

FORMULATION, DEVELOPMENT AND EVALUATION OF GINGER EXTRACT CAPSULES DELIVERY SYSTEM AS AN ADVANCED PHYTOTHERAPY APPROACH FOR CONTROLLING DIABETES**Mahmoud Mahyoob Alburyhi^{1*} and Amina El-Shaibany²**¹Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.²Professor Dr. of Pharmacognosy, Department of Pharmacognosy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.***Corresponding Author: Dr. Mahmoud Mahyoob Alburyhi**

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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. Ginger (*Zingiber officinale*) is a plant widely used all over the world. A flowering plant known as ginger is utilized for both culinary and medicinal purposes and traditional healing. Ginger (*Zingiber officinale*), a spice used in Chinese and Ayurvedic traditions to treat diseases ranging from gingivitis to asthma, contains many antioxidant compounds that are thought to exert strong anti-inflammatory effects by inhibiting cyclooxygenase, inducible nitric oxide synthase, and lipoxygenase, as well as suppressing prostaglandin synthesis. Ginger is rich in bioactive components that promote the prevention and treatment of chronic conditions like heart disease, cancer, and Type 2 diabetes, are inexpensive and have no side effects. A *Ginger* was formulated as capsules and evaluated for organoleptic properties and other evaluation parameters. It was concluded that among the all formulations of *Ginger* extract capsules the F1 was found to be as an optimized capsules according to drug release percentage 96% within 60 minutes, so the F1 was the best formulation of *Ginger* extract capsules delivery system as an advanced phytotherapy approach for controlling diabetes.

KEYWORDS: *Ginger*, Extract, Capsules, Controlling Diabetes, 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 healthy 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.

Pharmacological Activities of Ginger^[10-99]

The Zingiberaceae family, which is a member of ginger, has several species that are known for their anti-diabetic and hypoglycemic properties. As shown in Figure 1.



Fig. 1: Ginger (*Zingiber Officinale*).

According to the World Health Organization (WHO), "Herbal Preparations" contain plant parts or plant material in the crude or processed state as active ingredients and may contain excipients (foreign substances).

A flowering plant known as ginger is utilized for both culinary and medicinal purposes and traditional healing. Ginger (*Zingiber officinale*), a spice used in Chinese and Ayurvedic traditions to treat diseases ranging from gingivitis to asthma, contains many antioxidant compounds that are thought to exert strong anti-inflammatory effects by inhibiting cyclooxygenase, inducible nitric oxide synthase, and lipoxygenase, as well as suppressing prostaglandin synthesis. Ginger is rich in bioactive components that promote the prevention and treatment of chronic conditions like heart disease, cancer, and Type 2 diabetes, are inexpensive and have no side effects. India produced 4.3 million tons of ginger worldwide, accounting for 43% of the total. Nepal, China, and Nigeria all had sizable productions. It is an abundant source of phytochemicals and antioxidants with anti-inflammatory, antibacterial, and anticancer activities is ginger (*Zingiber officinale*). For many years, people have used ginger both as a condiment and to treat illnesses.

Ginger is commonly known as a natural remedy for all things gut-related.

Asian cultures have been using ginger as a digestive aid and anti-nausea remedy for centuries. Ginger has gained popularity in the United States as a natural remedy for digestion over the last decade, and for good reason. Not only does ginger have a spicy, soothing aroma and taste,

it also has a variety of properties that aid in digestion and stomach ailments. Ginger is a flowering plant whose root is used as a spice. Ginger root has a "knobby" appearance and has tan skin and a moist yellow interior. When you slice ginger, you can immediately smell the strong and spicy aroma. Many find it easiest to peel the skin off with a spoon since it has a lot of nooks and crannies. Once peeled, you can either use it in large slices to steep in tea or soups, or mince or grate for stir-fries and marinades. Gingerol is a natural component of ginger root that encourages efficient digestion and benefits gastrointestinal motility rate. Ginger is well known for relieving nausea, which is accomplished by its ability to encourage stomach emptying. It also cuts down on fermentation in the gut, which relieves bloating and gas. Additionally, ginger has antioxidants which help manage free radicals, which can damage cells when you have too many. Additionally, ginger may have anti-cancer, disease-preventative, antidiabetic and anti-cardiovascular effects. In certain studies animal have shown a significant hyperlipidemic effect and a lower degree of atherosclerosis when given ginger. Animal studies have also shown better glucose tolerance, lower serum glucose, lower cholesterol, and lower triacylglycerol levels. Overall, ginger has promising health benefits that anyone can take advantage of, from managing diabetes and heart disease.

As the U.S. becomes more interested in the health benefits of ginger, as well as an increasing interest in Asian cuisine, it's become relatively simple to include ginger into your diet! You can include it in stir-fries, soups, juices, and tea to reap the benefits. Ginger has a strong taste, so try tasting it in small amounts first such as adding a small knob to your smoothie or steeping it in soup. You can also make a "ginger shot" consisting of ginger, lemon, honey and cayenne (juiced or blended and strained) to throw it back and be done with it, although these are very intense in flavor so use caution! Otherwise, if you know that you enjoy the taste of ginger, check out these simple recipes to get started.

In review of different studies shown that the ginger extract showed a potent antioxidant activity, decreasing the diabetes associated oxidative stress and improved the fetal exocrine pancreas histo-cytological structure.

Diabetes is the most important growing health risk throughout the World. Based on the findings, it can be suggested that ginger may have an important role on glucose intolerance in diabetes though irisin and hepcidin metabolism. Also, irisin may be used as a marker of diabetes.

Red ginger (*Zingiber officinale* var *rubrum*) is a rhizome plant that is very popular as a spice and traditional medicine in Indonesian society. Ginger as a traditional medicine could be expected to lower the blood glucose of patients with diabetes mellitus type 2. Diabetes mellitus is a disease of high prevalence in the world,

including Indonesia. This disease is a group of metabolic diseases with the characterization of hyperglycemia that occurs due to abnormal insulin secretion, insulin action or both disorders. Determine the effect of the dried red ginger powder (*Zingiber officinale* var. *Rubrum*) on fasting blood glucose (FBG) and 2-hour postprandial blood glucose patients with type 2 diabetes mellitus.

Diabetic cardiomyopathy may result from the overproduction of ROS, TRPM2 and TRPV2. Moreover, the therapeutic role of ginger, omega-3 fatty acids, and their combinations on the expression of TRPM2 and TRPV2 and their relationship with apoptosis, inflammation, and oxidative damage in heart tissue of rats with type 2 diabetes have not yet been determined. A studied was conducted to evaluate the hypoglycemic effect of *Zingiber officinale* (Ginger) aqueous extract at a dose of 500mg/kg body weight (BW) once a day for six weeks.

Ginger role was significant in renal diabetic nephropathy. It is due to the antioxidant's components counteraction by free radicals and it also helps in improvement of increased blood sugar levels in blood with the help of pancreatic and extra pancreatic mechanisms. The data of the certain studied indicated that antiatherogenic effect of ginger could be attributed to its vital role in regulation of per-oxidation process, antioxidant activity and inhibition of monocyte migration and interaction accompanied with endothelial dysfunction. Diabetes Mellitus (DM) is caused by unhealthy lifestyle habits and one of the treatment efforts is naturopathic therapy by utilizing the gingerol content in red ginger (*Zingiber officinale*). The role of nurses in complementary fields as providers of interventions can improve public health status.

Lemongrass (*Cymbopogon citratus*) and ginger (*Zingiber officinale*) are herbs that have been used to flavor food and beverages, in addition, they are also believed to possess health benefits. One of them is their ability to control blood glucose levels. Blood glucose control not only is beneficial for those who already have blood glucose regulating problems, but it may also be beneficial for the prevention of blood glucose-related diseases such as type 2 diabetes.

Diabetes mellitus (DM) or diabetes is a disease caused by disorders related to the hormone insulin. Ginger, lemongrass and cinnamon are traditional plants that have the potential to be developed as herbal medicines. The combination of these traditional plants can be used as an alternative treatment for diabetes mellitus. Infusions of ginger, lemongrass and cinnamon contain secondary metabolites, namely flavonoids, terpenoids and tannins. These three active compounds have antioxidant, antidiabetic, and anti-inflammatory activities. Prostatic complications are common in patients with diabetes. Ginger improved insulin sensitivity and some fractions of lipid profile, and reduced CRP and PGE2 in type 2

diabetic patients. Therefore, ginger can be considered as an effective treatment for prevention of diabetes complications.

In pervious studied suggested that ginger and garlic powders can be used to ameliorate type 2 diabetes and might also help in preventing secondary diabetic complications.

The mechanism for the blood glucose lowering effect of different ginger extracts is yet to be clearly understood, that of raw ginger extracts has been sparsely explored while the mechanism for the cooked ginger extract, the form in which it is mostly consumed, has not been delved into. Ginger in both raw and cooked forms may therefore be beneficial in the prevention and management of diabetes mellitus. Diabetes mellitus (DM) is a metabolic disease, involving inappropriately elevated blood glucose levels. The combined use of herbs and antidiabetic drugs increases the like hood of pharmacokinetic and pharmacodynamic interactions. The use of ginger drink in different concentrations has a strong effect in increase the efficacy of glimepiride drug. Thus, ginger may be of great value in managing the effects of diabetic complications in human subjects. Anti-diabetic properties, Diabetes, Ginger Hypoglycemic properties, Hypolipidemic properties, Proteinuria Diabetes mellitus (DM) is the most common of the endocrine disorders. Despite of the advance in diabetic treatment, many patients seek alternative options due to various reasons. Complementary and alternative medicine (CAM) has gained popularity because of the possibilities it offers to patients. Annona and ginger have prominent uses in traditional medicine; their therapeutic properties have not been sufficiently explored. The ameliorative effect of Annona or ginger extracts on hyperglycemia associated with oxidative stress, inflammation, and apoptosis in experimentally induced diabetes was addressed.

Ginger (*Zingiber officinale*) is a plant widely used all over the world. Due to its rich aroma and characteristic, spicy taste, it has been used in the kitchen as a spice additive. However, the multitude of phytonutrients it contains makes ginger a plant with a positive effect on the human body. Ginger is one of the most well-liked spices in the world. In more recent times interest has shifted towards possible effects of ginger on cancer, blood clotting, inflammation and pain. However, lesser attention has been given to metabolic diseases such as diabetes. Current scientific research shows that ginger consumption can have a favorable impact on measurements of glucose and lipids in patients with diabetes.

Regarding the effects of physical activity and ginger supplement on FBS and lipid profiles, it is recommended to use ginger supplement along with physical activity to control blood glucose and lipids levels.

Indian kitchens use ginger (*Zingiber officinale*), a natural healing food. Ginger offers a variety of health-promoting properties and diverse phytochemistry. *Zingiber officinale* is one of the most commonly used species in the ginger family, and it can be found in various meals and drinks. Ginger is frequently used to alleviate nausea, indigestion, diarrhea, and upset stomachs. It also possesses antioxidant and anti-inflammatory qualities. It is determined that because of its antioxidants and anti-inflammatory qualities, it may be used to cure various illnesses, including cancer. It is also helpful in managing the aging process. Due to its biological properties, which include anti-inflammatory, antiviral, antibacterial, antifungal, antihyperlipidemic, anti-obesity, and hepatoprotective properties, ginger has been shown to benefit human health. Products made from the rhizomes of ginger were employed in herbal medicine, meals, and drinks. Because of its many applications and useful values, it is crucial to ensure its legitimacy. Ginger is a good source of medicinal and nutraceutical goods because of its biological activity.

Diabetes mellitus is a chronic disease with a multitude of effects on different organ-systems. Its chronic nature makes it a challenging disease for patients to manage. Today, patients have access to many different types of conventional therapies for diabetes, each with a different mode of action and side effects. Despite the wide range of therapeutic agents available today, patients seek help from complementary and alternative medicine.

Management of the blood glucose level is a critical strategy in the control of diabetes complications. Inhibitors of saccharide hydrolyzing enzymes have been useful as oral hypoglycemic drugs for the control of hyperglycemia especially in patients with type-2 diabetes mellitus.

Ginger (*Zingiber officinale* Rosco.) is a flowering plant belonging to the family Zingiberaceae, whose rhizome is widely used as a spice or a folk medicine. The ginger plants grown in India show the largest amount of genetic variation. Diabetes mellitus type 2 (also known as type 2 diabetes) is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Type 2 diabetes makes up about 90% of cases of diabetes the use of ginger can help in the treatment of people with diabetes, and data support the inclusion of this herbal drug in the clinical practice of nurses.

In recent studied the results indicated that when administrated together, ginger and cinnamon synergistically enhanced antioxidant, antiapoptotic and anti-inflammatory effects and induced antihyperglycemic effect comparable to metformin.

The hypoglycemic, hypolipidemic and antioxidative effects of ginger in type 2 diabetic patients have been recently noticed.

The capsule delivery system^[100-187]

Capsules offer many advantages: Capsules, because of their elongated shape, are easy to swallow, which is one reason for the number of capsule- shaped tablets manufactured today, flexibility of formulation is another advantage of the capsule dosage form. However, the biggest formulation advantage of capsules is that there is less need for additional excipients, since capsules are tasteless, they effectively mask any unpleasant taste or odor of their contents, they offer rapid release characteristics, due to the rapid dissolution rate of the capsules,

Herbal capsules are solid dosage forms containing drug and usually, appropriate filler (s) enclosed in a gelatin container. Capsules may be available in hard gelatin for dry powdered herbal ingredients or granules or soft gelatin shells for herbal oils and for herbal ingredients that are dissolved or suspended in oil. The gelatin shell readily ruptures and dissolves following oral administration. Drugs are normally more readily released from capsules compared to tablets. Capsules may help mask the unpleasant taste of its contents and uniformity of dosage can be relatively readily achieved. Herbal capsules normally consist of hard-shelled gelatin capsules with the plant material finely milled and sifted and filled into shell or extracts of the herbal material(s) with appropriate excipients such as fillers.

In the present study the *Ginger* extract powder solid dosage form of *Ginger* capsules delivery system was prepared and evaluated as an advanced phytotherapy approach for controlling diabetes.

MATERIALS AND METHODS

The extract of *Ginger* 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 0), Diluents, Lubricant, Hydrochloric Acid (0.1NHCl), Phosphate Buffer Solution, Ethanol and Methanol were obtained from Sigma Aldrich. All chemicals used were all of analytical grade and other materials were gift from (Shaphaco Pharmaceutical Industry Company-Yemen).

Formulation and Evaluation of *ginger* extract^[30-187]

Determination of the organoleptic properties of extract

The following organoleptic properties of the plant materials were assessed: physical appearance, odor and taste. For these samples of *Ginger* extracts were inspected and assessed using the natural senses (e.g. eyes, nose, mouth).

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 of Approximate 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 flowability of extract

Preformulation parameters like bulk density, tapped density, carr's index, 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, V_o , 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 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

Formulation of ginger extract capsules

A uniform powder is obtained by mixing the *Ginger* extract of with the appropriate adsorbent, diluents and

lubricant, the materials filled into the capsules as shown in Table 3.

Table 3: Formulation of ginger extract capsules.

Ingredients	Quantity Per Capsule (mg)		
	Formulation Code		
	F1	F2	F3
Ginger Extract	15%	15%	15%
Diluent I	45%	59%	25%
Diluent II	39%	25%	59%
Lubricant	1%	1%	1%

Evaluation of ginger extract capsules

Determination of Uniformity of Weight and The Amount of Ginger Capsules

For the determination of the uniformity of weight, the British Pharmacopoeia method was used. In which Twenty of the *Ginger* capsules prepared. 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, 20% of *Ginger* 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 ginger 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. Even a small amount of endotoxin in the body causes the formation of antibodies against the endotoxin. During gastrointestinal crises, the blood stream can be penetrated by a large amount of endotoxin, which leads to an anaphylactic reaction, which results in a hard shock. The moisture content of the material is a decisive economic factor both in production and in sales. This is one of the main factors that influences the course of production and stability of the finished product, determining the quality and prices of many pharmaceutical products. 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.

***In-Vitro* dissolution studies of ginger 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 the present study the basket method was used. The quantitation of the amount of extract dissolved was measured based on UV

absorbance measured at 281nm, the wavelengths for maximum UV absorbance of solutions of the *Ginger* extract determined by using a UV- Vis Spectrophotometer. For the dissolution study the following requirements and Procedure were used: Apparatus: Basket. Medium: 0.1N HCl. Volume of medium: 900ml. Temperature: $37 \pm 0.5^\circ\text{C}$. Rotation speed: 50 rpm. Dissolution time: 15, 30, 45 and 60 minutes.

900 ml of 0.1N HCl 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 basket was lowered into position and the apparatus were operated immediately at the rotation speed 50 rpm. At various time points, viz. at 15, 30, 45 and 60 minutes after start, 3 ml samples of the medium were withdrawn from a point half- way between the surface of the dissolution medium and the top of the rotating basket and not less than 10 mm from the wall of the vessel. Each time the withdrawn medium was immediately replaced by 3 ml of 0.1N HCl introduced into the vessel.

RESULTS AND DISCUSSION

The organoleptic properties of ginger extract

As shown in Table 4, the organoleptic properties of extract.

Table 4: The organoleptic properties of ginger extract.

Properties	Ginger Extract
Physical Appearance	Small Powder
Color	Yellowish
Odor	Aromatic and Penetrating Odor
Taste	Spicy, Pungent, Hot and Biting

The spicy, pungent, hot and biting taste, aromatic and penetrating odor, and yellowish color, 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.

The solubility of ginger 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 *Ginger* extract show that the extract is sparingly soluble in water as shown in Table 5.

Table 5: Evaluation parameters of ginger extract.

Testing	Ginger
The Solubility of Extract	Sparingly Soluble in Water
Carr's Index (%)	11%
Particle Size	Coarse Powder
The Moisture Content (%)	1.5%

The flowability of extract

The Carr's index of compressibility for *Ginger* extract is 11% show that the *Ginger* extract powders can all be categorized as having excellent flowability for the manufacture of capsule dosage form as shown in Table 5.

Moisture content of ginger extract capsules

The results of these tests are indicated that the moisture level of the contents of *Ginger* capsules when analyzed in the pre-formulation study, the moisture content for

Ginger extract was found to be 2%, as shown in Table 5.

The uniformity of weight and the amount of ginger extract capsules

The average deviation in weight from average for *Ginger* capsules were found to be 0.90% and average total content per capsule was 100%, within the limit on the acceptable deviation in weight from average for capsules therefore, mentioned results thus indicated that the *Ginger* capsules are within the limit of the British Pharmacopoeia specifications.

In-Vitro dissolution studies of ginger extract capsules**Table 6: The drug release percentage of ginger extract capsules.**

Drug Release %				
Formulation Code				
		F1	F2	F3
Time (min)	15	80	32	23
	30	84	53	44
	45	85	68	61
	60	96	82	74

The *in-vitro* dissolution percentage of *Ginger* extract capsules is one important of the results of dissolved active ingredient, *Ginger* extract, as shown in Table 6. The results of formulation have shown that the drug release of F1 was found to be 84% within 30 minutes in buffer medium. The results of formulation have shown that the drug release of F1 was found to be 85% within 45 minutes in buffer medium. The results of formulation have shown that the drug release of F1 was found to be 96% within 60 minutes in buffer medium.

CONCLUSION

Ginger (*Zingiber officinale*) is a plant widely used all over the world. Ginger is rich in bioactive components that promote the prevention and treatment of chronic conditions like heart disease, cancer, and Type 2 diabetes, are inexpensive and have no side effects. It was concluded that among the all formulations of *Ginger* extract capsules the F1 was found to be as an optimized capsules according to drug release percentage 96% within 60 minutes, so the F1 was the best formulation of *Ginger* extract capsules delivery system as an advanced phytotherapy approach for controlling diabetes.

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