55	6.3	4.2	2.9	1.8	0.9	-
76	35	3.2	1.8	1	0.9	-	-
77	51	1.9	1	-	-	-	-
78	45	4.8	3.2	1.7	0.9	-	-
79	40	4.8	2.1	1		-	-
80	17	16	12.2	9.3	6.2	4.1	1.1
81	50	4.9	4.1	2.1	0.9	-	-
82	50	3.7	1	-	-	-	-
83	20	3.1	2.7	1	-	-	-
84	51	5.1	2.3	1	-	-	-
85	55	4.1	2.7	1	-	-	-
86	50	6.6	4	1.9	0.9	-	-
87	39	4	2.1	1	-	-	-
88	47	6.9	4	2.7	1.3	0.9	-
89	37	5.7	2.9	1	-	-	-
90	40	3.7	1.9	0.8	-	-	-
91	51	6.7	3.2	2	0.9	-	-

92	47	8.4	6.2	5	3.9	2.1	0.9
93	49	10.7	7.4	4.9	2.1	0.9	-
94	39	3.2	1.9	1	-	-	-
95	35	4.9	2.3	1.7	0.9	-	-
Average		**6.0163**	**3.9042**	**2.7912**	**2.4062**	**1.775**	**1.18**

Table 5.15.a : P value of bilirubin after treatment with Hepatogard forte Tablet.

Group (week)	**Mean**	**Standard Deviation**	**Standard Error of Mean**	**Median**
Initial	6.016	3.702	0.3630	5.1
First	3.904	3.076	0.3045	2.9
Second	2.791	2.457	0.2665	1.7
Third	2.406	1.897	0.2656	1.7
Fourth	1.775	1.266	0.2351	1.2
Sixth	1.180	0.3816	0.1150	1.0

Table 5.15.b: Paired samples test of bilirubin after treatment with Hepatogard forte Tablet

pair	Paired Differences					t test	df	P value Significant. (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
A	2.1630	1.1126	.1075	1.949	2.3763	20.111	106	0.000*
B	3.8960	2.2020	.2347	3.429	4.3625	16.597	87	0.000*
C	5.9750	2.5549	.3476	5.277	6.6723	17.185	53	0.000*
D	8.3209	3.5607	.6395	7.014	9.6270	13.011	30	0.000*
E	12.554	4.5926	1.3847	9.469	15.6399	9.066	10	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week , D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.16: Comparative average bilirubin values for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Week	*Eclipta prostrata*	Livercare Churna	Hepatogard forte Tablet
Initial	6.338776	5.851613	6.016316
First	4.407143	3.648387	3.904211
Second	3.009302	2.737333	2.79125
Third	2.174194	2.165957	2.40625
Fourth	1.678788	1.451613	1.775
Sixth	1.107692	0.94	1.18

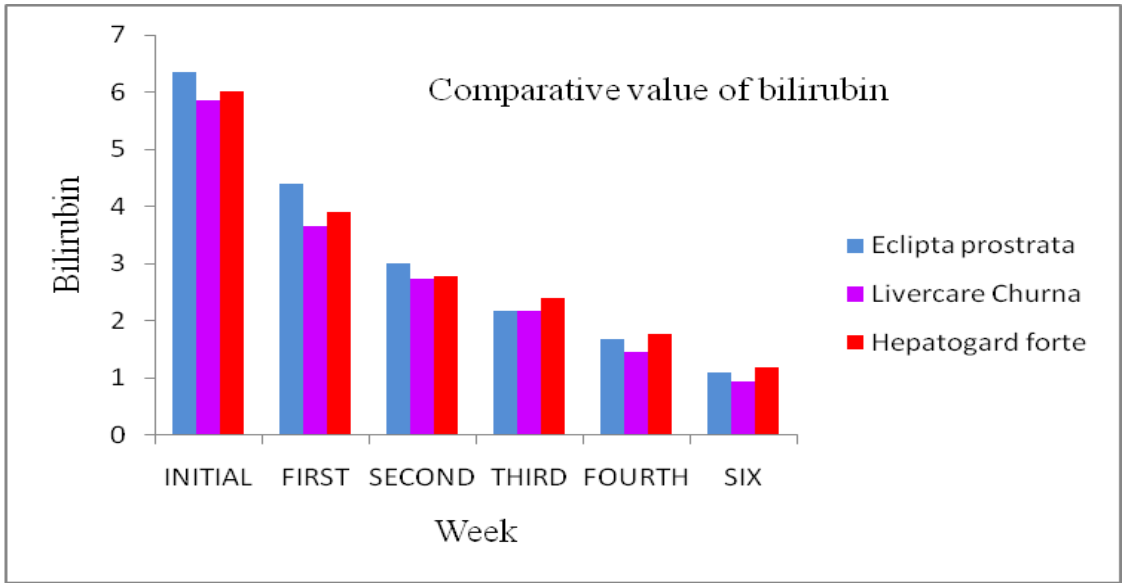


Figure 5.3: Bilirubin v/s Week. Column graph showing comparative values of bilirubin for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet as hepatoprotective drugs.

For *Eclipta prostrata* the mean bilirubin value of the group on zero day is considered as 100%. In comparison with zero week, bilirubin level are recovered on first week 30.15%, on second week 52.38%, on third week 65.55%, on fourth week 73.49% and sixth weeks 82.53% respectively. The P value is < 0.0001.

For Livercare Churna the mean bilirubin value of the group on zero day is considered as 100%. In comparison with zero week, bilirubin level are recovered on first week 37.7%, on second week 53.33%, on third week 63.07%, on fourth week 75.21% and sixth weeks 83.93% respectively. The P value is < 0.0001.

For Hepatogard forte Tablet the mean bilirubin value of the group on zero day is considered as 100%. In comparison with zero week, bilirubin level are recovered on first week 35.10%, on second week 55.07%, on third week 60.06%, on fourth week 70.46% and sixth weeks 80.36% respectively. The P value is < 0.0001.

Table 5. 17: Percentage recovery of bilirubin with different formulations

Treatment	%Recovery				
Formulation	First week	Second week	Third week	Fourth week	Sixth week
Eclipta prostrata	30.15	52.38	65.55	73.49	82.55
Livercare Churna	37.70	53.33	63.07	75.21	83.93
Hepatogard forte Tablet	35.10	55.07	66.06	70.46	80.36

Table 5.18: Haemoglobin values of the patients after treatment with *Eclipta prostrata.*

Sr. no of patients	**Age**	**Hb values after different weeks treatment**					
		Initial (zero week)	**First**	**Second**	**Third**	**Fourth**	**Sixth**
1	65	9.3	9.4	9.8	-	-	-
2	30	8.1	8.2	8.6	9.0	9.4	-
3	38	7.2	7.6	8	-	-	-
4	38	14.2	14.2	14.3	-	-	-
5	35	10.2	10.4	10.8	-	-	-
6	40	8.3	8.4	8.4	8.6	8.7	-
7	60	10.3	10.3	10.3	10.4	10.6	-

8	4.5	14.1	14.8	14.1	15.3	-	-
9	50	12.1	12.1	12.2	12.5	-	-
10	50	11.3	11.4	11.6	-	-	-
11	25	10.1	10.3	10.5	10.6	-	-
12	45	8.1	8.3	8.8	-	-	-
13	30	12.1	12.3	-	-	-	-
14	24	10.2	11.3	12.2	-	-	-
15	40	11.8	11.9	12.1	13.1	-	-
16	16	12.8	12.8	12.8	-	-	-
17	50	12.4	13.1	14.6	-	-	-
18	41	11.7	12.8	-	-	-	-
19	35	12	12.7	12.9	13.1	13.3	-
20	49	12.2	12.3	12.4	12.4	-	-
21	9	13	13	13.6	13.6	-	-
22	32	12.7	12.7	12.8	12.9	-	-
23	9	11.2	10.8	11.1	11.2	11.3	11.3
24	47	13.2	13.3	13.4	-	-	-
25	20	12.1	12.2	12.5	12.5	12.5	12.5
26	40	11.2	11.2	11.5	11.7	-	-
27	29	9.2	9.4	10.1	10.2	10.4	10.4
28	42	14.8	14.8	14.8	14.9	-	-
29	60	10.2	10.2	10.4	10.4	10.4	10.5
30	47	12.2	12.2	12.3	12.4	12.4	-
31	9	9.7	9.7	9.7	9.9	9.9	-

32	40	11.7	11.7	11.9	-	-	-
33	17	12.3	12.5	-	-	-	-
34	27	10.9	11	11	11	-	-
35	50	13.4	13.4	13.4	13.5	-	-
36	53	8.1	8.3	8.6	8.6	-	-
37	25	10.2	10.3	-	-	-	-
38	19	11.2	11.2	11.3	11.3	11.4	-
39	18	10.2	10.3	10.3	10.4	10.4	-
40	38	10.5	10.6	-	-	-	-
41	37	9.1	9.4	-	-	-	-
42	52	13.7	13.8	13.8	13.8	13.8	13.8
43	50	10.2	10.33	10.3	10.3	10.4	-
44	60	13.6	13.6	13.6	13.6	-	-
45	22	12	12.4	12.4	12.4	-	-
46	9	13.3	13.3	13.4	13.5	13.5	-
47	10	9	9.1	9.1	9.4	9.4	9.5
48	40	10.8	10.8	10.9	10.9	-	-
49	19	12.6	12.7	12.7	12.9	-	-
50	38	12.3	12.3	12.4	12.5	12.6	-
51	50	12.4	12.4	12.4	12.4	12.4	-
52	39	10.2	10.3	10.3	-	-	-
53	45	11.8	11.8	11.9	11.9	-	-
54	47	11.2	11.3	-	-	-	-
55	50	10.9	10.9	10.9	-	-	-

56	57	11.2	11.2	11.3	11.3	11.4	11.5
57	32	12.8	12.8	12.9	12.9	13	-
58	50	12.1	12.2	12.2	12.2	12.3	12.4
59	53	13.2	13.2	13.3	12.3	12.3	13.4
60	40	11.1	11.2	11.3	11.3	11.3	11.4
61	48	7.4	8.1	8.2	8.3	-	-
62	29	11.2	11.4	11.5	11.5	-	-
63	28	9.7	9.9	9.9	10	-	-
64	42	7.2	7.5	7.8	8.1	8.1	-
65	29	12.1	12.2	12.3	12.3	12.3	-
66	42	11.2	11.2	11.3	-	-	-
67	37	7.4	7.7	8	8.2	-	-
68	21	12.1	12.2	12.2	12.3	-	-
69	37	12.4	12.4	12.5	12.5	12.5	-
70	22	11.2	11.3	11.5	-	-	-
71	22	10.2	10.3	10.4	10.4	-	-
72	40	11.2	11.4	-	-	-	-
73	24	10.3	10.3	10.5	10.5	10.5	-
74	10	9.3	9.4	9.7	9.7	9.8	-
75	48	8.2	8.3	8.4	8.4	8.5	8.7
76	27	11.2	11.2	11.4	11.5	-	-
77	16	10.2	10.3	10.4	10.5	-	-
78	12	10.3	10.4	10.5	10.6	10.6	10.6
79	48	11.2	11.3	11.3	-	-	-

80	28	11.2	11.5	-	-	-	-
81	46	10.3	10.4	-	-	-	-
82	65	10.3	10.4	10.5	-	-	-
83	38	10.8	10.9	10.9	11	-	-
84	12	10.1	10.2	10.3	10.4	10.5	-
85	8	6.3	6.8	6.9	7.2	7.4	-
86	56	9.3	9.4	9.5	-	-	-
87	42	8.1	8.2	8.3	8.4	8.5	8.7
88	38	8.3	8.4	8.5	8.5	-	-
89	42	11.2	11.3	11.3	11.4	11.4	-
90	28	10.2	10.3	10.3	10.4	-	-
91	23	11.1	11.1	11.2	-	-	-
92	35	9.1	9.1	9.2	-	-	-
93	18	9.1	9.3	9.4	-	-	-
94	11	10.2	10.3	10.4	-	-	-
95	18	8.3	8.4	8.5	8.6	-	-
96	45	10.2	10.4	-	-	-	-
97	12	8.1	8.3	8.5	-	-	-
98	20	8.3	8.4	-	-	-	-
Average		**10.760**	**10.861**	**11.043**	**11.219**	**10.976**	**11.130**

Table 5.19. a: P value of Hb after treatment with *Eclipta prostrata*

Group (week)	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	10.760	1.755	0.1764	10.900
First	10.861	1.729	0.1737	11.000
Second	11.043	1.763	0.1890	11.100
Third	11.219	1.777	0.2239	11.300
Fourth	10.976	1.620	0.2739	10.976
Sixth	11.131	1.561	0.4173	11.215

Table 5.19.b: Paired samples test of Hb after treatment with *Eclipta prostrata*

	Paired Differences							
				95% Confidence Interval of the Difference				P value Significant
Pair	Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t test	Df	(2 tailed)
A	.077	.863	.083	-.089	.2433	.919	105	0.360
B	-.053	1.755	.183	-.416	.3102	-.291	91	0.772
C	.1384	1.968	.244	-.349	.6261	.567	64	0.573
D	.122	2.315	.385	-.661	.9058	.317	35	0.753
E	-.392	.284	.078	-.564	-.2205	-4.97	12	0.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week, D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.20: Haemoglobin values of the patients after treatment with Livercare Churna.

Sr. no of patients	Hb value after different weeks treatment						
	Age	Initial	First	Second	Third	Fourth	Sixth
1	17	11.5	11.6	11.7	-	-	-
2	47	10.5	10.6	10.7	10.7	-	-
3	49	11.2	11.4	11.5	-	-	-
4	51	9.6	9.8	9.9	10	10	10.1
5	31	11.6	11.7	11.9	-	-	-
6	53	12.1	12.3	12.4	12.5	-	-
7	47	9.1	9.4	9.5	9.5	-	-
8	40	12.2	12.4	12.6	12.7	12.8	12.8
9	47	8.6	8.7	8.8	8.9	9	-
10	50	11.4	11.6	11.7	11.8	11.9	-
11	44	11.4	11.6	11.7	-	-	-
12	46	10.7	10.9	11	11	11.5	11.6
13	35	9.6	9.7	9.8	9.8	-	-
14	55	10.9	11	11.1	-	-	-
15	50	12.2	12.4	12.5	12.5	12.5	-
16	60	10.1	10.4	10.7	10.8	10.8	10.8
17	43	10.3	10.6	-	-	-	-
18	45	10.2	10.4	10.5	-	-	-
19	40	9.4	9.6	9.7	9.7	9.8	9.9

20	29	10.7	10.9	11	-	-	-
21	44	8.9	9	9.1	9.3	9.4	-
22	25	12.1	12.3	12.4	12.4	12.5	-
23	17	10.3	10.4	10.5	10.6	10.6	-
24	40	10.2	10.7	-	-	-	-
25	35	11.2	11.4	11.4	11.5	11.6	-
26	25	11.2	11.3	11.4	11.6	11.6	-
27	21	10.1	10.4	10.6	10.7	10.9	-
28	52	10.1	10.4	10.8	-	-	-
29	45	8.7	8.8	8.9	9.1	9.2	-
30	62	8.2	8.6	9	9.2	9.3	9.5
31	50	9.2	9.4	9.6	-	-	-
32	45	11.2	11.3	11.4	11.5	-	-
33	50	10.7	10.8	10.8	10.9	10.9	-
34	30	9.3	9.5	9.8	10	10.1	-
35	19	11.2	11.2	11.3	11.4	11.5	-
36	45	9.3	9.4	9.6	-	-	-
37	25	9.3	9.6	9.8	9.9	-	-
38	25	11.4	11.6	11.7	11.8	-	-
39	27	9.3	9.6	9.8	10	10.1	-
40	17	11.3	11.6	11.7	11.8	-	-
41	57	13	13.2	13.3	13.4	-	-
42	45	13.2	13.3	13.4	-	-	-
43	60	12.6	12.8	12.9	-	-	-

44	49	12.1	12.2	12.4	-	-	-
45	36	12.7	12.7	12.8	-	-	-
46	49	8.7	8.8	9	9.2	9.3	9.5
47	50	9.3	9.4	9.6	9.9	-	-
48	40	8.2	8.4	8.6	8.7	8.8.	8.9
49	40	7.9	8.1	8.2	8.3	8.4	-
50	39	12.4	12.6	-	-	-	-
51	41	9.4	9.5	9.7	9.8	9.8	9.9
52	45	12.1	12.3	12.4	-	-	-
53	29	8.5	8.6	8.8	8.9	-	-
54	52	11.7	11.9	12	-	-	-
55	50	11.3	11.5	11.5	11.6	-	-
56	49	10.2	10.4	10.5	10.6	10.7	-
57	39	12.2	12.5	-	-	-	-
58	11	10.2	10.4	10.6	-	-	-
59	19	11.2	11.2	11.3	-	-	-
60	52	6	6.4	6.7	7.2	-	-
61	21	12.5	12.6	12.8	12.8	12.9	-
62	29	9.8	9.9	10	10.1	10.2	-
63	40	13.7	13.8	13.9	-	-	-
64	55	12.6	12.7	-	-	-	-
65	50	13	13.2	13.3	13.3	13.4	-
66	39	10.1	10.3	10.4	-	-	-
67	38	11.4	11.6	11.7	-	-	-

68	19	9.2	9.4	9.5	9.6	-	-
69	35	8.1	8.4	8.5	8.6	8.8	-
70	45	8.2	8.8	9	-	-	-
71	31	10.7	10.9	11	11.1	-	-
72	49	10.3	10.3	-	-	-	-
73	45	11.6	11.7	-	-	-	-
74	53	9.7	9.9	10	-	-	-
75	48	10.3	10.5	-	-	-	-
76	20	10.9	11	-	-	-	-
77	17	11	11.2	11.4	-	-	-
78	27	9.2	9.4	9.5	9.5	9.6	9.6
79	31	11.2	11.4	11.5	-	-	-
80	50	10.9	10.9	-	-	-	-
81	35	9.4	9.6	9.7	9.8	9.8	-
82	39	10.7	10.9	-	-	-	-
83	29	10.4	10.9	-	-	-	-
84	41	11.1	11.6	-	-	-	-
85	22	10.1	10.7	-	-	-	-
86	31	8.9	9.2	9.4	9.5	-	-
87	47	11.4	11.6	-	-	-	-
88	28	9.6	9.9	10	-	-	-
89	12	9.4	9.8	-	-	-	-
90	41	10.3	10.5	-	-	-	-
91	36	10.8	11.3	-	-	-	-

92	44	10.9	11	11.2	-	-	-
93	39	10.3	10.5	10.6	-	-	-
Average		**10.5064**	**10.7086**	**10.7386**	**10.5**	**10.63**	**10.26**

Table 5.21. a : P value of Hb after treatment with Livercare Churna

Group (week)	**Mean**	**Standard Deviation**	**Standard Error of Mean**	**Median**
Initial	10.506	1.395	0.1402	10.4
First	10.708	1.368	0.1389	10.709
Second	10.738	1.413	0.1599	10.719
Third	10.50	1.381	0.1972	10.5
Fourth	10.63	1.299	0.2296	10.615
Sixth	10.260	1.107	0.3339	9.9

Table 5.21.b : Paired samples test of Hb after treatment with Livercare Churna

Pair	Paired Differences					t test	Df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
A	.0234	.856	.0827	-.1407	.1874	.282	106	.778
B	-.0761	1.811	.1976	-.4693	.3170	-.385	83	.701
C	.1423	2.195	.3045	-.4689	.7536	.467	51	.642
D	.0250	2.459	.4348	-.8617	.9117	.057	31	.955
E	-.6900	.264	.0836	-.8791	-.500	-8.25	9	.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week, D=Initial-Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.22: Haemoglobin values of the patients after treatment with Hepatogard forte Tablet.

Sr. no of patients	Age	Hb values after different week treatments					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	12.3	12.4	12.4	-	-	-
2	34	13.6	13.7	13.7	13.7	-	-

3	50	11	11.1	11.2	11.2	11.2	11.3
4	39	11.2	11.2	11.3	11.4	11.4	11.4
5	39	10.1	10.1	10.2	10.3	10.3	10.4
6	60	11.2	11.2	11.3	11.3	11.3	11.4
7	32	9.3	9.3	9.4	9.4	9.5	-
8	49	11.8	12	12.1	12.1	12.1	-
9	55	10.6	10.6	10.7	-	-	-
10	60	11.4	11.5	11.5	-	-	-
11	35	10.3	10.4	10.4	10.5	-	-
12	36	13.4	13.4	13.5	-	-	-
13	58	12.1	12.2	12.2	12.2	12.3	12.3
14	40	11.2	11.3	11.4	-	-	-
15	50	12.1	12.2	12.3	-	-	-
16	29	12.7	12.8	12.8	-	-	-
17	38	12.7	12.7	12.8	-	-	-
18	42	12.8	12.8	12.9	-	-	-
19	59	11.9	12	12	-	-	-
20	11	12.1	12.2	12.2	-	-	-
21	32	10.4	10.5	10.5	10.6	10.6	-
22	60	11.4	11.5	11.6	11.6	11.6	-
23	35	12.3	12.4	12.4	-	-	-
24	59	9.6	9.7	9.7	9.7	-	-
25	49	11.2	11.3	11.3	11.4	-	-
26	21	11.4	11.4	11.5	11.5	-	-

27	60	9.8	9.9	9.9	-	-	-
28	45	12.9	13	13	13	-	-
29	50	11.4	11.5	11.6	11.6	11.7	-
30	55	10.2	10.3	10.3	10.4	-	-
31	51	11.2	11.4	11.4	11.5	-	-
32	23	10.2	10.4	10.5	10.5	10.6	-
33	20	13.7	13.7	13.7	-	-	-
34	22	8.1	8.2	-	-	-	-
35	48	5.4	2.8	1.1	-	-	-
36	47	10.1	10.3	10.3	10.4	10.5	-
37	41	11.7	11.8	11.9	12	-	-
38	32	11.3	11.4	11.5	11.5	11.5	-
39	21	10.7	10.9	11	-	-	-
40	21	14.5	14.5	14.5	14.6	-	-
41	22	9.8	10	-	-	-	-
42	50	11	11.1	-	-	-	-
43	42	13.1	13.2	-	-	-	-
44	30	12.4	12.4	12.4	-	-	-
45	18	10.8	10.9	10.9	11	-	-
46	30	13.2	13.3	-	-	-	-
47	40	12.1	12.2	12.2	12.3	-	-
48	35	11.2	11.3	-	-	-	-
49	28	11.7	11.7	11.8	11.8	11.9	-
50	37	12.2	12.2	12.3	12.4	12.4	12.5

51	49	9.9	10	10.3	-	-	-
52	30	10.8	10.9	11	-	-	-
53	29	11.2	11.4	-	-	-	-
54	41	8.9	9	9.1	9.2	-	-
55	42	8.4	8.7	8.9	-	-	-
56	37	12.3	12.4	-	-	-	-
57	18	10.8	10.9	11	11	11.1	-
58	13	10.3	10.5	-	-	-	-
59	23	11.6	11.8	11.9	11.9	12	12.1
60	28	13.2	13.4	-	-	-	-
61	45	12	12.2	12.5	12.5	12.6	-
62	15	11.6	11.8	11.9	12		-
63	50	9.6	9.8	9.9	10	10.1	-
64	32	9.3	9.4	-	-	-	-
65	43	8.3	8.5	8.6	8.7	8.8	8.8
66	36	9.1	9.2	9.4	9.5	9.6	-
67	38	10.2	10.3	-	-	-	-
68	35	10.1	10.2	10.3	-	-	-
69	51	6.8	6.9	7	-	-	-
70	55	11.1	11.2	11.3	11.3	11.4	-
71	43	12.3	12.5	12.5	-	-	-
72	46	12.1	12.3	12.3	-	-	-
73	59	13.2	13.4	-	-	-	-
74	39	8.3	8.4	8.6	8.7	8.8	-

75	55	10.9	11	11.1	11.2	11.2	-
76	35	8.2	8.4	8.5	8.5	-	-
77	51	12.1	12.2	-	-	-	-
78	45	12.2	12.3	12.4	12.4	-	-
79	40	8.9	8.9	9		-	-
80	17	7.3	7.5	7.6	7.7	7.8	7.8
81	50	11.7	11.8	11.9	11.9	-	-
82	50	12.7	12.7	-	-	-	-
83	20	13.6	13.9	14	-	-	-
84	51	11.4	11.6	11.7	-	-	-
85	55	12.5	12.6	12.7	-	-	-
86	50	10.9	11.1	11.1	11.3	-	-
87	39	13.7	13.9	14	-	-	-
88	47	11.4	11.6	11.6	11.7	11.7	-
89	37	12.4	12.5	12.6	-	-	-
90	40	13.7	13.9	14	-	-	-
91	51	12.6	12.8	12.8	12.9	-	-
92	47	10.7	10.9	11	11.1	11.1	11.1
93	49	8	8.3	8.3	8.3	8.4	-
94	39	9	9.3	9.3	-	-	-
95	35	9.2	9.3	9.4	9.4	-	-
Average		**11.0873**	**11.1778**	**11.1637**	**11.0645**	**10.8392**	**10.91**

Table 5.23.a : P value of Hb after treatment with Hepatogard forte Tablet

Group (week)	Mean	Standard Deviation	Standard Error of Mean	Median
Initial	11.087	1.682	0.1699	11.2
First	11.177	1.774	0.1801	11.4
Second	11.163	1.900	0.2099	11.4
Third	11.064	1.394	0.1972	11.3
Fourth	10.839	1.245	0.2311	11.2
Sixth	10.910	1.447	0.4362	11.3

Table 5.23. b: Paired samples test of Hb after treatment with Hepatogard forte Tablet

Pair	Paired Differences					t test	df	P value Significant (2 tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
A	-.0972	.2735	.0264	-.1496	-.0447	-3.676	106	.000*
B	-.1409	.4891	.0521	-.2445	-.0372	-2.703	87	.008
C	-.250	.1023	.0139	-.2779	-.2220	-17.953	53	.000*
D	-.3225	.1257	.0225	-.3687	-.2764	-14.286	30	.000*
E	-.3545	.1293	.0390	-.4414	-.2676	-9.092	10	.000*

A=Initial-First week, B=Initial- Second week, C= Initial- Third week , D=Initial Fourth week, E= Initial-Sixth week

Where * = The P value is < 0.001, considered significant.

Table 5.24: Comparative average haemoglobin values for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Week	*Eclipta prostrata*	Livercare Churna	Hepatogard forte Tablet
Initial	10.7602	10.50645	11.08737
First	10.86113	10.7086	11.17789
Second	11.04302	10.73867	11.16375
Third	11.21967	10.5	11.06458
Fourth	10.97647	10.63	10.83929
Sixth	11.13077	10.26	10.91

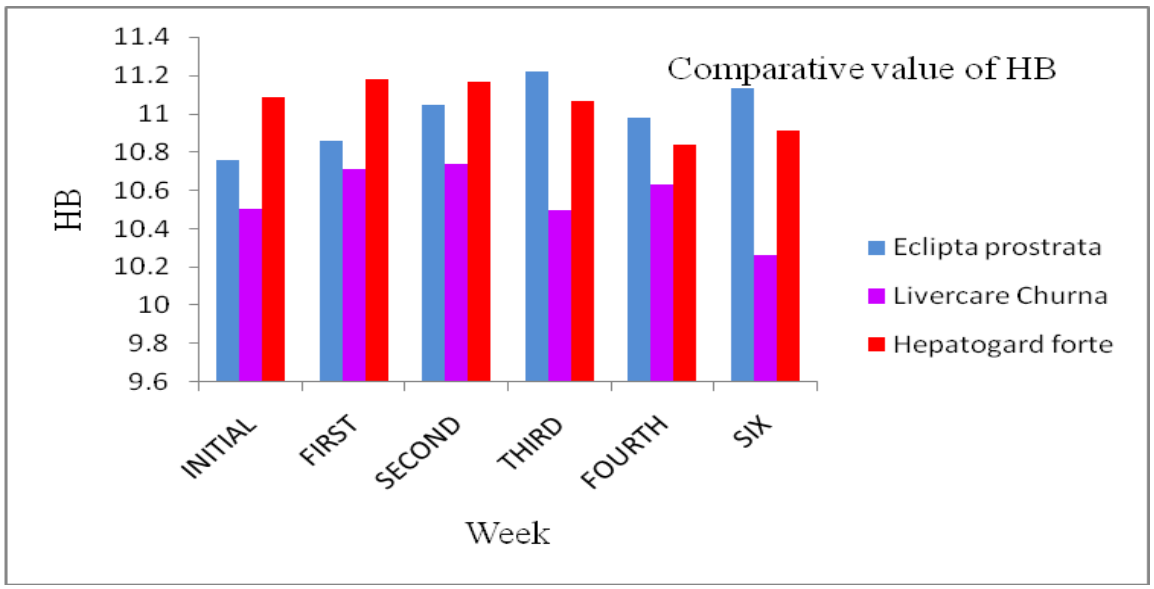


Figure 5.4: Haemoglobin v/s Week. Column graph showing comparative values of haemoglobin for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet as hepatoprotective drugs.

For *Eclipta prostrata* the mean haemoglobin values of group on zero day is 10.76 gm%. In comparison with zero week, haemoglobin level increase on first, second and third week, on fourth and sixth week haemoglobin level decreases slightly but in comparison with zero week it is increased. The P value is insignificant for haemoglobin.

For Livercare Churna the mean haemoglobin values of group on zero day is 10.50 gm%. In comparison with zero week, haemoglobin level increase on first, and second, on third and fourth week haemoglobin level decreases slightly but in comparison with zero week it is increased. On sixth week haemoglobin level decreased compared to zero week. The P value is insignificant for haemoglobin.

For Hepatogard forte Tablet the mean haemoglobin values of group on zero day is 11.087 gm%. In comparison with zero week, haemoglobin level increase on first and second week, on third, fourth and sixth week haemoglobin level decreases slightly but in comparison with zero week it is decreased. The P value is insignificant for haemoglobin.

Actually there is an increasing heamoglobin values in each patients in each group of treatment. However there is decrease in average heamoglobin values in third fourth and sixth week of treatment because number of patients being treated for longer duration are having severe liver damage and less heamoglobin. Number of patients are also less in these long (4 to 6 week) treatments, so mean heamoglobin decreases in these later weeks

Table 5.25: Blood pressure values of the patients after treatment with *Eclipta prostrata.*

Sr. no of patients	Age	Blood pressure after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	80-120	80-120	80-120	-	-	-
2	30	80-120	80-120	80-120	-	80-120	-
3	38	80-120	80-120	80-120	-	-	-
4	38	80-120	80-120	80-120	-	-	-
5	35	90-130	80-120	80-120	-	-	-
6	40	80-120	80-120	80-120	80-120	80-120	-
7	60	100-140	110-150	110-150	100-140	100-140	-
8	4.5	80-120	80-120	80-120	80-120	-	-
9	50	130-170	120-160	110-150	110-150	-	-
10	50	90-130	80-120	80-120	-	-	-
11	25	80-120	80-120	80-120	80-120	-	-
12	45	90-130	80-120	80-120	-	-	-
13	30	80-120	80-120	-	-	-	-
14	24	80-120	80-120	80-120	-	-	-
15	40	80-120	80-120	80-120	80-120	-	-
16	16	80-120	80-120	80-120	-	-	-
17	50	140-180	100-140	100-140	-	-	-
18	41	100-140	90-130	-	-	-	-

19	35	80-120	80-120	80-120	80-120	80-120	-
20	49	80-120	80-120	80-120	80-120	-	-
21	9	80-120	80-120	80-120	80-120	-	-
22	32	80-120	80-120	80-120	80-120	-	-
23	9	80-120	80-120	80-120	80-120	80-120	80-120
24	47	100-140	90-130	90-130	-	-	-
25	20	80-120	80-120	80-120	80-120	80-120	80-120
26	40	80-120	80-120	80-120	80-120	-	-
27	29	80-120	80-120	80-120	80-120	80-120	80-120
28	42	100-140	90-130	90-130	90-130	-	-
29	60	80-120	80-120	80-120	80-120	80-120	80-120
30	47	80-120	80-120	80-120	80-120	80-120	-
31	9	80-120	80-120	80-120	80-120	80-120	-
32	40	80-120	80-120	80-120	-	-	-
33	17	80-120	80-120	-	-	-	-
34	27	80-120	80-120	80-120	80-120	-	-
35	50	80-120	80-120	80-120	80-120	-	-
36	53	90-130	90-130	90-130	90-130	-	-
37	25	80-120	80-120	-	-	-	-
38	19	80-120	80-120	80-120	80-120	80-120	-
39	18	80-120	80-120	80-120	80-120	80-120	-
40	38	80-120	80-120	-	-	-	-
41	37	80-120	80-120	-	-	-	-
42	52	90-130	90-130	90-1130	90-130	90-130	90-130

43	50	90-130	90-130	90-1130	90-130	90-130	-
44	60	90-130	90-130	90-130	90-120	-	-
45	22	80-120	80-120	80-120	80-120	-	-
46	9	80-120	80-120	80-120	80-120	80-120	-
47	10	80-120	80-120	80-120	80-120	80-120	80-120
48	40	90-130	90-130	90-130	90-130	-	-
49	19	80-120	80-120	80-120	80-120	-	-
50	38	80-120	80-120	80-120	80-120	80-120	-
51	50	80-120	80-120	80-120	80-120	80-120	-
52	39	80-120	80-120	80-120	-	-	-
53	45	80-120	80-120	80-120	80-120	-	-
54	47	80-120	80-120	-	-	-	-
55	50	90-130	90-130	90-130	-	-	-
56	57	100-140	80-120	80-120	80-120	80-120	80-120
57	32	80-120	80-120	80-120	80-120	80-120	-
58	50	80-120	80-120	80-120	80-120	80-120	80-120
59	53	80-120	80-120	80-120	80-120	80-120	80-120
60	40	80-120	80-120	80-120	80-120	80-120	80-120
61	48	80-120	80-120	80-120	80-120	-	-
62	29	80-120	80-120	80-120	80-120	-	-
63	28	80-120	80-120	80-120	80-120	-	-
64	42	80-120	80-120	80-120	80-120	80-120	-
65	29	80-120	80-120	80-120	80-120	80-120	-
66	42	80-120	80-120	80-120	-	-	-

67	37	80-120	80-120	80-120	80-120	-	-
68	21	80-120	80-120	80-120	80-120	-	-
69	37	80-120	80-120	80-120	80-120	80-120	-
70	22	80-120	80-120	80-120	-	-	-
71	22	80-120	80-120	80-120	80-120	-	-
72	40	80-120	80-120	-	-	-	-
73	24	80-120	80-120	80-120	80-120	80-120	-
74	10	80-120	80-120	80-120	80-120	80-120	-
75	48	80-120	80-120	80-120	80-120	80-120	80-120
76	27	80-120	80-120	80-120	80-120	-	-
77	16	80-120	80-120	80-120	80-120	-	-
78	12	80-120	80-120	80-120	80-120	80-120	80-120
79	48	80-120	80-120	80-120	-	-	-
80	28	80-120	80-120	-	-	-	-
81	46	80-120	80-120	-	-	-	-
82	65	80-120	80-120	80-120	-	-	-
83	38	80-120	80-120	80-120	80-120	-	-
84	12	80-120	80-120	80-120	80-120	80-120	-
85	8	80-120	80-120	80-120	80-120	80-120	-
86	56	80-120	80-120	80-120	-	-	-
87	42	80-120	80-120	80-120	80-120	80-120	80-120
88	38	80-120	80-120	80-120	80-120	-	-
89	42	100-140	100-140	100-140	100-140	100-140	-
90	28	80-120	80-120	80-120	80-120	-	-

91	23	80-120	80-120	80-120	-	-	-
92	35	80-120	80-120	80-120	-	-	-
93	18	80-120	80-120	80-120	-	-	-
94	11	80-120	80-120	80-120	-	-	-
95	18	80-120	80-120	80-120	80-120	-	-
96	45	90-140	90-140	-	-	-	-
97	12	80-120	80-120	80-120	-	-	-
98	20	80-120	80-120	-	-	-	-

Table 5.26: Blood pressure values of the patients after treatment with Livercare Churna.

Sr. no of patients	Age	Blood pressure after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	17	80-120	80-120	80-120	-	-	-
2	47	90-130	80-120	80-120	80-120	-	-
3	49	100-140	100-140	90-130	-	-	-
4	51	80-120	80-120	80-120	80-120	80-120	80-120
5	31	80-120	80-120	80-120	-	-	-
6	53	80-120	80-120	80-120	80-120	-	-
7	47	90-130	90-130	80-120	80-120	-	-
8	40	80-120	80-120	80-120	80-120	80-120	80-120
9	47	80-120	80-120	80-120	80-120	80-120	-

10	50	80-120	80-120	80-120	80-120	80-120	-
11	44	80-120	80-120	80-120	-	-	-
12	46	80-120	80-120	80-120	80-120	80-120	80-120
13	35	80-120	80-120	80-120	80-120	-	-
14	55	90-130	80-120	80-120	-	-	-
15	50	100-140	90-130	90-130	90-130	80-120	-
16	60	80-120	80-120	80-120	80-120	80-120	80-120
17	43	80-120	80-120	-	-	-	-
18	45	80-120	80-120	80-120	-	-	-
19	40	80-120	80-120	80-120	80-120	80-120	80-120
20	29	80-120	80-120	80-120	-	-	-
21	44	80-120	80-120	80-120	80-120	80-120	-
22	25	80-120	80-120	80-120	80-120	80-120	-
23	17	80-120	80-120	80-120	80-120	80-120	-
24	40	80-120	80-120	-	-	-	-
25	35	80-120	80-120	80-120	80-120	80-120	-
26	25	80-120	80-120	80-120	80-120	80-120	-
27	21	80-120	80-120	80-120	80-120	80-120	-
28	52	80-120	80-120	80-120	-	-	-
29	45	80-120	80-120	80-120	80-120	80-120	-
30	62	80-120	80-120	80-120	80-120	80-120	80-120
31	50	80-120	80-120	80-120	-	-	-
32	45	90-130	90-130	80-120	80-120	-	-
33	50	80-120	80-120	80-120	80-120	80-120	-

34	30	80-120	80-120	80-120	80-120	80-120	-
35	19	80-120	80-120	80-120	80-120	80-120	-
36	45	80-120	80-120	80-120	-	-	-
37	25	80-120	80-120	80-120	80-120	-	-
38	25	80-120	80-120	80-120	80-120	-	-
39	27	80-120	80-120	80-120	80-120	80-120	-
40	17	80-120	80-120	80-120	80-120	-	-
41	57	80-120	80-120	80-120	80-120	-	-
42	45	80-120	80-120	80-120	-	-	-
43	60	80-120	80-120	80-120	-	-	-
44	49	80-120	80-120	80-120	-	-	-
45	36	80-120	80-120	80-120	-	-	-
46	49	90-130	90-130	90-130	90-130	90-130	90-130
47	50	80-120	80-120	80-120	80-120	-	-
48	40	80-120	80-120	80-120	80-120	80-120	80-120
49	40	90-130	90-130	90-130	90-130	90-130	-
50	39	80-120	80-120	-	-	-	-
51	41	80-120	80-120	80-120	80-120	80-120	80-120
52	45	80-120	80-120	80-120	-	-	-
53	29	80-120	80-120	80-120	80-120	-	-
54	52	80-120	80-120	80-120	-	-	-
55	50	80-120	80-120	80-120	80-120	-	-
56	49	100-140	80-120	80-120	80-120	80-120	-
57	39	80-120	80-120	-	-	-	-

58	11	80-120	80-120	80-120	-	-	-
59	19	80-120	80-120	80-120	-	-	-
60	52	80-120	80-120	80-120	80-120	-	-
61	21	80-120	80-120	80-120	80-120	80-120	-
62	29	80-120	80-120	80-120	80-120	80-120	-
63	40	80-120	80-120	80-120	-	-	-
64	55	80-120	80-120	-	-	-	-
65	50	80-120	80-120	80-120	80-120	80-120	-
66	39	80-120	80-120	80-120	-	-	-
67	38	80-120	80-120	80-120	-	-	-
68	19	80-120	80-120	80-120	80-120	-	-
69	35	80-120	80-120	80-120	80-120	80-120	-
70	45	80-120	80-120	80-120	-	-	-
71	31	80-120	80-120	80-120	80-120	-	-
72	49	80-120	80-120	-	-	-	-
73	45	80-120	80-120	-	-	-	-
74	53	90-130	90-130	80-120	-	-	-
75	48	80-120	80-120	-	-	-	-
76	20	80-120	80-120	-	-	-	-
77	17	80-120	80-120	80-120	-	-	-
78	27	80-120	80-120	80-120	80-120	80-120	80-120
79	31	80-120	80-120	80-120	-	-	-
80	50	90-130	80-120	-	-	-	-
81	35	80-120	80-120	80-120	80-120	80-120	-

82	39	80-120	80-120	-	-	-	-
83	29	80-120	80-120	-	-	-	-
84	41	80-120	80-120	-	-	-	-
85	22	80-120	80-120	-	-	-	-
86	31	80-120	80-120	80-120	80-120	-	-
87	47	80-120	80-120	-	-	-	-
88	28	80-120	80-120	80-120	-	-	-
89	12	80-120	80-120	-	-	-	-
90	41	80-120	80-120	-	-	-	-
91	36	80-120	80-120	-	-	-	-
92	44	80-120	80-120	80-120	-	-	-
93	39	80-120	80-120	80-120	-	-	-

Table 5.27: Blood pressure values of the patients after treatment with Hepatogard forte Tablet

Sr. no of patients	Age	Blood pressure after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	80-120	80-120	80-120	-	-	-
2	34	80-120	80-120	80-120	80-120	-	-
3	50	100-140	100-140	100-140	90-130	90-130	90-130
4	39	80-120	80-120	80-120	80-120	80-120	80-120
5	39	80-120	80-120	80-120	80-120	80-120	80-120

6	60	80-120	80-120	80-120	80-120	80-120	80-120
7	32	80-120	80-120	80-120	80-120	80-120	-
8	49	100-140	100-140	100-140	90-130	90-130	-
9	55	80-120	80-120	80-120	-	-	-
10	60	90-130	90-130	80-120	-	-	-
11	35	80-120	80-120	80-120	80-120	-	-
12	36	80-120	80-120	80-120	-	-	-
13	58	90-130	90-130	90-130	90-130	90-130	90-130
14	40	90-130	90-130	80-120	-	-	-
15	50	90-130	90-130	80-120	-	-	-
16	29	80-120	80-120	80-120	-	-	-
17	38	80-120	80-120	80-120	-	-	-
18	42	80-120	80-120	80-120	-	-	-
19	59	90-130	90-130	90-130	-	-	-
20	11	80-120	80-120	80-120	-	-	-
21	32	80-120	80-120	80-120	80-120	80-120	-
22	60	80-120	80-120	80-120	80-120	80-120	-
23	35	80-120	80-120	80-120	-	-	-
24	59	80-120	80-120	80-120	80-120	-	-
25	49	80-120	80-120	80-120	80-120	-	-
26	21	80-120	80-120	80-120	80-120	-	-
27	60	80-120	80-120	80-120	-	-	-
28	45	80-120	80-120	80-120	80-120	-	-
29	50	80-120	80-120	80-120	80-120	80-120	-

30	55	80-120	80-120	80-120	80-120	-	-
31	51	80-120	80-120	80-120	80-120	-	-
32	23	80-120	80-120	80-120	80-120	80-120	-
33	20	80-120	80-120	80-120	-	-	-
34	22	80-120	80-120	-	-	-	-
35	48	80-120	80-120	80-120	-	-	-
36	47	80-120	80-120	80-120	80-120	80-120	-
37	41	80-120	80-120	80-120	80-120	-	-
38	32	80-120	80-120	80-120	80-120	80-120	-
39	21	80-120	80-120	80-120	-	-	-
40	21	80-120	80-120	80-120	80-120	-	-
41	22	80-120	80-120	-	-	-	-
42	50	80-120	80-120	-	-	-	-
43	42	80-120	80-120	-	-	-	-
44	30	80-120	80-120	80-120	-	-	-
45	18	80-120	80-120	80-120	80-120	-	-
46	30	80-120	80-120	-	-	-	-
47	40	80-120	80-120	80-120	80-120	-	-
48	35	80-120	80-120	-	-	-	-
49	28	80-120	80-120	80-120	80-120	80-120	-
50	37	80-120	80-120	80-120	80-120	80-120	80-120
51	49	80-120	80-120	80-120	-	-	-
52	30	80-120	80-120	80-120	-	-	-
53	29	80-120	80-120	-	-	-	-

54	41	90-130	90-130	80-120	80-120	-	-
55	42	80-120	80-120	80-120	-	-	-
56	37	80-120	80-120	-	-	-	-
57	18	80-120	80-120	80-120	80-120	80-120	-
58	13	80-120	80-120	-	-	-	-
59	23	80-120	80-120	80-120	80-120	80-120	80-120
60	28	80-120	80-120	-	-	-	-
61	45	80-120	80-120	80-120	80-120	80-120	-
62	15	80-120	80-120	80-120	80-120	-	-
63	50	90-130	90-130	80-120	80-120	80-120	-
64	32	80-120	80-120	-	-	-	-
65	43	80-120	80-120	80-120	80-120	80-120	80-120
66	36	80-120	80-120	80-120	80-120	80-120	-
67	38	80-120	80-120	-	-	-	-
68	35	80-120	80-120	80-120	-	-	-
69	51	80-120	80-120	80-120	-	-	-
70	55	80-120	80-120	80-120	80-120	80-120	-
71	43	80-120	80-120	80-120	-	-	-
72	46	80-120	80-120	80-120	-	-	-
73	59	80-120	80-120	-	-	-	-
74	39	80-120	80-120	80-120	80-120	80-120	-
75	55	80-120	80-120	80-120	80-120	80-120	-
76	35	80-120	80-120	80-120	80-120	-	-
77	51	80-120	80-120	-	-	-	-

78	45	80-120	80-120	80-120	80-120	-	-
79	40	80-120	80-120	80-120	-	-	-
80	17	80-120	80-120	80-120	80-120	80-120	80-120
81	50	100-140	100-140	90-130	90-130	-	-
82	50	100-140	100-140	-	-	-	-
83	20	80-120	80-120	80-120	-	-	-
84	51	80-120	80-120	80-120	-	-	-
85	55	100-140	100-140	100-140	-	-	-
86	50	80-120	80-120	80-120	80-120	-	-
87	39	80-120	80-120	80-120	-	-	-
88	47	100-120	100-120	90-120	90-130	80-120	-
89	37	80-120	80-120	80-120	-	-	-
90	40	80-120	80-120	80-120	-	-	-
91	51	100-140	90-120	90-120	90-130	-	-
92	47	80-120	80-120	80-120	80-120	80-120	80-120
93	49	80-120	80-120	80-120	80-120	80-120	-
94	39	80-120	80-120	80-120	-	-	-
95	35	80-120	80-120	80-120	80-120	-	-

Table 5.28: Comparative blood pressure values for different week treatment using *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Sr no	Drug	Total num of patients	No of patients having BP	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	18	4	6	8
2	Livercare Churna	93	10	8	2	-
3	Hepatogard forte Tablet	95	14	6	4	4

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 18 patients have hypertension. After treatment with *Eclipta prostrata* 4 patients were normalized, 6 patients slightly reduced hypertension and 8 patients remained unchanged. 93 patients of Livercare Churna group were found infected with jaundice among them 10 patients have hypertension. After treatment with Livercare Churna 8 patients were normalized, 2 patients slightly reduced hypertension. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 14 patients have hypertension. After treatment with Hepatogard forte Tablet 6 patients were normalized, 4 patients slightly reduced hypertension and 4 patients remained unchanged.

Table 5.29: Urine sugar values of the patients after treatment with *Eclipta prostrata*

Sr. no of patients	Age	Urine sugar after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	X	X	Normal	-	-	-
2	30	Normal	Normal	Normal	Normal	Normal	-
3	38	Normal	Normal	Normal	-	-	-
4	38	Normal	Normal	Normal	-	-	-
5	35	Normal	Normal	Normal	-	-	-
6	40	Normal	Normal	Normal	Normal	Normal	-
7	60	X	X	X	X	X	-
8	4.5	Normal	Normal	Normal	Normal	-	-
9	50	Normal	Normal	Normal	Normal	-	-
10	50	Normal	Normal	Normal		-	-
11	25	Normal	Normal	Normal	Normal	-	-
12	45	XX	X	X	-	-	-
13	30	Normal	Normal		-	-	-
14	24	Normal	Normal	Normal	-	-	-
15	40	Normal	Normal	Normal	Normal	-	-
16	16	Normal	Normal	Normal	-	-	-
17	50	Normal	Normal	Normal	-	-	-
18	41	Normal	Normal	-	-	-	-

19	35	Normal	Normal	Normal	Normal	Normal	-
20	49	Normal	Normal	Normal	Normal	-	-
21	9	Normal	Normal	Normal	Normal	-	-
22	32	Normal	Normal	Normal	Normal	-	-
23	9	Normal	Normal	Normal	Normal	Normal	Normal
24	47	Normal	Normal	Normal	-	-	-
25	20	Normal	Normal	Normal	Normal	Normal	Normal
26	40	Normal	Normal	Normal	Normal	-	-
27	29	Normal	Normal	Normal	Normal	Normal	Normal
28	42	Normal	Normal	Normal	Normal	-	-
29	60	Normal	Normal	Normal	Normal	Normal	Normal
30	47	Normal	Normal	Normal	Normal	Normal	-
31	9	Normal	Normal	Normal	Normal	Normal	-
32	40	Normal	Normal	Normal	-	-	-
33	17	Normal	Normal	-	-	-	-
34	27	Normal	Normal	Normal	Normal	-	-
35	50	Normal	Normal	Normal	Normal	-	-
36	53	XX	X	X	X	-	-
37	25	Normal	Normal	-	-	-	-
38	19	Normal	Normal	Normal	Normal	Normal	-
39	18	Normal	Normal	Normal	Normal	Normal	-
40	38	Normal	Normal	-	-	-	-
41	37	Normal	Normal	-	-	-	-
42	52	X	X	X	X	X	X

43	50	Normal	Normal	Normal	Normal	Normal	-
44	60	Normal	Normal	Normal	Normal	-	-
45	22	Normal	Normal	Normal	Normal	-	-
46	9	Normal	Normal	Normal	Normal	Normal	-
47	10	Normal	Normal	Normal	Normal	Normal	Normal
48	40	Normal	Normal	Normal	Normal	-	-
49	19	Normal	Normal	Normal	Normal	-	-
50	38	Normal	Normal	Normal	Normal	Normal	-
51	50	Normal	Normal	Normal	Normal	Normal	-
52	39	Normal	Normal	Normal	-	-	-
53	45	Normal	Normal	Normal	Normal	-	-
54	47	Normal	Normal	-	-	-	-
55	50	X	X	X	-	-	-
56	57	Normal	Normal	Normal	Normal	Normal	Normal
57	32	Normal	Normal	Normal	Normal	Normal	-
58	50	Normal	Normal	Normal	Normal	Normal	Normal
59	53	Normal	Normal	Normal	Normal	Normal	Normal
60	40	Normal	Normal	Normal	Normal	Normal	Normal
61	48	X	X	X	X	-	-
62	29	Normal	Normal	Normal	Normal	-	-
63	28	Normal	Normal	Normal	Normal	-	-
64	42	Normal	Normal	Normal	Normal	Normal	-
65	29	Normal	Normal	Normal	Normal	Normal	-
66	42	Normal	Normal	Normal	-	-	-

67	37	Normal	Normal	Normal	Normal	-	-
68	21	Normal	Normal	Normal	Normal	-	-
69	37	Normal	Normal	Normal	Normal	Normal	-
70	22	Normal	Normal	Normal	-	-	-
71	22	Normal	Normal	Normal	Normal	-	-
72	40	Normal	Normal	-	-	-	-
73	24	Normal	Normal	Normal	Normal	Normal	-
74	10	Normal	Normal	Normal	Normal	Normal	-
75	48	Normal	Normal	Normal	Normal	Normal	Normal
76	27	Normal	Normal	Normal	Normal	-	-
77	16	Normal	Normal	Normal	Normal	-	-
78	12	Normal	Normal	Normal	Normal	Normal	Normal
79	48	Normal	Normal	Normal	-	-	-
80	28	Normal	Normal	-	-	-	-
81	46	Normal	Normal	-	-	-	-
82	65	X	X	X	-	-	-
83	38	Normal	Normal	Normal	Normal	-	-
84	12	Normal	Normal	Normal	Normal	Normal	-
85	8	Normal	Normal	Normal	Normal	Normal	-
86	56	Normal	Normal	Normal	-	-	-
87	42	Normal	Normal	Normal	Normal	Normal	Normal
88	38	Normal	Normal	Normal	Normal	-	-
89	42	Normal	Normal	Normal	Normal	Normal	-
90	28	Normal	Normal	Normal	Normal	-	-

91	23	Normal	Normal	Normal	-	-	-
92	35	Normal	Normal	Normal	-	-	-
93	18	Normal	Normal	Normal	-	-	-
94	11	Normal	Normal	Normal	-	-	-
95	18	Normal	Normal	Normal	Normal	-	-
96	45	Normal	Normal	-	-	-	-
97	12	Normal	Normal	Normal	-	-	-
98	20	Normal	Normal	-	-	-	-

Table 5.30: Urine sugar values of the patients after treatment with Livercare Churna.

Sr. no of patients	Age	Urine sugar after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	17	Normal	Normal	Normal	-	-	-
2	47	Normal	Normal	Normal	Normal	-	-
3	49	Normal	Normal	Normal	-	-	-
4	51	X	X	X	Normal	Normal	Normal
5	31	Normal	Normal	Normal	-	-	-
6	53	Normal	Normal	Normal	Normal	-	-
7	47	Normal	Normal	Normal	Normal	-	-
8	40	Normal	Normal	Normal	Normal	Normal	Normal
9	47	Normal	Normal	Normal	Normal	Normal	-

10	50	X	X	X	Normal	Normal	-
11	44	Normal	Normal	Normal	-	-	-
12	46	Normal	Normal	Normal	Normal	Normal	Normal
13	35	Normal	Normal	Normal	Normal	-	-
14	55	X	Normal	Normal	-	-	-
15	50	XX	XX	X	X	X	-
16	60	Normal	Normal	Normal	Normal	Normal	Normal
17	43	Normal	Normal	-	-	-	-
18	45	Normal	Normal	Normal	-	-	-
19	40	Normal	Normal	Normal	Normal	Normal	Normal
20	29	Normal	Normal	Normal	-	-	-
21	44	Normal	Normal	Normal	Normal	Normal	-
22	25	Normal	Normal	Normal	Normal	Normal	-
23	17	Normal	Normal	Normal	Normal	Normal	-
24	40	Normal	Normal	-	-	-	-
25	35	Normal	Normal	Normal	Normal	Normal	-
26	25	Normal	Normal	Normal	Normal	Normal	-
27	21	Normal	Normal	Normal	Normal	Normal	-
28	52	X	X	Normal			-
29	45	Normal	Normal	Normal	Normal	Normal	-
30	62	Normal	Normal	Normal	Normal	Normal	Normal
31	50	Normal	Normal	Normal	-	-	-
32	45	Normal	Normal	Normal	Normal	-	-
33	50	Normal	Normal	Normal	Normal	Normal	-

34	30	Normal	Normal	Normal	Normal	Normal	-
35	19	Normal	Normal	Normal	Normal	Normal	-
36	45	X	X	Normal	-	-	-
37	25	Normal	Normal	Normal	Normal	-	-
38	25	Normal	Normal	Normal	Normal	-	-
39	27	Normal	Normal	Normal	Normal	Normal	-
40	17	Normal	Normal	Normal	Normal	-	-
41	57	X	X	Normal	Normal	-	-
42	45	Normal	Normal	Normal	-	-	-
43	60	Normal	Normal	Normal	-	-	-
44	49	X	X	Normal	-	-	-
45	36	Normal	Normal	Normal	-	-	-
46	49	X	X	Normal	Normal	Normal	Normal
47	50	Normal	Normal	Normal	Normal	-	-
48	40	Normal	Normal	Normal	Normal	Normal	Normal
49	40	X	X	X	Normal	Normal	-
50	39	Normal	Normal	-	-	-	-
51	41	Normal	Normal	Normal	Normal	Normal	Normal
52	45	Normal	Normal	Normal	-	-	-
53	29	Normal	Normal	Normal	Normal	-	-
54	52	X	X	Normal	-	-	-
55	50	Normal	Normal	Normal	Normal	-	-
56	49	XX	XX	X	X	X	-
57	39	Normal	Normal	-	-	-	-

58	11	Normal	Normal	Normal	-	-	-
59	19	Normal	Normal	Normal	-	-	-
60	52	Normal	Normal	Normal	Normal	-	-
61	21	Normal	Normal	Normal	Normal	Normal	-
62	29	Normal	Normal	Normal	Normal	Normal	-
63	40	Normal	Normal	Normal	-	-	-
64	55	Normal	Normal	-	-	-	-
65	50	Normal	Normal	Normal	Normal	Normal	-
66	39	Normal	Normal	Normal	-	-	-
67	38	Normal	Normal	Normal	-	-	-
68	19	Normal	Normal	Normal	Normal	-	-
69	35	Normal	Normal	Normal	Normal	Normal	-
70	45	Normal	Normal	Normal	-	-	-
71	31	Normal	Normal	Normal	Normal	-	-
72	49	Normal	Normal	-	-	-	-
73	45	Normal	Normal	-	-	-	-
74	53	Normal	Normal	Normal	-	-	-
75	48	Normal	Normal	-	-	-	-
76	20	Normal	Normal	-	-	-	-
77	17	Normal	Normal	Normal	-	-	-
78	27	Normal	Normal	Normal	Normal	Normal	Normal
79	31	Normal	Normal	Normal	-	-	-
80	50	Normal	Normal	-	-	-	-
81	35	Normal	Normal	Normal	Normal	Normal	-

82	39	Normal	Normal	-	-	-	-
83	29	Normal	Normal	-	-	-	-
84	41	Normal	Normal	-	-	-	-
85	22	Normal	Normal	-	-	-	-
86	31	Normal	Normal	Normal	Normal	-	-
87	47	Normal	Normal	-	-	-	-
88	28	Normal	Normal	Normal	-	-	-
89	12	Normal	Normal	-	-	-	-
90	41	Normal	Normal	-	-	-	-
91	36	Normal	Normal	-	-	-	-
92	44	Normal	Normal	Normal	-	-	-
93	39	Normal	Normal	Normal	-	-	-

Table 5.31: Urine sugar values of the patients after treatment with Hepatogard forte Tablet

Sr. no of patients	Age	Urine sugar after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	Normal	Normal	Normal	-	-	-
2	34	Normal	Normal	Normal	Normal	-	-
3	50	X	X	X	X	X	X
4	39	Normal	Normal	Normal	Normal	Normal	Normal
5	39	Normal	Normal	Normal	Normal	Normal	Normal

6	60	Normal	Normal	Normal	Normal	Normal	Normal
7	32	Normal	Normal	Normal	Normal	Normal	-
8	49	Normal	Normal	Normal	Normal	Normal	-
9	55	XX	XX	XX	-	-	-
10	60	X	X	X	-	-	-
11	35	Normal	Normal	Normal	Normal	-	-
12	36	Normal	Normal	Normal	-	-	-
13	58	XX	XX	XX	XX	X	X
14	40	Normal	Normal	Normal	-	-	-
15	50	Normal	Normal	Normal	-	-	-
16	29	Normal	Normal	Normal	-	-	-
17	38	Normal	Normal	Normal	-	-	-
18	42	Normal	Normal	Normal	-	-	-
19	59	XX	XX	XX	-	-	-
20	11	Normal	Normal	Normal	-	-	-
21	32	Normal	Normal	Normal	Normal	Normal	-
22	60	X	X	X	X	X	-
23	35	Normal	Normal	Normal	-	-	-
24	59	Normal	Normal	Normal	Normal	-	-
25	49	Normal	Normal	Normal	Normal	-	-
26	21	Normal	Normal	Normal	Normal	-	-
27	60	X	X	X	-	-	-
28	45	Normal	Normal	Normal	Normal	-	-
29	50	Normal	Normal	Normal	Normal	Normal	-

30	55	Normal	Normal	Normal	Normal	-	-
31	51	X	Normal	Normal	Normal	-	-
32	23	Normal	Normal	Normal	Normal	Normal	-
33	20	Normal	Normal	Normal	-	-	-
34	22	Normal	Normal	-	-	-	-
35	48	Normal	Normal	Normal	-	-	-
36	47	Normal	Normal	Normal	Normal	Normal	-
37	41	Normal	Normal	Normal	Normal	-	-
38	32	Normal	Normal	Normal	Normal	Normal	-
39	21	Normal	Normal	Normal	-	-	-
40	21	Normal	Normal	Normal	Normal	-	-
41	22	Normal	Normal	-	-	-	-
42	50	Normal	Normal	-	-	-	-
43	42	Normal	Normal	-	-	-	-
44	30	Normal	Normal	Normal	-	-	-
45	18	Normal	Normal	Normal	Normal	-	-
46	30	Normal	Normal	-	-	-	-
47	40	Normal	Normal	Normal	Normal	-	-
48	35	Normal	Normal	-	-	-	-
49	28	Normal	Normal	Normal	Normal	Normal	
50	37	Normal	Normal	Normal	Normal	Normal	Normal
51	49	Normal	Normal	Normal	-	-	-
52	30	Normal	Normal	Normal	-	-	-
53	29	Normal	Normal	-	-	-	-

54	41	X	X	X	X	-	-
55	42	Normal	Normal	Normal	-	-	-
56	37	Normal	Normal	-	-	-	-
57	18	Normal	Normal	Normal	Normal	Normal	-
58	13	Normal	Normal	-	-	-	-
59	23	Normal	Normal	Normal	Normal	Normal	Normal
60	28	Normal	Normal	-	-	-	-
61	45	X	X	X	X	X	-
62	15	Normal	Normal	Normal	Normal	-	-
63	50	Xx	X	X	X	X	-
64	32	Normal	Normal	-	-	-	-
65	43	Normal	Normal	Normal	Normal	Normal	Normal
66	36	Normal	Normal	Normal	Normal	Normal	-
67	38	Normal	Normal	-	-	-	-
68	35	Normal	Normal	Normal	-	-	-
69	51	X	X	Normal	-	-	-
70	55	Normal	Normal	Normal	Normal	Normal	-
71	43	Normal	Normal	Normal	-	-	-
72	46	Normal	Normal	Normal	-	-	-
73	59	Normal	Normal	-	-	-	-
74	39	Normal	Normal	Normal	Normal	Normal	-
75	55	X	X	X	X	X	-
76	35	Normal	Normal	Normal	Normal	-	-
77	51	Normal	Normal	-		-	-

78	45	Normal	Normal	Normal	Normal	-	-
79	40	Normal	Normal	Normal	-	-	-
80	17	Normal	Normal	Normal	Normal	Normal	Normal
81	50	XX	XX	XX	X	-	-
82	50	XX	XX	-	-	-	-
83	20	Normal	Normal	Normal	-	-	-
84	51	Normal	Normal	Normal	-	-	-
85	55	Normal	Normal	Normal	-	-	-
86	50	X	X	X	X	-	-
87	39	Normal	Normal	Normal	-	-	-
88	47	XX	XX	XX	XX	X	-
89	37	Normal	Normal	Normal	-	-	-
90	40	Normal	Normal	Normal	-	-	-
91	51	XX	XX	XX	XX	-	-
92	47	Normal	Normal	Normal	Normal	Normal	Normal
93	49	Normal	Normal	Normal	Normal	Normal	-
94	39	Normal	Normal	Normal	-	-	-
95	35	Normal	Normal	Normal	Normal	-	-

Table 5.32: Comparative urine sugar values of *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet as hepatoprotective drug

Sr. no	Drug	Total number of patients	No of patients having urine sugar	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	8	1	2	5
2	Livercare Churna	93	12	10	2	-
3	Hepatogard forte Tablet	95	18	2	4	12

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 8 patients have higher urine sugar level. After treatment with *Eclipta prostrata* 1 patients was normalized, 2 patients reduced the sugar level and 5 patients remained unchanged. 93 patients of Livercare Churna group were found infected with jaundice among them 12 patients have higher urine sugar level. After treatment with Livercare Churna 10 patients were normalized, 2 patients reduced urine sugar and no patients with unchanged urine sugar. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 18 patients have higher urine sugar level. After treatment with Hepatogard forte Tablet 2 patients were normalized, 4 patients reduced the sugar level and 12 patients remained unchanged.

Table 5.33: Urine Creatinine levels of the patients after treatment with *Eclipta prostrata.*

Sr. no of patients	Age	Urine Creatinine after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	Positive	Positive	Normal	-	-	-
2	30	Positive	Positive	Positive	-	Normal	-
3	38	Positive	Positive	Normal	-	-	-
4	38	Positive	Positive	Normal	-	-	-
5	35	Positive	Positive	Normal	-	-	-
6	40	Positive	Positive	Positive	Positive	Normal	-
7	60	Positive	Positive	Positive	Positive	Normal	-
8	4.5	Positive	Positive	Positive	Normal	-	-
9	50	Positive	Positive	Positive	Normal	-	-
10	50	Positive	Positive	Normal	-	-	-
11	25	Positive	Positive	Normal	Normal	-	-
12	45	Positive	Positive	Normal	-	-	-
13	30	Positive	Normal	-	-	-	-
14	24	Positive	Positive	Normal	-	-	-
15	40	Positive	Positive	Positive	Normal	-	-
16	16	Positive	Positive	Normal	-	-	-
17	50	Positive	Positive	Normal	-	-	-
18	41	Positive	Normal	-	-	-	-

19	35	Positive	Positive	Positive	Positive	Normal	-
20	49	Positive	Positive	Positive	Normal	-	-
21	9	Positive	Positive	Positive	Normal	-	-
22	32	Positive	Positive	Positive	Normal	-	-
23	9	Positive	Positive	Positive	Positive	Positive	Normal
24	47	Positive	Positive	Normal	-	-	-
25	20	Positive	Positive	Positive	Positive	Positive	Normal
26	40	Positive	Positive	Positive	Normal	-	-
27	29	Positive	Positive	Positive	Positive	Positive	Normal
28	42	Positive	Positive	Positive	Normal	-	-
29	60	Positive	Positive	Positive	Positive	Positive	Normal
30	47	Positive	Positive	Positive	Positive	Normal	-
31	9	Positive	Positive	Positive	Positive	Normal	-
32	40	Positive	Positive	Normal	-	-	-
33	17	Positive	Normal	-	-	-	-
34	27	Positive	Positive	Positive	Normal	-	-
35	50	Positive	Positive	Positive	Normal	-	-
36	53	Positive	Positive	Positive	Normal	-	-
37	25	Positive	Positive	-	-	-	-
38	19	Positive	Positive	Positive	Positive	Normal	-
39	18	Positive	Positive	Positive	Positive	Normal	-
40	38	Positive	Normal	-	-	-	-
41	37	Positive	Normal	-	-	-	-
42	52	Positive	Positive	Positive	Positive	Positive	Normal

43	50	Positive	Positive	Positive	Positive	Normal	-
44	60	Positive	Positive	Positive	Normal	-	-
45	22	Positive	Positive	Positive	Normal	-	-
46	9	Positive	Positive	Positive	Positive	Normal	-
47	10	Positive	Positive	Positive	Positive	Positive	Normal
48	40	Positive	Positive	Positive	Normal	-	-
49	19	Positive	Positive	Positive	Normal	-	-
50	38	Positive	Positive	Positive	Positive	Normal	-
51	50	Positive	Normal	Positive	Positive	Normal	-
52	39	Positive	Positive	Normal	-	-	-
53	45	Positive	Positive	Positive	Normal	-	-
54	47	Positive	Normal	-	-	-	-
55	50	Positive	Positive	Normal	-	-	-
56	57	Positive	Positive	Positive	Positive	Positive	Normal
57	32	Positive	Positive	Positive	Positive	Positive	-
58	50	Positive	Positive	Positive	Positive	Positive	Normal
59	53	Positive	Positive	Positive	Positive	Positive	Normal
60	40	Positive	Positive	Positive	Positive	Positive	Normal
61	48	Positive	Positive	Positive	Positive	-	-
62	29	Positive	Positive	Positive	Positive	-	-
63	28	Positive	Positive	Positive	Positive	-	-
64	42	Positive	Positive	Positive	Positive	Normal	-
65	29	Positive	Positive	Positive	Positive	Normal	-
66	42	Positive	Positive	Normal	-	-	-

67	37	Positive	Positive	Positive	Normal	-	-
68	21	Positive	Positive	Positive	Normal	-	-
69	37	Positive	Positive	Positive	Positive	Normal	-
70	22	Positive	Positive	Normal	-	-	-
71	22	Positive	Positive	Positive	Normal	-	-
72	40	Positive	Normal	-	-	-	-
73	24	Positive	Positive	Positive	Positive	Normal	-
74	10	Positive	Positive	Positive	Positive	Normal	-
75	48	Positive	Positive	Positive	Positive	Positive	Normal
76	27	Positive	Positive	Positive	Normal	-	-
77	16	Positive	Positive	Positive	Normal	-	-
78	12	Positive	Positive	Positive	Positive	Positive	Normal
79	48	Positive	Positive	Normal	-	-	-
80	28	Positive	Normal	-	-	-	-
81	46	Positive	Normal	-	-	-	-
82	65	Positive	Positive	Normal	-	-	-
83	38	Positive	Positive	Positive	Normal	-	-
84	12	Positive	Positive	Positive	Positive	Normal	-
85	8	Positive	Positive	Positive	Positive	Normal	-
86	56	Positive	Positive	Normal	-	-	-
87	42	Positive	Positive	Positive	Positive	Positive	Normal
88	38	Positive	Positive	Positive	Normal	-	-
89	42	Positive	Positive	Positive	Positive	Normal	-
90	28	Positive	Positive	Positive	Positive	-	-

91	23	Positive	Positive	Normal	-	-	-
92	35	Positive	Positive	Normal	-	-	-
93	18	Positive	Positive	Normal	-	-	-
94	11	Positive	Positive	Normal	-	-	-
95	18	Positive	Positive	Positive	Normal	-	-
96	45	Positive	Normal	-	-	-	-
97	12	Positive	Positive	Normal	-	-	-
98	20	Positive	Normal	-	-	-	-

Table 5.34: Urine Creatinine levels of the patients after treatment with Livercare Churna.

Sr. no of patients	Age	Urine Creatinine after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	17	Positive	Positive	Normal	-	-	-
2	47	Positive	Positive	Positive	Normal	-	-
3	49	Positive	Positive	Normal	-	-	-
4	51	Positive	Positive	Positive	Positive	Positive	Normal
5	31	Positive	Positive	Normal	-	-	-
6	53	Positive	Positive	Positive	Normal	-	-
7	47	Positive	Positive	Positive	Normal	-	-
8	40	Positive	Positive	Positive	Positive	Positive	Normal
9	47	Positive	Positive	Positive	Positive	Positive	-

10	50	Positive	Positive	Positive	Positive	Normal	-
11	44	Positive	Positive	Positive	-	-	-
12	46	Positive	Positive	Positive	Positive	Positive	Normal
13	35	Positive	Positive	Positive	Normal	-	-
14	55	Positive	Positive	Normal	-	-	-
15	50	Positive	Positive	Positive	Positive	Normal	-
16	60	Positive	Positive	Positive	Positive	Positive	Normal
17	43	Positive	Normal	-	-	-	-
18	45	Positive	Positive	Normal	-	-	-
19	40	Positive	Positive	Positive	Positive	Positive	Normal
20	29	Positive	Positive	Normal	-	-	-
21	44	Positive	Positive	Positive	Positive	Positive	-
22	25	Positive	Positive	Positive	Positive	Normal	-
23	17	Positive	Positive	Positive	Positive	Normal	-
24	40	Positive	Normal	-	-	-	-
25	35	Positive	Positive	Positive	Positive	Normal	-
26	25	Positive	Positive	Positive	Positive	Normal	-
27	21	Positive	Positive	Positive	Positive	Normal	-
28	52	Positive	Positive	Normal	-	-	-
29	45	Positive	Positive	Positive	Positive	Normal	-
30	62	Positive	Positive	Positive	Positive	Positive	Normal
31	50	Positive	Positive	Normal	-	-	-
32	45	Positive	Positive	Positive	Positive	-	-
33	50	Positive	Positive	Positive	Positive	Normal	-

34	30	Positive	Positive	Positive	Positive	Positive	-
35	19	Positive	Positive	Positive	Positive	Normal	-
36	45	Positive	Positive	Positive	-	-	-
37	25	Positive	Positive	Positive	Normal	-	-
38	25	Positive	Positive	Positive	Normal	-	-
39	27	Positive	Positive	Positive	Positive	Normal	-
40	17	Positive	Positive	Positive	Normal	-	-
41	57	Positive	Positive	Positive	Normal	-	-
42	45	Positive	Positive	Normal	-	-	-
43	60	Positive	Positive	Normal	-	-	-
44	49	Positive	Positive	Normal	-	-	-
45	36	Positive	Positive	Normal	-	-	-
46	49	Positive	Positive	Positive	Positive	Positive	Normal
47	50	Positive	Positive	Positive	Normal	-	-
48	40	Positive	Positive	Positive	Positive	Positive	Normal
49	40	Positive	Positive	Positive	Positive	Normal	-
50	39	Positive	Normal	-	-	-	-
51	41	Positive	Positive	Positive	Positive	Positive	Normal
52	45	Positive	Positive	Normal	-	-	-
53	29	Positive	Positive	Positive	Normal	-	-
54	52	Positive	Positive	Normal	-	-	-
55	50	Positive	Positive	Positive	Normal	-	-
56	49	Positive	Positive	Positive	Positive	Normal	-
57	39	Positive	Normal	-	-	-	-

58	11	Positive	Positive	Normal	-	-	-
59	19	Positive	Positive	Normal	-	-	-
60	52	Positive	Positive	Positive	Normal	-	-
61	21	Positive	Positive	Positive	Positive	Normal	-
62	29	Positive	Positive	Positive	Positive	Normal	-
63	40	Positive	Normal	Normal	-	-	-
64	55	Positive	Normal	-	-	-	-
65	50	Positive	Positive	Positive	Positive	Normal	-
66	39	Positive	Positive	Normal	-	-	-
67	38	Positive	Positive	Normal	-	-	-
68	19	Positive	Positive	Positive	Normal	-	-
69	35	Positive	Positive	Positive	Positive	Normal	-
70	45	Positive	Positive	Normal	-	-	-
71	31	Positive	Positive	Positive	Normal	-	-
72	49	Positive	Normal	-	-	-	-
73	45	Positive	Normal	-	-	-	-
74	53	Positive	Positive	Normal	-	-	-
75	48	Positive	Normal	-	-	-	-
76	20	Positive	Normal	-	-	-	-
77	17	Positive	Positive	Normal	-	-	-
78	27	Positive	Positive	Positive	Positive	Positive	Normal
79	31	Positive	Positive	Normal	-	-	-
80	50	Positive	Positive	-	-	-	-
81	35	Positive	Positive	Positive	Positive	Normal	-

82	39	Positive	Normal	-	-	-	-
83	29	Positive	Normal	-	-	-	-
84	41	Positive	Normal	-	-	-	-
85	22	Positive	Normal	-	-	-	-
86	31	Positive	Positive	Positive	Normal	-	-
87	47	Positive	Normal	-	-	-	-
88	28	Positive	Positive	Normal	-	-	-
89	12	Positive	Normal	-	-	-	-
90	41	Positive	Normal	-	-	-	-
91	36	Positive	Normal	-	-	-	-
92	44	Positive	Positive	Normal	-	-	-
93	39	Positive	Positive	Normal	-	-	-

Table 5.35: Urine Creatinine levels of the patients after treatment with Hepatogard forte Tablet.

Sr. no of patients	Age	Urine Creatinine after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	Positive	Positive	Normal	-	-	-
2	34	Positive	Positive	Positive	Normal	-	-
3	50	Positive	Positive	Positive	Positive	Positive	Normal
4	39	Positive	Positive	Positive	Positive	Positive	Positive
5	39	Positive	Positive	Positive	Positive	Positive	Positive

6	60	Positive	Positive	Positive	Positive	Positive	Normal
7	32	Positive	Positive	Positive	Positive	Normal	-
8	49	Positive	Positive	Positive	Positive	Normal	-
9	55	Positive	Positive	Normal	-	-	-
10	60	Positive	Positive	Normal	-	-	-
11	35	Positive	Positive	Positive	Normal	-	-
12	36	Positive	Positive	Normal	-	-	-
13	58	Positive	Positive	Positive	Positive	Positive	Normal
14	40	Positive	Positive	Normal	-	-	-
15	50	Positive	Positive	Normal	-	-	-
16	29	Positive	Positive	Normal	-	-	-
17	38	Positive	Positive	Normal	-	-	-
18	42	Positive	Positive	Normal	-	-	-
19	59	Positive	Positive	Normal	-	-	-
20	11	Positive	Positive	Normal	-	-	-
21	32	Positive	Positive	Positive	Positive	Normal	-
22	60	Positive	Positive	Positive	Positive	Normal	-
23	35	Positive	Positive	Normal	-	-	-
24	59	Positive	Positive	Positive	Normal	-	-
25	49	Positive	Positive	Positive	Normal	-	-
26	21	Positive	Positive	Positive	Normal	-	-
27	60	Positive	Positive	Normal	-	-	-
28	45	Positive	Positive	Positive	Normal	-	-
29	50	Positive	Positive	Positive	Positive	Normal	-

30	55	Positive	Positive	Positive	Normal	-	-
31	51	Positive	Positive	Positive	Normal	-	-
32	23	Positive	Positive	Positive	Positive	Normal	-
33	20	Positive	Positive	Normal	-	-	-
34	22	Positive	Normal	-	-	-	-
35	48	Positive	Positive	Normal	-	-	-
36	47	Positive	Positive	Positive	Positive	Normal	-
37	41	Positive	Positive	Positive	Normal	-	-
38	32	Positive	Positive	Positive	Positive	Normal	-
39	21	Positive	Positive	Normal	-	-	-
40	21	Positive	Positive	Positive	Normal	-	-
41	22	Positive	Normal	-	-	-	-
42	50	Positive	Normal	-	-	-	-
43	42	Positive	Normal	-	-	-	-
44	30	Positive	Positive	Positive	-	-	-
45	18	Positive	Positive	Positive	Normal	-	-
46	30	Positive	Normal	-	-	-	-
47	40	Positive	Positive	Positive	Normal	-	-
48	35	Positive	Normal	-	-	-	-
49	28	Positive	Positive	Positive	Normal	Normal	-
50	37	Positive	Positive	Positive	Positive	Positive	Normal
51	49	Positive	Positive	Normal	-	-	-
52	30	Positive	Positive	Normal	-	-	-
53	29	Positive	Normal	-	-	-	-

54	41	Positive	Positive	Positive	Normal	-	-
55	42	Positive	Positive	Normal	-	-	-
56	37	Positive	Normal	-	-	-	-
57	18	Positive	Positive	Positive	Positive	Normal	-
58	13	Positive	Normal	-	-	-	-
59	23	Positive	Positive	Positive	Positive	Positive	Normal
60	28	Positive	Normal	-	-	-	-
61	45	Positive	Positive	Positive	Positive	Normal	-
62	15	Positive	Positive	Positive	Normal	-	-
63	50	Positive	Positive	Positive	Positive	Normal	-
64	32	Positive	Normal	-	-	-	-
65	43	Positive	Positive	Positive	Positive	Positive	Normal
66	36	Positive	Positive	Positive	Positive	Normal	-
67	38	Positive	Normal	-	-	-	-
68	35	Positive	Positive	Normal	-	-	-
69	51	Positive	Positive	Normal	-	-	-
70	55	Positive	Positive	Positive	Positive	Normal	-
71	43	Positive	Positive	Normal	-	-	-
72	46	Positive	Positive	Normal	-	-	-
73	59	Positive	Normal	-	-	-	-
74	39	Positive	Positive	Positive	Positive	Normal	-
75	55	Positive	Positive	Positive	Positive	Normal	-
76	35	Positive	Positive	Positive	Normal	-	-
77	51	Positive	Normal	-	-	-	-

78	45	Positive	Positive	Positive	Normal	-	-
79	40	Positive	Positive	Normal	-	-	-
80	17	Positive	Positive	Positive	Positive	Positive	Normal
81	50	Positive	Positive	Positive	Normal	-	-
82	50	Positive	Normal	-	-	-	-
83	20	Positive	Positive	Normal	-	-	-
84	51	Positive	Positive	Normal	-	-	-
85	55	Positive	Positive	Normal	-	-	-
86	50	Positive	Positive	Positive	Normal	-	-
87	39	Positive	Positive	Normal	-	-	-
88	47	Positive	Positive	Positive	Positive	Normal	-
89	37	Positive	Positive	Normal	-	-	-
90	40	Positive	Positive	Normal	-	-	-
91	51	Positive	Positive	Positive	Normal	-	-
92	47	Positive	Positive	Positive	Positive	Positive	Normal
93	49	Positive	Positive	Positive	Positive	Normal	-
94	39	Positive	Positive	Normal	-	-	-
95	35	Positive	Positive	Positive	Normal	-	-

Table 5.36: Comparative urine Creatinine levels for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr. no	Drug	Total number of patients	No of patients having Jaundice	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	98	98	-	-
2	Livercare Churna	93	93	93	-	-
3	Hepatogard forte Tablet	95	95	93	02	-

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 98 patients were urine Creatinine positive. After treatment with *Eclipta prostrata* all 98 patients were normalized. 93 patients of Livercare Churna group were found infected with jaundice among them 93 patients were urine Creatinine positive. After treatment with Livercare Churna all 93 patients were normalized. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 95 patients were urine Creatinine positive. After treatment with Hepatogard forte Tablet all 93 patients were normalized and 2 patients decreases the urine Creatinine level.

Table 5.37: HBsAg values of the patients after treatment with *Eclipta prostrata*

Sr. no of patients	Age	HBsAg after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	65	Negative	Negative	Negative	-	-	-
2	30	Negative	Negative	Negative	-	Negative	-
3	38	Negative	Negative	Negative	-	-	-
4	38	Negative	Negative	Negative	-	-	-
5	35	Negative	Negative	Negative	-	-	-
6	40	Positive	Negative	Negative	Negative	Negative	-
7	60	Positive	Negative	Negative	Negative	Negative	-
8	4.5	Positive	Negative	Negative	Negative	-	-
9	50	Negative	Negative	Negative	Negative	-	-
10	50	Negative	Negative	Negative	-	-	-
11	25	Positive	Negative	Negative	Negative	-	-
12	45	Negative	Negative	Negative	-	-	-
13	30	Negative	Negative	-	-	-	-
14	24	Negative	Negative	Negative	-	-	-
15	40	Positive	Negative	Negative	Negative	-	-
16	16	Negative	Negative	Negative	-	-	-
17	50	Positive	Negative	Negative	-	-	-
18	41	Negative	Negative	-	-	-	-

19	35	Negative	Negative	Negative	Negative	Negative	-
20	49	Negative	Negative	Negative	Negative	-	-
21	9	Negative	Negative	Negative	Negative	-	-
22	32	Negative	Negative	Negative	Negative	-	-
23	9	Negative	Negative	Negative	Negative	Negative	Negative
24	47	Negative	Negative	Negative	-	-	-
25	20	Negative	Negative	Negative	Negative	Negative	Negative
26	40	Positive	Negative	Negative	Negative	-	-
27	29	Negative	Negative	Negative	Negative	Negative	Negative
28	42	Negative	Negative	Negative	Negative	-	-
29	60	Positive	Negative	Negative	Negative	Negative	Negative
30	47	Positive	Negative	Negative	Negative	Negative	-
31	9	Negative	Negative	Negative	Negative	Negative	-
32	40	Negative	Negative	Negative	-	-	-
33	17	Negative	Negative	-	-	-	-
34	27	Negative	Negative	Negative	Negative	-	-
35	50	Positive	Negative	Negative	Negative	-	-
36	53	Positive	Negative	Negative	Negative	-	-
37	25	Negative	Negative	-	-	-	-
38	19	Negative	Negative	Negative	Negative	Negative	-
39	18	Negative	Negative	Negative	Negative	Negative	-
40	38	Negative	Negative	-	-	-	-
41	37	Negative	Negative	-	-	-	-
42	52	Negative	Negative	Negative	Negative	Negative	Negative

43	50	Negative	Negative	Negative	Negative	Negative	-
44	60	Positive	Negative	Negative	Negative	-	-
45	22	Negative	Negative	Negative	Negative	-	-
46	9	Negative	Negative	Negative	Negative	Negative	-
47	10	Negative	Negative	Negative	Negative	Negative	Negative
48	40	Positive	Negative	Negative	Negative	-	-
49	19	Negative	Negative	Negative	Negative	-	-
50	38	Negative	Negative	Negative	Negative	Negative	-
51	50	Positive	Negative	Negative	Negative	Negative	-
52	39	Negative	Negative	Negative	-	-	-
53	45	Positive	Negative	Negative	Negative	-	-
54	47	Negative	Negative	-	-	-	-
55	50	Negative	Negative	Negative	-	-	-
56	57	Positive	Negative	Negative	Negative	Negative	Negative
57	32	Negative	Negative	Negative	Negative	Negative	-
58	50	Negative	Negative	Negative	Negative	Negative	Negative
59	53	Negative	Negative	Negative	Negative	Negative	Negative
60	40	Positive	Negative	Negative	Negative	Negative	Negative
61	48	Negative	Negative	Negative	Negative	-	-
62	29	Negative	Negative	Negative	Negative	-	-
63	28	Negative	Negative	Negative	Negative	-	-
64	42	Negative	Negative	Negative	Negative	Negative	-
65	29	Negative	Negative	Negative	Negative	Negative	-
66	42	Negative	Negative	Negative	-	-	-

67	37	Positive	Negative	Negative	Negative	-	-
68	21	Negative	Negative	Negative	Negative	-	-
69	37	Negative	Negative	Negative	Negative	Negative	-
70	22	Negative	Negative	Negative	-	-	-
71	22	Negative	Negative	Negative	Negative	-	-
72	40	Negative	Negative	-	-	-	-
73	24	Negative	Negative	Negative	Negative	Negative	-
74	10	Positive	Negative	Negative	Negative	Negative	-
75	48	Positive	Negative	Negative	Negative	Negative	Negative
76	27	Negative	Negative	Negative	Negative	-	-
77	16	Negative	Negative	Negative	Negative	-	-
78	12	Positive	Negative	Negative	Negative	Negative	Negative
79	48	Negative	Negative	Negative	-	-	-
80	28	Negative	Negative	-	-	-	-
81	46	Negative	Negative	-	-	-	-
82	65	Negative	Negative	Negative	-	-	-
83	38	Negative	Negative	Negative	Negative	-	-
84	12	Negative	Negative	Negative	Negative	Negative	-
85	8	Positive	Negative	Negative	Negative	Negative	-
86	56	Negative	Negative	Negative	-	-	-
87	42	Positive	Negative	Negative	Negative	Negative	Negative
88	38	Negative	Negative	Negative	Negative	-	-
89	42	Negative	Negative	Negative	Negative	Negative	-
90	28	Negative	Negative	Negative	Negative	-	-

91	23	Negative	Negative	Negative	-	-	-
92	35	Negative	Negative	Negative	-	-	-
93	18	Negative	Negative	Negative	-	-	-
94	11	Negative	Negative	Negative	-	-	-
95	18	Negative	Negative	Negative	Negative	-	-
96	45	Negative	Negative	-	-	-	-
97	12	Negative	Negative	Negative	-	-	-
98	20	Negative	Negative	-	-	-	-

Table 5.38: HBsAg values of the patients after treatment with Livercare Churna

Sr. no of patients	Age	HBsAg after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	17	Negative	Negative	-	-	-	-
2	47	Negative	Negative	Negative	-	-	-
3	49	Negative	Negative	-	-	-	-
4	51	Positive	Negative	Negative	Negative	Negative	Negative
5	31	Negative	Negative	-	-	-	-
6	53	Negative	Negative	Negative	-	-	-
7	47	Positive	Negative	Negative	-	-	-
8	40	Positive	Negative	Negative	Negative	Negative	Negative
9	47	Positive	Negative	Negative	Negative	-	-

10	50	Negative	Negative	Negative	Negative	-	-
11	44	Negative	Negative	-	-	-	-
12	46	Positive	Negative	Negative	Negative	Negative	Negative
13	35	Negative	Negative	Negative	-	-	-
14	55	Positive	Negative	-	-	-	-
15	50	Positive	Negative	Negative	Negative	-	-
16	60	Positive	Negative	Negative	Negative	Negative	Negative
17	43	Negative	-	-	-	-	-
18	45	Positive	Negative	-	-	-	-
19	40	Positive	Negative	Negative	Negative	Negative	Negative
20	29	Negative	Negative	-	-	-	-
21	44	Negative	Negative	Negative	Negative	-	-
22	25	Positive	Negative	Negative	Negative	-	-
23	17	Negative	Negative	Negative	Negative	-	-
24	40	Negative	-	-	-	-	-
25	35	Positive	Negative	Negative	Negative	-	-
26	25	Positive	Negative	Negative	Negative	-	-
27	21	Negative	Negative	Negative	Negative	-	-
28	52	Negative	Negative	-	-	-	-
29	45	Negative	Negative	Negative	Negative	-	-
30	62	Positive	Negative	Negative	Negative	Negative	Negative
31	50	Negative	Negative	-	-	-	-
32	45	Negative	Negative	Negative	-	-	-
33	50	Positive	Negative	Negative	Negative	-	-

34	30	Negative	Negative	Negative	Negative	-	-
35	19	Positive	Negative	Negative	Negative	-	-
36	45	Negative	Negative	-	-	-	-
37	25	Negative	Negative	Negative	-	-	-
38	25	Positive	Negative	Negative	-	-	-
39	27	Negative	Negative	Negative	Negative	-	-
40	17	Negative	Negative	Negative	-	-	-
41	57	Negative	Negative	Negative	-	-	-
42	45	Negative	Negative	-	-	-	-
43	60	Negative	Negative	-	-	-	-
44	49	Negative	Negative	-	-	-	-
45	36	Negative	Negative	-	-	-	-
46	49	Positive	Negative	Negative	Negative	Negative	Negative
47	50	Negative	Negative	Negative	-	-	-
48	40	Positive	Negative	Negative	Negative	Negative	Negative
49	40	Negative	Negative	Negative	Negative	-	-
50	39	Negative	-	-	-	-	-
51	41	Positive	Negative	Negative	Negative	Negative	Negative
52	45	Negative	Negative	-	-	-	-
53	29	Negative	Negative	Negative	-	-	-
54	52	Negative	Negative	-	-	-	-
55	50	Negative	Negative	Negative	-	-	-
56	49	Positive	Negative	Negative	Negative	-	-
57	39	Negative	-	-	-	-	-

58	11	Negative	Negative	-	-	-	-
59	19	Negative	Negative	-	-	-	-
60	52	Negative	Negative	Negative	-	-	-
61	21	Positive	Negative	Negative	Negative	-	-
62	29	Negative	Negative	Negative	Negative	-	-
63	40	Negative	Negative	-	-	-	-
64	55	Negative	-	-	-	-	-
65	50	Positive	Negative	Negative	Negative	-	-
66	39	Negative	Negative	-	-	-	-
67	38	Negative	Negative	-	-	-	-
68	19	Negative	Negative	Negative	-	-	-
69	35	Positive	Negative	Negative	Negative	-	-
70	45	Negative	Negative	-	-	-	-
71	31	Negative	Negative	Negative	-	-	-
72	49	Negative	-	-	-	-	-
73	45	Negative	-	-	-	-	-
74	53	Negative	Negative	-	-	-	-
75	48	Negative	-	-	-	-	-
76	20	Negative	-	-	-	-	-
77	17	Negative	Negative	-	-	-	-
78	27	Positive	Negative	Negative	Negative	Negative	Negative
79	31	Negative	Negative	-	-	-	-
80	50	Positive	Negative	-	-	-	-
81	35	Positive	Negative	Negative	Negative	-	-

82	39	Negative	-	-	-	-	-
83	29	Negative	-	-	-	-	-
84	41	Negative	-	-	-	-	-
85	22	Positive	-	-	-	-	-
86	31	Positive	Negative	Negative	-	-	-
87	47	Negative	-	-	-	-	-
88	28	Negative	Negative	-	-	-	-
89	12	Negative	-	-	-	-	-
90	41	Negative	-	-	-	-	-
91	36	Negative	-	-	-	-	-
92	44	Negative	Negative	-	-	-	-
93	39	Positive	Negative	-	-	-	-

Table 5.39: HBsAg values of the patients after treatment with Hepatogard forte Tablet.

Sr. no of patients	Age	HBsAg after different weeks treatment					
		Initial (zero week)	First	Second	Third	Fourth	Sixth
1	32	Negative	Negative	Negative	-	-	-
2	34	Negative	Negative	Negative	Negative	-	-
3	50	Negative	Negative	Negative	Negative	Negative	Negative
4	39	Positive	Negative	Negative	Negative	Negative	Negative
5	39	Positive	Negative	Negative	Negative	Negative	Negative

6	60	Positive	Negative	Negative	Negative	Negative	Negative
7	32	Negative	Negative	Negative	Negative	Negative	-
8	49	Negative	Negative	Negative	Negative	Negative	-
9	55	Negative	Negative	Negative	-	-	-
10	60	Negative	Negative	Negative	-	-	-
11	35	Negative	Negative	Negative	Negative	-	-
12	36	Negative	Negative	Negative	-	-	-
13	58	Positive	Negative	Negative	Negative	Negative	Negative
14	40	Positive	Negative	Negative	-	-	-
15	50	Negative	Negative	Negative	-	-	-
16	29	Negative	Negative	Negative	-	-	-
17	38	Negative	Negative	Negative	-	-	-
18	42	Positive	Negative	Negative	-	-	-
19	59	Negative	Negative	Negative	-	-	-
20	11	Negative	Negative	Negative	-	-	-
21	32	Negative	Negative	Negative	Negative	Negative	-
22	60	Positive	Negative	Negative	Negative	Negative	-
23	35	Negative	Negative	Negative	-	-	-
24	59	Negative	Negative	Negative	Negative	-	-
25	49	Negative	Negative	Negative	Negative	-	-
26	21	Positive	Negative	Negative	Negative	-	-
27	60	Negative	Negative	Negative	-	-	-
28	45	Negative	Negative	Negative	Negative	-	-
29	50	Negative	Negative	Negative	Negative	Negative	-

30	55	Positive	Negative	Negative	Negative	-	-
31	51	Negative	Negative	Negative	Negative	-	-
32	23	Negative	Negative	Negative	Negative	Negative	-
33	20	Negative	Negative	Negative	-	-	-
34	22	Negative	Negative	-	-	-	-
35	48	Negative	Negative	Negative	-	-	-
36	47	Negative	Negative	Negative	Negative	Negative	-
37	41	Negative	Negative	Negative	Negative	-	-
38	32	Negative	Negative	Negative	Negative	Negative	-
39	21	Negative	Negative	Negative	-	-	-
40	21	Negative	Negative	Negative	Negative	-	-
41	22	Negative	Negative	-	-	-	-
42	50	Negative	Negative	-	-	-	-
43	42	Negative	Negative	-	-	-	-
44	30	Negative	Negative	Negative	-	-	-
45	18	Positive	Negative	Negative	Negative	-	-
46	30	Negative	Negative	-	-	-	-
47	40	Negative	Negative	Negative	Negative	-	-
48	35	Negative	Negative	-	-	-	-
49	28	Positive	Negative	Negative	Negative	Negative	-
50	37	Positive	Negative	Negative	Negative	Negative	Negative
51	49	Negative	Negative	Negative	-	-	-
52	30	Positive	Negative	Negative	-	-	-
53	29	Negative	Negative	-	-	-	-

54	41	Negative	Negative	Negative	Negative	-	-
55	42	Negative	Negative	Negative	-	-	-
56	37	Negative	Negative	-	-	-	-
57	18	Positive	Negative	Negative	Negative	Negative	-
58	13	Negative	Negative	-	-	-	-
59	23	Positive	Negative	Negative	Negative	Negative	Negative
60	28	Negative	Negative	-	-	-	-
61	45	Negative	Negative	Negative	Negative	Negative	-
62	15	Negative	Negative	Negative	Negative	-	-
63	50	Positive	Negative	Negative	Negative	Negative	-
64	32	Negative	Negative	-	-	-	-
65	43	Negative	Negative	Negative	Negative	Negative	Negative
66	36	Positive	Negative	Negative	Negative	Negative	-
67	38	Negative	Negative	-	-	-	-
68	35	Negative	Negative	Negative	-	-	-
69	51	Negative	Negative	Negative	-	-	-
70	55	Positive	Negative	Negative	Negative	Negative	-
71	43	Negative	Negative	Negative	-	-	-
72	46	Negative	Negative	Negative	-	-	-
73	59	Negative	Negative	-	-	-	-
74	39	Negative	Negative	Negative	Negative	Negative	-
75	55	Positive	Negative	Negative	Negative	Negative	-
76	35	Negative	Negative	Negative	Negative	-	-
77	51	Negative	Negative	-	-	-	-

78	45	Negative	Negative	Negative	Negative	-	-
79	40	Negative	Negative	Negative	-	-	-
80	17	Positive	Negative	Negative	Negative	Negative	Negative
81	50	Positive	Negative	Negative	Negative	-	-
82	50	Negative	Negative	-	-	-	-
83	20	Negative	Negative	Negative	-	-	-
84	51	Negative	Negative	Negative	-	-	-
85	55	Negative	Negative	Negative	-	-	-
86	50	Negative	Negative	Negative	Negative	-	-
87	39	Positive	Negative	Negative	-	-	-
88	47	Negative	Negative	Negative	Negative	Negative	-
89	37	Positive	Negative	Negative	-	-	-
90	40	Negative	Negative	Negative	-	-	-
91	51	Negative	Negative	Negative	Negative	-	-
92	47	Positive	Negative	Negative	Negative	Negative	Negative
93	49	Positive	Negative	Negative	Negative	Negative	-
94	39	Positive	Negative	Negative	-	-	-
95	35	Positive	Negative	Negative	Negative	-	-

Table 5.40: Comparative HBsAg values for different week treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr no	Drug	Total no of patients	No of patients having Hepatitis B	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	23	23	-	-
2	Livercare Churna	93	30	30	-	-
3	Hepatogard forte Tablet	95	27	27	-	-

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 23 patients were Hepatitis B positive. After treatment with *Eclipta prostrata* all 23 patients were normalized. 93 patients of Livercare Churna group were found infected with jaundice among them 30 patients were Hepatitis B positive. After treatment with Livercare Churna all 30 patients were normalized. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 27 patients were Hepatitis B positive. After treatment with Hepatogard forte Tablet all 27 patients were normalized.

Table 5.41: Comparative asthma values for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Sr. no	Drug	Total no. of patients	No of patients having Asthma	No. of patients Normalized from asthma	Reduction in severity of asthma	No of patients remain unchanged
1	*Eclipta prostrata*	98	3	-	3	-
2	Livercare Churna	93	2	-	2	-
3	Hepatogard forte Tablet	95	2	-	1	1

During clinical study selected 98 patients of *Eclipta prostrata* group were found to be infected with jaundice among them 3 patients had problem of asthma. After treatment with *Eclipta prostrata,* there was reduction in asthmatic severity in all the three patients. 93 patients of Livercare Churna group were found infected with jaundice among them 2 patients had a problem of asthma. After treatment with Livercare Churna, there was reduction in asthmatic severity in all the two patients. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 2 patients had a problem of asthma. After treatment with Hepatogard forte Tablet there was improvement in the condition of asthmatic one patient while there was no improvement in another patient in asthma.

Table 5.42: Comparative hair growth values for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet.

Sr. no	Drug	Total no. of patients	Increase in hair growth in number of patients	Remain unchanged in number of patients
1	*Eclipta prostrata*	98	66	32
2	Livercare Churna	93	18	75
3	Hepatogard forte Tablet	95	13	82

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them patient's hair growth was observed. After treatment with *Eclipta prostrata* 66 patients have shown about 1-2 cm growth of hair. 32 patients remained unchanged. 93 patients of Livercare Churna group were found infected with jaundice among them patient's hair growth was observed. After treatment with Livercare Churna 18 patients have shown about 1-1.5 cm growth of hair and 75 patients remained unchanged. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them patient's hair growth was observed. After treatment with Hepatogard forte Tablet 13 patients have shown about 1 cm growth of hair and 82 patients remained unchanged.

Table 5.43: Comparative kidney stone study for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr no	Drug	Total no. of patients	No of patients having Kidney stone	Patient number/stone size / place	Stone size after treatment
1	*Eclipta prostrata*	98	2	57/5mm/right kidney 6/4mm/left kidney	3mm 4mm
2	Livercare Churna	93	1	66/ 6mm / left kidney	4mm
3	Hepatogard forte Tablet	95	-	-	-

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 2 patients have complain of pain of kidney stone. Pain and Sonography report showed presence of stone. After the treatment with *Eclipta prostrata* there was reduction in the stone size from 5mm to 3mm and in one patient there was no change in the stone size. 93 patients of Livercare Churna group were found infected with jaundice among them 1 patient showed presence of kidney stone in Sonography report. After the treatment with Livercare Churna the size of stone was reduced from 6mm to 4mm.

Table 5.44: Comparative pimples values for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr no	Drug	Total no. of patients	No of patients having Pimples	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	3	-	1	2
2	Livercare Churna	93	7	-	5	2
3	Hepatogard forte Tablet	95	4	-	2	2

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 3 patients have pimple. After the treatment with *Eclipta prostrata* there was reduction in size in 1 patient and in 2 patients it remained unchanged. 93 patients of Livercare Churna group were found infected with jaundice among them 7 patients have pimples. After treatment with Livercare Churna no patients was normalized but there was reduction in pimples size in 5 patients and it remained unchanged in 2 patients. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 4 patients have pimples. After treatment with Hepatogard forte Tablet there was reduction pimple size in 2 patients and no change in remaining 2 patients.

Table 5.45: Comparative cough values for different weeks treatment *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr. no	Drug	Total no of patients	No of patients having Cough	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	3	-	2	1
2	Livercare Churna	93	2	-	1	1
3	Hepatogard forte Tablet	95	2	-	1	1

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 3 patients have problem of cough. After the treatment with *Eclipta prostrata* there was relief in cough in 2 patients and 1 patient remained unchanged. 93 patients of Livercare Churna group were found infected with jaundice among them 2 patients have problem of cough. After the treatment with Livercare Churna there was relief in cough of one patient and 1 patient remained unchanged. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 2 patients have problem of cough. After the treatment with Hepatogard forte Tablet there was relief in cough of 1 patient and 1 patient remained unchanged.

Table 5.46: Comparative study of arthritis condition for different weeks treatment with *Eclipta prostrata*, Livercare Churna and Hepatogard forte Tablet

Sr. no	Drug	Total no of patients	No of patients having Arthritis	Normalized	Reduced	Remain unchanged
1	*Eclipta prostrata*	98	3	-	-	3
2	Livercare Churna	93	2	-	1	1
3	Hepatogard forte Tablet	95	1	-	-	1

During clinical study selected 98 patients of *Eclipta prostrata* group were found infected with jaundice among them 3 patients have a problem of arthritis. After the treatment with *Eclipta prostrata* there was no improvement in arthritis of above three patients. 93 patients of Livercare Churna group were found infected with jaundice among them 2 patients have a problem of arthritis. After the treatment with Livercare Churna there was relief in pain of arthritis in 1 patient and 1 patient remained unchanged. 95 patients of Hepatogard forte Tablet group were found infected with jaundice among them 1 patient has a problem of arthritis. After the treatment with Hepatogard forte Tablet there was no improvement in the pain of above arthritic patient.

Summary

SUMMARY

Liver is a versatile organ in the body concerned with regulation of internal chemical environment. Therefore, damage to the liver inflicted by hepatotoxic agents is of grave consequence. There is an ever increasing need for an agent which could protect liver damage especially of one which facilitates regeneration by the proliferation of parenchymal cells after damage and arrests growth of fibrous tissue.

In the present study of hepatoprotective activity was observed in the patients having liver damage.

- In the present study, fresh herb of *Eclipta prostrata* was collected, authentified and shade dried. The dried material was reduced to a powder of required particle size.
- Study of physicochemical parameters of fresh powdered material of *Eclipta prostrata* was carried out which comply with the parameters given in Ayurvedic Pharmacopoeia of India and Indian herbal Pharmacopoeia.
- Marketed hepatoprotective formulations (Hepatogaurd forte Tablet and Livercare Churna) were collected from the local market. On TLC study the alcoholic extract of above two formulations and the collected *Eclipta prostrata* herb showed presence of wedelolactone an active constituent of *Eclipta prostrata.*
- Evaluation of parameters such as SGPT, Billirubin, Hb, Creatinine, HBsAg, urine sugar were carried out in the patients of jaundice after forming an Ethical committee and taking the written consent of the patients.

- Treatment with *Eclipta prostrata* powder, Livercare Churna and Hepatogard forte Tablets orally for the period of 1 to 3weeks, to 4 and 6weeks was carried out as per severity of the condition and recovery of the patients.
- Evaluation parameters such as SGPT, Billirubin showed significant P value <0.001 on treatment with *Eclipta prostrata* herb powder, Livercare Churna and Hepatogard forte Tablets.
- Drug *Eclipta prostrata*, and marketed formulation Livercare Churna showed better hepatoprotective effects than marketed formulation Hepatogaurd forte Tablet.
- There was also improvement in Hb, reduction in blood pressure, urine sugar, removal of HBsAg, reduction in kidney stone size, reduction in asthmatic discomfort, reduction in pimples, increase in hair growth.
- The multiple claims described for a single herb in Ayurveda or traditional system of medicines seems to be true. *Eclipta prostrata* and its formulations have hepatoprotective activity and also tonic (increase Hb %), Hair tonic (increasing hair length), reduce blood pressure, dissolve kidney stone, useful in asthma, cough, etc.

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Annexure

ANNEXURE

Annexure I

Eclipta Prostrata is utilized as Hepatoprotective drug

1) Patients name:
2) Address:

3) Contact number:
4) Patients age:
5) Patients sex:
6) Patients weight:
7) Patients diagnosis: Hepatitis A/ Hepatitis B/ Hepatitis C

8) Drug is given:
   (a) Eclipta Prostrata
   (b) Hepatogard forte
   (c) Liver care

9) Dose of drug: OD/BD/TD

10) Duration of illness:1) One day 2)2-3 days 3)Week
    4) Fort night 5) Month 6) Chronic

11) Patient habituated like:
    - House wife yes/no
    - Farmer yes/no
    - Business yes/no
    - Smoking yes/no
    - Tobacco consumption yes/no
    - Alcohol consumption yes/no
    - Narcotic consumption yes/no
    - Pregnancy yes/no
    - Feeding yes/no

12) Laboratory tests

SR no	SGPT Liver problem	HB (tonicity)	Urine (Creatinine)	Billirubin	Urine Sugar (Diabetes)	HBsAg
1st						
2nd						
3rd						
4th						
6th						

13) Patient improvement in other disease

SR no	Blood pressure	Kidney stone	Hair growth/ dandruff	Pimples	Arthritis	Asthma	Cough
1st							
2nd							
3rd							
4th							
6th							

Annexure II

Date: 05/10/2006

ETHICAL COMMITTEE MEETING

Ethical committee for Clinical trial of *Phyllanthus amarus* and *Eclipta prostrata* as hepatoprotective and their marketed formulations.

For liver disease (jaundice, hepatitis) there is a no modern medicines mostly Ayurvedic formulation are prescribed along with B- complex, sorbitol and rest. Actually herbal drugs / ayurvedic drugs have activity in liver disease. For above drugs we do not have clinical trial data / documentation. If we have enough clinical data we can strongly advice and market these drug.

1) We want to study effect of the marketed formulation in patient with jaundice and hepatitis B.
2) We want to also study effect of single herb in patient with jaundice and hepatitis.
3) Which is prescribed in ayurveda and is reported to have very good hepatoprotective action in pharmacological and clinical studies.
4) We want to see effect of these ayurvedic formulation and the herbs on other parameter on body like hemoglobin, blood sugar, hair, hair color, skin, etc.

For these purpose we form a advisory committee to advise the workers. The committee consists of a social worker, a scientist, a modern physician, modern surgeon and modern advocate.

Name	Address	sign
Social worker **Dr. P. G. Shah** M.D. Medicine District Chairman and Past president of Lions Club, Bayad.	Shreeji Heart and Medical Hospital, Sanjivani complex Bayad	
Committee member **Dr. M. S. Patel** M.S.	Gayatri Surgical Hospital and Sonography clinic, Sanjivani complex Bayad	
Committee member **Dr. S. P. Shah** M.D. D.T.C.D. Physician	Anand hospital, Uday complex. near Bus stand, Bayad	
Research scientist **Dr. N. M. Patel** M. Pharm. Ph.D.	B. M. Shah College of Pharmaceutical Edu. and Res, Modasa.	
Advocate **Mr. A. M. Chauhan** B.A., L.L.B.	Giriraj society. Bayad.	
Project in charge **Dr. M. J. Shah.** M.S.	Sapan hospital and Sonography clinic. Bayad	
Project in charge **Dr. B. H. Patel** B.S.A.M.M.R.S.H.	Sapan hospital and Sonography clinic. Bayad	
Research guide **Dr. K. N. Patel** M. Pharm. Ph.D.	Arihant school of pharmacy and bio research institute, Adalaj, Ahmedabad	
Research student **Mr. Jitendra S. Patel** M. Pharm.	H. N. Shukla College of Pharmaceutical Edu. and Res., Rajkot	J. S. Patel
Research student **Mrs. Hemangi J. Patel** M. Pharm.	H. N. Shukla College of Pharmaceutical Edu. and Res., Rajkot	H. J Patel

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Annexure III

Date: 07/06/2007

ETHICAL COMMITTEE MEETING

Ethical committee for Clinical trial of *Phyllanthus amarus* and *Eclipta prostrata* as hepatoprotective and their marketed formulations.

We want to study the effect of these herbs and herbal formulation in the liver patients. We want to systematically study the gradual change / improvement in body profile like SGPT , Billirubin, Urine, Blood sugar, Hb, Cholesterol, etc. We plan to give these drugs to the liver patients at normal cost for the test. We take consent letter and study the effect for three weeks under the guidance of advisory committee / ethical committee.

For these purpose we form a advisory committee to advise the workers. The committee consists of a social worker, a scientist, a modern physician, modern surgeon and modern advocate.

1

Name	Address	sign
Social worker **Dr. P. G. Shah** M.D. Medicine District Chairman and Past president of Lions Club, Bayad.	Shreeji Heart and Medical Hospital, Sanjivani complex Bayad	
Committee member **Dr. M. S. Patel** M.S.	Gayatri Surgical Hospital and Sonography clinic, Sanjivani complex Bayad	
Committee member **Dr. S. P. Shah** M.D. D.T.C.D. Physician	Anand hospital, Uday complex, near Bus stand, Bayad	
Research scientist **Dr. N. M. Patel** M. Pharm. Ph.D.	B. M. Shah College of Pharmaceutical Edu. and Res, Modasa.	
Advocate **Mr. A. M. Chauhan** B.A., L.L.B.	Giriraj society, Bayad.	
Project in charge **Dr. M. J. Shah.** M.S.	Sapan hospital and Sonography clinic, Bayad	
Project in charge **Dr. B. H. Patel** B.S.A.M.M.R.S.H.	Sapan hospital and Sonography clinic, Bayad	
Research guide **Dr. K. N. Patel** M. Pharm. Ph.D.	Arihant school of pharmacy and bio research institute, Adalaj, Ahmedabad	
Research student **Mr. Jitendra S. Patel** M. Pharm.	H. N. Shukla College of Pharmaceutical Edu. and Res., Rajkot	J. S. Patel
Research student **Mrs. Hemangi J. Patel** M. Pharm.	H. N. Shukla College of Pharmaceutical Edu. and Res., Rajkot	H. J Patel

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Annexure IV

ગાયત્રી સર્જીકલ હોસ્પિટલ અને સોનોગ્રાફી ક્લિનીક

સંજીવની કોમ્પલેક્ષ, એસ.ટી.ડેપો પાસે, બાયડ. ફોન : (હો.) ૨૨૨૩૭

ડૉ. મહેન્દ્ર એસ. પટેલ
એમ.એસ. સર્જન (ગોલ્ડ મેડાલીસ્ટ)
હોજરી, આંતરડા, મળાશય, પ્રોસ્ટેટ, પથરી, સારણગાંઠ, લેપ્રોસ્કોપી, પ્રસુતિ, સ્ત્રી રોગો તથા વંધત્વના નિષ્ણાત.

ડૉ. અમીત ડી. ચૌહાણ
એમ.ડી. ગાયનેક
પ્રસુતિ, સ્ત્રી રોગો તથા વંધ્યત્વના નિષ્ણાત
ફોન :(રહે.) ૨૨૦૧૧૧

તા. - -૨૦૦

TO WHOM SO EVER IT MAY CONCERN

Sub. : Regarding the ethical committee.

As mention above subject I Dr. Mahendra S. Patel (M.S.) accept the membership of ethical committee formed for the Ph.D. research on clinical trial as hepatoprotactive on the drug *E.alba* and *P.amarus* by Jitendra S. Patel and Hemangi J. Patel at Sapal Hospital, Bayad.

With regards

Dr. M. S. Patel

Annexure V

Dr. SUNIL P. SHAH
M. D. D.T.C.D. Physician
Uday Complax, Near Purohit Hotal
opp. S.T. stand, BAYAD-383325
Date.

TO WHOM SOEVER IT MAY CONCERN

Sub. : Regarding the ethical committee.

As mention above subject I Sunil P. Shah (M.D. D.T.C.D. Physician) accept the membership of ethical committee formed for the Ph.D. research on clinical trial as hepatoprotactive on the drug *E.alba* and *P.amarus* by Jitendra S. Patel and Hemangi J. Patel at Sapal Hospital, Bayad.

With regards

Dr. Sunil P. Shah

Annexure VI

Adesinh M. Chauhan
B. A, LL. B.
Advocate
Res. Giriraj Society
BAYAD Dist. Sabarkantha

અદેસિંહ એમ. ચૌહાણ
બી. એ. એલ એલ. બી.
એડવોકેટ
રે. ગિરિરાજ સોસાયટી,
બાયડ, ડી. સાબરકાંઠા

Ref. No. Date ;

TO WHOM SOEVER IT MAY CONCERN

Sub. : Regarding the ethical commitee.

As mention above subject I Adesinh M. Chauhan (Advocate) accept the membership of ethical committee formed for the Ph.D. research on clinical trial as hepatoprotactive on the drug *E.alba* and *P.amarus* by Jitendra S. Patel and Hemangi J. Patel at Sapal Hospital, Bayad.

With regards

Adesinh M. Chauhan

Annexure VII

ડૉ.પ્રકાશ જી. શાહ
એમ.ડી. (મેડીસીન)
કન્સલ્ટીંગ ફિજીશીયન
હૃદય, લકવો, ફેફસાં, ડાયાબીટીસ, કીડની,
લીવર અને ખેંચના રોગોના નિષ્ણાત
શ્રીજી હાર્ટ એન્ડ
મેડીકલ હોસ્પિટલ
સંજીવની કોમ્પ્લેક્ષ, એસ. ટી. ડેપો પાસે,
બાયડ, જી. સાબરકાંઠા.
ફોન : (૦૨૭૭૯) (H) ૨૨૨૨૩૭ (R) ૨૨૨૩૩૩

TO WHOM SO EVER IT MAY CONCERN

Sub. : Regarding the ethical committee.

As mention above subject I Dr. Prakash G. Shah (M.D. Physician) accept the membership of ethical committee formed for the Ph.D. research on clinical trial as hepatoprotactive on the drug *E.alba* and *P.amarus* by Jitendra S. Patel and Hemangi J. Patel at Sapal Hospital, Bayad.

With regards

Dr. P. G. Shah

ફરીથી બતાવવા આવો ત્યારે આ કાગળ સાથે લાવવો.
ડોકટરને મળવાનો સમય : સવારે ૧૦ થી ૧ + સાંજે ૫ થી ૭ + રવિવારે રજા -
+ મૌખિક સૂચના અને પરેજીનું બરાબર પાલન કરવું +