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EXCIPIENT PROFILE OF SODIUM ALGINATE: FUNCTIONAL CHARACTERISTICS AND EMERGING TRENDS IN DRUG DELIVERY

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ABSTRACT
Sodium alginate is a useful polymer that is extracted naturally and found in brown seaweed, and is used as an excipient in the food, medicinal, and environmental industries. In immediate release formulations, its primary role as a disintegrating agent can deal with penetration of liquids and disintegration of the tablet. Sodium alginate can be applied in the fields of food preservation, corrosion inhibition and wastewater treatment due to its biosafety, biocompatibility and biodegradability characteristics. Active additions enhance its filming ability that encourages food packing and enhances its antibacterial and antioxidant effects. Sodium alginate was discovered in 1881 and came to be famous in culinary, pharmaceutical and textile industries due to its gelling and thickening property. It is a hydrophilic, ionotropically gellable, hydrophilic polymer. To address its limitations, sodium alginate has been engineered and incorporated with other polymers, though its common applications are controlled-release pesticide formulations, 3D bioprinting, antimicrobial hydrogels and drug delivery. The extraction methods also involve the use of acidic and alkaline solutions to treat seaweed. Sodium alginate is typically stable, but it must be kept and stored cautiously to maintain its viscosity and other helpful properties. Its potential continues to expand in spheres where people value environmentally friendly solutions and sustainability.

KEYWORDS: Sodium Alginate, 3D bioprinting, Disintegrant, Biocompatible polymer, Hydrogels.

1. INTRODUCTION
The process in which the immediate release tablets in the fluid, absorb the liquid and conformational changes appear to cause the tablet to disintegrate into small particles is known as disintegration. Due to disintegration, the particles of the drug are exposed easily to the dissolving medium.[1] Disintegrants are excipients which facilitate disintegration by favoring the penetration of liquids into the pill and then swelling on hydration. The particle size of disintegrant makes the particles break the bonds which held the tablet together.[2] Alginates are natural polymers that can be used as a disintegrating agent of tablets. They are derived out of brown seaweed and are used in numerous areas, including dentistry, medicine, and pharmaceutical. There are various types of alginates; sodium alginate, calcium alginate and alginic acid.[3] Sodium alginate (SA) is a material produced by brown algae, sargassum or kelp. SA is a naturally occurring polymer, which has such remarkable properties as biosafety, biocompatibility and renewability, which are applied to a variety of industries, including the food industry. These are just a few of the advantages of sodium alginate which are: (a) it has numerous sources, (b) it has a low preparation cost, and (c) it is relatively cheap to make. Consequently, sodium alginate hydrogel can be an effective biodegradable material to remove microplastics.[4] To treat polluted water, man has employed various modification methods of sodium alginate and still the technology is being continuously enhanced and explored.[5] Sodium alginate is one material that should be considered and used in wastewater treatment due to its potential properties that include biosafety, biocompatibility and renewability. Modern adsorbents to treat polluted water are graphene, bentonite, chitosan, activated carbon, and the generation of packaging films can be based on the biodegradability

and strong film-forming properties of such substances as sodium alginate (SA), zein, carrageenan, and others. The film-forming, gelation, biodegradability, and biocompatibility properties of sodium alginate have made it ideal in a range of applications, especially in bio-based food packaging substrate.[6]

2. GENERAL DESCRIPTION

Sodium alginate is the sodium salt form of alginic acid and gum mainly extracted from the cell walls of brown algae, with chelating activity. Upon oral administration sodium alginate binds to and blocks the intestinal absorption of radioactive isotopes, such as radium Ra 226 (ra-226) and strontium Sr 90 (Sr-90).[9]

3. HISTORY & DISCOVERY

Alginate was first discovered by E.C.C. Stanford in 1881, while searching for useful products from kelp. He developed the process of alkali extraction of a viscous material, ‘algin’, from the algae and later precipitated it using mineral acid (Stanford, 1883, Stanford, 1884). Algin was isolated 15 years later by Krefting (Krefting, 1896). In 1929, the commercial production of algin was initiated by the Kelco Co. in California.[7-10]

Sodium alginate is a natural polysaccharide product, originally described in a patent application by the British chemist Edward C Stanford in 1881. Brown algae continue to be the primary source used to obtain sodium alginate to date. At the close of the nineteenth century This group contains most of the seaweeds, such as kelps, which grow in cold seas in the north. Along with the food industry, the gelling capabilities of sodium alginate have been utilized in medical, dental and cosmetic applications over the years.[11]

- 1930s: The industrial process of extracting alginates, such as sodium alginate, was invented. This was mainly necessitated by the growing need of alginates in food industry.
- 1960s-1980s: Studies on sodium alginate were broadened to biomedical uses. Its biocompatibility and gel forming capability made it a good wound dressing, drug delivery system and dental impression.
- 1990s: Sodium alginate was used to develop an important component in tissue engineering and encapsulation methods, especially in the production of hydrogels in cell culture and transplantation [12].
- Mid-20th Century: Sodium alginate was popularized in the food industry as a stabilizer, emulsifier and thickener. It was also a common ingredient in ice creams, sauces and jellies [13].
- Textile Industry: The use of Sodium alginate as a thickener in textile printing has been adopted because it has excellent compatibility with reactive dyes as sharp and vivid patterns are obtained.

Figure 1: SodiumAlginate.

4. SYNONYMS[14]

SodiumAlginate 9005-38-3
Alginic Acid, Sodium Salt C269C4G2ZQ
Ascophyllum
Sodium polymannuronate Algiline
Arcrane

5. TYPES OF SODIUM ALGINATE[15]

5.1 High Viscosity Sodium Alginate

More than 3500 mPas Used to thicken foods, like ice cream and yogurt.

5.2 Low Viscosity Sodium Alginate

Less than 240 mPas Used in drug delivery systems, such as tablet coatings and capsules.

5.3 Powdered Sodium Alginate

Used as a thickening agent in food products, like instant soups and sauces.

5.4 Granular Sodium Alginate

Used in food products, such as bakery and dessert products, as a gelling agent.

5.5 Pharmaceutical Grade Sodium Alginate

Used in drug delivery, such as wound dressings and implants.

5.6 Food Grade Sodium Alginate

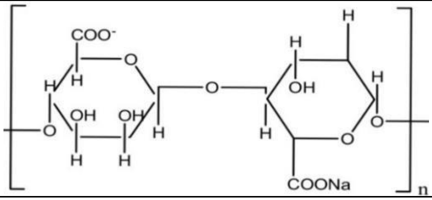
Used in food products, like beverages, dressings and sauces, as a thickener and stabilizer.

The thickness of sodium alginate may depend on the seaweeds it is sourced from, the extraction method and the amount of alginate present.

6. PHYSICO-CHEMICAL PROPERTIES

Physico-chemically, sodium alginate is a dry white or slightly yellowish powder, which is hydrophilic, soluble in water and able to form gels in the presence of divalent cations. Alginate is useful as a drug delivery agent and for cell immobilization [16]. The ratio and structure of the two uronic acid groups, the molecular weight of the polymer, the type of functional groups present in the structure, and the concentration of the reticular agent are some of the physico-chemical properties that influence the properties of alginates (mechanical properties, swelling and diffusion).[17] The origin of the alginates can result in different characteristics.[18]

Table 1: Physico-chemical properties of Sodium Alginate.

S. No:	Physico-chemical Properties	Detailed Description
1	Name	Sodium Alginate
2	Structure	
3	chemical Name	$NaC_6H_7O_6$
4	IUPAC Name	Sodium 3,4,5,6-tetrahydroxyoxane-2-carboxylate
5	Solubility	Soluble in water, but not in organic solvent
6	Melting point	between 99°C and 300°C
7	Molecular weight	216.121 grams per mole (g/mol)
8	Taste	Tasteless
9	Density	1.0g/cm^3 at 25°C

7. METHODS OF SYNTHESIS [19]

L-cysteine was covalently linked to sodium alginate through the formation of amide bonds between the primary amino group of the amino acid and a carboxylic acid group of the polymer. At first, 10 grams of sodium alginate was hydrated with 1 liter of demineralized water. By adding 1-ethyl-3-(3 dimethylaminopropyl) carboxyimide hydrochloride (EDAC) to a final concentration of 50 mM, the carboxylic acid groups of hydrated sodium alginate became activated and the reaction was allowed to proceed for 45 minutes. L-cysteine monohydrate hydrochloride was added in a weight ratio of 2:1 and the pH was adjusted to 4.0 with 1 M HCl. The reaction mixtures were allowed to stir at room temperature for two hours. The alginate cysteine conjugates were isolated by dialyzing.[19]

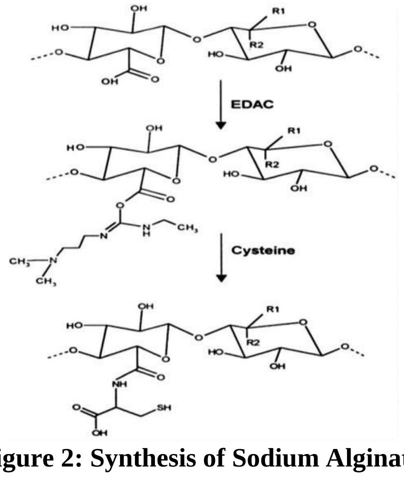


Figure 2: Synthesis of Sodium Alginate.

8. SOURCE [20]

Sodium alginate (NaC6H7O6) is a linear polymer and a derivative of alginic acid, which is made of 1,4-β-d-mannuronic (M) and α-l-guluronic (G) acids. Alginic acid makes up 30-60% of sodium alginate, which is found in the cell walls of marine brown algae. Sodium alginate is derived from alginic acid and is water-soluble and easily extractable. Sodium alginate is a typical polysaccharide that can be widely used in any application that requires a 1-4 linked b-D-mannuronic acid (M). Further, at its C-5 epimer, it has a group called L-guluronic acid (G). Different types of sodium alginate have been extracted from different types of algae. For example, it was extracted from sargassum (30-35%).[20]

Figure 3: Brown Algae Sargassum.

9. EXTRACTION OF SODIUM ALGINATE[30]

Sodium alginate was extracted following the procedure described by Murdinah et al. (2005). After being soaked in 1% (v/v) HCl for one hour (the ratio of dry seaweed to HCl solution was 1:30 (w/v), kg of dry seaweed (11.96+0.03% moisture content) was suspended and neutralized by running fresh water. Neutral raw materials were used to extract sodium alginate in 2% (w/v) Na2CO3 solution at 60-70°C for two hours. The ratio of dry seaweed to Na2CO3 solution was 1:30 (w/v). The suspended material from the previous extraction was bleached for 30 minutes by slowly adding 4% (v/v) NaOCl after the second extraction, filtration, and combining the supernatant with the original extract. Once the extraction was complete, 10% (v/v) HCl solution was added to the alginate solution until a pH of two or three was reached. The solution was then filtered using a vibrator screen.

10. METHOD OF PREPARATION[29]

1) The production of alginic acid and sodium alginate by brown algae includes pre-treatment of the initial algae feed with an acid chemical reagent, treatment with an alkaline reagent, purification of the alginates extracted from the algae by flotation and decolorization, for example, with hydrogen peroxide or hypochlorite, precipitation of alginic acid with an acid reagent, and neutralization with an alkaline reagent for sodium alginate production. The process is unique in using electrolyte, an aqueous solution of alkali metal salts, such as sodium chloride, in the anode and cathode chambers of a two-chamber electrolyze.
2) The electrolyte used in the process according to claim 1 is mainly an aqueous solution of NaCl (1% to 2% in fresh water, such as tap water).
3) According to any one of claims 1 or 2, the process is defined by the acidic and alkaline treatment of algal raw materials with a mixture of anolyte (acidic solution) and catholyte (alkaline solution) in the anode and cathode chambers of the electrolyze, respectively. The pH values, temperature, hydraulic module and current density depend on the physicochemical properties of the initial algal feed and properties of the final product.
4) The process, according to any one of claims 1-3, is characterised by heating the mixture either simultaneously with the electrochemical treatment in the anode chamber of the electrolytic cell with heating or after the electrochemical treatment is completed in another tank (reactor with a heating system). The first acid treatment is performed with a ratio of algal feed: electrolyte solution of 1: 10-1: 15 until the pH of mixture reaches not more than 2 and the temperature is not higher than 40-50℃.
5) According to any one of claims 1 to 4, the process is characterised by heating the mixture either during the electrochemical processing in the cathode chamber of the electrolytic cell with heating or after the electrochemical treatment in an additional tank, such as a reactor with a heating system. The alkaline treatment is performed at a ratio of algal raw materials: electrolyte solution in the range of 1: 30-1: 50 until the pH of the mixture is at least 12 and the temperature is not higher than 60℃

11. EVALUATION TEST FOR SODIUM ALGINATE

11.1 Assay of sodium Alginate. (90% to 110%) Titrimetric Method

Sodium alginate reacts with HCl to form insoluble alginic acid. The excess Hcl is titrated with NaOH to determine the sodium alginate content.

11.2 Gravimetric Method

Sodium alginate is converted to alginic acid, which is precipitated, dried, and weighed. The sodium alginate content is calculated from the weight of the alginic acid.

1) pH(6.0 to 8.0)

By using pH meter dissolve a small amount of sodium alginate in distilled water (if its liquid use a dilute solution). Calibrate the pH meter with standard buffers. immerse the pH Probe in the solution and record the pH value.

2) Loss on drying (10 to 15%)

By using oven drying weigh a clean, dry container and record its weight. Add a known amount of sodium alginate sample and reweigh place the sample in a drying oven at 105℃ for 2-4 hours. After drying, cool the sample in a desiccator and reweigh calculate:
Loos on drying= (loss in weight/initial weight) ×100

3) Ultraviolet spectroscopy

By using ultraviolet- vis spectrophotometry, prepare a sample solution scan the sample between 200-400 nm using a UV-Vis spectrophotometer to observe characteristic absorption peaks (typically around 290nm), compare with standard values to assess quality.

4) Infrared spectroscopy

By using Fourier transform infrared spectroscopy, prepare the sample in pellet form using Kbr or directly place a sample on the Fourier transform infrared sample holder run the flourier transform infrared scan over the range of 4000 – 400cm^{-1} compare the resulting spectrum with a reference or standard sodium alginate spectrum to confirm the functional groups.

5) Size distribution and size analysis

The gel beads were separated into various size ranges by a sieve test for 10 min with a mechanical shaker with standard sieves as per Indian pharmacopoeia specification. The size distribution was studied and the mean size of gel beads was calculated using the formula.

6) Study of morphology of gel beads

The diameter of 50 dried beads and morphological observation of dried beads were done by optical microscopy.

7) Scanning electron microscopy (SEM)

The sample for the Scanning electron microscope were prepared by spreading the gel beads on one side of the double-sided tape. The stub was then coated with fine gold dust. The gel beads were then observed with the scanning electron microscope (JEOL Model JSM- 6390 LV) at 15 kv.[21]

11.3 Evaluation of floating property

To study the floating behaviour, approximately 100 beads were stuck to the glass slide with the help of a double-sided tape on one side of the United States pharmacopoeia dissolution apparatus. The apparatus was operated for 5 hours and at regular interval (30min) the slide was removed and the beads adhering to the slide were counted.[22]

12. INCOMPATIBILITIES[23]

Sodium alginate is incompatible with acridine derivatives, crystal violet, phenyl mercuric acetate and nitrate, calcium salts, heavy metals and ethanol at a concentration more than 5%. Sodium alginate is salted out by high electrolyte concentrations (more than 4% sodium chloride) but the viscosity is increased by low electrolyte concentrations.

13. DRAWBACK[24]

This polymer has limited industrial applicability due to a variety of issues. Although sodium alginate is utilized in many medications, it frequently causes gastrointestinal adverse effects such nausea, diarrhea, and bloating following use. Its acidic nature, which comes from alginic acid, makes it unsuitable for nutritious foods. Low mechanical strength and cell adhesion, low drug loading, hydrophilicity, microbial breakdown, and burst release are some of its characteristics. In order to address these issues, sodium alginate has been combined with several natural and synthetic polymers, which improve its characteristics.

14. USES [25,26]

- You can use sodium alginate as a flavorless gum.
- The food industry uses it as an emulsifier and to make foods more viscous. Additionally, it is utilized in the creation of dental imprints and indigestion pills.
- Sodium alginate (NaAlg) and its derivatives have been extensively used as membranes for pervaporation (PV) separation of aqueous-organic mixtures due to its hydrophilic nature and ease of modification/tuning of its structure to obtain the desired performance.
- Sodium alginate is a polymer that can be sourced from brown seaweeds and kelps. It is one of the constituents of the cell walls.
- It can be used for several purposes and has some unique properties.

15. APPLICATIONS

Modified sodium alginate is mainly used for dye removal, heavy metal ion removal, aromatic compound removal, phosphate removal and precious metal recovery.

1) Nano drug delivery system

Sodium alginate is a natural hydrophilic polysaccharide isolated from marine brown algae. Due to its biocompatibility and biodegradability, it is widely used in the field of drug delivery.

2) Antimicrobial hydrogels

Sodium alginate is a linear polysaccharide, a water-soluble salt of alginic acid, extracted from brown algae. It has the property of forming ionic tropical gels, which makes it very useful in various industrial applications.

3) 3D bioprinting technology

Sodium alginate is a natural polysaccharide extracted from kelp or Sargassum. It can be ionized in aqueous solution, but in the presence of divalent cations Ca^{2+} and Mg^{2+}, it quickly coordinates with these ions to form hydrogels.

4) Controlled release pesticide formulations

Sodium alginate is an anionic hydrophilic biopolymer extracted from brown algae. It forms gels by cross-linking divalent cations such as Ca^{2+}.

5) Tumor targeting

Alginate is a polysaccharide component of the cell wall of brown algae and has been widely used in tissue engineering. Calcium salts or calcium alginate are usually used for enzyme immobilization or embedding in industry or laboratories.

6) Environmental impact

The application of sodium alginate rarely affects the pH of the treated wastewater, which provides it with an additional advantage in pH-sensitive areas.[27,28]

16. STORAGE[31]

Sodium alginate is hygroscopic but it can be stored at low temperatures and relative humidities. The optimum pH stability zone for aqueous solutions of sodium alginate is 4-10. At pH less than 3, alginic acid precipitates. The remaining viscosity of a 1% w/v sodium alginate aqueous solution after two years of storage (at different temperatures) was 60-80%. Solutions should not be stored in metal containers. The viscosity of sodium alginate solutions can also be affected by spoiling. While sterile filtration of solutions through a 0.45 mm filter also has only a small negative effect on solution viscosity, ethylene oxide is the preferred method of sterilizing solutions. The depolymerization of sodium alginate solutions to render them non-viscous occurs when heated to over 70°C.

17. ADVERSE EFFECTS[32,33]

1. Gastrointestinal problems:

Esophageal obstruction
Diarrhea

2. Allergic Reaction:

Anaphylactic shock

3. Respiratory problems:

Bronchospasm
Asthma
Exacerbation

4. Skin irritation

5. Others

Hypophophatemia
Electrolyte imbalance

18. HANDLING PRECAUTIONS

1. Physical precautions

- Put on protective gear: To avoid dust inhalation and irritation of the skin and eyes, wear gloves, safety

glasses, and a dust mask.
- Prevent inhalation: Powdered sodium alginate can be airborne and lead to respiratory problems.
- Protect your skin: After handling, wash your hands well [34].

2. **Handling precautions**
- Use in spaces with adequate ventilation: To avoid dust inhalation, handle sodium alginate in places with adequate ventilation.
- Don't produce dust: Because sodium alginate might irritate the respiratory system, avoid creating dust when working with it.
- Clean up spills right away: Spills should be cleaned up right away to avoid contamination and trip hazards.[35]

19. MARKETED PRODUCTS

Table 3 Marketed formulation of Sodium Alginate

S. NO:	TYPES	BRAND NAME	COMPANY NAME	DOSE	PRIZE
1	Syrup	Ethiraft	Ethics health care company	170ml	1990/-
2	powder	Meron	Marine hydrocolloids	100gm	360/-
3	Suspension	Digeraft	Adeline pharmacueticals company	150ml	189/-
4	Tablet	Gavicid	Arlak biotech company	250mg	990/-
5	powder	Creme caramel pudding	Marine hydrocolloids	850gm	700/-
6	Tablet	Argicon	Aeron life science company	250mg	135/-

20. CONLCUSION

Sodium alginate is a naturally occurring and versatile polymer used in many applications, including food and pharmaceuticals, and environmental applications. Its unique characteristics, including gel formation, biocompatibility, and biodegradability, make it an ideal candidate for many applications, including as a disintegrant in immediate-release tablets, thickening and stabilizer in food products and as a wastewater treatment and packaging agent. Sodium alginate has a number of limitations, such as poor mechanical properties, hydrophilicity, and gastrointestinal side effects, which can be overcome by blending with other polymers. To make the most of its potential applications and improve its value for sustainable and 'green' products, further research is needed. Sodium alginate remains a potential material for the development of innovations in business, medical and environmental preservation.

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