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Review Article

A Comprehensive Overview of Edible Natural Excipients and their Potential Use in Pharmaceutical Formulation Development

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ABSTRACT

This review aims to explore the prospective scope of excipients obtained from edible natural sources and its unique application in the field of pharmaceutical formulation development. A systematic literature search was conducted using data base like PubMed, Science Direct, Embase, and Google Scholar. A total of 50 articles were identified and reviewed, which primarily focused on the unique application of edible natural sources as excipients in the field of pharmaceutical formulation development. The results revealed that edible natural sources like *Dillenia indica, Abelmoschus esculentus; Oryza sativa* L; *Artocarpus heterophyllus; Tamarindus indica; Musa paradisiaca; Mangifera indica; Ipomoea batatas; Hibiscus sabdariffa* and *Solanum tuberosum* are a promising source of excipients and have great potential to be used in the formulation of pharmaceutical dosage form. Furthermore, the use of these sources may potentially reduce the costs associated with the production of pharmaceuticals dosage form and could also improve the safety profile of the drugs. The review highlights the importance of the use of edible natural sources as excipients and their potential to revolutionize the field of pharmaceutical formulation development.

Keywords Edible natural substance, Excipients, Diluents, Natural binders, Pharmaceutical formulation.

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INTRODUCTION

The pharmaceutical formulation development industry is increasingly making use of excipients derived from edible natural sources, as they have been proven to effectively stabilize, boost solubility, absorption, and bioavailability of Active Pharmaceutical Ingredients (APIs). Some natural excipients that have been explored as an alternative to synthetic ones are starches, celluloses, gums, and pectins.[1] These natural excipients have the potential to improve the properties of formulations, reduce manufacturing costs, and increase patient compliance.[2] Some of the potential applications of edible natural excipients in pharmaceutical formulation development include use of Natural excipients such as Hydroxypropyl Methylcellulose (HPMC) and Polyethylene Glycol (PEG) can be used to solubilize poorly soluble APIs.[3] Natural excipients such as gum arabic, xanthan gum, and carrageenan can be used to stabilize and suspend poorly soluble APIs in aqueous media. Further, natural excipients like pectin and carrageenan can be used to form micro- and nano-encapsulated particles of APIs.[4] Again natural excipients such as starches, celluloses, and gums are used as binders, fillers, and disintegrants in formulation of tablet dosage form. Similarly, gum arabic can be used to form enteric and resistance coatings on tablets.[5] These are just a few examples of the potential applications of edible natural excipients in pharmaceutical formulation development. With the increasing demand for natural, safe, and effective formulations, there is a great opportunity for further exploration of edible natural excipients in pharmaceutical formulation development.[6] Considering the above fact this article has been prepared to explore the prospective scope of excipients obtained from edible natural sources and their unique application in the field of pharmaceutical formulation development

METHODOLOGY

The search strategy for this systematic review was designed to identify relevant studies on the prospective scope of excipients obtained from edible natural sources and its unique application

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in the field of pharmaceutical formulation development. The search was conducted using the following databases: PubMed, ScienceDirect, Wiley Online Library, and Google Scholar. The following keywords were used: "excipient", "natural source", "edible", "formulation", "development", and "pharmaceutical". The search was limited to articles published in the English language from 2010 to 2022. Studies were included if they addressed the prospective scope of excipients obtained from edible natural sources and its application in the field of pharmaceutical formulation development. The reported literature provides conclusive information about the various natural sources that serve as effective excipients Figure 1. Hence, the outputs of the present study are expected to lead towards the findings of effective excipients.

DISCUSSION

The information about some edible natural resources that play a significant role as excipient in the field of formulation design and development are as follows (Table 1).

Abelmoschus esculentus

The plant *Abelmoschus esculentus* belongs to the family of Malvaceae. It is popularly known as lady's-fingers, okra and bhindi in India and Southeast Asia. It is a tropical to subtropical plant that is generally appropriated across Africa to Asia, Southern Europe, and America. Apart from its use as edible vegetables, the polysaccharides obtained from the fruit part play certain clinical role in design of modern dosage form.[7] The research conducted on okra has revealed that its mucilage, which is retrieved from the seed and fruit part, is a great source of pectin. This mucilage showed considerable suspending properties when tested in Acetaminophen pediatric suspension at low concentrations.[8] Moreover, okra powder was discovered to possess disintegrating properties when used in small amounts.[9] Recently, there has been an increasing focus on the role of okra mucilage as a binder in tablet formulations. It has also been suggested as an alternative excipient for the development of sustained-release tablet formulations.[10] Additionally, the gum from okra has been explored for gastric floating dosage forms, yet it has been reported to have limited buoyancy. [11]

Artocarpus heterophyllus

Artocarpus heterophyllus belongs to the family of Moraceae and commonly known as jackfruit or Ceylon jack. It contains tacky or sticky white latex. Veggie lovers and vegans regularly utilize this organic product as a substitute of meat. It is reported

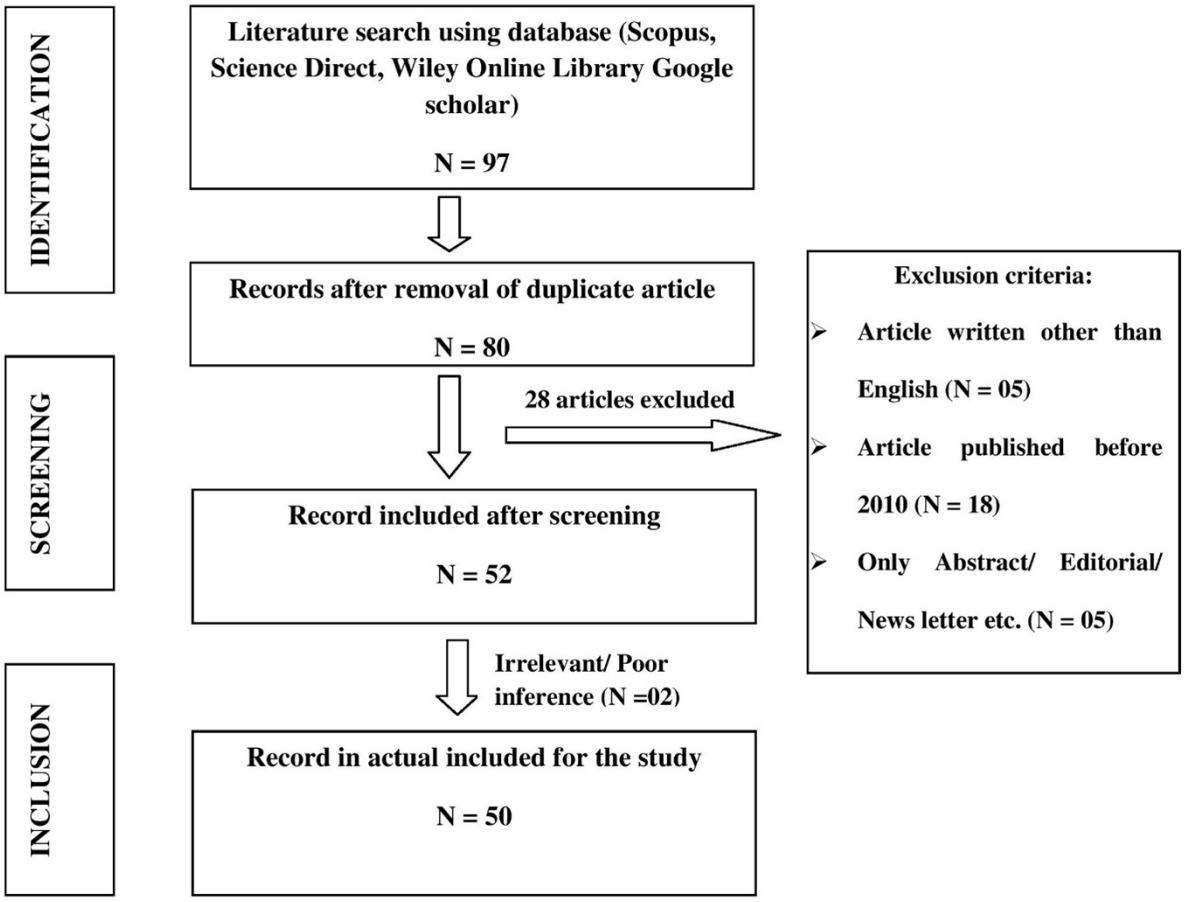

Figure 1: Literature selection process for the study.

that Jackfruit seeds is a good source of starch.[12] The powder of *Artocarpus heterophyllus* seeds has been found to be an effective binder in the formulation of paracetamol tablets.[13] In comparison to commercial starch, the binding ability of jackfruit seed starch is significantly superior.[14] A recent study has developed Cross-Linked Carboxymethyl Jackfruit Starch (CL-CMJF) and used it effectively as a tablet disintegrant.[15] Additionally, jackfruit seed starch powder was employed as a super disintegrant in the formulation of fast dissolving tablets.[16] Further, Jackfruit latex has been identified as a potential natural binder that can be used to construct mucoadhesive solid dosage forms and oral sustained-release tablets.[17] The mucilage obtained from the ripe fruit pulp of *A. heterophyllus* has multifunctional properties, which could be beneficial in various applications.

Colocasia esculenta

Colocasia esculenta, a yearly herbaceous plant of the family Araceae, has been utilized in traditional medicine in many nations for centuries. This tropical plant is primarily grown for its edible corms, which are also known as taro and are used as a vegetable in numerous cuisines all over the world. A recent study compared the use of *Colocasia esculenta* starches with that of maize starch and found it to be a viable substitute for binder and disintegrant in tablet production due to its high starch content.[18] Taro (*Colocasia esculenta*) starch has been found to be a more efficient disintegrant than potato or maize starch. In order to modify its structure, pregelatinizing is done. This modified form of Taro starch has been successfully used as diluents in the production of Thiamine Hydrochloride tablets.[19] Matrix tablets with antiviral properties for sustained release were designed using Taro gum, a natural polymer derived from Taro corms (Taro root). This gum has been explored for its mucoadhesive strength and its capacity to slow the rate of release of the drug.[20] As such, it has been found to be a suitable excipient for the design of controlled drug delivery.[21]

Hibiscus sabdariffa

Hibiscus sabdariffa, commonly known as roselle or Tenga mora, is a restorative plant that is widely distributed in tropical and subtropical areas across the world. It is capable of adapting to a variety of soils in hot and humid environments. Roselle is popular for its high source of beta-carotene, vitamin C, protein, and total sugar, as well as its nutritional and medicinal properties. Different parts of the plant, such as seeds, leaves, fruits, and roots, are used in various foods as herbal supplements and are believed to treat various medical conditions, including various cardiovascular problems, helminthic diseases, and cancer.[22] *Hibiscus sabdariffa* has traditionally been used as a food, herbal drink, seasoning or flavouring agent in the food industry, and as a natural or herbal medication. In a recent study, the efficacy of the mucilage obtained from the fresh leaves of *H. sabdariffa* as a binder was evaluated in an Orodispersible tablet.[23] The mucilage from the *Hibiscus sabdariffa* leaves was compared with other binding agents such as starch and Poly Vinyl Pyrrolidine (PVP) and was found to have a higher binding capacity than starch and PVP. Additionally, in another study, *H. sabdariffa* calyx extract was used as a colouring agent in a pharmaceutical formulation.[24] In a further study of the development and evaluation of Fast Dissolving Tablets, the effective disintegration properties of *H. sabdariffa* mucilage were evaluated and found to be satisfactory.[25]

Ipomoea batatas

Ipomoea batatas are commonly known as sweet potatoes belong to the family Convolvulaceae. It is dicotyledonous plants that are utilized as a root vegetable. They are a decent or good source of fiber, potassium, vitamins, and other fundamental nutrients.[26] Sweet potato starch could be obtained from the root of *Ipomoea batatas*. Sweet potato roots contain around 70% starch. It is used as a binder, disintegrant, and diluents. The modified sweet potato starch has better pharmaceutical properties than native starch. Starch from local sweet potato needs a chemical modification process to produce derivatives with better specific pharmaceutical characteristics for the production of tablets. Sweet potato starch was used as a binder in the development of lozenge dosage form.[27] As per the literature, sweet potato starch shows its efficiency as disintegrant as well as binding agent in preparation of different tablet formulation. A comparative study states that sweet potato starch has better binding capacity compared to maize starch. Further, A study by Jubril *et. al.*, reflect that due to the high hydration and swelling capacities the modified sweet potato starch shows stronger disintegrant property than the unmodified sweet potato starch.[28] The high-density nature of sweet potato starch makes it choice suitable as diluents.[29,30]

Mangifera indica

Mangifera indica most commonly known as mango tree belongs to the family Anacardiaceae, is a huge evergreen tree. Mango the fruit of the tree is the most tropical organic product that are originated from the region between northwestern Myanmar, Bangladesh, and India[31] Mango fruits are reported to have a high nutritional value and pharmacological properties like antioxidant, immunomodulation, cardio tonic, hypotensive, wound healing, anti-degenerative, and antidiabetic activities.[32] The mature seeds of *Mangifera indica* is a as rich sources of starch. The starch obtained from seeds of *M. indica* was used as an excipient (binder and disintegrating agent) in the formulation of Paracetamol and Ibuprofen tablet.[33] Further, the *Mangifera indica* peel contains a good percentage of pectin.[34] Fast dissolving tablets of furosemide were formulated by direct compression method using pectin derived from mango peel as natural disintegrants, the result of the study states that pectin powder of *M. indica* shows better drug release and disintegration time as compared to tablets prepared from other natural and synthetic disintegrants.[35] The Mango *(Mangifera indica)* gums were successfully used in the design of

matrix tablets of Glibenclamide and sustained-release tablets of Diclofenac sodium at a lower concentration.[36]

Musa paradisiaca

Musa paradisiaca is popularly known as a banana belongs to the family, Musaceae. More than 700 varieties, 30 notable species within the genus Musa are available. It is a popular fruit with high nutritional value and a wide range of health benefits.[37] Banana starch has been obtained from the unripe fruit of the plant *Musa paradisiaca*. The binding properties of *Musa paradisiaca* were investigated, evaluated, and found that it could be used as a binding agent in the formulation of solid dosage form.[38] A comparative binding study of banana starch with maize BP and Polyvinyl Pyrrolidone (PVP) reflect the advantages of banana starch as an effective binder.[39] Further, a comparative study of banana starch with potato starch and corn starch for the disintegrant properties reflect superiority of the banana starch powder as disintregant in a fast disintegrating tablet.[40] Further, pectin obtained from banana peels were successfully used as pharmaceutical excipient to prepare solid as well as the semisolid dosage form. The waste peel of the banana was processed and employed as adhesive in paracetamol tablets. Moreover, mucoadhesive property of Crude banana powder was also found to be effective.[41]

Oryza sativa

Oryza sativa, usually known as Asian rice, is the plant species most commonly referred as English rice. Further, "Bora Chaval" is a nutritious grain crop mostly consumed by people of North-east India having high amylopectin content. The Bora rice is the rich source of pregelatinized starch (90%) that is used in directly compressible tablet as excipient.[42,43] It is also reported that the level of crystallinity of Assam Bora rice starch is significantly

Table 1: Plants and their parts used as natural excipients.

Sl. No.	Botanical Name	Family	Local name	Parts used	Excipient use	References
1	*Abelmoschus esculentus* Linn.	Malvaceae	Bhindi, Okra	Fruit	Binder, Disintegrant, Suspending agent, Polymer.	8-11
2	*Artocarpus heterophyllus*	Moraceae	Jackfruit	Seed starch, Mucilage, Fruit latex	Binder, Disintegrant, Super disintegrant, Polymer.	14-17
3	*Solanum tuberosum*	Solanaceae	Potato	Starch tuber	Binder, Diluent, Disintegrant.	47
4	*Colocasia esculenta*	Araceae	Taro	Taro gum, Starch	Binder, Disintegrant, Diluent, Polymer.	18-21
5	*Hibiscus sabdariffa*	Malvaceae	Roselle, Tenga mora	Mucilage from leaves and fruit catalyce	Binder, Disintegrant, Colouring agent.	22,24,26
6	*Ipomoea batatas*	Convolvulaceae	Sweet Potato	Starch	Binder and Diluent, Disintegrant, Polymer.	27,28,30
7	*Mangifera indica*	Anacardiaceae	Aam	Gum, Mango peel (Pectin)	Binder, Disintegrant, Polymer.	34-37
8	*Musa paradisiaca*	Musaceae	Banana	Starch, Peel pectin	Binder, Disintegrant, Polymer.	38-41
9	*Oryza sativa* L.	Gramineae	Bora rice	Starch	Binder, Disintegrant, Polymer.	44-46
10	*Tamarindus indica*	Fabaceae	Tamarind	Seed gum	Binder, Disintegrant.	49,50

higher than potato starch, which mirrors its obstruction towards enzymatic hydrolysis during digestion in the gastrointestinal tract. It shows better binding property as compared to gelatin powder.[44,45] Further, in an evaluation of several native starches, rice starch proved to have much better compaction properties than potato, maize, and tapioca starch. The starch of *Oryza sativa* L. was reported to use as a biopolymer. Further, it was successfully used as natural mucoadhesive matrix agent for the formulation of controlled release drug delivery. Assam Bora rice starches also possess good disintegrating properties.

Solanum tuberosum

Solanum tuberosum, commonly known as potatoes, is a member of the Solanaceae family and is often referred to as the 'king of vegetables.' It is the fourth most important food crop in India after rice, wheat, and maize.[46] In addition, potatoes have industrial uses such as the production of starch and alcohol. Potato starch, obtained from the root tubers of Solanum tuberosum, is a multifunctional excipient in solid dosage forms, used as a filler/diluent, binding agent, and disintegrating agent.[47] Its amylose-amylopectin ratio, crystallinity, and gelatinization properties can strongly affect its swelling and compaction behavior and make it an ideal binder for various solid dosage forms.[48] Moreover, potato starch is a sustainable, biodegradable resource that can be modified to obtain products with specific properties.[49]

Tamarindus indica

Tamarind (*Tamarindus indica* Linn.), belonging to the Fabaceae family, is a tropical plant found in tropical and subtropical regions. Its sweet-sour pulp is used as food, beverage, and traditional medicine, especially in the African region and India. In traditional medicine, tamarind has been used to treat diarrhea, constipation, fever, and peptic ulcers, as well as to promote wound healing by using its bark and leaves. The tamarind seed gums are used as binders and have been modified by carboxymethylation to improve their binding properties. These modified binders were used to successfully formulate Ibuprofen tablets, with slow dissolution profiles. Raw and chemically modified gums from *Tamarindus indica* seeds were also evaluated as potent disintegrants and diluents, and tested in sustained-release matrix formulations as a coating agent. Consequently, raw and modified tamarind polysaccharides can be utilized as versatile pharmaceutical excipients in novel drug delivery systems.[50]

CONCLUSION

This review paper aimed to explore the use of excipients derived from the most common edible natural sources in pharmaceutical formulation development. It was found that natural excipients are becoming increasingly popular due to several advantageous features, such as their abundance, minimal side effects, low toxicity, biocompatibility, patient acceptance, renewable source, and environment-friendly processing. The most commonly used natural sources of excipients, including *Dillenia indica, Abelmoschus esculentus, Oryza sativa* L, *Artocarpus heterophyllus, Tamarindus indica, Musa paradisiaca, Mangifera indica, Ipomoea batatas, Hibiscus sabdariffa,* and *Solanum tuberosum*, have proven to be significant contributors to pharmaceutical formulation design and development.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

API: Active Pharmaceutical Ingredients; **HPMC:** Hydroxy propyl methyl cellulose; **PEG:** Polyethylene Glycol; **CL-CMJF:** Cross-Linked Carboxymethyl Jackfruit Starch; **PVP-** Poly Vinyl Pyrrolidine.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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