

Formulation and Evaluation of Liver Protective Herbal Capsule

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Abstract: *Liver is an essential metabolic organ. It can be damaged due to prolonged use and higher doses of drugs, exposure to some chemicals, toxins, or infectious agents. One of the most important organs, the liver is in charge of detoxification and the production of crucial proteins, among other metabolic functions. However, a number of things, including oxidative stress, pollutants, and chronic illnesses, can harm it. Because of their strong hepatoprotective, anti-inflammatory, and antioxidant qualities, herbal medicines have drawn interest as a natural alternative for liver protection. This study describes the creation and composition of herbal capsules that protect the liver by combining a variety of plant-based substances that have long been recognized for their hepatoprotective properties. The chosen herbs, which have demonstrated potential in promoting liver function and averting harm from free radicals and toxins, include Phyllanthus amarus, Andrographis paniculata (King of Bitters), Picrorhiza kurroa, and Silybum marianum (Milk Thistle). The active ingredients of the herbal composition were standardized, guaranteeing steady therapeutic results. The formulation's promise as a natural supplement for liver health maintenance was supported by preliminary research on its bioavailability, safety, and effectiveness, which showed notable liver protective effects. To confirm its long-term advantages and therapeutic use in liver-related conditions, more clinical research is necessary.*

Keywords: oxidative stress, detoxification, Silybum marianum, Andrographis paniculata, Picrorhiza kurroa, Phyllanthus amarus, hepatoprotective, herbal capsules, and liver protection

I. INTRODUCTION

The liver is the largest solid organ, the largest gland and one of the most vital organs that functions as a centre for metabolism of nutrients and excretion of waste metabolites.^[1] Its Primary function is to control the flow and Safety of substances absorbed from the digestive system before distribution of these substances to the systemic circulatory system.^[2] A total loss Of liver function could leads to death within Minutes, demonstrating the liver 's great Importance.^[3] origin of the Liver The cells that will eventually make up the adult Liver originated during embryogenesis from the Ventral foregut definitive endoderm.^[4] The Different developmental stages of the liver Involves establishment of competence for liver Formation, after which liver specification, Hepatic bud formation, growth and finally Differentiation will occur.^[5] Numerous additional organs interact with the liver. The hepatic arteries provide the liver with its arterial blood supply once blood flows through them [3]. In essence, the gallbladder serves as the liver's bile duct overflow area. Lymph glands, which drain fluid and support the immune system, are abundant in the liver. Numerous blood proteins are synthesized by the liver, demonstrating its connection to those organs. Additionally, the liver contains nerves, demonstrating its connection to the neurological system. Last but not least, liver disease frequently results in issues with the renal system, indicating a connection with the kidneys. The liver plays a number of vital roles in preserving the body's physiological equilibrium.

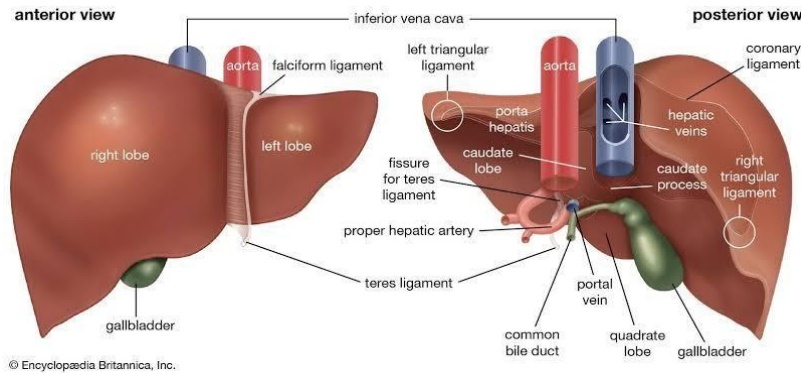


Figure 1. Diagram of the liver showing the right and left lobes and its posterior and anterior veins.

Source : *Encyclopaedia Britannica, 2010*

Diseases of the Liver: The impact of chronic illness on society is rapidly growing. According to estimates from the World Health Organization (WHO), that chronic diseases account for 59% of deaths and 46% of all diseases worldwide. Chronic disease claims the lives of 35 million people worldwide each year, and the figure is rapidly rising.[6] It is anticipated that the steady rise in healthcare costs over the past few decades will continue—indeed, pick up speed. After cancer, heart disease, stroke, and chest illness, liver disease is currently the fifth leading cause of mortality in the United Kingdom, according to the Office for National Statistics.[7]

HEPATITIS B: 257 million people worldwide suffer from chronic HBV. If left untreated, hepatocellular cancer and liver failure will cause about 20% of people to die too young.[8]

HEPATITIS C: Five out of six countries—China, India, Egypt, Russia, the United States, and Pakistan—are home to 51% of the 71 million people with chronic HCV infection globally.[9]

Non-alcoholic fatty liver disease, or NAFLD, is thought to affect 24% of people worldwide, with a prevalence of over 30% in the Middle East and South America. [10]

Herbal hepatotherapeutic medications : Herbal medicine was originally used in ancient China during the Xia dynasty around 2100 BC, and in India during the Vedic era. The Charaka Samhita of India dates the earliest written books to 600 BC.[11]

Details of the capsule: For phase I/IIa clinical studies, the pharmaceutical industry frequently favors capsule dose forms for a number of reasons. Early development aims to create a straightforward and reliable exploratory formulation that satisfies clinical discovery objectives to assess compound safety and proof-of-concept in the planned treatment. Compared to tablets, stable small-scale capsule formulations can be developed more quickly and easily and require fewer active pharmaceutical ingredients (API). There is typically very little API available for early formulation development. Furthermore, phase I research' strict deadlines sometimes necessitate the use of capsule dose forms. For phase I investigations, the clinical supply needs can vary from a modest batch size of a few hundred capsules to a few thousand based on the drug product stability process, clinical protocols, multiple-dose studies, and first-in-human dose in single-dose safety studies. There are numerous choices for encasing APIs or formulations in hard shell capsules The In-Cap works similarly to the large-Wi Er tamping devices that are detailed in the book *Pharmaceutical Capsules with schematics*. [12]

II. MATERIAL AND METHOD OF PREPARATION

SR.NO.	INGREDIENTS	COLLECTION	USES
1.	Turmeric	LOCAL MARKET	Anticeptic, antitussive
2.	Fennel	LOCAL MARKET	Anti-inflammatory, laxative
3.	Liquorice	LOCAL MARKET	Anti-inflammatory, spasmolytic,

			laxative
4.	Garlic powder	LOCAL MARKET	Antioxidant ,Digestant
5.	Punarnava	LOCAL MARKET	Anti-inflammatory,anti-inflammatory

Table no.1.1

Turmeric extraction:Raw Material The rhizomes of *Curcuma longa*, or turmeric, which contain 6% curcumin, were gathered from the Narayana brand variety.

Solvents: E-Merck provided the AR/HPLC quality solvents that were used.

Procedure: Using a mortar, the turmeric roots must be pounded into a powder for the extraction. Following air drying to eliminate any remaining moisture from the feed or ground powder, a known quantity of turmeric powder—say 10 grams—is precisely weighed and then cleaned or treated in an extraction column with an appropriate solvent, such as ethanol, acetone, etc., to extract the solute or curcumin from the powder for the desired amount of time. The mixture of solvent and solute is subsequently separated by distillation. It is carried out merelyThe mixture is heated to the boiling point of either the solvent or the solute. In this case, the solvent is heated to the boiling point because its boiling point is lower than that of the solute. Selective solvents are used to further cleanse the resulting oleoresin. Here, hexane is utilized as a solvent due to its high coefficient of absorption. Following washing, it has been completed.excludes curcumin powder.[13]

Fennel: A member of the Apiaceae (Umbelliferae) family, fennel (*Foeniculum vulgare*) is mostly used to add flavor to a variety of dishes, including pickles, soups, sauces, breads, cakes, and more. Fennel is a shrub with a strong scent that grows to a height of 80 to 150 cm. It is native to the Mediterranean region and is grown in South America, China, Vietnam, Germany, England, and Tyrol. Anethole and fenchone are the two main constituents of fennel volatile (essential) oil. Anti-inflammatory, antispasmodic, carminative, diuretic, expectorant, laxative, analgesic, stimulator of gastrointestinal movement, and for the treatment of neurological disturbances are only a few of the medical uses for fennel extracts.Extraction conditions .ASE was used to extract the pigments and phenols from fennel seeds. conducted using an Accelerated Solvent Extractor Dionex™ ASETM 350.

(Sunnyvale, CA, USA: Thermo Fisher Scientific Inc). Extracting

The following procedure was established: 3 grams of the material combined with 2 grams of 34 mL stainless steel containers were filled with diatomaceous earth and equipped with Dionex™ 350/150 Extraction Cell Filters, Thermo, two cellulose filters near the base of the cell (Fisher Scientific Inc., Sunnyvale, CA, USA). In To ascertain the best extraction parameters for maximizing yields

Among target chemicals, temperature parameters for extraction (80 and 110 °C), the number of extraction cycles, and the static extraction time (5 and 10 min).

Table 1 shows that (1, 2, 3, and 4) were modified. 10.34 MPa was the fixed parameter.

30 seconds 50% flushing and 50% nitrogen purge. The extracted materials were filled with the extraction solvent to the full volume in a 50 mL volume flask. 96% ethanol. Two replicates (n=2) were used for each extract. [14]

Liquorice :The roots and rhizomes of licorice (*Glycyrrhiza glabra*) are widely employed in herbal remedies because of its anti-inflammatory, antiviral, anti-allergic, antioxidant, gastro-protective, and anti-cancer effects. It is extensively utilized in food, confections, and medicinal items all over the world, including cough syrups, chewing gum, beverages, herbal supplements, and candies. With 50–170 times the sweetness of sucrose, it is a potent natural sweetener. Glycyrrhizin (about 16%), various sugars (up to 18%), flavonoids, saponoids, sterols, starches, amino acids, gums, and essential oils are among the bioactive compounds found in the roots. [15]

Garlic powder:

1. Pick Fresh Garlic Bulbs: Pick healthy, ripe garlic bulbs. There should be many garlic cloves in each bulb.
2. Peel and Slice the Garlic: Remove the skins from the garlic cloves after separating them from the bulb. To enable quicker drying, thinly slice the cloves.
3. Let the garlic dry: How to Use a Dehydrator: Arrange the garlic slices on the dehydrator trays in a single layer. For 8 to 12 hours, or until the garlic is totally dry and brittle, set the temperature to 125°F (52°C).

When using an oven, preheat it to the lowest setting possible, which is approximately 140°F (60°C). Line a baking sheet with the garlic slices, then put the oven door slightly open to allow air to circulate. Dry for two to four hours, checking periodically.

Using Air Drying: If you live in a dry climate, you can air dry the garlic by hanging it in small bundles or spreading the slices on a mesh screen, but this method takes longer (several days).

4. Once the garlic is completely dry and brittle, grind it into a fine powder using a spice grinder, mortar and pestle, or coffee grinder.

5. Store the Garlic Powder: Store the freshly ground garlic powder in an airtight container in a cool, dark place. Proper storage will keep the powder fresh for several months.

For better flavor, make small batches and use them within a reasonable timeframe, as garlic powder can lose potency over time.[16]

Punarnava: Found all over India, punarnava is a trailing herb with the botanical name Boerhaavia diffusa Linn. (Nyctaginaceae). The medication Punarnava was first administered both internally and externally during the Vedic era. One

Punarnava literally translates as "a renewer of the body. Root of Punarnava is Indicated in diseases affecting various systems of the body which includes Kasa(cough), Gara (poison), Hridroga (cardiac disorders), Soola (abdominal colic), Pandu (anaemia), Gulma (abdominal tumor), Pleeha roga (splenic disorders), Arsas(haemorrhoids), Vasthi soola (pain in urinary bladder), Vrana (wounds) etc.3,4,5Numerous pharmacological and clinical investigations describing the unique Bioactivity of plant extracts have added credence to these traditional uses. There Are several researches which proves the hepatoprotective activity, antioxidant Property, immunomodulatory effect, anthelmintic activity etc of the root of Boerhaavia diffusa Linn. [17]

COMPOSITION OF CHEMICAL-

Sr No.	INGREDIENTS	F1	F2	F3
1.	Turmeric	100mg	105mg	110mg
2.	Fennel	100mg	110mg	80 mg
3.	Liquorice	100mg	95mg	105mg
4.	Garlic powder	100mg	105mg	110mg
5.	Punarnava	100 mg	85 mg	95 mg

Table. no. 1.2

Procedure:

Take a petri plate put all drug drug extract one of each

Put it in hot air oven for drying and for removing moisture content 10 min.

Mix it well after drying in mortar paster

Use sieve no.120 and sieve it

After that fill the capsule by capsule filling machine

Then close the capsule cap and remove from machine

Evaluation parameter

Physical Examination (Colour , odour, taste, humidity)



Prepared capsules

Sr. No.	Parameters	Observation	Result
1.	Colour	Brownish, light orange colour	pass
2.	Odour	Characterised odour	pass
3.	Particle size	Fine size	pass
4.	Disintegration test	The capsule is dissolve in 30 min.	pass

Table. no. 1.3

Disintegration test

A regulated method for figuring out how long it takes for a capsule to fragment or disintegrate into smaller pieces in a particular liquid media is the disintegration test for capsules. This is crucial for making sure the capsule releases its contents efficiently and in the allotted amount of time following administration. Procedure for the Capsule Disintegration Test: Equipment: The disintegration tester, the most often used device, is made up of several tubes (usually six or twelve) that contain the capsules and are submerged in a liquid medium.

The liquid medium's temperature is regulated, usually at $37 \pm 2^\circ\text{C}$ to approximate body temperature.

Moderate: Depending on the needs of the particular test, the liquid employed is frequently either water or a buffer solution. formulation. The medium ought to replicate the circumstances in which the capsule will break down after being taken.

Method:

Equipment Preparation: Verify that the medium's temperature is stable and that the disintegration tester is properly configured.

Capsule placement: Put one capsule into each of the disintegration tester's tubes.

Testing: The disintegration test is initiated. In order to replicate the mechanical activity in the gastrointestinal tract, the tester typically works vertically, with each tube vibrating or moving up and down.

Keep an eye out for capsule disintegration during the test. Depending on the kind of capsule and any applicable regulations, the capsule should disintegrate in a predetermined amount of time, usually within 30 minutes.

Test End: When all of the capsules have been taken, the test is deemed finished. have either achieved the maximum time limit or completely disintegrated.[18]

III. CONCLUSION

The liver protective herbal capsule's formulation and assessment show encouraging potential for promoting liver health. A stable dosage form was successfully created by combining a number of carefully chosen medicinal herbs that are well-known for their hepatoprotective qualities. The capsule's assessment revealed that it satisfied all necessary quality requirements, including those related to appearance, homogeneity, dissolution, and disintegration. Furthermore, the phytochemical components of the used herbs demonstrated strong anti-inflammatory and antioxidant properties that support liver detoxification and protection. To verify the herbal capsule's safety and therapeutic effectiveness in vivo, more clinical research and long-term assessments are advised. All things considered, this formulation has a lot of potential as a natural substitute for promoting liver health and averting diseases linked to the liver.

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