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Pre-Formulation and Formulation Study of *Plicosepalus acacia* Capsules Dosage Forms



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ABSTRACT

The objective of this study was to formulate and evaluate *Plicosepalus acacia* extract as capsule dosage form. *Plicosepalus acacia* powder was done by microcrystalline cellulose (80%) as an adsorbent by the non-thermal method. The pre-formulation parameters like bulk density, tap density, Carr's index, Hausner's ratio, the angle of repose and drug excipient compatibility were checked. The *Plicosepalus acacia* powder with a suitable excipient was capsulated and the designed formulations were evaluated for organoleptic properties, solubility, IR compatibility, Thin layer chromatography, content uniformity, weight variation, moisture content, dissolution, and stability. It was found that *Plicosepalus acacia* extract was compatible with Microcrystalline Cellulose, Sodium Starch Glycolate, and Methylparaben, and no significant change in the Rf value of *Plicosepalus acacia* was observed. The extracts also freely soluble in water and partially soluble in methanol. Uniformity of weight and content and dissolution profile of *Plicosepalus acacia* capsules are within the BP specification. As the stability was concerned for two formulas after 12 weeks storage at 30±2°C / 70%±5% relative humidity (RH) and at 45±2°C / 75%±5% relative humidity (RH) in glass bottle container indicated that the manufactured capsules essentially had the same organoleptic properties during storage, moisture content, chromatographic pattern and had near dissolution profiles after storage and still within the British Pharmacopoeia single point specification. It concluded that *Plicosepalus acacia* extract can be formulated as a capsule stored in a glass bottle.



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INTRODUCTION:

The majority of drug substances in use today occur as solid materials. Most of them are pure chemical compounds of either crystalline or amorphous constitution. Some are powdered drugs(1). Herbal formulations may exist as fluid extracts (infusions, decoctions, macerates, and tinctures), dry extracts and special extracts. It is important to provide patients with dosage forms which are convenient to their needs and encourage compliance in order to ensure maximum therapeutic effect(2).

Prior to the development of dosage forms, it is essential that certain fundamental physical and chemical properties of the drug molecule and other properties of the herbal drug powder are determined. This information dictates many of the subsequent events and approaches in formulation development(3).

The pre-formulation is an important step in the development of a new drug. It influences the safety, effectiveness, controllability, stability, and compliance of the drug and the physical and chemical properties are part of preformulation studies(4).

These studies give clues as to how to achieve the desired performance of the finished product. (5)

Plicosepalus acacia is one of this medicinal plant, its belong to the family Loranthaceae, which is the largest family that belong to the order Santalales, it is a parasitic plant which is generally known as " Enab Ala'mq – kurad "(in Arabic) and it is found in northeast Africa, Yemen, Jordan, and Saudi Arabia. In Yemen, it is widely distributed in Taiz and Suhban valley, Ibb city. and it parasiting in different trees which grew in Yemen.

Plicosepalus acacia used in folk medicine to treat various diseases as smallpox, diarrhea and hookworms infections. Also, treatment of tonsillitis and otitis media were reported(6,7). In addition, it used for the treatment of diabetes mellitus and to enhance wound healing(8,9).

The plant's flowers are dried and blended to make a powder, the powder is mixed with honey and taken as one teaspoonful daily.

There are many studies regarding antioxidant and antimicrobial activities of *Plicosepalus acacia* plant but there is no any study about hepatoprotective of *Plicosepalus acacia* flower(10, 11, 12, 13).

For this study, *Plicosepalus acacia* extract powder was prepared and analyzed in the pre-formulation study. Total assessments were performed in the pre-formulation study of *Plicosepalus acacia* capsules.

MATERIALS AND METHODS:

Materials: The *Plicosepalus acacia* semisolid extract.

Microcrystalline cellulose, starch, Carboxymethylcellulose, colloidal silicon dioxide (Aerosil), Methylparaben, Sodium starch glycolate, Crospovidone, Methanol, water, ethyl acetate, and chloroform. All of Laboratory grades of mater were obtained from the chemical store of the Department of quality control, Shaphaco pharmaceutical industries, Sana'a, Yemen.

Equipment: UV spectrophotometry (Jasco, Japan), Electronic balance (Metler, Germany), Disintegrator Erweka, Germany), water bath (Triup international CORP).

METHODS:

Drying methods: A Nonthermal method for drying the *Plicosepalusacacia* semisolid extract with different adsorbent powder were used.

The adsorbent powder, each one of them, was sprinkling added onto the extract and thoroughly mixed until the semisolid became the dump mass, then turn into the incoherent powder and eventually reach the crumbly(14), as shown in the table(1)

Table 1: Drying the total extract with different adsorbent powder:

Ingredient mg /capsule	F1	F2	F3	F4
Total extract	500	500	500	500
MCC	500	---	---	---
Starch	---	500	----	---
CMC	----	-----	500	----
Aerosil	----	----	----	500

Determiration of the organoleptic properties of the plant extracts: Physical appearance, odor, and taste. For these samples of *Plicosepalus acacia*, extracts were inspected and

assessed using the natural senses (e.g. eyes, nose, mouth).

Determination of the solubility of the plant extracts:

The total extract of *Plicosepalus acacia* was solubilized in water and methanol according to descriptive solubility(15).

Determination of extract particle size: (16)

Sieves of numbers (0.71, 0.80, 0.90) were arranged in a descending order on the sieve shaker. Then 10 g of *Plicosepalus acacia* extract was poured in the top sieve. Finally, the cover was put on the top, and the shaker was started.

The process of shaking took 30 minutes. Thereafter the powder collected on each of the sieves was weighed and the percentage (w/w) of each fraction determined(16, 17).

Determination of extract density:

Pre-formulation parameters like bulk density, tap density, Carr's index, Hausner's ratio and angle of repose were obtained for the laboratory granules (18).

Method: A known quantity of powder was poured into the measuring cylinder carefully level the powder without compacting, if necessary and read the unsettled apparent volume.

Calculate the bulk density, in gm per ml, by the formula.

Bulk density = Bulk Mass/ Bulk Volume(19).

Carr's compressibility index(3).

Carr's index (%) = (Tapped density – Poured density) / Tapped density

Determination of flowability of plant extracts:

Method: Funnel was kept vertically in a stand at a specified height above a paper placed on a horizontal surface. The funnel bottom is closed and 10 gm of the sample powder is filled in the funnel.

Then funnel was opened to release the powder on the paper to form a smooth conical heap, is found by measuring in a different direction. The height of the heap was measured by using a

scale. The values of angle of repose are calculated by using the following formula(20, 15).

$\tan \theta = h / r$. Where: θ : Angle of repose, h: height, r: radius of the conical mound.

Drug-excipient compatibility studies:

Excipients play a wide variety of functional roles in pharmaceutical dosage form(21, 22)and techniques commonly employed in drug-excipient compatibility screening are:

- a chromatographic technique using either HPLC or TLC.
- differential thermal analysis.
- diffused reflectance spectroscopy.

In preformulation the excipient that used to form *Plicosepalus acacia* capsule were: Microcrystalline Cellulose, Starch, Carboxymethylcellulose and colloidal silicon, Dioxide(Aerosol)as an adsorbent, Sodium Starch Glycolate and Crospovidone as disintegrant and methylparaben as a preservative.

Method: In this approach, binary use (1:1 or customized) mixtures of the drug and excipient(23) and then analyzed using IR Spectroscopy and TLC Chromatography.

IR Spectroscopy:

Samples were prepared by weighing ingredients (1:1) similar quantities of drug and excipient. Each sample was mixed with KBr by grinding in a mortar and the mixture is compressed into a small pallet. The spectrum was scanned over a frequency range of 3500 – 400 cm^{-1} . The IR spectra obtained were compared for similarities and differences.

Thin layer chromatography.

TLC is a reliable tool for the detection of chemical incompatibility especially when herbal extracts are involved. The individual extracts used in the formulation have been standardized to specific marker compound(s). The markers of *Plicosepalus acacia* extract were taken as a standard. The major spot when extracts and two or more excipients were combined and eluted in homogeneous chromatographic conditions signifies the compatibility(24).

Procedure:

1- Preparation of: Extract and Microcrystalline Cellulose (1:1): Dilute (1mg of total extract + 1mg of Microcrystalline Cellulose) in s.q of methanol. Use the filtrate for chromatography applying.

Extract and Microcrystalline Cellulose and Sodium Starch Glycolate(1:1:1): Dilute (1mg of total extract + 1mg of Microcrystalline Cellulose+1mg of Sodium Starch Glycolate) in s.q of methanol.-Use the filtrate for chromatography applying.

2- Reference substance :(STD): Dilute 1mg of total extract + s.q of methanol. Use the filtrate for chromatography applying.

3-Development: Develop the spotted plate at room temperature. Mark the front and allow the solvent to evaporate off at room temperature.

4- Detection: - visualization the spot that appears after that heat the plate and examines in UV light(254nm & 366nm)

Formulation of *Plicosepalus acacia* capsules:

A uniform powder is obtained by mixing the semisolid extract of *Plicosepalus acacia* with the appropriate adsorbent Microcrystalline cellulose. Then mixed with sodium starch glycolate and methylparaben and filled into the capsules using the bench scale filling method. Each capsule of *Plicosepalus acacia* extract must contain:

R_x

Plicosepalusacacia extract1g

Microcrystallinecellulose0.8g

SodiumStarchglycolate0.072g

Methylparaben 0.0018g

Consequently the number of materials per capsule 1.87g, and from the volume of these materials the size of capsule selected was "000".

Pre-formulation studies:

Pre-formulation studies were carried out for the investigation of the physicochemical character of a drug substance alone and when combined with excipients. The overall objective of the pre-formulation testing was to generate information useful in developing stable and bioavailable dosage form(25).

Method: In pre-formulation studies, the formulas were designed as (PF1, PF2) with different concentration of excipients. In PF1with (sodium starch glycolate), in PF2 with (Crospovidone) as a disintegrant.

Table 2: Pre-formulation of two formula (PF1 and PF2):

Ingredient mg /capsule	Pre-formulation	
	PF1	PF2
Total extract	200	200
Microcrystalline Cellulose	160(80%)	160(80%)
Methylparaben	0.36	0.36
Sodium starch glycolate	14.4	---
Crospovidone	---	14.4

Determination of the appropriate PF by Disintegration.

The disintegration of capsules was tested in disintegration tester. Water was used as a testing medium, temperature set at 37°C. Six capsules were evaluated for their time of disintegration by putting each capsule into the disintegrating tube and covered by the disc, testing until powdered *Plicosepalus acacia* totally disintegrated from the capsule shell. The disintegration times were recorded and the average time was consequently calculated(14).

Table 3: Pre-formulations disintegration times

Pre-formulation	Average disintegration time
PF1 (Sodium starch glyconate)	5.23
PF2 (Crospovidone)	6.27

Determination of uniformity of weight.

For the determination of the uniformity of weight, was carried according to the BP(26).

In which twenty of the *Plicosepalus acacia* capsules prepared were taken at random, their contents individually weighed and the average weight (mass) of the content determined. Not more than two of the individual weights (masses) had to deviate from the average weight (mass) by more than 7.5% and none of the deviates by more than twice that percentage.

The amount of powder actually filled into the capsules was also compared with the desired quantity and the difference (in percentage) between the desired and actual quantity calculated. According to the formulation, 468mg of *Plicosepalus acacia* extract was to be filled in each capsule.

Determination of Moisture content.

In this study, the shell of the capsules was removed and the moisture level of the contents of the capsules determined by using the moisture content analyzer(3, 27).

Determination of dissolution profile (27).

Procedure: In which 900 ml of pH 0.1 hydrochloric acid buffer was degassed, introduced into the vessel of the apparatus, warmed to $37\pm 0.5^{\circ}\text{C}$ in the water bath. One capsule was placed in each vessel, the paddle was lowered into position and the apparatus were operated immediately at the rotation speed 50 rpm. A sample of 3 ml withdrawn from the dissolution medium at a various time interval, at 0, 10, 20, 30, 40 and 45 minutes.

Each time the withdrawn medium was immediately replaced by 3 ml of pH 0.1 hydrochloric acid buffer introduced into the vessel.

The UV absorbance of the solution was determined at the wavelengths 437nm. and using the solution of one of the empty capsule shell dissolved in the 900 ml volume of dissolution medium as a blank reference solution.

From the standard curve of known concentrations of plant material versus UV absorbance, the amounts of dissolved plant material in the dissolution media were determined, the percent material dissolved at each time point calculated and the percent dissolved over time profiles for plant capsule derived.

For the plant product the dissolution profile of 6 capsules was determined and for each capsule, not less than 70% of the stated amount had to dissolve within 45 min in order for the product to meet the specification for immediate release (British Pharmacopoeia). If one of the capsules did not meet this requirement a further six had to be tested individually and all had to comply.

Determination of stability of *Plicosepalus acacia* capsules(3, 17, 28).

Using a climate chamber, capsules were stored in a glass bottle under two conditions, 30±2 °C (70%±5% RH) and 45±2 °C (75%±5% RH).

The sample was taken every 2 weeks, 6 weeks, 10 weeks and 12 weeks from each site and assessed for organoleptic properties (i.e. gross physical nature, color and odor of the powder content and overall size, shape and appearance of the capsule).

At 6 weeks and at the end of 12 weeks, the moisture content of the capsules and the dissolution of the capsules were again tested. The organoleptic properties and the moisture level of the content of the test capsules were compared with that of the content of *Plicosepalus acacia* capsules before storage. The dissolution profile of *Plicosepalus acacia* capsules was assayed at the beginning, 6 weeks later and after 12 weeks were compared with each other.

RESULTS AND DISCUSSION

Table 4: Pre-formulation testing results of *Plicosepalus acacia* extract.

Test	Total extract of P. extract
Drying	By absorbent MCC
The solubility of extracts (g/ml)	1gm/10 ml of water
Particle size	Fine powder
Carr’s index (%)	13.3%
Angle of repose (°)	11.9°
Pre-formulation studies	PF1

Yield of drying total extract of *Plicosepalusacacia*:

Extracted *Plicosepalus acacia* in a form of thick semisolid with some moisture content was

dried by mixing separately with adsorbent powders the most appropriate adsorbent was microcrystalline cellulose It used in different percentage start from 20% reach to 80% it is appropriate percentage maxed with total extract to produce the powder.

Table 5: The organoleptic properties of the total extract of *Plicosepalus acacia* powder:

Proprieties	Total extract
Physical appearance	Free-flowing, small particulate powder
Color	Brown
Odor	Characteristic Odor
Taste	Better

As shown in the table (5), *Plicosepalus acacia* powder was found Free-flowing, small particulate powder, brown in color, with characteristic odor and better taste

The solubility of the total extract of *Plicosepalusacacia*:

As shown in the table (6), the solubility of total extract of *Plicosepalusacacia* performed was freely soluble in water and partially soluble in methanol.

Table 6: Solubility testing for a total extract of *Plicosepalusacacia*.

Solvent	Solubility
Water	Freely soluble
Methanol	Partially soluble

The particle size of *Plicosepalus acacia* extract powder was found moderately fine powder based on the British Pharmacopoeia standard and possessed appropriate flowability for the manufacture of the capsule dosage form.

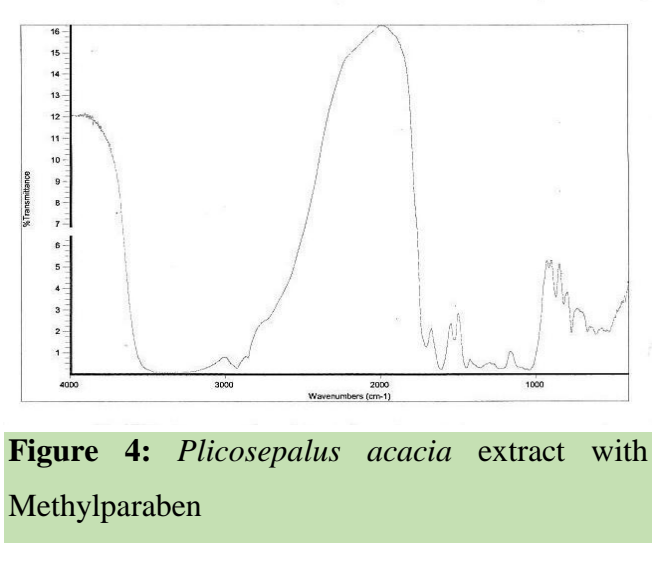
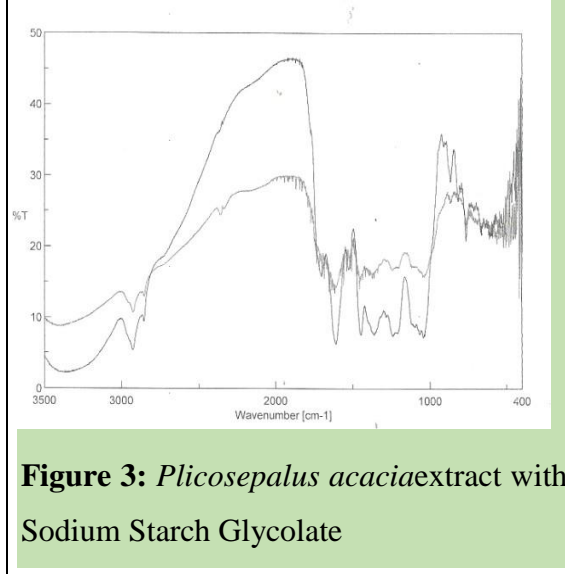
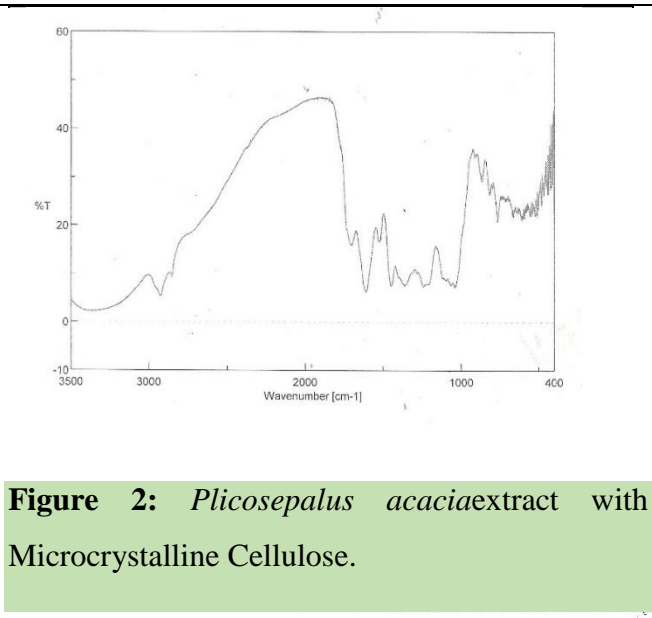
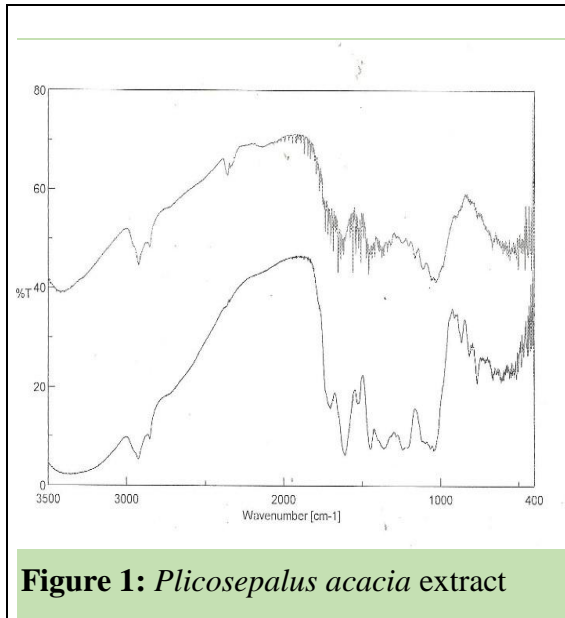
The density study results show that the *Plicosepalus acacia* extract powders can be categorized as having excellent flow properties and Carr’s index of Compressibility for *Plicosepalus acacia* extract is 13.3%.

As the flowability concerned, *Plicosepalus acacia* extract powders show angles of repose of (11.9 °) means, having excellent flow properties. This implicated that the *Plicosepalus acacia* extract powders possessed appropriate flowability for the manufacture of capsule dosage

form.

Drug-excipient compatibility studies:

IR Spectroscopy: The result of drug excipient compatibility is recorded as follows:



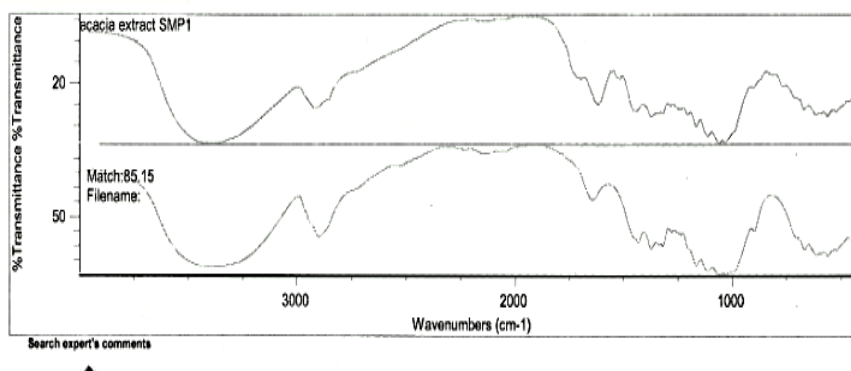


Figure 5: *Plicosepalus acacia* extract with Microcrystalline Cellulose, Sodium Starch Glycolate and Methylparaben.

As shown in Figure 2, 3,4, it was found that *Plicosepalus acacia* extract was compatible with Microcrystalline Cellulose, Sodium Starch Glycolate, and Methylparaben, as there was a peak corresponding to pure *Plicosepalus acacia* extract.

IR spectra of all the compatibility samples possess the bands and this all was same as that for pure *Plicosepalus acacia* extract in Figure 1, which indicate the compatible nature of *Plicosepalus acacia* extract with all selected excipients.

Some alteration was observed in Figure 5, due to Samples were not prepared by carefully weighing ingredients, to ensure similar quantities of drug and excipient in drug-excipient and pure component samples. Further, this mixture was subjected to the TLC analysis.

As in Figure 6 and 7TLC study, R_f value of pure *Plicosepalus acacia* was compared with R_f value of *Plicosepalus acacia* of different mixtures. And thus show no significant change in R_f value of *Plicosepalus acacia* observed. These confirm the compatible nature of *Plicosepalus acacia* with these excipients.

From the TLC: The spots of A & B & C that have same RF, the extract compatible with an excipient.

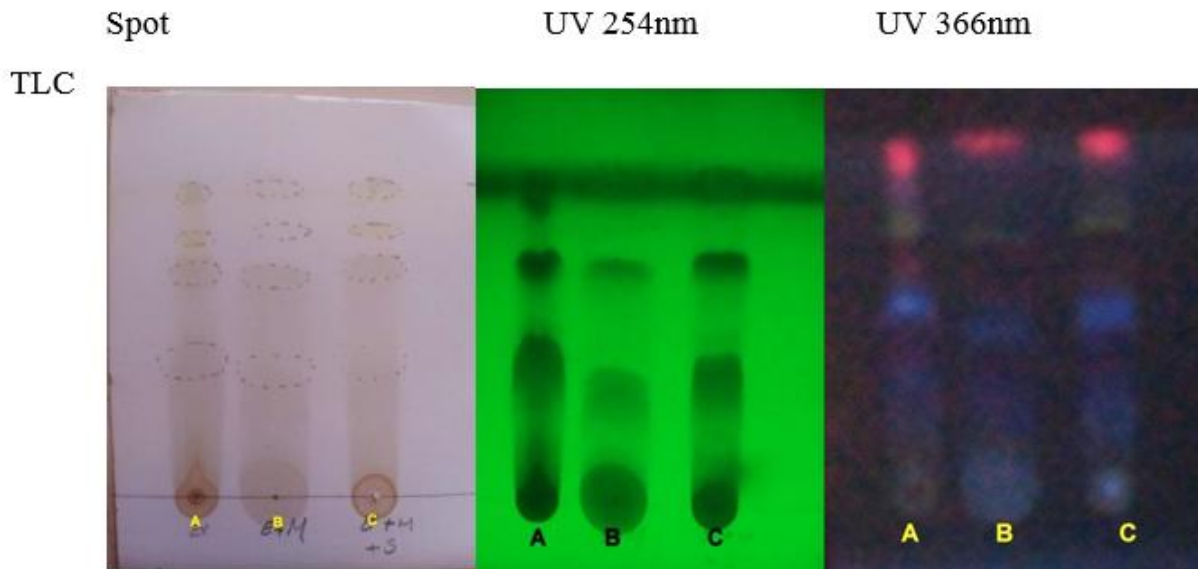


Figure (6): TLC compatibility of pure *Plicosepalus acacia* & *Plicosepalus acacia* with different excipient Where A: total extract, B: total extract + Microcrystalline Cellulose, C: total extract + Microcrystalline Cellulose + Sodium Starch Glycolate



Figure (7): TLC compatibility of *Plicosepalus acacia* & excipient Where
 A: extract,
 B: extract + Microcrystalline Cellulose,
 C: extract + Microcrystalline Cellulose + Sodium Starch Glycolate,
 D: extract + Microcrystalline Cellulose + Sodium Starch Glycolate + methyl paraben.

Table 7: pre-formulations disintegration times.

Pre-formulation	Average disintegration time
PF1 (Sodium starch glyconate)	5.23
PF2 (Crospovidone)	6.27

As shown in Table 7, all pre-formulations PF1 and PF2 passed the criteria of capsule disintegration in British Pharmacopoeia.

The results of the uniformity of weight and content of the *Plicosepalus acacia* capsules were calculated. The average deviation in weight from average for *Plicosepalus acacia* capsules were 0.1% and the average total content per capsule 92.72%.

The results indicated that the *Plicosepalus acacia* capsules met the British Pharmacopoeia specifications.

The percentage of moisture content of *Plicosepalus acacia* was found to be 6 %.

As shown in figure (8) the dissolution study of *Plicosepalus acacia* capsules showed that 76.8% of the *Plicosepalus acacia* capsule contents dissolved in the dissolution medium within 45 minutes. These results are within the BP. specification and indicated that *Plicosepalus acacia* capsules were immediate release solid oral dosage forms with good *in-vitro* bioavailability.

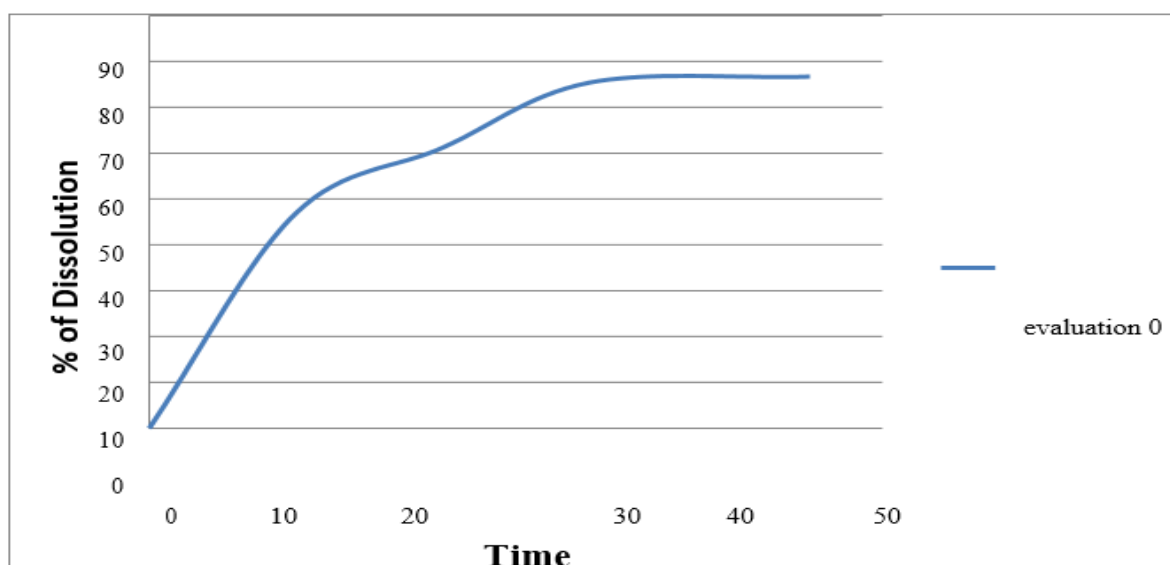


Figure (8): Dissolution profile of *Plicosepalus acacia* capsules. Dissolution conditions: paddle method, 900ml pH 0.2 hydrochloric acid buffer; 37±0.5°C, samples quantitated by UV assay.

For stability study, the two batches of capsules (PF1 and PF2), stored under the different conditions at $30\pm 2^{\circ}\text{C} / 70\%\pm 5\%$ RH and $45\pm 2^{\circ}\text{C} / 75\%\pm 5\%$ RH, show that:

As illustrated in table (8), for organoleptic properties, of the *Plicosepalus acacia* capsules, stored in the glass container, at $30\pm 2^{\circ}\text{C} / 70\%\pm 5\%$ RH and $45\pm 2^{\circ}\text{C} / 75\%\pm 5\%$ RH, remained relatively unchanged during the 12 weeks storage.

Table 8: Organoleptic properties during storage of *Plicosepalus acacia* capsules.

No of Weeks	Size, the shape of Capsule	Gross nature of powder in capsule	Color of Powder	Odor of Powder
0	Regular "0" size & shape	Powder	Brown	No change
2	No change	Powder	Brown	No change
6	No change	Powder	Brown	No change
10	No change	Powder	Brown	No change
12	No change	Powder	Brown	No change

For the moisture levels of the *Plicosepalus acacia* capsules contents at 6 weeks and at the end of 12 weeks were determined as in table (9), and the results were compared with that of the content of *Plicosepalus acacia* capsules before storage as depicted in figure (9).

Table 9: The moisture levels of the *Plicosepalus acacia* capsules

Time	Percentage of moisture %
Before storage	6.0%
After 6 weeks at $30\pm 2^{\circ}\text{C} / 70\%\pm 5\%$ (RH)	6.8%
After 6 weeks at $45\pm 2^{\circ}\text{C} / 75\%\pm 5\%$ (RH)	6.8%
After 12 weeks at $30\pm 2^{\circ}\text{C} / 70\%\pm 5\%$ (RH)	7.0%
After 12 weeks at $45\pm 2^{\circ}\text{C} / 75\%\pm 5\%$ (RH)	7.1%

As illustrated in table (9), figure (9), the results show no large change in the moisture levels of the *Plicosepalus acacia* capsules stored in the glass bottle containers under at $45\pm 2^{\circ}\text{C} / 75\%\pm 5\%$ (RH) and $30\pm 2^{\circ}\text{C} / 70\%\pm 5\%$ (RH), and it is strongly suggested that storage in glass bottle containers protect *Plicosepalus acacia* capsules against moisture.

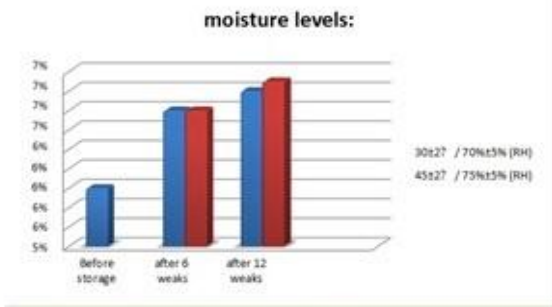


Figure 9: Moisture content of *Plicosepalus acacia* capsules

(A) Before storage; (B) After 6 weeks at 30±2°C and 70% ± 5% RH
 (C) After 6 weeks at 45±2°C and 75% ± 5% RH (D) After 12 weeks at 30±2°C and 70% ± 5% RH (E) After 12 weeks at 45±2°C and 75% ± 5% RH

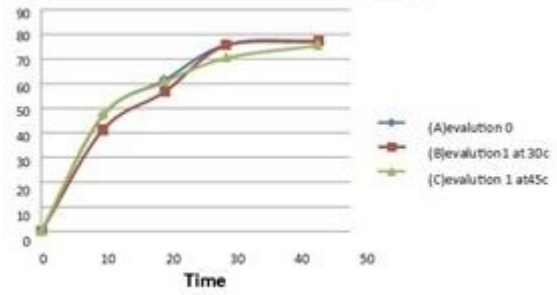


Figure 10: Dissolution profile of *Plicosepalus acacia* capsules at 6 weeks

(A) Dissolution profile before storage
 (B) Dissolution profile after 6 weeks storage at 30±2°C and 70% ± 5% RH
 Dissolution profile after 6 weeks storage at 45±2°C and 75% ± 5% RH

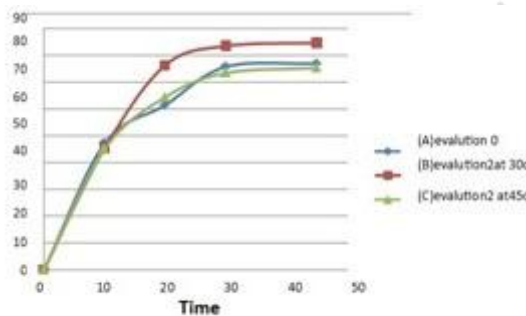


Figure 11: Dissolution profile of *Plicosepalus acacia* capsules at 12 weeks

(A) Dissolution profile before storage
 (B) Dissolution profile after 12 weeks storage at 30±2°C and 70% ± 5% RH
 Dissolution profile after 12 weeks storage at 45±2°C and 75% ± 5% RH

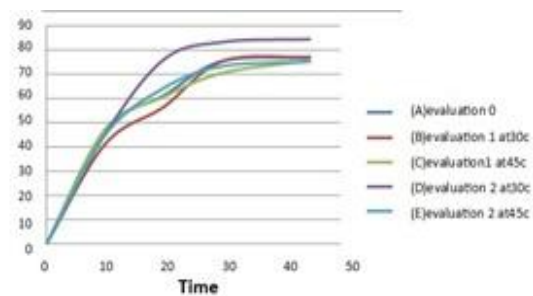


Figure 12: Dissolution profile of *Plicosepalus acacia* capsules during storage

(A) Dissolution profile before storage
 (B) Dissolution profile after 6 weeks storage at 30±2°C and 70% ± 5% RH
 (C) Dissolution profile after 6 weeks storage at 45±2°C and 75% ± 5% RH
 (D) Dissolution profile after 12 weeks storage at 30±2°C and 70% ± 5% RH
 (E) Dissolution profile after 12 weeks storage at 45±2°C and 75% ± 5% RH

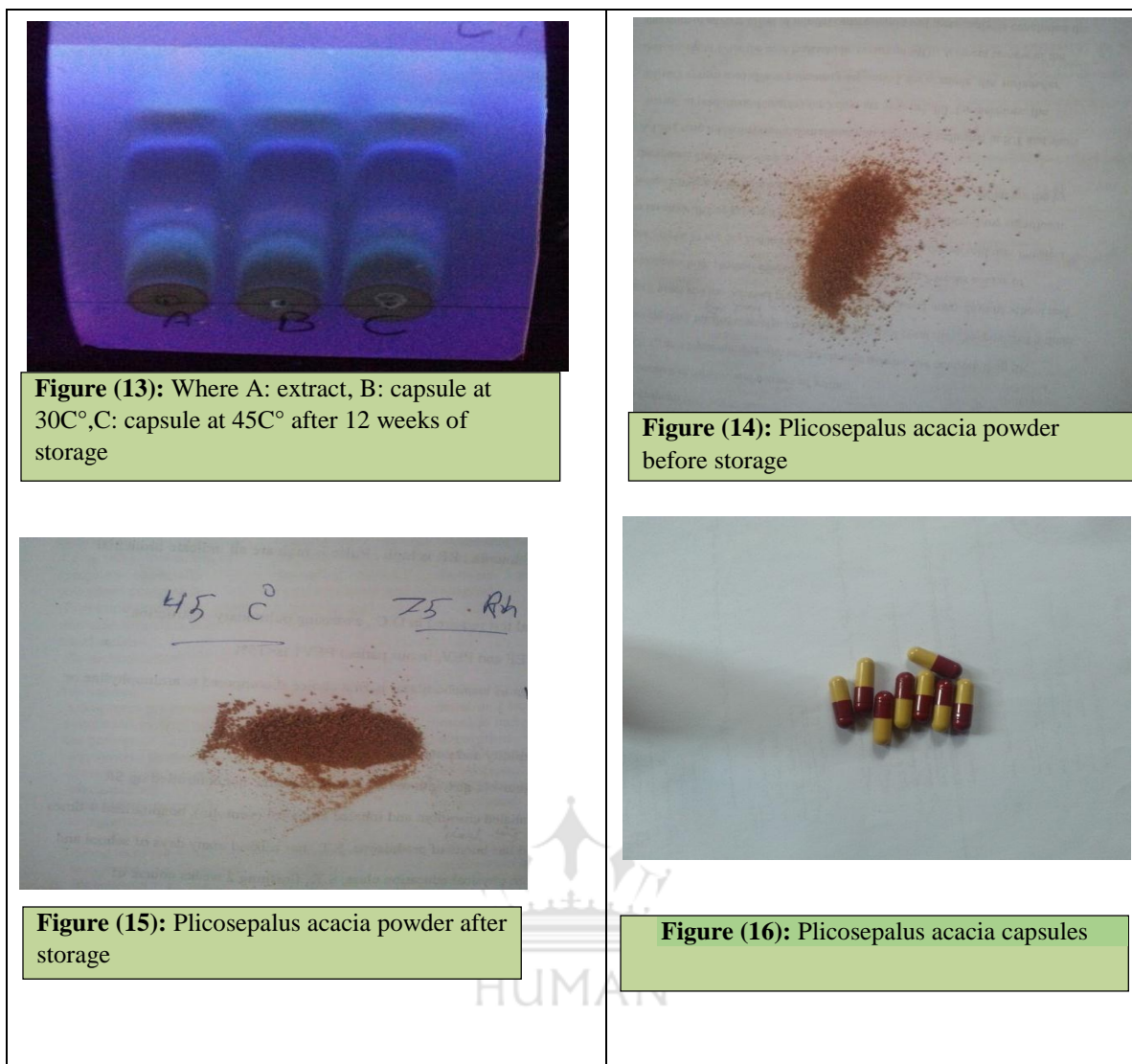


Figure (13): Where A: extract, B: capsule at 30°C, C: capsule at 45°C after 12 weeks of storage

Figure (14): *Plicosepalus acacia* powder before storage

Figure (15): *Plicosepalus acacia* powder after storage

Figure (16): *Plicosepalus acacia* capsules

Dissolution profile of *Plicosepalus acacia* capsules.

The Percentages of dissolution during storage were calculated as in Table 10. A comparison of the dissolution profiles of the *Plicosepalus acacia* capsules tested at the beginning of the tests, at 6 weeks and at the end of the storage period obtained in this study are shown in Figures 10, 11, 12.

Table 10: The Percentage of Dissolution of the *Plicosepalus acacia* capsules

Time	Percentage of Release % after 45 min
Before storage	76.8%
After 6 weeks at 30±2°C / 70%±5% (RH)	77.2%
After 6 weeks at 45±2°C / 75%±5% (RH)	75.5%
After 12 weeks at 30±2°C / 70%±5% (RH)	84.6%
After 12 weeks at 45±2°C / 75%±5% (RH)	75.1%

Figure 14, 15 show the *Plicosepalus* acacia powder before and after storage, while Figure 13 show that, The Chromatographic Comparison between *Plicosepalus* acacia capsules before storage, after 6 weeks and after 12 weeks of storage indicated that there was no change and it has the same chromatographic pattern and the *Plicosepalus* acacia capsules were still within the British Pharmacopoeia specification and figure (16) represent the capsule formulated.

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