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FORMULATION, DEVELOPMENT AND EVALUATION OF *PLICOSEPALUS ACACIA* EXTRACT CAPSULES DELIVERY SYSTEM AS AN ADVANCED PHYTOTHERAPY APPROACH FOR CONTROLLING DIABETES

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ABSTRACT
Diabetes is a serious health concern in many countries with high blood glucose, obesity, and multiple organ failures in late stages. Treating diabetes with effective drugs is still a challenging issue since most of the available diabetic drugs are not effective in combating diabetes, especially in secondary disease complications like obesity retinopathy, and nephropathy associated diabetes. Hence search for effective anti-diabetic medication, especially from natural sources is mandatory with no adverse side effects. The *Plicosepalus acacia* plant widely distributed in Yemen. The *Plicosepalus acacia* is plant widely distributed in Yemen, a large number of medicinal plants have been tested and found to contain active principles with curative properties against a variety of diseases. Liver protective plants contain a variety of chemical constituents like flavonoids, Phenol, Tannins, Steroids, Amino acid and Triterpene glycoside. Therefore, a large number of plants and formulations have been claimed to have anti-diabetic medication so the development of plant based diabetic drugs has been given importance in the global market. *Plicosepalus acacia* is commonly used in traditional medicine for a wide range of ailments including hepatoprotective activity. *A Plicosepalus acacia was f*ormulated as capsules and evaluated for organoleptic properties and other evaluation parameters. It was concluded that the formulation of *Plicosepalus acacia* extract medicinal herbs capsules delivery system as an advanced phytotherapy approach for controlling diabetes according to the best results of *in-vitro* dissolution was found to be 76.8% within 45 minutes in acid medium and were evaluated.

KEYWORDS: *Plicosepalus acacia*, Extract, Capsules, Medicinal herbs**,** Antidiabetic, Phytotherapy.

INTRODUCTION

Diabetes Mellitus[1-9]

Diabetes is a serious health concern in many countries with high blood glucose, obesity, and multiple organ failures in late stages. Treating diabetes with effective drugs is still a challenging issue since most of the available diabetic drugs are not effective in combating diabetes, especially in secondary disease complications like obesity retinopathy, and nephropathy associated diabetes. Hence search for effective anti-diabetic medication, especially from natural sources is mandatory with no adverse side effects.

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood glucose. Hyperglycaemia, also called raised blood glucose or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

In 2014, 8.5% of adults aged 18 years and older had diabetes. In 2019, diabetes was the direct cause of 1.5 million deaths and 48% of all deaths due to diabetes occurred before the age of 70 years. Another 460 000 kidney disease deaths were caused by diabetes, and raised blood glucose causes around 20% of cardiovascular deaths.

Between 2000 and 2019, there was a 3% increase in age-standardized mortality rates from diabetes. In lower-middle-income countries, the mortality rate due to

diabetes increased 13%. By contrast, the probability of dying from any one of the four main noncommunicable diseases (cardiovascular diseases, cancer, chronic respiratory diseases or diabetes) between the ages of 30 and 70 decreased by 22% globally between 2000 and 2019.

Symptoms of diabetes may occur suddenly. In type 2 diabetes, the symptoms can be mild and may take many years to be noticed. Symptoms of Diabetes Include: feeling very thirsty, needing to urinate more often than usual, blurred vision, feeling tired and losing weight unintentionally.

Over time, diabetes can damage blood vessels in the heart, eyes, kidneys and nerves. People with diabetes have a higher risk of health problems including heart attack, stroke and kidney failure. Diabetes can cause permanent vision loss by damaging blood vessels in the eyes. Many people with diabetes develop problems with their feet from nerve damage and poor blood flow. This can cause foot ulcers and may lead to amputation.

Type 1 Diabetes: Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production and requires daily administration of insulin. In 2017 there were 9 million people with type 1 diabetes; the majority of them live in high-income countries. Neither its cause nor the means to prevent it are known.

Type 2 Diabetes: Type 2 diabetes affects how your body uses sugar (glucose) for energy. It stops the body from using insulin properly, which can lead to high levels of blood sugar if not treated.

Over time, type 2 diabetes can cause serious damage to the body, especially nerves and blood vessels.

Type 2 diabetes is often preventable. Factors that contribute to developing type 2 diabetes include being overweight, not getting enough exercise, and genetics. Early diagnosis is important to prevent the worst effects of type 2 diabetes. The best way to detect diabetes early is to get regular check-ups and blood tests with a healthcare provider.

Symptoms of type 2 diabetes can be mild. They may take several years to be noticed. Symptoms may be similar to those of type 1 diabetes but are often less marked. As a result, the disease may be diagnosed several years after onset, after complications have already arisen.

More than 95% of people with diabetes have type 2 diabetes. Type 2 diabetes was formerly called non-insulin dependent, or adult onset. Until recently, this type of diabetes was seen only in adults but it is now also occurring increasingly frequently in children. Gestational diabetes: Gestational diabetes is hyperglycaemia with blood glucose values above normal but below those diagnostics of diabetes. Gestational diabetes occurs during pregnancy. Women with gestational diabetes are at an increased risk of complications during pregnancy and at delivery. These women and possibly their children are also at increased risk of type 2 diabetes in the future. Gestational diabetes is diagnosed through prenatal screening, rather than through reported symptoms.

Impaired glucose tolerance and impaired fasting glycaemia: Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) are intermediate conditions in the transition between normality and diabetes. People with IGT or IFG are at high risk of progressing to type 2 diabetes, although this is not inevitable.

Prevention: Lifestyle changes are the best way to prevent or delay the onset of type 2 diabetes. To help prevent type 2 diabetes and its complications, people should: reach and keep a health body weight, stay physically active with at least 30 minutes of moderate exercise each day, eat a healthy diet and avoid sugar and saturated fat, not smoke tobacco. Diagnosis and treatment: Early diagnosis can be accomplished through relatively inexpensive testing of blood glucose. People with type 1 diabetes need insulin injections for survival. One of the most important ways to treat diabetes is to keep a healthy lifestyle. Some people with type 2 diabetes will need to take medicines to help manage their blood sugar levels. These can include insulin injections or other medicines. Some examples include: metformin, sulfonylureas, and sodium-glucose co-transporters type 2 (SGLT-2) inhibitors.

Along with medicines to lower blood sugar, people with diabetes often need medications to lower their blood pressure and statins to reduce the risk of complications. Additional medical care may be needed to treat the effects of diabetes: foot care to treat ulcers, screening and treatment for kidney disease and eye exams to screen for retinopathy.

WHO Response: WHO aims to stimulate and support the adoption of effective measures for the surveillance, prevention and control of diabetes and its complications, particularly in low- and middle-income countries. To this end, WHO: provides scientific guidelines for the prevention of major noncommunicable diseases including diabetes; develops norms and standards for diabetes diagnosis and care; builds awareness on the global epidemic of diabetes, marking World Diabetes Day (14 November); and conducts surveillance of diabetes and its risk factors.

In April 2021 WHO launched the Global Diabetes Compact, a global initiative aiming for sustained improvements in diabetes prevention and care, with a particular focus on supporting low- and middle-income countries.

In May 2021, the World Health Assembly agreed a Resolution on strengthening prevention and control of diabetes. In May 2022 the World Health Assembly endorsed five global diabetes coverage and treatment targets to be achieved by 2030.

***Plicosepalus Acacia* Herbal Medicine**[10-25]

Herbal medicine is the oldest form of health care known to mankind. It is an integral part of the development of modern civilization. The World Health Organization estimates that in some Asian and African countries 80% of the population depend on traditional medicine for primary health care; in many developed countries, 70% to 80% of the population has used some form of alternative or complementary medicine.

The WHO recognizes the value of plant medicines in health care delivery and endorses the use of those which have been scientifically proven to be efficacious, safe for use and of good quality.

Herbal medicines are in great demand in the developed world for primary health care because of their efficacy, safety and lesser side effects. A detailed investigation and documentation of plants used in health traditions and pharmacological evaluation of these plants and their taxonomical relatives can lead to the development of invaluable plant-based drugs for many dreaded diseases.

A large number of plants and purified natural substances have been screened for liver disorders.

One of these herbal medicine plants is *Plicosepalus acacia* which widely used in traditional medicine for treatment of variable diseases. *Plicosepalus acacia* which is generally known as "Enab Ala'mq-kurad "(in Arabic) is a parasitic plant belongs to the family *Loranthaceae*, under the order *Santalales*. And it is distributed through the high mountains of some countries. In Yemen it is widely distributed in Taiz and suhban valley, Ibb city and it is parasiting in different trees which growth in Yemen.

Loranthaceae species(*Plicosepalus acacia*) play an important and complex rule in the biological system where they live by interacting with insects, birds and mammals.

It is spreading along the host by birds that transfer the seed of these plant from host to another host, the Flowers of *Plicosepalus acacia* attract birds' pollinators, they swallow the fruits whole and defecated viable seeds that were covered in a viscid pulp, which allowed the seeds to adhere to the substrate when voided seeds. dispersal and germination occur. The germination establishment with First Haustoria follow by Parasite development, this mechanism illustrates in Figures.[1-16]

Parasitim Development Mechanism Figures

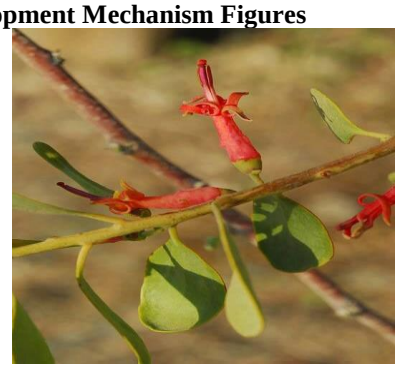

Fig. 1: The Plant Flowers.

Fig. 2: The Whole Plant and the Host (*Acacia Asak*).

Fig. 3: The Whole Plant and the Host (*Euphorbia Ammak).*

Fig. 4: Flowers Attract Birds Pollinator

Fig. 5: Birds Pollinators.

Fig. 6: Fruits.

Fig. 7: Seeds Dispersal.

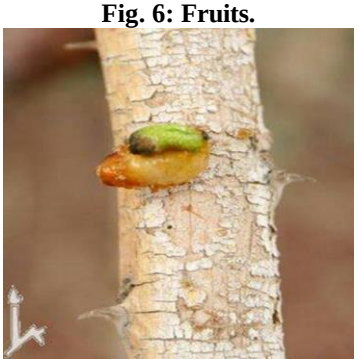

Fig. 8: Seed Germination.

Fig. 9: Germination Establishment with First Haustoria.

Fig. 10: Parasite Development.

Fig. 11: The Whole Parasite After Development.

Fig. 12: The Host: *Acacia Asak.*

Fig. 13: The Host: *Acacia Asak.*

Fig. 14: The Host: *Euphorbia Ammak.*

Fig. 15: The Host: *Euphorbia Ammak* Leave and Spines.

Fig. 16: The Host: *Euphorbia Ammak Flowers.*

To enhance the acceptability of the Herbal Medicine by consumers, many of the herbs have been converted into conventional dosage forms such as tablets, capsules, suspensions, solutions and powders.

So, it is necessary to formulate the medicinal product into the dosage forms that are practical to use in order to gain the patient compliance and to meet the prescribed medicine delivery requirement while manufacturing is capable. These criteria are the challenge for most researcher and formulation scientist. Capsules are the common dosage form considered for many oral drugs that perceive good patient compliance and more simply to manufacture with less cost compare to the manufacturing of tablet.

There is a considerable need to dry the extracted plant prior to the capsule filling process in order to eliminate the moisture content. Thus, drying of the extracted plant to obtain semisolid powder, a free flowing, non-adherent, crumbly look powder form of semisolid medication, is a challenging option.

In herbal medicine plant-based formulations are used to alleviate the diseases. But the most important challenges faced by these formulations arise because of their lack of complete evaluation. So evaluation is necessary to ensure quality and purity of the herbal product.

Plicosepalus acacia is a plant belong to the family Loranthaceae, which is a largest family under the order *Santalales*. Some of the species of the Loranthaceae family are parasites on the roots while the remaining parasites on branches and stems trees like *Plicosepalus acacia* and known as Mistletoe.[7-10]

The *Plicosepalus acacia* is plant widely distributed in Yemen. Plant materials are used through developed and developing countries as home remedies, over the counter drug products and raw materials for the pharmaceutical industry, and represent a substantial proportion of the global drug market. Herbal medicines have been used in the treatment of diabetes for a long time so the maintenance of a health care is got possible.[10-25]

The use of medicinal herbs and phytonutrients or nutraceuticals continues to expand rapidly across the world with many people now resorting to these products for treatment of various health challenges in different national healthcare settings. This past decade has obviously witnessed a tremendous surge in acceptance and public interest in natural therapies both in developing and developed countries, with these herbal remedies being available not only in drug stores, but now also in food stores and supermarkets. It is estimated that up to four billion people (representing 80% of the world's population) living in the developing world rely on herbal medicinal products as a primary source of healthcare and traditional medical practice which involves the use of herbs is viewed as an integral part of the culture in those community's herbal medicine is still the mainstay of about 75 - 80% of the world population, mainly in the developing countries, for primary health care.[25-30]

The Indian traditional medicine the herbal drugs have gained importance and popularity in recent years because of their safety, efficacy and cost effectiveness. Several Indian medicinal plants have been extensively used in the Indian traditional system of medicine for the management of liver disorder. The use of natural remedies for the treatment of liver diseases has a long history and medicinal plants and their derivatives are still used all over the world in one form or the other for this purpose. Scientific evaluation of plants has often shown that active principles in these are responsible for therapeutic success.[25-46]

Several studies on pharmacological effects of plants belonging to *Loranthaceae* family indicated anti-diabetic vascular protective and potential anticancer activities.

It is established that the antioxidant efficacy of an extract or a pure compound is strongly correlated to a number of activities including hepatoprotective, neuroprotective, anti-diabetic and protection against cardiovascular diseases.

Pharmacological studies have confirmed that *Plicosepalus acacia* exhibit a broad range of biological effects, some of which are very interesting for promising future herbal drug discovery.

Several hundred plants have been examined to date, but

only a handful has been studied thoroughly. The increasing use of herbal medicines reflects their perceived effectiveness in the treatment and prevention of disease, and the belief that these treatments are safe because they are 'natural'. Previous studies showed that the evaluates the effects of herbal extracts in the treatment of liver diseases, provides a general understanding of the actions of herbal medicines, a background for understanding the hepatoprotective of herbs, and the challenges that are faced by the scientific community in researching thoroughly of each and every compound of the herbs.[34-70]

Capsules[71-154]

Capsules are a common form of dosage for oral administration of pharmaceutical and nutraceutical products. They are produced in various shapes, sizes and materials, each capsule generally containing a single dose of active ingredient. In addition to the active drug ingredient or principal nutrient, other excipients are incorporated into the fill material, including antimicrobial preservatives, fillers, flavoring agents, sweeteners and coloring agent. Branding and dosage information may be printed on the outer surface of the capsule medication or ingredients inside the capsule may be in solid, liquid or paste form, depending on the drug component or, in the case of nutraceuticals, on the form of the main nutrient. The API filled in the capsules may contain solvents or excipients but these do not affect the integrity of the capsule shell.

Advantages and Disadvantages of Capsules

The Advantages of Capsules: Hard-gelatin capsules suitable for extemporaneous compounding so that the dose and combination of ingredients may vary depending on the patient's needs. More stable than liquid dosage forms. Small-particle size so that the dissolution and absorption in body fluids faster than pills and tablets. Can cover up the taste and smell unpleasant medicine liquid preparations can be made with a certain concentration and can be used for depot capsules and enteric coated capsule.

The Disadvantages of Capsules: Not suitable for very soluble ingredients when the capsule is broken contact with the wall of the stomach, then the solution will be concentrated so that irritate the stomach and the stomach becomes tense. Cannot be used for materials that are very efflorescent or deliquescent. Efflorescent material make capsule become soft while deliquescent material causing the capsule to become brittle and easily broken and the bitter-medicine will cause vomiting and corrosive which are difficult to overcome and it took a relatively long compounding.

Hard Gelatin Capsule: Hard gelatin capsules contain solid active ingredients. The capsules are formed by dipping finger-shaped pin forms into liquid gelatin solution and then extracting them and allowing the resulting surface film of gelatin to dry out. Once the film dries, each capsule is trimmed and then removed from the pins. The caps and body pieces of the capsule are supplied unlocked to be filled with the appropriate drug or nutraceutical ingredients. More than one type of drug can be encased in a pharmaceutical capsule. In such a case, it is common to have the drugs in different forms, e.g., one as a tablet and one as a smaller capsule. Both drugs can then be encased in the larger capsule.

Soft Gelatin Capsule: Soft gelatin capsules, also called soft gels, are thicker than hard gelatin capsules and are sometimes the gelatin is plasticized by adding glycerin or sorbitol. The thickness of the gelatin is chosen by the manufacturer according to the requirements of the encased material and the environmental conditions outside the capsule (e.g., air temperature and humidity). The composition of the gelatin used to prepare soft capsules may include preservatives, pigments and dyes. Flavorings and sweeteners may also be added.

Modified Release Capsule: Both hard or soft gel capsules can be chemically modified to control the release of the active ingredient(s). Delivery of the active ingredient is usually affected by dissolution, degradation or disintegration of an excipient in which the active compound is formulated. In the case of capsules, the capsule body may be coated with a material through which the drug diffuses or it may be a slowly dissolving coat that slowly releases the drug over time. A more recent innovation is a system utilizing a semipermeable membrane that blocks the drug from diffusing out through the membrane, but where the water on the exterior of the membrane can diffuse into the formulation, allowing the drug to be released through channels within the membrane.

Enteric Capsule: Enteric capsules are another form of modified release capsule, and again they maybe in the hard or soft form. The encapsulating material is designed to resist the stomach acid until it reaches the intestinal fluid where at a higher pH it breaks down and releases the active ingredients. It is important to observe during the manufacturing, packaging, storing and distribution of capsules that microbial contamination is possible as the capsules made of gelatin are susceptible to microbial attack and growth.

In the present study the *Plicosepalus acacia* freeze -dried extract powder solid dosage form medicinal herbs capsules delivery system was prepared and evaluated as an advanced phytotherapy approach for controlling diabetes.

MATERIALS AND METHODS

The Freeze-dried dried ethanol extract of *Plicosepalus acacia* was prepared and gift from (Prof Dr. Amina El-Shaibany, Professor Dr. of Pharmacognosy, Department of Pharmacognosy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen). Hard Gelatin Capsules (Size 00), microcrystalline cellulose, starch,

carboxymethylcellulose, colloidal silicon dioxide (Aerosil), methylparaben, sodium starch glycolate, crospovidone, methanol, water, ethyl acetate, and chloroform. All chemicals used were all of analytical grade and other materials were gift from (Shaphaco Pharmaceutical Industry Company-Yemen).

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

Formulation and Evaluation of *Plicosepalus Acacia* Extract[28-154]

Determination of The Organoleptic Properties of Extract

The following organoleptic properties of the extract were assessed: Physical appearance, odor and taste. For the powder of *Plicosepalus acacia* extracts were inspected and assessed using the natural senses (e.g. eyes, nose, mouth). As shown in Figure 17.

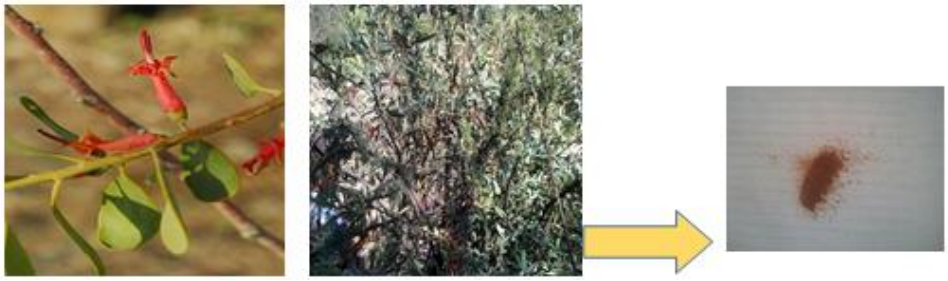

Fig. 17: Semisolid and Powder of *Plicosepalus Acacia* Flowers Extract.

Determination of The Solubility of Extract

The solubility of a substance fundamentally depends on the solvent used as well as on temperature and pressure. The extent of solubility of a substance in a specific solvent is measured as the saturation concentration where adding more solute does not increase its concentration in the solution. Oral ingestion is the most convenient and commonly employed route of drug delivery due to its ease of administration, high patient compliance, cost-effectiveness, least sterility constraints, and flexibility in the design of dosage form. As a result, many of the generic drug companies are inclined more to produce bioequivalent oral drug products. So, the solubility application according to standard parameters of solubility as shown in Table 1.

Table 1: Standard Parameters of Solubility.

Description	Part of The Solvent Required Per Part of Solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Practically insoluble	More than 10,000

Determination of The Density of Extract

Preformulation parameters like bulk density, tap density and carr's index, were obtained for the powders. 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, Vo, to the nearest graduated unit as shown in Table 2.

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

Bulk density = Bulk Mass/ Bulk Volume

Carr's compressibility index:

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

Table 2: Carr's Index Parameters of Powder Flowability.

Carr's Index%	Type of Flow
5 -15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
23 – 35	Poor
33 – 38	Very Poor
>40	Extremely Poor

Determination of the Flowability of Extract

The angle of repose **(θ)** is another important parameter that can be used to describe the flowability of a powder. In this study a special apparatus was used for the test. The apparatus consisted of a glass cylinder kept in the center of the plate, a plate with scale and a ruler for measuring the height of powder mound. To determine the angle of repose, the glass cylinder was filled with 10g of plant extract (pass 180 sieve), the cylinder smoothly lifted allowing the powder to flow out at the bottom into the plate leaving a conical mound as shown in Table 3. The height and radius of the mound was measured and angle of repose then calculated using the following equation:

$$\mathbf{Tan\ \theta = h / r}$$

θ: Angle of repose.

h: height of the conical mound. **r:** radius of the conical mound.

Table 3: The Flow Properties of Powder and Angle of Repose.

Flow Property	Angle of Repose (Degrees)
Excellent	<20
Good	20-30
Passable	30-34
Very poor	>40

Formulation of *Plicosepalus Acacia* Extract Capsules[28-154]

A uniform powder is obtained by mixing the semisolid of *Plicosepalus acacia* extract with the appropriate adsorbent microcrystalline cellulose, sodium starch glycolate and methyl paraben the materials filled into the capsules as shown in Table 4.

Table 4: The Formulation of *Plicosepalus Acacia* Extract Capsules.

Ingredients	Amount (g)
Plicosepalus Acacia	0.5g
Microcrystalline Cellulose	0.8g
Sodium Starch glycolate	0.072g
Methyl Paraben	0.0018g

Evaluation of *Plicosepalus Acacia* Extract Capsules[28-154]

Determination of Uniformity of Weight and The Amount of *Plicosepalus Acacia* Capsules

For the determination of the uniformity of weight, the British Pharmacopoeia method was used. In which Twenty of the *Plicosepalus acacia* capsules prepared, 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 between the desired and actual quantity calculated. According to the formulation, 1.37g *Plicosepalus acacia* extract was to be filled in one capsule. Twenty capsules were thus randomly chosen, their contents weighed, the percentage difference between this and the desired weight calculated and averaged for the 20 capsules to assess the accuracy of the filling process.

Determination of Moisture Content of *Plicosepalus Acacia* Extract Capsules

The presence of water plays an important role in the physical and chemical stability of the active pharmaceutical ingredients, and pharmaceutical preparations, because they may lead to their degradation. Water in pharmaceutical substances and preparations, provides a favorable environment for bacterial growth. Once a composition which contains a certain number of bacteria enters the organism, in the gastrointestinal tract may come to the death of bacteria and release of endotoxin. Therefore, the presence of water in the pharmaceutical substances affect; quality of the finished product, commercial reasons, i.e. process ability of the product, storage of the finished product, accuracy of the finished product, analytical indicators on the dry matter, since it is necessary to know the water content for their calculations. The amount of water contained in the solid substance is not constant and depends on: nature of the substance, degree of its fragmentation, solution in which the substance is formed, ambient humidity and temperature.

Determination of The *In-Vitro* Dissolution of *Plicosepalus Acacia* Extract Capsules

The dissolution test measures the rate at which a drug is released into solution from a dosage form and is used as an indication of the bioavailability of a pharmaceutical product and of product quality. In order to simplify testing procedures. In this study the paddle method was used. The quantitation of the amount of extract dissolved was measured based on UV absorbance measured at 437nm, the wavelengths for maximum UV absorbance of solutions of the *Plicosepalus acacia* extract determined by using a UV- Vis Spectrophotometer. For the dissolution study the following requirements and Procedure were used:

- Apparatus: paddle
- Medium: 0.1N HCL
- Volume of medium: 900ml
- Temperature: 37±0.5℃
- Rotation speed: 50 rpm
- Dissolution time: 10, 20, 30, 40 and 45 minutes.

RESULTS AND DISCUSSION

The Organoleptic Properties of The Freeze -Dried Extract of *Plicosepalus Acacia*

As shown in Table 5, and Figure 18, the organoleptic properties of the freeze -dried extract.

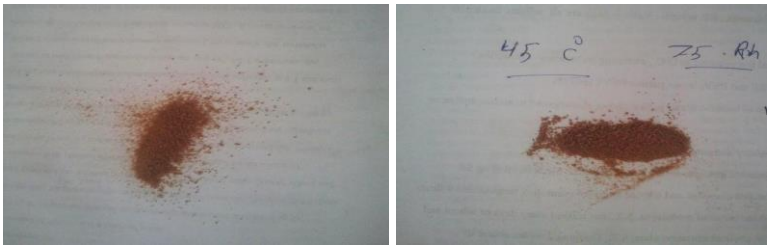

Fig. 18: The Organoleptic Properties of *Plicosepalus Acacia* Extract.

Table 5: The Organoleptic Properties of *Plicosepalus Acacia* Extract.

Properties	*Plicosepalus Acacia* Extract
Physical Appearance	Free-Flowing, Small Particulate Powder
Color	Brown
Odor	Characteristic Odor
Taste	Bitter

The bitter taste and unpleasant odors normally result in poor patient acceptance of dosage forms. Hopefully these negative characteristics still present in the extract can be masked when incorporated in capsule form.

Table 6: Solubility Test.

Solvent	Solubility
Water	Freely soluble
Methanol	Partially soluble

The Solubility of The Freeze -Dried of *Plicosepalus Acacia* Extract

For oral solid dosage forms aqueous solubility is a crucial factor influencing the bioavailability of drugs. The results obtained in the solubility testing of the extract *Plicosepalus acacia* show that the extract is freely soluble in water and partially soluble in methanol as shown in Table 6.

Table 7: The Results of Evaluation Parameters of *Plicosepalus Acacia* Extract.

Testing	*Plicosepalus Acacia*
The Solubility of Extract	1gm/10 ml of water
Particle size	Fine powder
Carr's Index (%)	13.3%
Angle of Repose (°)	11.9°
Moisture Level of The Content	6 %

Yield of Drying Total Extract of *Plicosepalus acacia*

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%rach to 80% it is appropriative percentage maxed with total extract to produce powder.

The Particle Size of the Total Extract of *Plicosepalus Acacia* Powder

Particle size and shape are crucial parameter. They are important for the manufacture of the dosage forms, influence dissolution and bioavailability. *Plicosepalus acacia* extract powder was moderately fine powder based on the British Pharmacopoeia standard and possessed appropriate flowability for the manufacture of the capsule dosage form.

The Densities of the *Plicosepalus Acacia* Total Extract Powders

The results of the Carr's index of Compressibility for *Plicosepalus acacia* extract is 13.3%. The density study results shows that the *Plicosepalus acacia* extract powders can be categorized as having excellent flow properties as shown in Table 7.

The Flowability of the *Plicosepalus Acacia* Total Extract Powders

The *Plicosepalus acacia* extract powders have angles of repose of (11.9 °) can be categorized as having Excellent flow properties.This implicated that the *Plicosepalus acacia* extract powders possessed appropriate flow ability for the manufacture of capsule dosage form as shown in Table 7.

Moisture Level of The Content of *Plicosepalus Acacia* Extract Capsules

The results of these tests are given and indicated that the moisture level of the contents of *Plicosepalus acacia* capsules when analyzed in the preformulation study, the moisture content for *Plicosepalus acacia* extract were however 6 %. Thus, appeared to have a slight increase in the moisture level of *Plicosepalus acacia* material after encapsulation. This suggested that this extract absorbed some moisture during the filling procedure, presumably because it was hygroscopic.

The Uniformity of Weight and The Amount of *Plicosepalus Acacia* Extract Capsules

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%. According to the British Pharmacopoeia, the limit on the acceptable deviation in weight from average for capsules is ±7.5% and the limits on the amount of content in the capsules 90% to 110%. The afore-mentioned results thus indicated that the *Plicosepalus acacia* capsules met the British Pharmacopoeia specifications.

The *In-Vitro* Dissolution Test of *Plicosepalus Acacia* Extract Capsules

The result of the dissolution study on the *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 specification set in the British Pharmacopoeia and indicated that *Plicosepalus acacia* capsules were immediate release solid oral dosage forms with good in vitro bioavailability.

CONCLUSION

It was concluded that the formulation of *Plicosepalus acacia* extract medicinal herbs capsules delivery system

as an advanced phytotherapy approach for controlling diabetes according to the best results of *in-vitro* dissolution was found to be 76.8% within 45 minutes in acid medium and were evaluated.

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