



## Formulation and evaluation of herbal based capsule and soft chew for liver disorders

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### Abstract

Chronic liver diseases (CLD) represent a major health burden worldwide. According to WHO, approximately 75% of people use herbs to treat CLD globally. The plants traditionally used by native healers to support CLD have been the subject of extensive research in recent years. The combination of herbal plants such as Swarnakshiri, Guduchi, Pipali, and Haridra, Bhringraj was used as an Ayurvedic treatment of diseases. The study aimed to formulate the selected plant extract's hard gelatin and soft chewable capsules with the wet granulation method. The extraction of plant materials was carried out by the Soxhlet extraction method using aqueous water-alcohol media. A chromatographic study was performed to identify active constituents which include Berberine, Tinosporoside, Piperine, Curcumin and Wedelolactone respectively. The hard gelatin capsule was formulated by a combination of Berberine, Tinosporoside, and Piperine, and the soft gelatin capsule was formulated by a combination of Curcumin and Wedelolactone. Capsules were evaluated. The batch F7 optimised was selected for dissolution study for both formulations, weight variation, pH determination, disintegration and dissolution test. Both types of capsules showed 50% of drug release within 2h in buffer and HCl media. The stability study was performed for the prepared formulations for 6 months and the results obtained do not show any significant changes in the drug release profile two formulations. The study's findings suggest that the prepared formulations provide a long-term, safe, and permanent cure for liver disorders with better patient compliance and no side effects.

**Keywords:** Liver, Herbal Drugs, Capsule, Extraction, Ayurvedic Formulations.

## **Introduction**

Chronic disease constitutes a fast-increasing burden to society. The World Health Organization (WHO) estimates that 46% of global diseases and 59% of mortality are due to chronic disease<sup>1</sup>. The liver is an important vital organ in our body which performs a very important role in regulating, maintaining, and conducting several physiological functions such as metabolization of nutrients<sup>2</sup>. As a result, it is frequently exposed to illnesses, which can lead to a variety of clinical syndromes<sup>3</sup>. Healthcare professionals were rarely able to offer a specific course of treatment due to the wide range of liver dysfunctions and the challenges in making an accurate diagnosis. Though significant progress has been made in the last few decades in understanding how to treat chronic liver diseases, most treatments still do not provide satisfactory results.<sup>4</sup> There are more than 300 preparations in the Indian system of medicine for the CLD. In India currently, more than 87 medicinal plants are used in different combinations as herbal drugs for CLD<sup>5</sup>. In the pharmaceutical field soft gelatin capsules are increasingly being chosen for strategic reasons (line extension), technological issues (high content uniformity of low-dose drugs), safety aspects (reduced operator and environmental contamination with highly potent or cytotoxic compounds) and consumer preference (easy to swallow) capsule are a trusted oral dosage<sup>6</sup> Among all dosage forms, capsules are among the most widely used because they are physically and chemically stable, simple to use, appealing, and simple to compound. More than one drug can be included in each capsule to reduce the number of dosages forms the patient must take<sup>7</sup>. Modern dosage forms for medicinal use, such as hard gelatin capsules, result from the increased focus on pharmacokinetics in drug development today. This has greatly increased the variety of formulations that can use hard gelatin capsules as a straightforward dosage form for oral drug delivery<sup>8</sup>. Large-scale applications of highly developed soft capsules are currently found in the pharmaceutical, chemical, food, and cosmetic industries. This is due to the characteristics of soft gels, such as their appealing aesthetic qualities and "swallowability," safety enclosure, precise contents, and appealing appearance. This has made it possible for them to be used as an efficient delivery system for a range of healthcare products, including hydrophobic drugs, low-melting-point drugs, and easily oxidized drugs<sup>9</sup>. They can be easily customized to meet the needs of specific patients regarding dosing ingredients, etc. This convenient container enables consistent dosage, portability, and high consumer compliance. Alternative formulations come as liquids, powders, or pastes and are more expensive<sup>10</sup>. Due to the because filled by volume, computations are normalized using the fill volumes of the capsule, which vary based on capsule size and powder density<sup>11</sup>. The medicinal properties of these plants are primarily due to the chemical molecules that aid in discovering new drugs. Bhringraj offers protection against damaging chemicals that can harm the live<sup>12</sup> and contains some chemical elements with toxic-adapting properties that aid in the regeneration of liver cells.<sup>13</sup> The clinical properties such as which include analgesic, anti-inflammatory, anti-

hepatotoxic, antioxidant immunomodulatory, and good rejuvenating properties<sup>14,15</sup>. A variety of effects can be seen in the stem of Guduchi (Willd), including bitterness, astringency, sweetness, thermogenic, anodyne, anthelmintic, alternate, and -periodicity, antispasmodic, antipyretic, antiemetic, digestive, carminative, appetizing, stomach, constipating, cardiotoxic, depurative, haematinic, expectorant<sup>16</sup>. Since ancient times, it has been used to treat a number of ailments, such as burning sensations, hyperdipsia, vomiting, fever, jaundice, chronic diarrhoea, cancer, dysentery, bone fractures, pain, asthma, skin diseases, deadly bug bites, snake bites, and abnormalities in the eyes<sup>17</sup>.

The acrid root and fruit of pipali are used to treat tumours, ascites, bronchitis, abdominal discomfort, spleen disorders, and biliousness. They are also said to have stomachic, laxative, anthelmintic, and carminative properties. The fruits and roots are both said to have a number of medicinal advantages, including the treatment of cough, bronchitis, asthma, and other respiratory conditions<sup>13,18</sup>. The initial objective of this study is to manufacture and evaluate hard gelatin and soft chewable capsules containing plant extract.

## **Materials and Methods.**

### **1. Materials:**

The herbal plants used in current studies were Swarnakshiri, Guduchi, Haridra, Pipalai, and Bhringraj. The chemicals such as Jaggery from Nature Gruha Udyog, Aurangabad, Capsule shell from ARS Pharmatech, Mumbai, Starch from Surya min chem, Mumbai, MCC ph. 102 were from Glycerin Sigma Aldrich, Mumbai.

### **2. Methods:**

#### **2.1 Morphological and Pre-Formulation Study of Plants and Extract.**

The morphological characteristics were performed which included odour, taste and colour<sup>11</sup>

##### **2.2.1 Extraction of Selected Plants**

The extraction of the selected plant was carried out by the Soxhlet extraction method which involved extracting the solvent and evaporating it<sup>19</sup>. The chosen plants were precisely weighed after being extracted separately. A thimble was used to keep Swarnakshiri roots (SW)(100g), Guduchi plant (GP)(100gm), Haridra rhizomes (HR)(50g), and Pipali dried fruit (PDF) (50g), Ethanol was chosen as the solvent for making an extract of crushed Bhringraj (BHG) extraction<sup>19</sup>. In a flask with a spherical bottom that was attached to the heating metal, distilled water was employed as an extracting solvent. As the solvent heated up, it began to evaporate and go through the device to the condenser. Condensate dripped into the reservoir where the thimble is kept. When the solvent is reinserted into the flask after going through the syphon, the cycle is resumed. The operation was run for 16 hours for SW and GP, 7 hours for HR and PDF, and 10 hours for BHG respectively, to finish a cycle<sup>20</sup>. Each extract was then dried, crushed and combined with a sequence of solvents, beginning with 70% Methanol, then chloroform extract, and ultimately ethyl acetate.<sup>21, 22</sup>

### 2.2.2 Pre-Formulation test of Plants and Extract.

The extractable amount and % yield are calculated using the formula. Determination of Loss on Drying (LOD) was performed by, the powder of each plant was precisely weighed 5gm and kept on a plate which was covered in tar, and dried in an oven which was preheated between 100°C and 105°C. The LOD was measured by the amount of dried powder consumed and calculated by using the formula. Using a typical simple glass electrode pH meter, various extracts of chosen plants were taken in 1 per cent w/v (1 gm: 100 ml) of water-soluble parts was measured.

**Yield %** = Weight of dry extract obtained

$$\text{-----} \times 100$$

The weight of the dry part of the plant used <sup>23</sup>

**LOD (%)** = wt. of a sample before drying – wt. of a sample after drying

$$\text{-----} \times 100$$

Wt. of a sample before drying a sample

For particle size analysis, extracts were poured into a graduated cylinder via a large funnel and calculated the bulk density with the respective weight and volume of extract in a cylinder. The tapped density was determined by placing a graduated cylinder containing a known mass of extract and mechanical tapper apparatus, which was operated for a fixed number of taps until the extract volume reached a minimum volume. The determination of solubility, water and methanol extract value was calculated by using the formula, the air-dried plants were weighed at 5 gm and mixed with alcohol, chloroform and water in 100 ml of two different flasks respectively. The extract was immediately weighed after drying at 105°C for 6 hours and 30 minutes of cooling in a desiccator. The extractable amount was calculated using the formula:

**Bulk density** = Weight of extract

$$\text{-----} \times 100$$

The volume of extract in the measuring cylinder <sup>24</sup>

**Tapped density** = Weight of extract

$$\text{-----}$$

The tapped volume of extract <sup>24</sup>

$$\text{Water Soluble Extractive (\%)} = \frac{\text{Initial mass-mass of water-soluble extraction residue}}{\text{Initial mass}} \times 100$$

### 2.3 UV Spectroscopy Analysis of Extracted Plants

Accurately weighed 10 mg extracts of plants were dissolved in 100 ml distilled water, and 100 ml of 6.8pH phosphate buffer, methanol, and ethanol were taken separately in different volumetric flasks to obtain a standard solution of 100 µl each. This solution was then scanned in the range of 200-400 nm against diluent as blank.<sup>25 26</sup>

### 3. Drug-Drug Interaction

The components may be synergistic with each other and enhance the effect of each other. They may be antagonistic to each other and counteract the effect of each other. The drug-drug interaction study was determined by FTIR spectroscopy. The extracts were performed by FTIR, placing the extract and physical mixture directly on the diamond sampling window and then the sample press tip was lowered in such a way that it comes in contact with the sample placed on the diamond sampling cavity and spectra determined by FT-IR spectrophotometer (Agilent Technologies Cary 650 FT-IR) in the 4000-650 cm<sup>-1</sup>. The same procedure was followed for the comparison of an extract with granules.<sup>27 28</sup>

### 4. Development of Granules.

Following the steps below, granules for Argemone Mexicana, Guduchi, and Piper longum were prepared. For the preparation and evaluation of granules, three plant extracts were granulated using the wet granulation technique. Using the procedure, 10% (w/w) of MCC PH 102 served as a binder to create wet granules. A 12.5 w/v percentage of MCC PH 102 was used to weigh and granulate the Solid Dry Extract (SDE). After completely blending the mixture until it reached the proper consistency for granulation, it was strained through a sieve with a nominal aperture of 1 mm. The produced granules were screened, dried for two hours in the oven circulating air at 25 °C, and then stored<sup>29</sup>. The evaluation of size distribution and flow properties of granules was performed by using a 425 m sieve, and the prepared granules were screened and divided into coarse and fine granules. Further indirect methods were used to characterize the flow characteristics of the granules designed for encapsulation, including bulk density measurements (Hausner ratio and Car's index) and angle of repose (fixed height cone method)<sup>30</sup>. Determination of granules particle size is considered one of the important parameters for getting the optimum efficacy of the therapeutic moiety. Particle size analysis was done to obtain an equivalent diameter to interpret the size of granules. Granules were passed through different sieves mesh # 40 and 60. The angle of repose was analyzed by the flow properties of powders, pellets, or granules, and the angle of repose was used. Pour the powder or granules into a conical heap on a level, flat surface, and measure

the included angle with the horizontal to determine the angle of repose, bulk and tapped density were calculated by formula<sup>10</sup>.

$$\tan(\theta) = h/r$$

Where, h = height of the heap, r = Radius of the heap

## 5. Formulation of Hard Gelatin and Soft Chewable Capsule

The prepared granules were mixed in a ratio of 1:0.5:0.1 and the aqueous extract was prepared and dried.

### A. For the formulation of Hard Gelatin Capsules

Argemone Mexicana, Guduchi, and Piper longum extract (150 mg), MCC pH 102 (170 mg), starch (170 mg), and talc 10mg were combined in granules to create 300 capsules, each with a nominal weight of 500 mg (10 mg). The plant extract and MCC pH 102 were thoroughly combined to prepare a homogenous paste that was dried at 60 °C in a hot air oven and filtered through an 850 m sieve before starch was added. For each formulation, the produced dry extract-absorbent granules were placed into size 1 hard gelatin capsule shells that had been manually filled with talc (Model TMP Mini T-50)<sup>31</sup>.

### B. For the formulation of Soft Chewable Capsules

Curcuma longa (CCL) and Eclipta alba (EA) were mixed with jaggery formulated. Capsules 100 each with a nominal weight of CCL and EA were prepared with jaggery (14000), MCC pH 102 (150 mg), and glycerin. These capsules were filled by using a silicon mould. Among all batches of formulation, the F7 batch was found to have a good appearance, it was selected for further studies. After evaluation, the soft chew was evaluated for physical appearance, weight, and colour<sup>32</sup>

Sr. No	Ingredients	Quantity per capsule (mg)							
		F1	F2	F3	F4	F5	F6	F7	F8
<b>Hard Gelatine capsule</b>									
1.	Dried Extract of Argemone Mexicana+ Guduchi + Piper longum	150	150	150	150	150	150	150	150
2.	MCC pH 102 (Diluent)	170	140	200	150	119	100	260	60
3.	Starch (Diluent)	170	200	140	190	150	260	100	300
4.	Talc (Lubricant)	10	10	10	10	10	10	10	10
<b>Soft chewable capsule</b>									
5.	Curcuma longa	60	60	60	60	60	60	60	60
6.	Eclipta alba	30	30	30	30	30	30	30	30
7.	MCC pH 102	190	200	90	300	240	150	195	280
8.	Jaggery	1400	1400	1400	1400	1400	1400	1400	14000
		0	0	0	0	0	0	0	
9.	Glycerin (ml)	QS	QS	QS	QS	QS	QS	QS	QS

**Table 1: Formula for preparation of Hard Gelatin and Soft Chewable capsule.**

## 6. Evaluation of Hard Gelatin and Soft Chewable Capsule

The developed capsule formulation was evaluated for various parameters. The weight variation test which was performed for twenty herbal capsules, selected from the mixture which was used to determine variable amount of powder in each herbal capsule. The % weight variation was calculated by USP's (2010) Specification. The herbal capsule's weight must be between 90% and 110% of the theoretically anticipated weight of each unit. Practical size, flow property, Hausner's ratio, tapped density and bulk density were performed. In the disintegration test, 6 herbal capsules were chosen from the formulation. During the experiment, the equipment was kept at a temperature of 37°C + 2°C. The pill was put in each tube before being suspended for 30 minutes in beakers containing simulated gastric fluid (SGF, pH 1.2) <sup>33</sup>.

In vitro-dissolution Test, for both batches of prepared capsules containing herbal extracts are placed in two different solvents, with pH 6.8 phosphate buffer and 0.1 N HCl at 37.0°C, the USP dissolution test apparatus (Electro lab dissolution tester), which uses a basket stirrer, was used. A 1 ml aliquot of the dissolving media was

taken out using a pipette at 15, 30, 45, 60, 90, and 120 minutes<sup>34</sup>. The components were properly diluted and subjected to their respective maximum levels of spectrophotometric analysis (UV- 1800, Shimadzu, Japan)<sup>11</sup>.

### **6.1 For the determination of moisture content**

The storage temperatures were kept between 15 and 25 °C, and relative humidity levels were preserved between 45 and 55%, to retain the moisture content of the capsules. Maintaining this moisture level and preventing exposure to extremely high or low temperatures are also very important. The capsules will become flaccid when exposed to high humidity levels, and the excess moisture content may interact with an embedded material and impact stability problems. Low humidity levels cause capsules to crack<sup>35</sup>. For the Determination of pH, using an Elico LI 120 pH meter, the produced soft chewable capsule formulation had its pH assessed. Estimates were made in triplicate. The pH range for soft chewable formulas should be 2.5 to 7.5<sup>36</sup>.

## **7. HPTLC Study of Formulated Capsules.**

### **7.1 Selection of plate and adsorbent**

The 10 x 10 cm percolated aluminium plates with Silica Gel 60F254 (E. Merck, India) were used for the detection, and their thickness was 0.2 mm. The plates were pre-washed with methanol and activated at 60°C for 5 min. before chromatography. Accurately weighed into a separate iodine flask were 1 g of extract and an end product that was comparable to 1 g of extract. Then, each flask received 50 ml of methanol and refluxed for an hour. Cleanse the cure. The filtrate was then condensed into 1-2 cc. This approach was used for HPTLC fingerprinting. use of the illustration One band of 6 mm was seen with different extract and end product solution concentrations, namely 5 and 10 l. The "CAMAG LINOMAT V," was used to apply a single band of 6 mm in width.

### **7.2 Development**

In a CAMAG glass twin-through chamber (10-10 cm) that had previously been soaked in the solvent and maintained the temperature at 25.2 °C and 40% relative humidity, the plate was developed for 60 minutes. The development distance was 8 cm. After that, scanning was done. Chloroform: Methanol: Solvent system (9:1).

### **7.3 Detection**

The plate was scanned with the CAMAG TLC Scanner-3 and LINOMAT-V at UV wavelengths of 366 nm and 254 nm. The peak area of each band and the R<sub>f</sub> value of each compound that was separated on a plate were noted for both raw materials and finished commodities<sup>27</sup>.



## 8 Stability studies

Stability of the formulation was performed at accelerated conditions as per ICH Q1A standard (R2) standards. Optimized capsules were packed separately in suitable packaging and kept in a stability compartment at  $40 \pm 2$  °C and 75 % RH for 6 months.<sup>37</sup>

## 9. Results and Discussions

### 1. Morphological and Pre-Formulation Study of Plants and Extract.

The Soxhlet Extraction Method was used to extract the chosen plant. Additionally, these extracts were evaluated, with the results showed in the table 3. Based on the findings from the above studies done on extracts, the values obtained from morphological parameters and the extractive values were significantly lesser than they were for crude drugs.

Name of Study	Swarnakshiri	Haridra	Pipali	Bhringraj	Guduchi
Odour	Characteristics	Characteristics	Characteristics	Aromatic	Characteristics
Taste	Bitter	Astringent	Pungent	Bitter	Sweet, Sore
Colour	Brown	Yellow	Slightly brown	White	Green
% Yield	91.09	85.63	92.07	87.56	92.63
LOD%	5.03	22.05	3.12	3.27	2.69
pH	5.7	5.1	6.0	5.07	5.04
Bulk Density	0.242 g/cm <sup>3</sup>	0.238g/cm <sup>3</sup>	0.361g/cm <sup>3</sup>	0.252g/cm <sup>3</sup>	0.233g/cm <sup>3</sup>
Tapped Density	0.244 g/cm <sup>3</sup>	0.236 g/cm <sup>3</sup>	0.359 g/cm <sup>3</sup>	0.248 g/cm <sup>3</sup>	0.231 g/cm <sup>3</sup>
Solubility	Soluble in DMSO, ethyl acetate, Insoluble in water	Soluble in methanol, insoluble in water	Soluble in alcohol Insoluble in water	Insoluble in water, soluble in an organic solvent	Water soluble, organic

**Table 3: Morphological and pre-formulation study of Plants and Extract.**

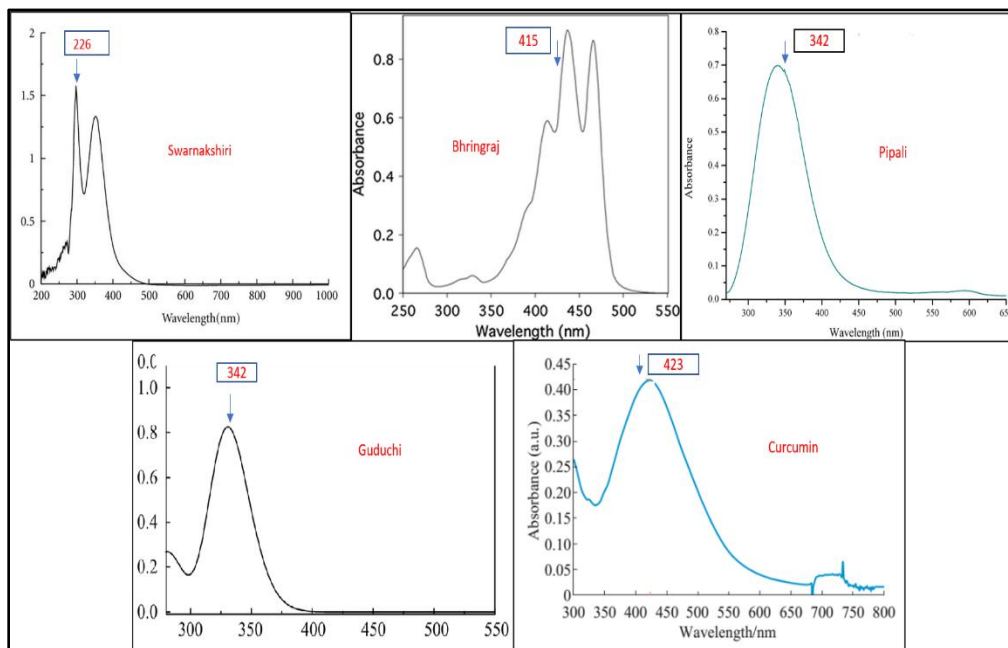
The morphological study such as odour ,taste and colour was performed .The %yield was calculated .The pH indicated the extract of the plant is acidic which is similar to stomach ph. The table 3 shows the results of LOD, Bulk Density, Tapped density and Solubility study indicates the solubility of extracts in water, alcohol and organic solvent.

## 2. UV Spectroscopy Analysis of Extracted Plants

From the UV-Spectrometry study, it was found that the Swarnakshiri solution in ethyl acetate exhibited maximum absorption at 226 nm. The maximum absorption of the haridra solution in methanol was discovered to occur at 423 nm, pipali solution in alcohol was at 342nm. bhringraj and guduchi were found to absorb the most in methanol and water, at 415 and 348 nm, respectively.

**Table 4: Observed wavelength of the extracts by UV spectrometry.**

Extracts	Observed wavelength(nm)
Swarnakshiri	226
Haridra	423
Pipali	342
Bhringraj	415
Guduchi	348



**Figure 1: UV spectrums of extracts.**

The absorbance maxima of plant extracts were recorded. It exhibits the maximum absorbance of the respective plant extract selected for further studies.

### 3. Drug-Drug interaction study

Two extracts were combined in dosage formulation. Drug-drug interaction study was performed as a result of the potential for drug-drug interactions. In the current study, Haridra and Bhringraj are combined to create soft gelatin capsules, and Swarnakshiri, Guduchi, and Pipali are combined to formulate hard gelatin capsules. The FTIR spectrum of Curcumin (CRM) and Wedelolactone (WDA) is shown in figure 2.

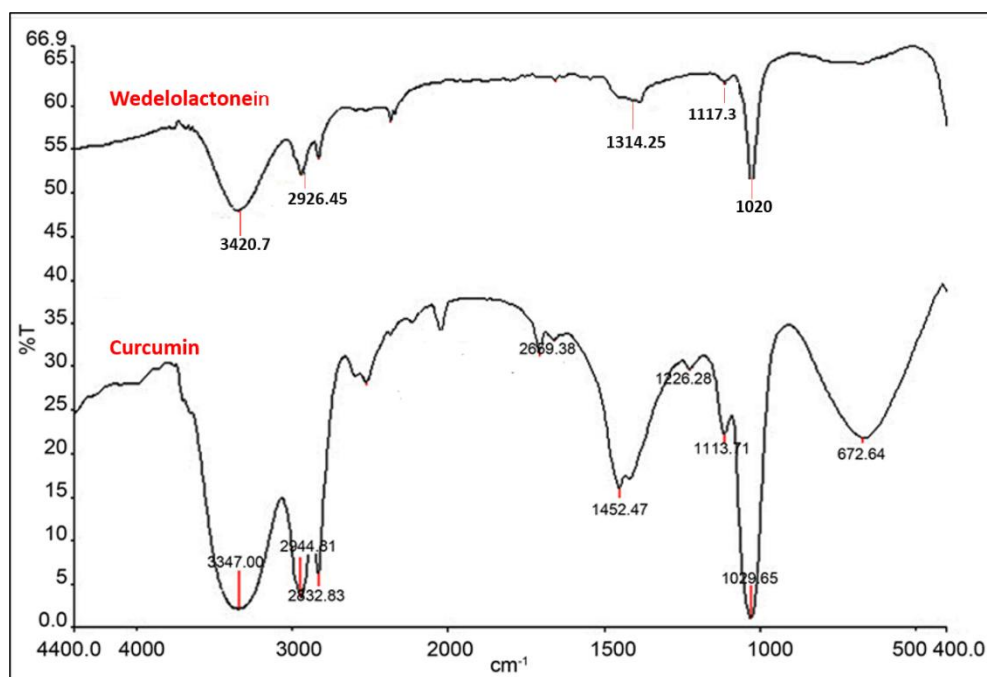


Figure 2: FTIR spectrum of Curcumin+ Wedelolactone mixture.

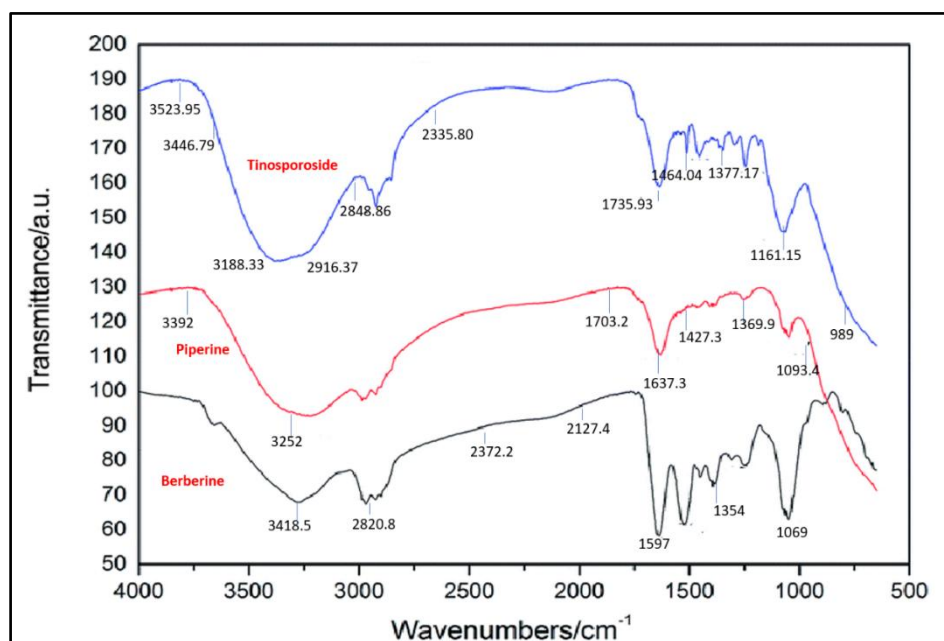


Figure 2.1: FTIR spectrum of Berberine+ Piperine+ Tinosporoside mixture.

The figure shows the FTIR spectrum of Tinosporosidein (TPD) and Berberine (BRB) Piperine (PRN), all drug ranges are displayed in table 6. It was found from the data collected for the drug-drug interaction study that there was no drug-drug interaction.

**Table 6: FTIR Peak Interpretation of drugs mixture.**

Functional group	Wavelengths (nm)	
	CRM + WDA	BRB+PRN+TPD
<b>C=O</b>	3347	1637.3
<b>C-H</b>	2922.25	3312.71
<b>C=C</b>	1660.77	3289.71
<b>C-H</b>	1429.30	1417.34
<b>CH<sub>3</sub>C-H</b>	-	2834.14
<b>C-O, COOH, -COO-</b>	1207.48	1530
<b>C-O-C</b>	1024.24	1232.4
<b>N-H</b>		3252.89
<b>O-H</b>	3429.78	3392.6

Hence there were no drug-drug interactions were found, the drugs were used to prepare chewable and hard gelatin capsules were selected from a drug mixture.

#### 4. Evaluation of Hard Gelatin and Soft Chewable Capsules

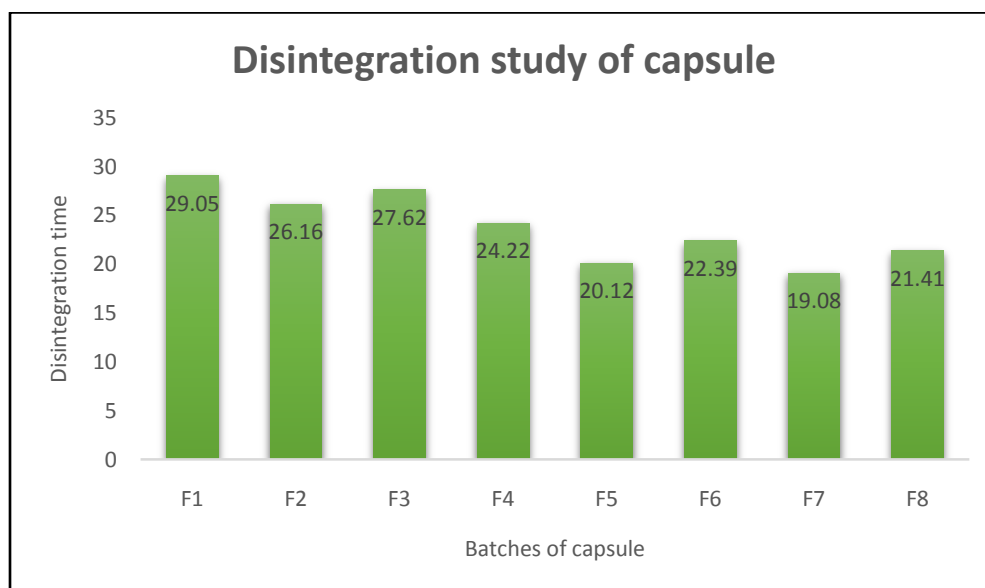
The granules of Berberine, Piperine, & Tinosporoside mixtures were prepared by the wet granulation method. The granules were examined using standard granule testing procedures. The table shows the evaluation parameters When compared to the specifications in the literature, the angle of repose, Hausner's ratio, particle size, and flow property of the granules all demonstrate that they are appropriate for use in a capsule formulation. As a result, granules and excipients are combined to prepare capsules. The disintegration test for capsules (DT), was determined by using the method outlined in the USP/BP, and the range was set to 5 to 30 minutes. None of the samples exceeded the disintegration study's time specifications, but the F7 batch took less time overall than the other batches, so it is regarded as an optimised batch for further research.

Sample code	Average weight per	Disintegration Time	Evaluation Parameters	Granules
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capsule (mg)				
F1	276.1	29.05	Particle size	356 μm
F2	187.5	26.16	Flow Property	Freely Flowing
F3	215.2	27.62	Hausner's Ratio	1.11
F4	178.5	24.22	Angle of repose	24.58 <sup>0</sup>
F5	234.6	20.12	Bulk Density	0.42gm/ml
F6	254.2	22.39	Tapped Density	0.46gm/ml
F7	167.1	19.08		
F8	267.7	21.41		

**Table 7: Evaluation test for Hard Gelatin and Soft Chewable capsules.**

The in vitro release was performed using phosphate buffer pH 6.4 and 0.1 N HCL as a medium for the optimised formulation. Batch F7 demonstrated satisfactory drug release rates of 76.14% in phosphate buffer and 62.08% in 0.1 N HCL after 120 minutes. Following a steady drug release, the formulated capsule displayed the most favourable within 120 minutes.



**Figure 3: Disintegration time of various batches of capsules.**

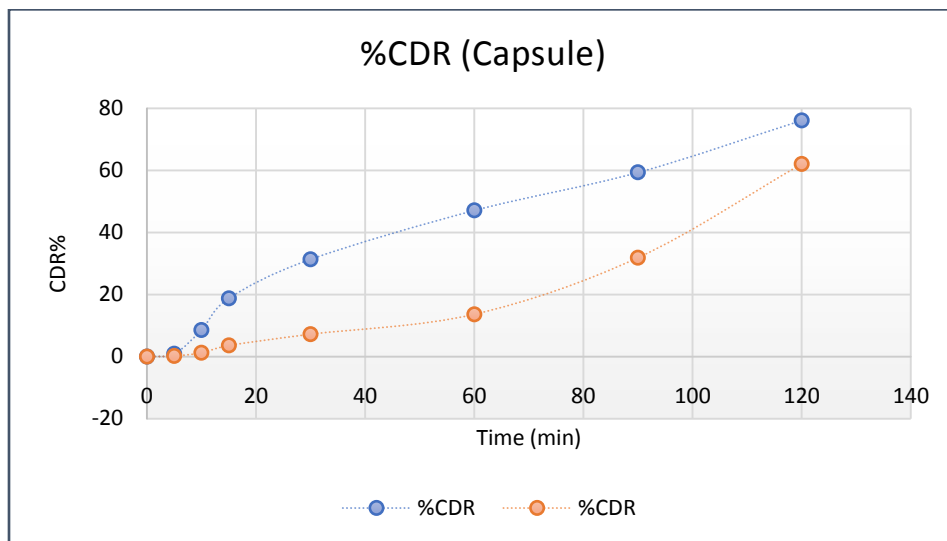


Figure3.1. In-vitro Dissolution Study of Hard Gelatin Capsules.

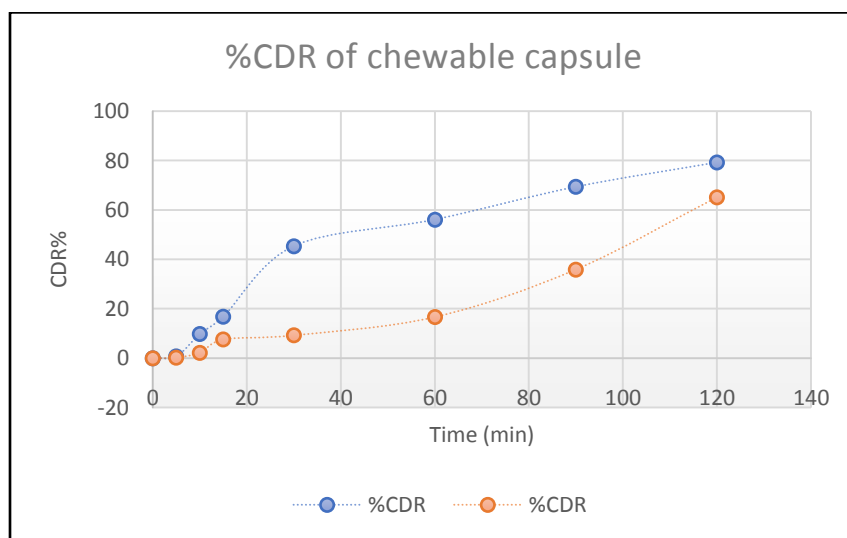


Figure 4: In vitro dissolution study of Soft chewable capsules

### 3.3 Determination of Moisture content:

To determine the moisture content of the capsule formulation, the three capsules were stored at a temperature of 15 to 25 °C and a relative humidity of 45 to 55 %.

The result shows that the influence of factors like temperature and humidity on capsule appearance and properties remained stable.

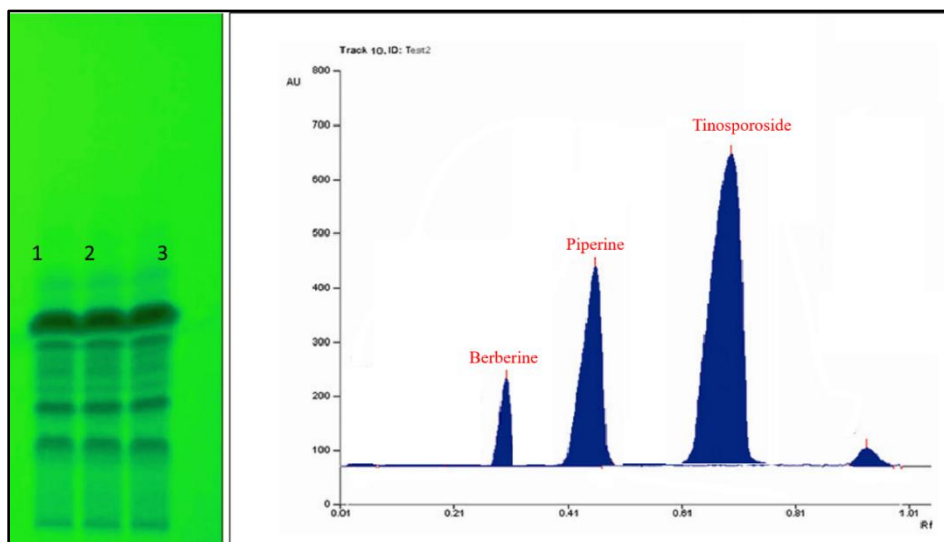
**Table 8.2: Data for Changes Observed in Capsules**

Parameters	C1	C2	C3
Temperature (15-25°C)	No change	No change	No change
Relative humidity	No change	No change	No change

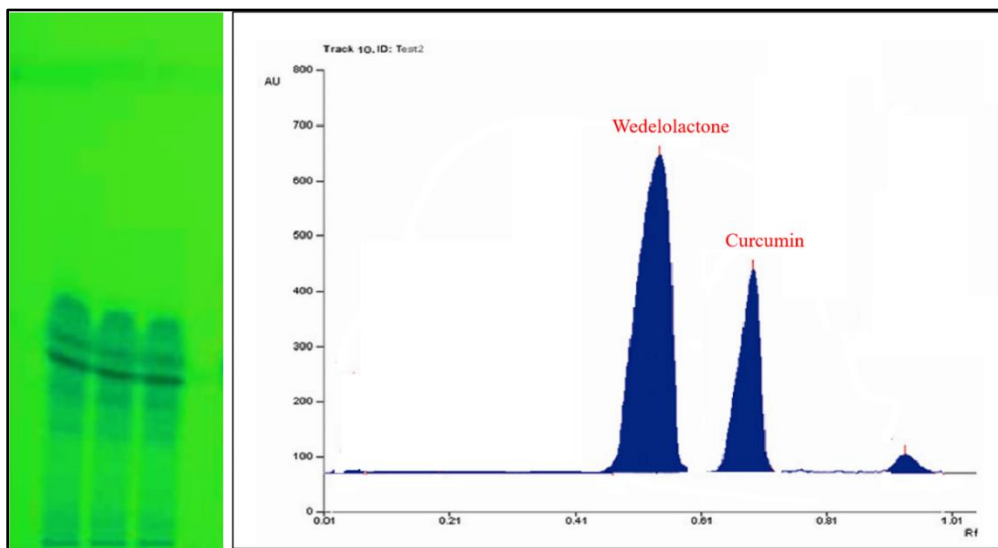
### 5. HPTLC study of Formulated Capsules.

When the formulation is run into the mobile phase Petroleum ether: ethyl acetate, methanol, and water at the ratio of (1.5:3:2.1:2) v/v revealed three major active constituents, one of which was berberine, another was piperine, and the third was tinosporoside at R<sub>f</sub> values of 0.37, 0.41 and 0.69, respectively shown in Figure 5.

The formulation when run into the mobile phase Petroleum ether: ethyl acetate: methanol: water at the ratio of (1.5:3:2.1:2) v/v showed two major active constituents one was curcumin and another was wedelolactone at R<sub>f</sub> value 0.69 and 0.56 respectively. The chromatogram and plate of formulation showed in Figure 5.1.



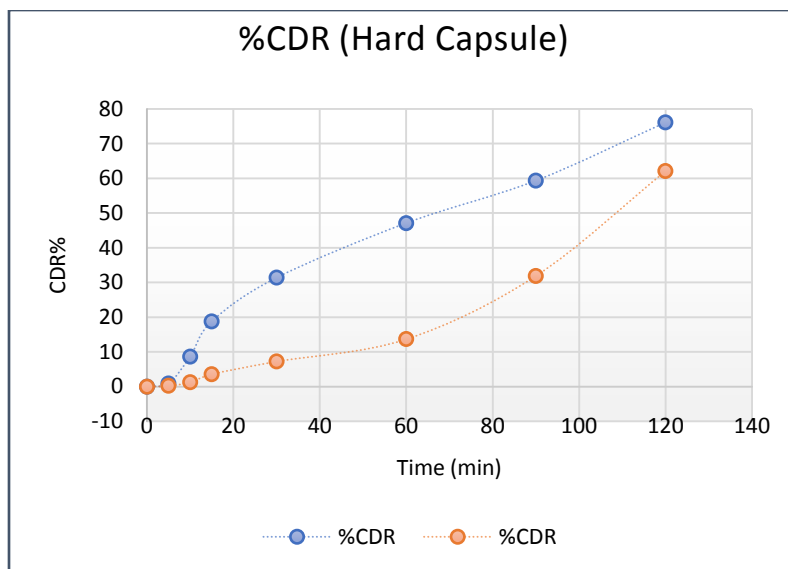
**Figure 5: HPTLC fingerprint and chromatogram of hard gelatin capsule.**



**Figure 5.1: HPTLC fingerprint and chromatogram of the soft chewable capsule.**

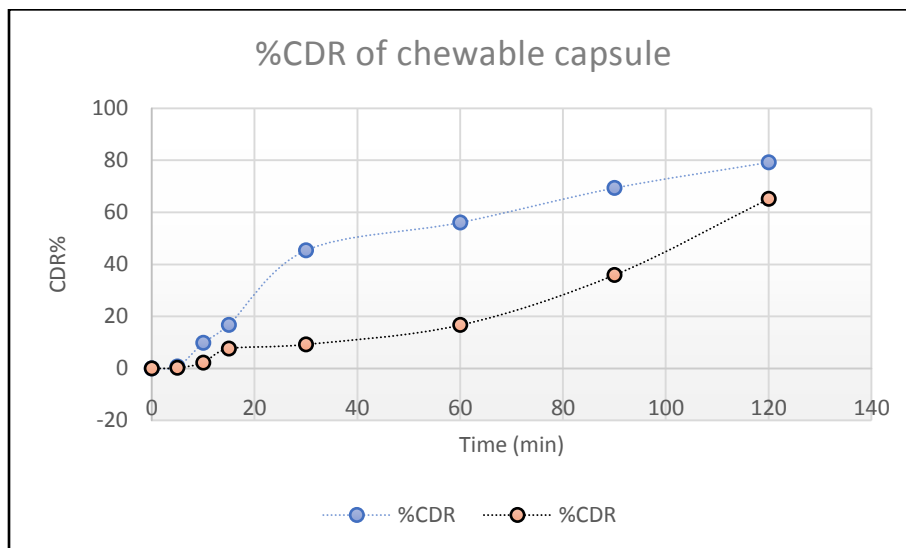
When the formulation run in the mobile phase with an Rf value of 0.69 for curcumin and 0.56 for wedelolactone, respectively, petroleum ether, ethyl acetate, methanol, and water at a ratio of (1.5:3:2.1:2) v/v revealed two major active constituents.

## 6. Stability Studies



**Figure 6: In vitro Dissolution Study of hard gelatin capsules after stability study**





**Figure 6.1: In vitro Dissolution Study of chewable Capsules after stability study.**

After a six-month stability study, the in vitro dissolution study for the prepared capsule formulation did not reveal any appreciable changes in the drug release (%). The above studies indicate these herbal capsules are stable at room temperature for 6 months. This aims to develop a method for maintaining the stability, safety, and quality of various herbal products. Stability testing is important for determining factors such as a product's shelf life, optimal storage conditions, retest period, and assuring its overall quality for the patient.

## Conclusion

The health of humans is significantly influenced by medicinal plants. Today, several medicinal plants are frequently used to treat various liver diseases (also known as phytomedicines or herbal drugs). Some medicinal plants have the potential to be both hepatogenic and hepatoprotective against hepatotoxicity brought on by a variety of hepatotoxicants. Medicinal plants have diverse antioxidant, immunomodulatory, and phagocytic activities, which may make them effective against diseases of the liver. The tridosha principle is used by Ayurveda, according to conventional medical systems, to understand diseases and balance. It will undoubtedly help them gain more popularity if formulations are made more acceptable and significant scientific data about traditional system medicines are produced. In the current study, hepatoprotective hard gelatin capsules and soft chewable capsules with improved physicochemical characteristics, such as dissolution and disintegration profiles, were successfully prepared using 5 different plant extracts. According to the study's findings, the prepared formulations provide a long-term, safe, and effective cure for liver disorders with better patient compliance.

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