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FORMULATION, DEVELOPMENT AND EVALUATION OF *CELERY* EXTRACT CAPSULES DELIVERY SYSTEM AS AN ADVANCED PHYTOTHERAPY APPROACH FOR GOUT

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ABSTRACT

Gout is an inflammatory arthritis that belongs to a group of arthropathies called the 'crystalline arthropathies'. Gout is caused by a robust inflammatory response to *uric acid crystals* which occurs in the setting of hyperuricemia. Supersaturation of uric acid can lead to crystal accumulation and deposition in the joints and tissues to which the immune system reacts. Uric acid tophi appear as hard nodules under the skin and can cause considerable destruction and discomfort. *Celery* is widely used throughout the world. Some of their pharmacological properties include anti-inflammation, gout-rheumatism arthritis, antioxidant, aphrodisiac, anthelmintic, antispasmodic, carminative, diuretic, emmenagogue, laxative, sedative, antimicrobial, hepatoprotective, appetizer, antiasthma, anti-bronchitis, anticancer, antifungal, nematocidal, anticonvulsant, breast milk inducer, anti-jaundice, antihypertensive, anti-dysmenorrhea, spermatogenesis induction and prevention of cardiovascular diseases. In the present study the *Celery* extract was formulated and evaluated as capsules. It was concluded that among the all formulations of *Celery* extract capsules the F1 was found to be as an optimized capsules according to drug release percentage 96% within 45 minutes, so the F1 was the best formulation of *Celery* extract capsules delivery system as an advanced phytotherapy approach for gout.

KEYWORDS: *Celery*, Extract, Capsules**,** Antigout, Phytotherapy.

INTRODUCTION

Background of Gout[1-9]

Gout is a form of arthritis caused by a build-up of uric acid in the blood. This builds up uric acid and causes crystals to form and accumulate in and around joints. What are Purines? Purines are natural chemical substances found in your body and in some foods and drinks. Uric acid is produced when the body breaks down purines. Uric acid is typically eliminated from your body in urine. In people with gout, this process is altered, so uric acid builds up in the blood forming crystals that settle in joints. Other foods and drinks influence the amount of uric acid in your blood, for example, fructose, a type of sugar, generates uric acid within minutes of being ingested.

The gout diet is low in purines, so while you can't control the number of purines that occur naturally in your body, you can control how much purines you consume, and therefore, lower the amount of uric acid your body produces. This will help control the pain from gout. It won't cure your gout and you may still need medication, but it can lower the risk of recurring gout attacks and slow the progression of joint damage. What are the Goals of the Gout Diet? The gout diet is designed to help you achieve a healthy weight and good eating habits, avoid foods high in purines, and control uric acid levels.

Gout is a type of arthritis. It is a disorder that results from the build-up of uric acid in the tissues or a join most often the joint of the big toe. If levels of uric acid are high for prolonged periods, needle-like crystals can start to form in your tissues, resulting in swollen, painful joints all of which are signs of inflammation. Uric acid is present in small amounts in our blood. It is made as our bodies break down natural substances called purines.

Gout arthritis usually come on suddenly. You may go to bed feeling fine but wake up with extreme joint pain. The first gout arthritis usually occurs in the large joint of the big toe. However, other joints and areas around the joints can be affected, like foot arches, ankles, heels and knees. Common symptoms include swelling, stiffness, tenderness, warmth and redness in and around joints. The pain may last hours or weeks. The build-up of uric acid can look and feel like lumps under the skin (tophi). It can also collect in the kidneys and cause small, hard deposits (kidney stones).

Gout arthritis is caused by deposits of crystallized uric acid in the joint. Uric acid is present in the blood and eliminated in the urine, but in people who have gout, uric acid prolonged periods and crystallizes in the joints. Uric acid is the result of the breakdown of purines, chemicals that are found naturally in our bodies and in food. Some people develop gout because their kidneys have difficulty eliminating normal amounts of uric acid, while others related too much uric acid. Other factors that put a person at risk for developing gout include high blood pressure, diabetes, obesity, surgery, chemotherapy, stress, and certain medications and vitamins. Such as, the body's ability to remove uric acid can be negatively affected by taking aspirin, some diuretic medications, and the vitamin niacin. While gout is more common in men aged 40 to 60 years, it can occur in younger men and also occurs in women.

In diagnosing gout arthritis, your doctor will take your personal and family history and examine the affected joint. Laboratory tests and x-rays are sometimes ordered to determine if the inflammation is caused by something other than gout arthritis.

Initial treatment of gout arthritis typically includes the following: Medications. Prescription medications or injections are used to treat the pain, swelling, and inflammation. Dietary restrictions. Foods and beverages that are high in purines should be avoided, since purines are converted in the body to uric acid. Fluids. Drink plenty of water and other fluids each day, while also avoiding alcoholic beverages, which causes dehydration. Immobilize and elevate the foot. Avoid standing and walking to give your foot a rest. Also, elevate your foot (level with or slightly above the heart) to help reduce the swelling. Cortisone Injection. A combination of numbing and cortisone injected into the joint can help relieve pain and reduce the inflammation. The symptoms of gout arthritis t and the inflammatory process usually resolve in 3-10 days with treatment. If gout symptoms continue despite the initial treatment, or if repeated attacks occur, you may need to see your primary care physician for maintenance treatment that may involve daily medication. In cases of repeated episodes, the underlying problem must be addressed, as the build-up of uric acid over time can cause arthritic damage to the joint.

To understand more about your medicines and any risks or side effects that they may have, read the Consumer Medicine Information (CMI) leaflet that is available from your doctor or pharmacist.

Which foods should be avoided: As uric acid is made in the body from the breakdown of purines that come from your diet, it is advisable to reduce the amounts of foods that you eat that are high purines. High purine foods include: (avoid) offal - liver and kidneys, heart and sweetbreads, game - pheasant, rabbit, venison, oily fish - anchovies, herring, mackerel, sardines, sprats, whitebait, trout, seafood - especially mussels, crab, shrimps and other shellfish, fish roe, caviar, meat and yeast extracts - marmite, bovril, and commercial gravy as well as beer. Moderate purine foods (eat in moderation), meat - beef, lamb chicken, pork, poultry - chicken and duck, dried peas, beans and legumes - baked beans, kidney beans, soya beans and peas etc. Mushrooms and mycoprotein, some vegetables - asparagus, cauliflower, spinach, wholegrains - bran, oatbran, whole meal bread Low purine foods, dairy - milk, cheese, yoghurt, butter, eggs, bread, cereals, pasta, noodles, fruit and vegetables.

How much protein do you need: Generally, you need about 1g of protein per kg of body weight (70kg man only requires 70g of protein daily), unless you on a protein restricted diet e.g., some people with kidney disease may need to restrict their intake. Here are some examples of protein content of food: 100g chicken breast contains 22g protein, 100g cod fillet contains 21g protein. Large egg contains 6g, 30g hard cheese contains 8g protein, 30g cottage cheese contains 14g protein, 30g almonds contain 5g protein.

Recommended Foods to Eat: Fresh cherries, strawberries, blueberries, and other red-blue berries, bananas, celery, tomatoes, vegetables including kale, cabbage, parsley, green-leafy vegetables, foods high in vitamin C (red cabbage, red bell peppers, tangerines, mandarins, oranges, potatoes), drink fruit juices and purified water (8 glasses of water per day).

Natural or Alternative Therapies: There are many promises made for non-medical cures or treatments of gout. there is evidence that supplements such as celery seed or garlic are helpful in reducing the symptoms of gout. Because herbal, homeopathic, ayurvedic or Chinese medicines may affect the treatments prescribed by your doctor, please tell your GP and specialist what other treatments you are thinking about using. You may feel concerned that your doctor or other members of your healthcare team will disapprove of complementary therapies. However, it is very important to keep your healthcare team informed, even if they do not approve. Your healthcare team, particularly your doctor and pharmacist, can't give you the best professional advice without knowing all the treatments you are using. This includes vitamin supplements, herbal medicines and other therapies.

Plant Description and Pharmacological Activities of Celery[10-71]

Celery is a branched biennial plant. The leaves are triangular, diamond, or spear-shaped. Leaf edges are lobed and serrated. The fruit is brown with black stripes on the outer layer. The fruit is 1-2 mm in diameter, sub-orbicular, aromatic, schizocarps, and has two mericarps. The seeds are brown and serrated. Small flowers are greenish white. There is one seed in each carpel, or two carpels joined to one fruit. Flowers are oval shaped and have five petals. *Celery* plant morphology as shown in Figure 1. The celery seasoning has a distinctive, but pleasant aroma. *Celery* plant parts can be used for flavoring foods such as stalks, leaves, oleoresins, and seeds. *Celery*, Apium graveolens L., is a plant with high taste, dietetic, and medicinal values. A possible reason for it being so widely known is that it was a useful herbal remedy. The seeds and leaves were used as a carminative, stomachic, stimulant, emmenagogue, anodyne poultice and nerve tonic, and for rheumatism and arthritis.

Apium graveolens or *Celery* belongs to the *Apiaceae* family and are included among plants that have been in use in traditional medicine for thousands of years worldwide, including in the Mediterranean, as well as the tropical and subtropical regions of Asia, Europe, and Africa. Some highlighted medical benefits include prevention of coronary and vascular diseases. Their phytochemical constituents consist of bergapten, flavonoids, glycosides, furanocoumarins, furocoumarin, limonene, psoralen, xanthotoxin, and selinene. Some of their pharmacological properties include anti-inflammation, gout-rheumatism arthritis, antioxidant, aphrodisiac, anthelmintic, antispasmodic, carminative, diuretic, emmenagogue, laxative, sedative, antimicrobial, hepatoprotective, appetizer, antiasthma, anti-bronchitis, anticancer, antifungal, nematocidal, anticonvulsant, breast milk inducer, anti-jaundice, antihypertensive, anti-dysmenorrhea, spermatogenesis induction and prevention of cardiovascular diseases. Also, *Celery* has antiflatulence and griping pains. In the medicinal –herbal market, celery oil or oil extract as well as ground seed or root are touted as herbal and dietary supplement that "promote and regulate" healthy blood pressure, joint health and uric acid levels. Root tinctures have been used as a diuretic in hypertension and urinary disorder.

In the previous studies it was found that the Celeriac advance tablet effectively improves joint pain, stiffness, physical function and quality of life in OA patients. it is the first clinical evidence generation study that supports the potential use of Celeriac advance, a novel combination of *Celery* seed extract and Sallaki extract as an adjuvant in the management of knee OA. Alternative strategies are under ongoing development, many of which have a basis

in traditional and complementary paradigms and Current management is achieved through pharmacotherapy; however, conventional gout-specific medications may be contraindicated in the presence of various comorbidities including diabetes, chronic kidney disease and metabolic syndrome.

The *Celery* leaves have been shown to have the potential to be developed and utilized as a nonmedical therapy for hypertension sufferers. The chemical content of *Celery* leaves has been proven to be effective in helping people with hypertension control their blood pressure. Diversification of celery leaves into *Celery* tisane products is an effort to make it easier for people with hypertension to use *Celery* leaves as a non-medical therapy in controlling their blood pressure. The anecdotal evidence indicates a potential interaction between thyroxine and celery seed tablets.

In the other review summarized study that the anti-gout potential of Malaysian medicinal plants treat gout based on research conducted over the last 17 years. Taking all results into consideration, M. charantia, C. indicum, C. cassia, K. galanga, A. vulgaris, and M. elliptica were found to have the highest xanthine oxidase inhibitory potential in vitro. It was found in pervious review study suggests that further research on the natural xanthine oxidase inhibitors, especially in *in-vivo* studies, clinical studies, investigation of active compounds, safety of the plants as well as the pharmacokinetic and bioavailability studies, which remain to be elucidated. The CSAE and CSOL exhibited the effect of suppressing serum UA levels in mice with hyperuricemia and the swelling rates of ankle joints in rats with gouty arthritis, which may be associated with the modulation of XO activity and inflammation response by oxidative stress regulation, providing experimental evidence to support the further evaluation of CSAE and CSOL as agents for gout treatment.

Fig. 1: *Celery* Plant, *Apium Graveolens L. (Apiaceae).*

The Capsule Delivery System[72-81]

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 *Celery* extract solid dosage form of *Celery* capsules delivery system was prepared and evaluated as an advanced phytotherapy approach for gout.

MATERIALS AND METHODS

The extract of *Celery* 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), Microcrystalline Cellulose MCC, Lactose, Talc, 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 as gift from (Shaphaco Pharmaceutical Industry Company-Yemen).

Formulation and Evaluation of *Celery* Extract[82-117]

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 *Celery* extract was 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, 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 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 *Celery* Extract Capsules[82-117]

A uniform powder is obtained by mixing the *Celery* extract of with the appropriate adsorbent microcrystalline cellulose and lactose, lubricant as talc, the materials filled into the capsules as shown in Table 3.

Table 3: Formulation of *Celery* Extract Capsules.

Ingredients	Quantity Per Capsule (mg)		
	Formulation Code		
	F1	F2	F3
***Celery* Extract**	20%	20%	20%
Microcrystalline Cellulose	59%	40%	20%
Lactose	20%	39%	59%
Talc	1%	1%	1%

Evaluation of *Celery* Extract Capsules[82-117]

Determination of Uniformity of Weight and The Amount of *Celery* Capsules

For the determination of the uniformity of weight, the British Pharmacopoeia method was used. In which Twenty of the *Celery* 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 *Celery* 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 *Celery* 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 *Celery* 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 290 nm, the wavelengths for maximum UV absorbance of solutions of the *Celery* 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±0.5°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±0.5°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. The UV absorbance of the solution was determined at the wavelengths mentioned earlier and using the solution of one of the empty capsule shells dissolved in the 900 ml volume of dissolution medium as a blank reference solution.

RESULTS AND DISCUSSION

The Organoleptic Properties of *Celery* Extract

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

Table 4: The Organoleptic Properties of *Celery* Extract.

Properties	***Celery* Extract**
Physical Appearance	Small Particulate Powder
Color	Light Green
Odor	Celery Smell
Taste	Slightly Bitter

The slightly taste and *Celery* smell odor 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 *Celery* 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 *Celery* extract show that the extract is soluble in water as shown in Table 5.

Table 5: Evaluation Parameters of *Celery* Extract.

Testing	***Celery***
The Solubility of Extract	Soluble in Water
Carr's Index (%)	12%
Particle Size	Coarse Powder
The Moisture Content (%)	10%

The Flowability of Extract

The carr's index of compressibility for *Celery* extract is 12% show that the *Celery* 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 *Celery* Extract Capsules

The results of these tests are indicated that the moisture level of the contents of *Celery* capsules when analyzed in the pre-formulation study, the moisture content for *Celery* extract was found to be 10%, as shown in Table 5.

The Uniformity of Weight and The Amount of *Celery* Extract Capsules

The average deviation in weight from average for *Celery* capsules were found to be 0.75% and average total content per capsule was 100.88%, within the limit of the acceptable deviation in weight from average for capsules therefore, mentioned results thus indicated that the *Celery* capsules are within the limit of the British Pharmacopoeia specifications.

***In-Vitro* Dissolution Studies of *Celery* Extract Capsules**

Table 6: The Drug Release Percentage of *Celery* Extract Capsules.

Formulation Code	Drug Release %			
	Time (min)			
	15	**30**	**45**	**60**
F1	75	83	96	97
F2	45	68	84	88
F3	30	55	77	80

The *in-vitro* dissolution percentage of *Celery* extract capsules is one important of the results of dissolved active ingredient, *Celery* extract, as shown in Table 6. The results of formulation have shown that the drug release of F1 was found to be 83%, 96% and 97% within 30, 45 and 60 minutes respectively. It was concluded that the formulation of *Celery extract* capsules F1 can be taken as an optimized capsules for drug release percentage 96% within 45 minutes and drug release so, it was found to be among the all formulations the F1 was the best formulation.

CONCLUSION

It was concluded that among the all formulations of *Celery* extract capsules the F1 was found to be as an optimized capsules according to drug release percentage it was found 96% within 45minutes, so the F1 was the best formulation of *Celery* extract capsules delivery system as an advanced phytotherapy approach for gout.

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