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FORMULATION AND EVALUATION OF VEGETABLE CAPSULE FILM & CAPSULE SHELLS OF STARCHES OBTAINED FROM RED LENTILS, WATER CHESTNUT AND TAMARIND SEED POWDER

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ABSTRACT

Biodegradable films were developed using red lentil, water chestnut and tamarind seed starches as base raw materials. The physical and mechanical properties of the film were compared with gelatin and HPMC films. Starches with high amylase content had excellent films and hard capsule forming abilities and properties compared to the starches with low amylase content. The tensile strength value of starch film was not significantly different from gelatin and HPMC films. In the case of elongation properties, starch films lower value than gelatin film, but higher than HPMC films. The physical viscosity characterization of vegetable starches indicated that the starches with high amylase content produced better biopolymers films and capsule compared to the starches with low amylase and high amylopectin content. Biodegradable films and hard capsule for pharmaceutical applications could be developed from vegetable starches with similar physical and mechanical properties as synthetic and gelatin product.

KEYWORDS: Tamarind Seed, Red lentils, water chestnut and vegetables capsule shells.

INTRODUCTION

Synthetic polymeric food packaging materials, developed in the past 50–60 years, are durable and inert or resistant to microbial degradation. These synthetic polymeric materials have wide applications in food packaging due to various advantages such as high strength, elongation, gas barrier properties, low cost, lightness and water resistance. Packaging materials account for approximately 30% by weight of municipal solid waste and two thirds of the volume are trash cans, due to their bulk. Among the 30% packaging waste, 13% is due to plastic materials which are convenient, safe, strong and economical; but do not biodegrade. Incineration is a common method of disposing of polyolefin's, but this result in high emissions of carbon dioxide. Since the 1970s, polar biopolymers such as polysaccharides and proteins have been studied as potential alternatives for synthetic polymers in the film and plastic industries, due to environmental concerns. Several studies have been conducted investigating the properties of protein, polysaccharide, and lipid-based films; and these raw materials were successfully formed into films or coatings. These edible/biodegradable films were reported to have been successfully utilized in a number of commercial applications: (a) gelatin for capsules, supplements, drugs, and flavor encapsulation; (b) corn zein for coatings, confections, supplements, and drug tablets; (c) collagen for wraps and casings for meat products; (d) starch coatings for drug tablets, confections and dried Fruits; € HPMC, MC, and HPC coatings for supplements and drug tablets; (f) fatty acid sucrose esters for coatings for fresh produce; (g) wax, oil, and shellac coatings for fresh produce, confections, supplements, and drug tablets.

Starch and starch derivative films have been widely studied due to their great molding and film forming properties, high oxygen barrier and good mechanical strength. Even though there have been numerous studies conducted on the properties of starch based films, few studies have related starches from different sources with the resulting film forming characteristics, mechanical and physical properties. In a previous study, films were developed using starches from different plant sources as the base raw materials (rice, sweet rice, potato, sweet potato, tamarind seed, mung bean, Lentil, waterchestnut, amaranth, wheat, and buck wheat starches). The physical and mechanical properties of the starch based films were evaluated. Among the starch films, tamarind seed, Lentil and waterchestnut were selected due to their superior film-forming properties when compared with synthetic films. The gelatin and hydroxyl propylated methyl cellulose (HPMC) were selected as the control because of the popularity of these films in food and pharmaceutical industries as a result of their good film forming properties, oxygen/water barrier properties, mechanical strength, raw materials availability, and biodegradability. Thin-film drug delivery uses a dissolving film or oral drug strip to administer drugs via absorption in the mouth (buccally or sublingually) and/or via the small intestines (enterically). A film is prepared using hydrophilic polymers that rapidly dissolves on the tongue or buccal cavity, delivering the drug to the systemic circulation via dissolution when contact with liquid is made.

Thin-film drug delivery has emerged as an advanced alternative to the traditional tablets, capsules and liquids often associated with prescription and OTC medications. Similar in size, shape and thickness to a postage stamp, thin-film strips are typically designed for oral administration, with the user placing the strip on or under the tongue (sublingual) or along the inside of the cheek (buccal). These drug delivery options allow the medication to bypass the first pass metabolism thereby making the medication more bioavailable. As the strip dissolves, the drug can enter the blood stream enterically, buccally or sublingually. Evaluating the systemic transmucosal drug delivery, the buccal mucosa is the preferred region as compared to the sublingual mucosa.

Different buccal delivery products have been marketed or are proposed for certain diseases like trigeminal neuralgia, Meniere's disease, diabetes, and addiction. There are many commercial non-drug product to use thin films like Mr. Mint and Listerine Pocket Paksbreath freshening strips. Since then, thin-film products for other breath fresheners, as well as a number of cold, flu, anti-snoring and gastrointestinal medications, have entered the marketplace. Several projects in development that will deliver prescription drugs using the thin-film dosage form.

Formulation of oral drug strips involves the application of both aesthetic and performance characteristics such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents. From the regulatory perspectives, all excipients used in the formulation of oral drug strips should be approved for use in oral pharmaceutical dosage forms.

Fast dissolving film is prepared using hydrophilic polymers that rapidly. Dissolve/disintegrate in the mouth within few seconds without water and eliminates the fear of chocking as an alternative to fast dissolving tablets. Mainly the fast dissolving film can be considered as an ultra-thin strip of postage stamp size with an active pharmaceutical ingredient and other excipients. Most fast dissolving films are having taste masked active ingredients. These masked active ingredients are swallowed by the saliva of patients along with the soluble and insoluble excipients. The advantages of convenience of dosing and portability of mouth dissolving film have led to wider acceptability of this dosage form by pediatric as well as geriatric patients. They also impart unique product differentiation, thus enabling use as line extensions for existing commercial products. This novel drug delivery system can also be beneficial for meeting the current needs of the industry are improved solubility/stability, biological half life and bioavailability enhancement of drugs. Also due to ease of transportation of mouth dissolving film than ODT helpful for reducing damage cost compared to ODT and other liquid formulation.

TYPES OF FILMS

Buccal Film
Orodispersible Film
Oral Film (Oral Thin Film)
Oral Soluble Film
Wafer
Oral Strip
Mucoadhesive Film,
Ophthalmic Film,
Transmucosal Film

MATERIAL AND METHODS

1) Lentil (Lens culinaris or Lens esculenta)

Composition

According to the USDA National Nutrient Database, 100 g of raw lentils (variety unspecified) provide 353 calories; the same weight of cooked lentils provides 116 calories. Raw lentils are 8% water, 63% carbohydrates including 11% dietary fiber, 25% protein, and 1% fat (table). Lentils are a rich source (20% or more of the Daily Value, DV) of numerous essential nutrients, including foliate (120% DV), thiamin (76% DV), pantothenic acid (43% DV), vitamin B6 (42% DV), phosphorus (40% DV), iron (50% DV), and zinc (35%), among others (table). When lentils are cooked by boiling, protein content declines to 9% of total composition, and B vitamins and minerals decrease due to the overall water content increasing (protein itself is not lost). Lentils have the second-highest ratio of protein per calorie of any legume, after soybeans. Lentils contain the carotenoids, lutein and zeaxanthin, and polyunsaturated fatty acids.

Digestive Health Benefits

The low levels of readily digestible starch (5%) and high levels of slowly digested starch make lentils of potential value to people with diabetes. The remaining 65% of the starch is a resistant starch classified as RS1. A minimum of 10% in starch from lentils escapes digestion and absorption in the small intestine (therefore called "resistant starch"). Additional resistant starch is synthesized from gelatinized starch, during cooling, after the lentils were cooked.

Lentils also have anti nutrient factors, such as trypsin inhibitors and a relatively high phytates content. Trypsin is an enzyme involved in digestion, and phytates reduce the bioavailability of dietary minerals. The phytates can be reduced by prolonged soaking and fermentation or sprouting.

2) Water Chestnut (Eleocharisdulcis)

Composition

Raw water chestnuts are 74% water, 24% carbohydrates, 1% protein, and contain no fat. In a 100 gram reference amount, raw water chestnuts supply 97 calories, are rich (20% or more of the Daily Value, DV) in vitamin B6 (25% DV), and contain moderate amounts of other B vitamins, manganese, and potassium (10% to 17% DV, table).

Digestive Health Benefits

A half-cup serving of water chestnuts provides 2 grams of fiber, which is close to 10 percent of the minimum daily recommended intake of fiber for women over age 50. For other adults, who require closer to 25 to 38 grams of fiber per day, water chestnuts can be paired with other fiber-rich foods, such as dark leafy greens, or in a stir-fry for a high-fiber entrée. Water chestnuts are also, as the name suggests, rich in water. The quantity of fluids we take in daily is another important aspect of digestive health and can help prevent or manage constipation.

3) Tamarind Seed (Tamarindusindica)

Composition

The fatty acid composition of the oil is linoleic 46.5%, oleic 27.2%, and saturated fatty acids 26.4%. The oil is usually bleached after refining. Tamarind is rich in a number of essential nutrients. For instance, if you eat

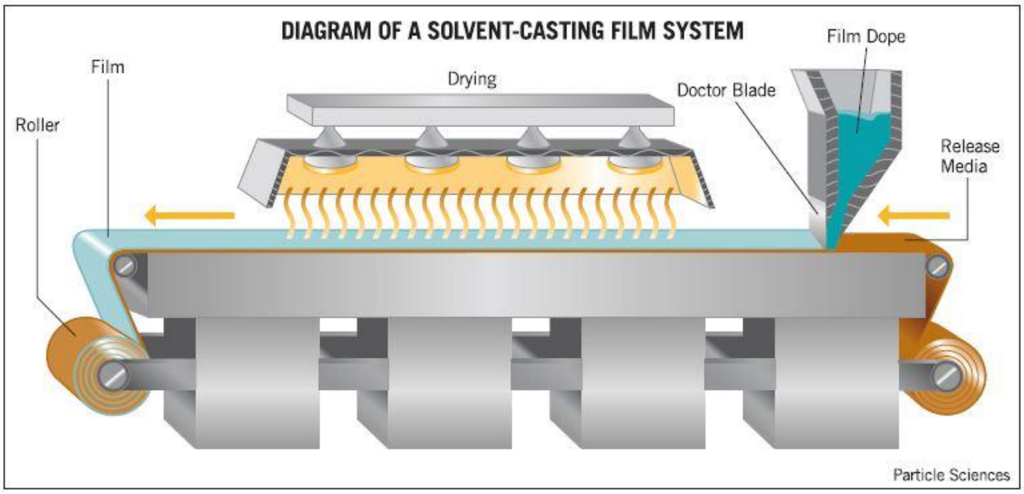
100 grams of tamarind a day, you will get 36% of thiamin, 35% of iron, 23% of magnesium and 16% of phosphorus recommended for you daily. It also has plenty of niacin, calcium, vitamin C, copper, and pyridoxine.

Digestive Health Benefits

Tamarind is good for your digestive system due to two main reasons. For starters, it is a good laxative, which means that it stimulates the bowel movements and excretion. Secondly, it also has high dietary fiber content, which helps bulk up the stool, making it easier for it to move around. As a result, your digestive system is kept clean. Moreover, with healthy and regular digestion, your stomach and other organs do not need to secrete a ton of acids and bile to break down the food. It protects the stomach lining and can prevent pain ulcers and inflammations from taking place.

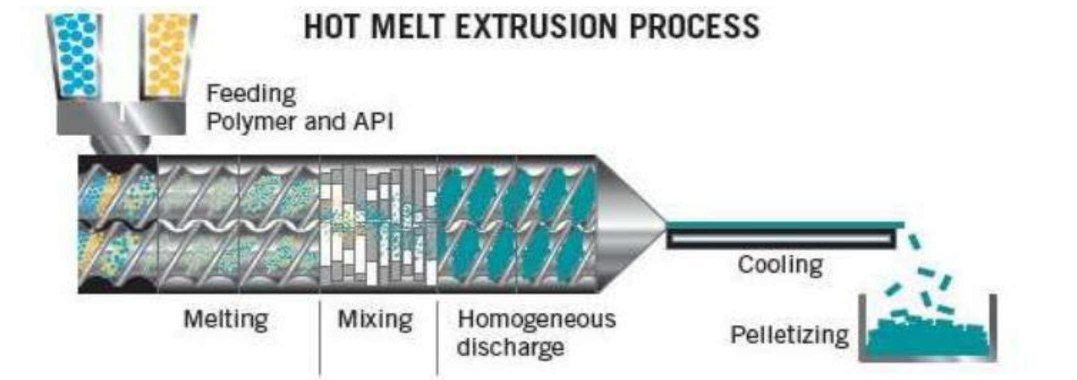
1) Solvent casting method

Figure 1



Films are preferably formulated using the solvent casting method, whereby the water soluble ingredients are dissolved to form a clear viscous solution and the drug along with other excipients are dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted in to the Petri plate and dried.

Water soluble ingredients are dissolved in water and API and other agents are dissolved in suitable solvent.



2) HOT MELT EXTRUSION

Hot melt extrusion method has various benefits; those are fewer operation units, minimum product wastage, better content uniformity, an anhydrous process, absence of organic solvents. In hot melt extrusion method.

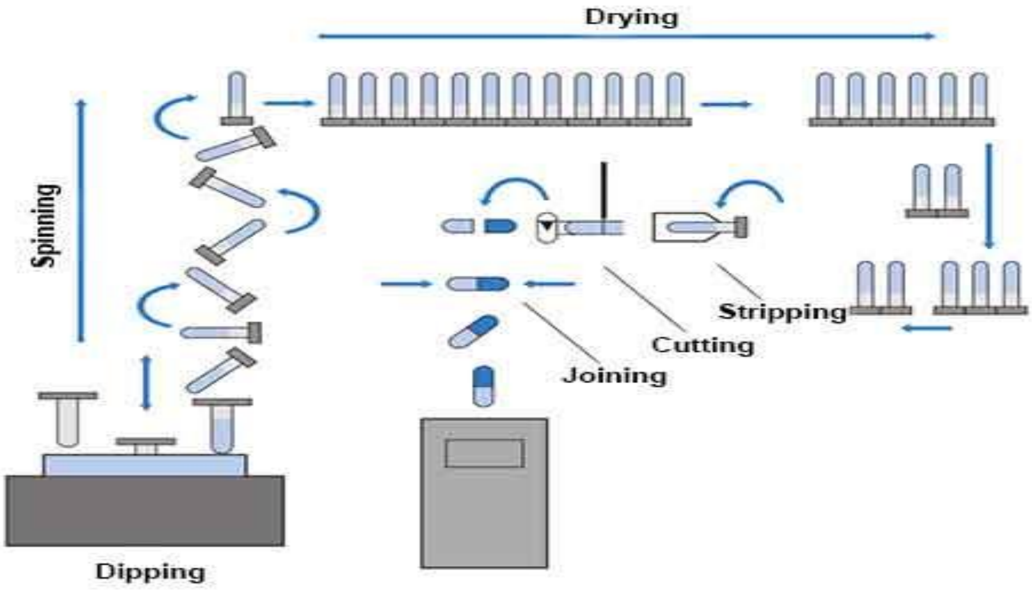
3) Solid Dispersion Extrusion Method

The term solid dispersions refer to the dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers.

4) Rolling Method

In this method the film is prepared by preparation of a pre-mix, addition of an active and subsequent formation of a film.

Steps Involved in Manufacturing of Hard Capsule Shell



1) Dipping
2) Spinning
3) Drying
4) Stripping
5) Trimming and Joining
6) Polishing.

Evaluation Parameters for Hard Capsules Shell.
1) Visual Inspection (Shape, size & Colour Texture)
2) Thickness of capsule shell
3) Melting Point: by fusion tube Starch content
4) Disintegration Test: 370C+2°C For 60 min
5) Accelerated Stability study (for 1month of 40°C±2°C 75% RH ±5%. Disintegration Time, Melting Point, Shape Size And Text.

RESULT AND DISCUSSION

Formulation Detail of Films Of TSP, WCS And RL Starches

Ingredient mg	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
RL	100	150	200	---	---	---	---	---	---	---
WCS	---	---	---	100	150	200	---	---	---	---
TSP	---	---	---	---	---	---	100	150	200	200
HEC	---	---	---	---	---	---	---	---	---	200
Titanium dioxide	1	1.50	2	1	1.50	2	1	1.50	2	4
Tween 80	1	1	1	1	1	1	1	1	1	1
Polyethylene Glycol (PEG400)	5	7.50	10	5	7.50	10	5	7.50	10	20
Benzalkonium Chloride	0.10	0.15	0.20	0.10	0.15	0.20	0.10	0.15	0.20	0.40
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

DISCUSSION

The formulation of Red Lentil (F1 to F3) was prepared and the due to non tackiness and other parameter's result (which is shown in Table 7.3) the next formulation of Waterchestnut (F4 to F6) was prepared hear also the same results found (which is shown in Table 7.3) therefore move forward toward the Tamarind Seed Powder. In F7 there also result but in F8 & F9 the satisfactory result obtain therefore the next batch was prepare by adding the HEC (F10) in the F9 formula then the good results was found.

Formu - lation	Tack Test	Appearance	Weight Mean (mg)	Folding Endurance Mean	Thickness Mean (mm)	Tensile Strength (MPa)	D.T Mean (min)	Starch Content (%)	Moisture Permeation Test(mm/Hg)
F1	Non Tacky	Transparent reddish brown	19±1.5	30±2	1±0.1	0.381±0.05	32±0.5	95.00	0.09±0.01
F2	Non tacky	Transparent reddish brown	25±1.5	28±2	0.6±0.1	0.346±0.05	35±0.5	97.00	0.15±0.01
F3	Non tacky	Transparent reddish brown	28±1.5	26±2	0.9±0.1	0.358±0.05	39±0.5	99.45	0.19±0.01
F4	Non Tacky	Transparent yellowish brown	22±1.5	31±2	0.8±0.1	0.421±0.05	28±0.5	96.34	0.16±0.01
F5	Non Tacky	Transparent yellowish brown	18±1.5	24±2	0.6±0.1	0.451±0.05	32±0.5	97.43	0.21±0.01
F6	Non Tacky	Transparent yellowish brown	29±1.5	32±2	1.2±0.1	0.334±0.05	38±0.5	99.96	0.27±0.01
F7	Non Tacky	Transparent yellowish brown	18±1.5	27±2	1±0.1	0.417±0.05	30±0.5	98.65	0.18±0.01
F8	Tacky	Transparent yellowish brown	22±1.5	25±2	0.8±0.1	0.488±0.05	34±0.5	99.54	0.25±0.01
F9	Tacky	Transparent yellowish brown	30±1.5	36±2	0.8±0.1	0.502±0.05	35±0.5	99.75	0.31±0.01
F10	Tacky	Transparent yellowish brown	33±1.5	40±2	0.7±0.1	0.498±0.05	38±0.5	99.80	0.34±0.01

DISCUSSION

The F1 to F7 batches shows Non-Tackiness and F8 to F10 shows Tackiness. The F1 to F3 shows Transparent reddish brown and F4 to F10 Shows Transparent yellowish brown appearance the weight, Folding Endurance, Thickness, Tensile Strength, disintegration time, starch contain and Moisture Permeation test was observe and above evaluation the F9 and F10 are take as the optimise batch to prepare Capsule Shell.

Disintegration test of capsule shell

n=6 (Mean ± SD).

Discussion: The disintegration time study was perform by regular method of 6 capsule Shell of each batch of formulation and mean was noted in the table.

CONCLUSION

Biodegradable films were developed using starches from various plant sources, and their physical and mechanical properties evaluated. Among the tested samples Red Lentil, Water Chestnut And Tamarind Seed as comparedwith gelatin and HPMC and other LDPE films. Starch films had better tensil strength and improved H2O barrier properties than gelatin and HPMC films. The Red Lentil, Water Chestnut And Tamarind Seed were also utilized to develop hard capsules for the pharmaceutical industry. The developed capsules had good molding properties and formed quality, hard capsules with conventional dip coating technique. The developed starch capsules were clear, smooth surfaced, and flexible. Starches with high amylose produced better films and capsules than the ones with low amylose and high amylopectin. It was possible to develop hard capsules without the gelling agent with high amylose starches (Red Lentil and water chestnut). The developed starch capsules did not completely dissolve and had some fragments in water or HCl solution. Starch based hard capsules have the potentials for utilization in the pharmaceutical industry as a substitute for gelatin or animal protein based products.

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