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GALACTOMANNAN AS A NATURAL SOURCE OF PHARMACEUTICAL EXCIPIENT FOR SUSTAINED RELEASE DOSAGE FORM: A REVIEW

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ABSTRACT

Galactomannans are neutral hemicellulose biopolymers that strengthen the plant cell walls by interacting with cellulose in the form of storage polysaccharides. They are abundant in nature and are majorly present in the secondary walls of flowering plants. They are primarily extracted from the leguminous seed endosperms and display a wide variation at the structural and abundance level amongst different plant species. There are four major sources of seed galactomannans: locust bean (Ceratonia siliqua), guar (Cyamopsis tetragonoloba), tara (Caesalpinia spinosa Kuntze), and fenugreek (Trigonella foenum-graecum L.). Through keen references of reported literature on galactomannans, in this review, we have described occurrence of various galactomannans, its physicochemical properties, characterization, applications, and overview of some major galactomannans.

Keywords *– Galactomannans, Natural Polymers, Excipient, Dosage form.*

1. INTRODUCTION

Sustained release (SR) dosage form is mainly designed for maintaining therapeutic blood or tissue levels of the drug for extended period of time with minimized local or systemic adverse effects. Economy and greater patient compliance are other advantages. Sustained release dosage forms would be most applicable for drugs having low therapeutic indices and short elimination half-lives [1]. Advantage of sustained release preparations other than a prolonged response is found in a reduction of the fluctuations in concentrations of drug and/or metabolites in the circulation, the tissues and the gastro-intestinal tract. Unnecessarily high and toxic peak concentration with consequently adverse reactions and sub-therapeutic levels of relatively high elimination rates with possible consequences of symptom breakthroughs can be avoided [2].

Many new drug delivery systems have been developed to deliver drugs with relatively short duration of action or narrow therapeutic indices at a controlled rate, which will maximize the pharmacological benefits and minimize the potential side effects [3]. A typical controlled release system is designed to provide constant or nearly constant drug levels in plasma with reduced fluctuations via slow release over an extended period. In practical terms, an oral controlled release should allow a reduction in dosing frequency as compared to when the same drug is presented as a conventional dosage form [4]. Controlled drug release

from the delivery systems is in most cases achieved by the use of polymers. Hence, the polymer is a key component of the controlled drug delivery systems. Evaluation of polymers for controlled release properties is also a major area of research in the development of controlled drug delivery systems.

Among different technologies used in controlled drug delivery, matrix systems are the most popular because of the simplicity of formulation, ease of manufacturing, low cost and applicability to drugs with wide range of physicochemical properties. Drug release from these systems is the consequence of controlled matrix hydration, followed by gel formation, textural/ rheological behavior, matrix erosion, and/or drug dissolution and diffusion, the significance of which depends on drug solubility, concentration, and changes in matrix characteristics [5].

Hydrophobic polymers such as ethyl cellulose, carnauba wax and beeswax and hydrophilic polymers such as hydroxypropyl methylcellulose, sodium carboxy methyl cellulose, hydroxyl ethyl cellulose and hydroxyl propyl cellulose and natural gums including guar gums, xanthan and karaya gum, sodium alginate and pectin's have been investigated for preparation of controlled release matrix systems [6-12].

Hydrophilic polymers are becoming more popular in formulating oral controlled release tablets. As the dissolution medium or biological fluid penetrates the dosage form, the polymer material swells and drug molecules begin to move out of the system by diffusion at a determined rate by the nature and composition of the polymer as well as formulation type [13].

The use of naturally occurring hydrophilic biocompatible polymeric materials has been focused in recent research activity to design dosage form for oral controlled release of highly water-soluble drugs compare to synthetic polymers. The use of matrix devices to control the release of variety of therapeutic agents has become very important in the development of controlled release dosage form [14-17].

Hydrophilic matrix sustained release dosage form is one of the popular drug delivery systems in which a therapeutic agent is dispersed in a compressed matrix made of water swellable polymers. When exposed to aqueous medium, the surface of the polymer hydrates to form a viscous-gel layer.

Industrially there is growing interest in the formulation of mixed hydrophilic gum systems. Blends of two or more hydrophilic gums exhibit complex and often spectacular properties which depend not only on total polymer concentration, relative proportions of polymeric components, solvent medium characteristics and temperature and also on the thermal and mechanical history experienced by the systems themselves. In other situations, the addition of small amount of a non-gelling polymer to a gelling one may induce a strengthening of the resulting gel or even, some polymer that are individually non-gelling can yield gel on mixing. Many such mixed systems of hydrophilic gums show this additive behaviour, which is currently termed Synergism [18].

For the formulation scientist, a hydrophilic matrix system is the most popular and preferred approach in the development of controlled drug delivery system of a drug. This is because these can be easily processed and polymers used in these systems are from natural origin, are easily available and cost effective [19].

Galactomannans are vegetable, heterogeneous polysaccharides widely distributed in nature. Generally, they possess (1-->4)-linked D-mannopyranose (Man) main chains to which are attached (1-->6)-linked D-galactopyranosyl (Gal) units (Fig. 1).

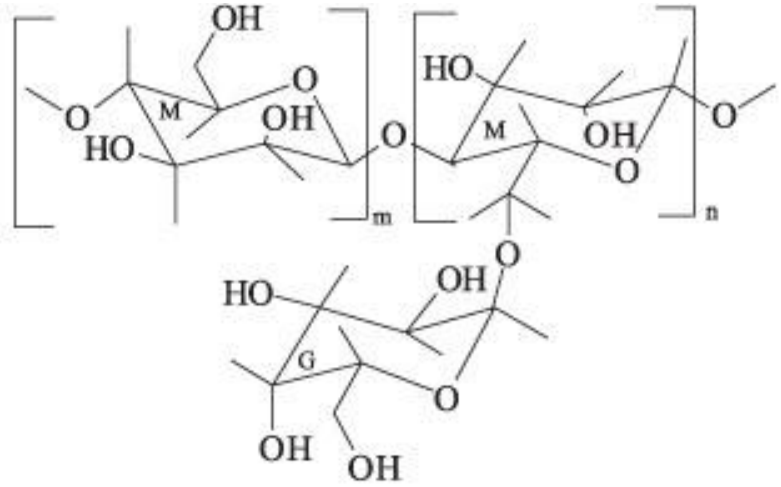

Fig. 1: Generic Structure of Galactomannans (M: Mannose, G: Galactose)

The Man/Gal ratios differ from gum to gum, resulting in a change in structure, which, in turn, determines the various industrial applications of seed galactomannans. There are four major sources of seed galactomannans: locust bean (*Ceratonia siliqua*), guar (*Cyamopsis tetragonoloba*), tara (*Caesalpinia spinosa* Kuntze), and fenugreek (*Trigonella foenum*-graecum L.). These materials are important in paper, textile, petroleum-drilling, pharmaceutics, food, cosmeceuticals, and explosives industries. The pharmaceutical use of galactomannans from different sources, commercial and noncommercial, has been extensively studied over the past decade. Galactomannans show potential in the global trend towards the use of more plant-based products for ecological motives, and their production and application do not cause pollution or disturb the ecosystem. There is a variety of galactomannan sources and various pharmaceutical forms of application, such as tablets or capsules, hydrogels and films. Besides the simple use as inert excipient these polysaccharides play role in the modification of drug release, especially in colonic environmental, as a matrix or coating material.

In this review, the biodiversified applicability of galactomannan gums is discussed, particularly with respect to source, structural aspects, properties, and pharmaceutical applications.

2. VARIOUS PLANT SOURCES REPORTED IN LITERATURE FOR GALACTOMANNANS

Vandana S. et al have isolated a non-ionic water-soluble galactomannan having a galactose and mannose in 1:2 molar ratio from endosperm of the seeds of *Ipomoea turpethum*. The seed gum was shown to have a branched structure consisting of a linear chain of β(1-4) linked mannopyranosyl units with D-galactoseside chains attached through α(1-6) linkage to the main chain, a fundamental structural pattern found in other seed galactomannans like guar, carob, locust bean, tara and dhaincha commercial gums. The seed gum from Ipomoea turpethum showed similarity in structural pattern and properties to guar gum [20].

Patel N.C.et al have isolated mucilage from the seeds of *Cydonia vulgaris* Pers. and explored it as tablet disintegrant. The disintegrating efficiency of isolated mucilage was equivalent to cross-povidone [21].

Brummera et al have investigated fenugreek gum isolated from the defatted and deactivated fenugreek seeds (produced in Canada) at 10.8oC for 2 hr with a yield of 22% with only 2.36% protein contaminate. Further purification of the fenugreek gum was achieved by treating the gum solution with pronase to reduce the protein contaminates to 0.57%. Monosaccharide and

methylation analysis suggested that the extracted fenugreek galactomannans were highly substituted and the ratios of galactose to mannose were from 1.00:1.02 to 1.00:1.14. Although fenugreek gum exhibited higher molecular weight compared to locust bean gum and guar gum, it's the intrinsic viscosity and rheological behavior of fenugreek gum was reduced. This was attributed to the influence of the substitution patterns of the galactose on the mannosyl backbone chain. The purified fenugreek gum demonstrated less surface activity compared to the unpurified gum [22].

Kapoor V. P. has isolated galacto-mannan composed of n-galactose (1 mol) and D-mannose (2 mol) from the seeds of *Delonix regia*. Hydrolysis of the methylated galactomannan yielded 2, 3, 4, 6-tetra-O-methyl-o-galactose (l.02 mol), 2.3,~tri-Omethyl-D-mannose (1.05 mol) and 2,3-di-0-methyl-D-mannose (1 mol). The periodate consumption was l-30 mol for each hexose unit with concomitant liberation of O-31 mol of formic acid. Hydrolysis of the reduced oxopolysaccharide gave only glycerol (1 mol) and erythritol (1.04 mol). It was established that galactomannan is a highly branched polysaccharide consisting of the main chain of mannose united linked through α (l-4) and the side chain of single galactose units linked through β (1-6) [23].

Subhas B. B. et al have carried out investigations on the purification of the whole gum exudate from the drum-stick plant (*Morirz gaoleifera*) and showed that L-arabinose, D-galactose, u-glucuronic acid. L-rhamnose, D-mannose, and D-xylose were present in the gum in the molar ratio of 14.5:11.3:3:2:1:1. A homogeneous, degraded-gum polysaccharide consisting of D-galactose, D-glucuronic acid and D-mannose in the molar ratio of 11.7: 3.9: 1 was obtained on mild hydrolysis of the whole gum with acid. Per-methylation studies were conducted on the whole gum, the degraded gum, and their carboxyl-reduced products. On the basis of the results obtained from these studies a tentative structure was assigned to the average repeating unit of the gum [24].

Sarika G. et al have isolated a polysaccharide from the seeds of *Cassia occidentalis*, an annual weed occurring throughout India, and a rich source of galactomannan gum. The gum derived from seed endosperm can be potentially utilized in a number of pharmaceutical industries to replace the conventional gums. With a view to utilize the gum for broader applications, carbamoylethylation of Cassia occidentalis seed gum was carried out with acrylamide in presence of sodium hydroxide under different reaction conditions. Variables studied were concentration of sodium hydroxide, acrylamide, gum–solvent ratio, reaction time and temperature. The nitrogen content, carboxyl content and total ether content were also determined [25].

Sadhan K. R. et al have isolated a water soluble polysaccharide from the aqueous extract of the pods of *Morin gaoleifera*. The polysaccharide contains D-galactose,6-O-Me-D-galactose, D-galacturonic acid, L-arabinose, and L-rhamnose in the molar ratio of 1:1:1:1:1. On the basis of total hydrolysis, methylation analysis, periodate oxidation, and NMR studies a tentative structures were assigned [26].

Samil K. M. et al have studied the composition of a higher quality refined locust bean gum (rLBG) and compared it with lower quality crude locust bean gum (cLBG) samples to understand the differences in functionality. Mannose/Galactose (M/G) ratio has a great bearing on the viscosity and gelling properties of the material. The M/G ratio of cLBG and rLBG samples obtained range from 3.1 to 3.9, respectively. A high level of arabinose was, however, found in cLBG. This indicates the presence of polysaccharides which could contain galactose or mannose, are present in the less refined materials [27].

Puja G. et al have investigated a polysaccharide isolated from tamarind kernel powder and showed that it is a rich source of xyloglucan and can be utilized in a number of pharmaceutical industries. With a view to utilize the gum for broader applications, carboxymethylation of the tamarind kernel powder was carried out. The reaction conditions were optimized with respect to

concentrations of sodium hydroxide, monochloroacetic acid, solvent ratio, reaction time and the reaction temperature. Carboxymethylation of tamarind kernel powder increased its solubility in cold water and the stability of its paste to microorganisms [28].

Amiza M. A. et al have investigated gum isolated from defatted local durian seeds. The yield was 18% of light brown crude gum powder. Further purification was carried out by barium complexing to give a yield of 1.2% of pure air-dried gum or 0.5% of freeze-dried gum. The pure durian seed gum was characterized in terms of moisture, ash content, mineral content, effect of temperature and pH on viscosity and sugar composition of the gum. The purified durian seed gum had 17.9% moisture and 29.8% total ash. Mineral content of the gum was comparable to commercial gum except for zinc content which was quite high in durian seed gum. The gum solutions were fairly stable over a wide range of pH (2.0–10.0). Sugar analysis by PC and HPLC revealed the presence of L-rhamnose, glucose and D-galactose sugars in the hydrolysed durian seed gum in the ratio of 3:9:1 [29].

Sujja A.J. et al have examined the swelling, erosion and solvent front penetration properties of mini-matrices containing xanthan (X), locust bean (LB) and karaya (K) gums using diclofenac sodium as a model drug. Mini-matrices were produced with drug: gum ratio of 1:1 as well as formulations of drug and X in combinations of 2:1, 2:3 and 1:2. The rank order of decreasing swelling index (SI) in both axial and radial dimensions was X, K, LB and each gum showed almost Fickian swelling behaviour. The solvent front penetration rates were consistent with the rates of swelling. The order of decreasing drug release and erosion rates was LB, X, K and all formulations demonstrated anomalous (non-Fickian) drug release kinetics. The dominant mechanism depended on the nature and content of the gum, as well as the stage in the dissolution time period [30].

Panda D. S. et al have isolated a water swellable polysaccharide from exudates of *Morin gaoleifera* by hot water extraction followed by ethanol precipitation. The phytochemical screening and physiochemical properties of the isolated polysaccharide proved its suitability for sustained release purposes. Sustained release matrix tablets were prepared using propranalol hydrochloride by the wet granulation method. The binding property of the gum was also investigated using different concentrations of the gum solution as a binder. The in vitro drug release studies with different polymer concentrations and different fillers (Calcium sulphate dihydrate, lactose) showed prolonged drug release from matrix tablets and moderate binding capacity [31].

Durcilene A. S. et al have isolated a polysaccharide from cashew tree exudes and carboxymethylated the same in aqueous alkaline medium using monochloroacetic acid (MCA) as the etherifying agent [32].

Ian M.S. et al have isolated a gum that exudes from the wounded trunk of the New Zealand native tree *Meryta sinclairii*. They also carried out a complete chemical investigation and the structure of the gum and compared it with the structure of gum Arabic [33].

Sumathi S. et al isolated a polysaccharide from the seeds of tamarind kernel powder. They investigated its sustained release behaviour using both water soluble (acetaminophen, caffeine, theophylline and salicylic acid) and water insoluble (indomethacin) drugs. The effect of incorporation of diluents like microcrystalline cellulose and lactose on the release of caffeine and partial cross-linking of the polysaccharide on release of acetaminophen were also studied. The rate of release was shown to vary with the type and the amount of blend in the matrix. The mechanism of release due to effect of diluents was found to be anomalous. The rate of release of the drug decreased on partial cross-linking and the mechanism of release was found to be super case II [34].

Sanya H. et al have isolated a crude pharmaceutically useful water-soluble polysaccharide from durian rinds (*Durio zibethinus*) by hot water extraction followed by ethanol precipitation. The polysaccharide was fractionated by anion exchange chromatography and size exclusion chromatography. The characterization of the sub fractions by methanolysis, methylation analysis and NMR spectroscopy revealed that the principal components were pectic polysaccharides with starch as a contaminant. The physical features, namely, molecular weight and intrinsic viscosity of the main fractions were investigated by size exclusion chromatography coupled to multi angle laser light scattering and capillary viscometer, respectively [35].

Suresh K. G. et al have isolated an α-D-galactose-specific lectin from the seeds of jack fruit (*Artocarpus integra*) in pure form by affinity chromatography on immobilized guar gum (a galactomannan). The lectin was shown to be a glycoprotein containing 3% carbohydrate having a molecular weight of 39,500 as determined by gel filtration. Sodium dodecyl sulphate gel electrophoresis revealed a single polypeptide of 10,500 dalton, indicating that the native lectin is a tetramer of identical subunits. The hem agglutinating activity of the lectin towards erythrocytes of all blood groups was found to be the same [36].

Silvana C.P. et al have isolated a serine proteinase inhibitor from the *Delonix regia* seeds, a leguminosae tree of the Caesalpinioideae subfamily. The inhibitor, named Dr TI, inactivated trypsin and human plasma kallikrein with Kivalues 2.19X10-8 M and 5.25 nM, respectively. Its analysis by SDS-PAGE 10–20%showed that the inhibitor is a protein with a single polypeptide chain of Mr 22 h Da. The primary sequence of the inhibitor was determined by Edman degradation that indicated 185 amino acids and showed that it belongs to the Kunitz type family. Its reactive site did not contain Arg or Lys at the putative reactive site (position 63, Sb TI numbering) [37].

Sandra K. et al have studied on the three-dimensional structure of a novel Kunitz (STI) family member an inhibitor purified from *Delonix regia* seeds (DrTI) and solved by molecular replacement method and refined, respectively, to R-factor and R-free values of 21.5% and 25.3% respectively at 1.75A resolution. The structure has a classical b-trefoil fold that different from canonical Kunitz type (STI) inhibitors. Its reactive site loop has an insertion of one residue, Glu68, between the residues P1and P2. Surprisingly DrTI is an effective inhibitor of trypsin and human plasma kallikrein, but not of chymotrypsin and tissue kallikrein. Putative structural grounds of such specificity were discussed [38].

Panda D. et al78 have investigated the gelling potential of a natural gum obtained from *Morin gaoleifera* exudates. The gum was extracted by using water and precipitated using acetone as non-solvent. Physical characteristics such as solubility, swelling index, loss on drying and pH were studied. Diclofenac sodium was used as a model drug for formulating gels. Seven batches of drug loaded gels with concentration of mucilage ranging from 5.5, 6.0, 7.0, 7.5, 8.0 and 8.5 were formulated by using glycerine as a plasticizer and methyl paraben as the preservative. The gels prepared with 8.0% of mucilage were found to be ideal and comparable with commercial gels [39].

3. CONCLUSION

Galactomannans are natural biopolymers possessing efficient biocompatibility, biodegradability, and sustainability, leading to diverse industrial applications. Over the last few decades, galactomannans have attracted huge attention due to their unique functional, solution and rheological properties, generally defined by their molar mass and the degree of substitution by galactosyl side chain, which differs between plants. Further, they are nontoxic, originate from renewable sources, fairly inexpensive, and are amenable to both chemical and biochemical modification. Moreover, excellent thickening, stabilizing and gelling abilities of these

biopolymers have found extensive use in sustained release drug delivery system. The studies reported herein indicate the potential pharmaceutical uses of galactomannans from different sources. The wide range of potential pharmaceutical applications of galactomannans may be an important factor for the economic and social growth of developing countries that possess a rich biodiversity for safe exploitation, and may provide an alternative to synthetic or semisynthetic polymers currently used in the pharmaceutical industry.

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5. CONFLICT OF INTEREST

Author has no conflicts of interest to disclose.

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