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IN PROCESS TESTING FOR SUSTAINED RELEASE BEADS

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ABSTRACT

Novel Drug Delivery Systems (NDDS) are advanced approaches designed to deliver drugs at the right site, at the right time, and in the right concentration to achieve maximum therapeutic effect with minimal side effects. Unlike conventional dosage forms (tablets, capsules, injections), NDDS aim to overcome limitations such as poor bioavailability, frequent dosing, and fluctuating plasma drug levels. These systems use modern carriers like microspheres, nanoparticles, liposomes, niosomes, transdermal patches, implants, and beads to control the release, target specific sites, or protect drugs from degradation. NDDS can provide sustained, controlled, or targeted release, which improves patient compliance, reduces side effects, and enhances the overall safety and efficacy of therapy. Sodium alginate has been used as a matrix material to achieve controlled-release drug delivery due to its hydrogel forming properties. The ability of alginate sodium salt, to rapidly form viscous solutions and gels on contact with aqueous media has been exploited by the pharmaceutical industry in sodium alginate's wide application as a carrier in hydrophilic matrix controlled-release oral dosage forms. Matrices incorporating alginate salts have been employed to successfully prolong the release of many drugs. Evaluation parameters and in process testing of sodium alginate, Stability studies ensuring the maintenance of product quality, safety and efficacy throughout the shelf life are considered as pre-requisite for the acceptance and approval of any pharmaceutical product. Various parameters like size, friability, drug loading, swelling index, mathematical models of release kinetics.[1]

KEYWORDS: Sodium alginate, Microbeads, NDDS, In-process Testing, Evaluation Parameter, Release kinetics.

INTRODUCTION

Sustained release beads are a type of drug delivery system designed to release medication gradually over a prolonged period. These beads are tiny particles containing medicine that dissolve or degrade slowly, providing a controlled and steady effect. The goal of sustained release beads is to improve treatment effectiveness and patient convenience by reducing the need for frequent dosing. the basic goal of therapy is to achieve a steady state blood or tissue level that is therapeutically effective and nontoxic for an extended period of time. The design of proper dosage regimen is an important element in accomplishing this goal. A basic objective in dosage form design is to optimize the delivery of medication so as to achieve a measure of control of therapeutic effect in the phase of uncertain fluctuation in the in vivo environment in which the drug release takes place. This is usually accomplished by maximizing drug availability, i.e. by attempting to attain maximum rate and extent of drug absorption however control of drug action through formulation also implies controlling bioavailability to reduce drug absorption rates. Multiple unit dosage forms such as microspheres or micro beads have gained in popularity as oral drug delivery systems because of more uniform distribution of the drug in the gastrointestinal tract, more uniform drug absorption, reduced local irritation and elimination of unwanted intestinal retention of polymeric material, when compared to non-disintegrating single unit dosage form. Microbeads are small, solid and free flowing particulate carriers containing dispersed drug particles either in solution or crystalline form that allow a sustained release or multiple release profiles of treatment with various active agents without major side effects.[2-3]

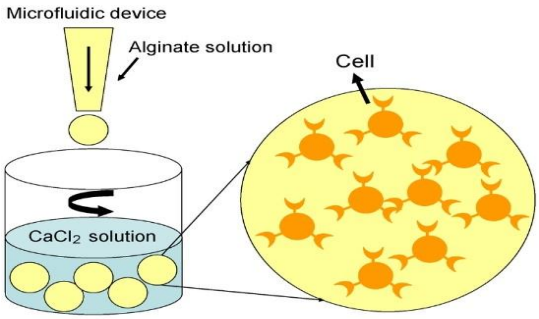

Fig. 1: Sodium Alginate Beads.

Advantages[4]

1. Biocompatibility: Alginate is a naturally derived polymer, making it biocompatible and non-toxic.
2. Mild Gelation Conditions: Alginate beads can be formed under mild conditions, preserving the activity of sensitive compounds.
3. Controlled Release: Alginate beads can provide sustained release of encapsulated compounds.
4. Targeted Delivery: Alginate beads can be designed for targeted delivery to specific sites in the body.

Disadvantages[4]

1. Limited Stability: Alginate beads can be unstable in certain environments, such as high pH or presence of chelating agents.
2. Rapid Release: Alginate beads can exhibit rapid release of encapsulated compounds, which may not be desirable.
3. Limited Mechanical Strength: Alginate beads can be fragile and prone to breakage.
4. Difficulty in Scaling Up: Alginate bead production can be challenging to scale up while maintaining uniformity.

METHODS OF PREPARATION OF ALGINATE BEADS

Alginate beads are made in different ways to get beads of uniform size and good production rate. These beads are usually made by pushing alginate solution (with drug) through a needle into a calcium solution, where they form solid beads. Methods like air-jet, electrical, and vibration systems can help make the process faster and more efficient.

1. Air Atomization

In this method, an extrusion device with a small opening (orifice) is used. The alginate solution containing the drug is pushed out through this small hole using air. Beads formed are between 5 to 200 micrometers in size. The bead size can be changed by adjusting the air pressure, liquid flow, or distance between the orifice and the calcium solution surface.[5]

2. Coaxial Bead Generator

In this method, air is used to pull droplets from the needle tip into a gelling bath (usually calcium solution). The beads formed are spherical and about 400 micrometers in size.

3. Dropping Method

This is the simplest and most common method. A syringe or pipette is used to drop the alginate solution into a calcium solution.[6]

4. Electrostatic Bead Generator

In this method, electrostatic (electric) force pulls small drops of alginate solution from the needle tip into a gelling bath. Beads formed are about 150 to 1000 micrometers in size. The size of beads depends on: The voltage used, The distance between the needle and gelling bath, The thickness (viscosity) and flow rate of the alginate solution, And the diameter of the needle.

5. Emulsification

This method is used only for stable drugs, because it needs strong chemicals to remove oil at the end. It forms small particles ranging from 1 to 150 micrometers. The size of the micro beads depends on: The stirring speed, And the rate of adding the cross-linking (gelling) solution.

6. Laminar Jet Break-up

Uses a device that breaks a liquid stream into beads (300-600 micrometers) by vibrating.

7. Mechanical Cutting

Cuts a liquid stream into small pieces that turn into round beads in a gel bath. Makes beads of 150 micrometers to 3 millimeters.

8. Spinning Disk Atomization

Uses a spinning disk to make beads of 300 to 600 micrometers.

9. Vibrating nozzle technique

This uses a special nozzle that vibrates to make tiny particles (more than 200m particles).[7]

10. Complex coacervation

This method uses stuff like gelatin and gum Arabic. When you mix them under certain conditions (like pH 3.9, ionic strength of 1mM, and polyion concentration of 0.15% w/v), they form microbeads.[8]

Sodium alginate beads are commonly prepared using the following method

1. Ionotropic Gelation Method

Ionotropic gelation (IG) is a phenomenon in which polyelectrolytes (PEs) come in contact with oppositely charged small molecules or macromolecules causing a liquid-gel phase separation, with the formation of a polymer-rich phase (gel) and a polymer-poor phase (liquid) surrounding the former.[9] The process is strictly governed by the experimental variables of the buffer medium, such as pH or ionic strength and the physico-chemical composition of the polyelectrolyte. This

method is usually employed for the synthesis of natural water-soluble polymeric nanoparticles with a high control in the release of bioactive materials by polymer relaxation. The hydrogel beads are synthesized by addition of drug-loaded polymeric solution drops to the aqueous solution containing a cationic polyelectrolyte.[10-12] Polymers usually involved in these processes are natural, hydrophilic and biodegradable ones, such as sodium alginate, gelatin, carboxymethyl cellulose and chitosan. Synthetic polymers can be also used (Table 1)[13-16]

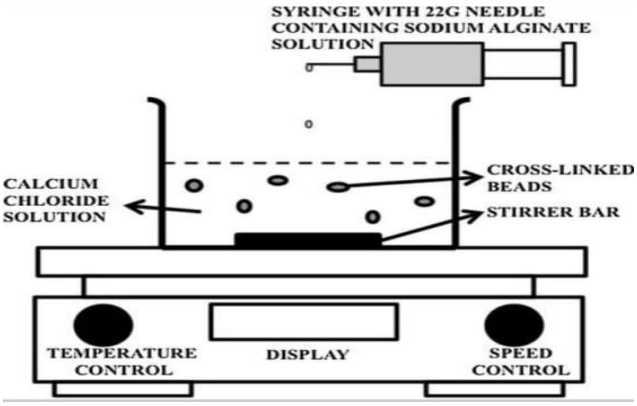

Fig. 2: Ionotropic Gelation Method.

Table 1[17]

Polymers and polyelectrolytes used in ionotropic gelation. Adapted from under open access CC-BY license.

Natural polymer	Synthetic monomers/Polymers	Multivaent Cation/ Anions
Chitosan	Hydroxyethyl methacrylate	Ca^{2+}, $Mo_7O_2^{6-}$,$(PW_{12}O_{40})^{3-}$
Alginate	N- (2-Hydoxypropyl) Methacrylate	K^+
Fibrin	N-Vinyl-2-Pyrrolidone	Fe^{2+}, Ba^{2+}, Na^+, Mg^{2+}
Collagen	N-isopropylacrylamide	Al^{3+}
Gelatin	Vinyl acetate	Zn^{2+}

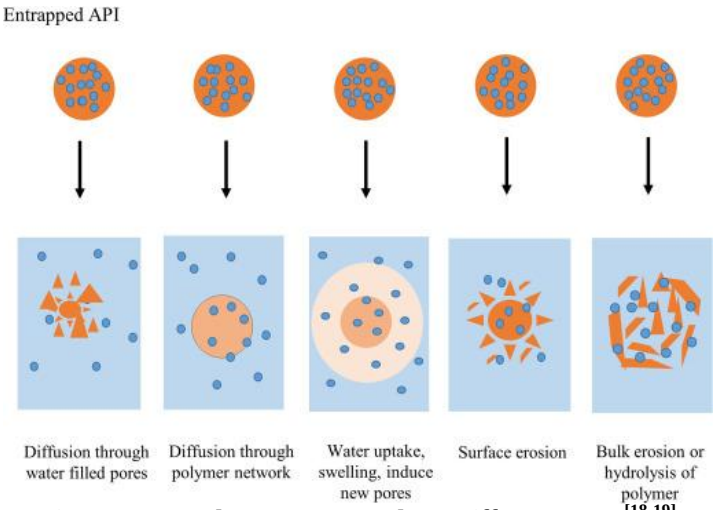

Fig. 3: Drug Release From Beads In Different Way.[18-19]

Advantages[20]

1) Mild conditions — suitable for heat- and solvent-sensitive drugs.
2) No need for harsh organic solvents.
3) Easy, low-cost, and reproducible.
4) Good control over size and drug release profile.

Disadvantages[21]

1) Poor mechanical strength of beads (especially alginate-based).
2) Possible burst release of drug.
3) Swelling or instability in physiological fluids (depending on polymer and cross-linker).

Table 2.

Sr. No	Drug Of Sustained Release Beads	Class of drugs	Methods Of Preparation	Mechanism Of Action	Application
1	Diclofenac Sodium[22]	NSAID	Ionotropic Gelation (Using Sodium Alginate Crosslinked With Cacl2)	It Inhibits Cyclooxygenase Enzymes (COX-1 And COX-2), Leading To Decreased Synthesis Of Prostaglandins, Which Are Responsible For Pain, Inflammation, And Fever.	Sustained Release To Reduce Dosing Frequency And Side Effects In Pain And Inflammation
2	Venlafaxine	Antidepressant	Ionotropic Gelation	1. Inhibiting Serotonin	Sustained Release

	Hydrochloride[23]	(SNRI)	With Sodium Alginate, Gelatin, Pectin	Reuptake: Increasing Serotonin Levels In The Brain. 2. Inhibiting Norepinephrine Reuptake: Increasing Norepinephrine Levels In The Brain.	For Prolonged Antidepressant Effect
3	Propranolol Hcl[24]	Beta-Blocker	Gelatin Bead Formation Method	1. Blocking Beta-1 Receptors: Decreasing Heart Rate, Contractility, And Cardiac Output. 2. Blocking Beta-2 Receptors: Reducing Smooth Muscle Contraction And Vasodilation.	Sustained Release For Hypertension And Cardiac Conditions
4	Metformin[25-26]	Anti-Diabetic Drugs	Ionotropic Gelation. Extrusion-Spheronization	1. Decreasing Hepatic Glucose Production: Reducing Gluconeogenesis. 2. Increasing Insulin Sensitivity: Enhancing Peripheral Glucose Uptake.	- Manage Type 2 Diabetes Mellitus: Improving Glycemic Control. - Reduce Risk Of Complications: Like Cardiovascular Events.
5	Aceclofenac[27]	BCS Class II Drug	Floating Beads Nanosponge-Based Drug Delivery System	Aceclofenac Works By Inhibiting Cyclooxygenase Enzyme (COX), Specifically COX-2, Which Is Involved In The Synthesis Of Prostaglandins. This Leads To Reduced Inflammation, Pain, And Swelling.	Aceclofenac Is Used To Treat Various Conditions, Osteoarthritis Rheumatoid Arthritis
6	Valsartan[25-26]	Angiotensin II Receptor Blocker (ARB)	Ionotropic Gelation Extrusion-Spheronization	- Blocking Angiotensin II Receptors: Reducing Vasoconstriction And Aldosterone-Mediated Volume Expansion. - Lowering Blood Pressure: By Relaxing Blood Vessels And Reducing Peripheral Resistance.	- Treat Hypertension: Managing High Blood Pressure. - Manage Heart Failure: Reducing Morbidity And Mortality.
7	Ceftriaxone Sodium[25-26]	Cephalosporin Antibiotic.	Ionotropic Gelation	Inhibiting Bacterial Cell Wall Synthesis: Binding To Penicillin-Binding Proteins (Pbps) And Disrupting Peptidoglycan Synthesis.	- Bacterial Infections: Such As Meningitis, Pneumonia, And Urinary Tract Infections. - Surgical Prophylaxis: To Prevent Surgical Site Infections.

- **Evaluation parameters and In-process testing of sodium alginate beads**

1. Size
2. Drug Entrapment
3. Swelling Index
4. Dissolution Test
5. In Vitro Drug Release Study

1. Size

An optical microscope fitted with an ocular and stage micrometer, having accuracy of 0.01 mm, was used to determine the particle size of the beads. Analysis of the prepared beads was performed using a resolution of 30× to determine the diameter of 10 randomly selected beads. The instrument was calibrated at 1 unit of eyepiece

micrometer equal to 1/30 mm (33.33 µm), and the average diameter of the beads was calculated using the following equation,[28]

$$X = \frac{\sum(X_i)}{N}$$

2. Drug Loading and Entrapment

Drug loading quantifies the actual amount of drug incorporated in the beads compared to the total bead weight, while entrapment efficiency measures the percentage of the initial drug amount successfully encapsulated inside the beads.[29]

$$\text{Drug Loading} = \frac{\text{Actual drug weight in beads}}{\text{Total weight of beads}} \times 100$$

$$\text{Drug Entrapment} = \frac{\text{Actual drug conent}}{\text{Theoretical drug content}} \times 100$$

3. Swelling Index

This study was conducted to estimate the percentage swelling of the beads that causes leaching or degradation of the drug in the gastric fluid. Only batches with an entrapment efficiency of more than 30 % were selected for further studies. Dried ionically, cross-linked beads increase their volume after few minutes in water or in buffers due to matrix rehydration that is dependent on the degree of cross-linking. 200 mg of beads were suspended in 50 ml of simulated gastric fluid (pH 1.2) and samples were shaken at 60 rpm speed in a mechanical shaker (Thermo Scientific™ Precision reciprocating shaker bath, USA) and allowed to swell for 2 h at 37 ± 0.5 °C, simulating the gastric medium. After 2 h, the beads were carefully removed, blotted dry and weighed. The difference between the initial and final weights of the beads was used to determine water sorption, and the swelling index was calculated using the following formula,[29-31]

$$\text{Swelling index} = \frac{W_f - W_o}{W_O}$$

Where,
W o is the initial weight of beads and
W f is the final weight of the beads after swelling.

4. Dissolution Test

Dissolution testing is a critical quality control and performance evaluation tool for sustained release (SR) dosage forms, including polymeric beads. The test simulates drug release from dosage forms under physiological conditions and helps to predict in vivo performance. The dissolution test plays a crucial role in assessing the release profile and ensuring batch-to-batch uniformity. It provides insight into the mechanism of drug release, which is essential for regulatory approval and formulation optimization. Beads are accurately weighed and introduced into the dissolution medium. Typically 37 ± 0.5°C with stirring speeds of 50–100 rpm. Aliquots are withdrawn at predetermined intervals and replaced with fresh medium. Drugcontent is determined spectrophotometrically or by HPLC.[32-35]

5. In Vitro Drug Release Study

The in vitro drug release studies were performed using Dissolution test apparatus. The dissolution medium was hydrochloric acid buffer (pH 1.2) for first 2 h and 7.4) for subsequent h. The microbeads were efficiency was calculated by the following 1601, Japan)16. Each double-sided carbon adhesive tapze and the scanning electron phosphate buffer (pH allowed to sink in the vessel containing 900 ml of dissolution medium and the release of Diclofenac sodium was investigated at about 50 rpm at temp 37 ± 0.5°C. During dissolution 10 ml aliquot was withdrawn at interval of 1 h and same was replaced with equal volume of fresh medium. The withdrawn samples were filtered through Whatmann filter paper no.42 and diluted with the same buffer to 10 ml. Absorbance was measured at 282 nm using UV-Visible Spectrophotometer.[36-37]

Comparative Study of In-Vitro Release

1. Comparative study of in-vitro release and bioavailability of sustained release diclofenac sodium from certain hydrophilic polymers and commercial tablets in beagle dogs
2. The study made beads of diclofenac sodium using sodium alginate or sodium CMC, crosslinked with aluminum.
3. In vitro, the beads showed no release in 0.1 N HCl for 2 h, then sustained release in pH 6.8 buffer over 24 h.
4. Bead size, polymer type/concentrations, and pH of dissolution medium affected release rate.[38]

➢ In vitro release study:

- Select release media: e.g. 0.1 N HCl for 2 h (simulate stomach), then pH 6.8 phosphate buffer (simulate intestine)
- Temperature: 37 ± 0.5 °C
- Agitation/stirring: e.g. USP dissolution apparatus I or II, rotation speed etc.
- Sampling at time points (e.g. 0.5, 1, 2, 4, 6, 8, 12, 24 h)
- Replace withdrawn volume with fresh medium to maintain sink conditions.[39]

Application of sustained release beads[40]

1. Sustained release beads serve as an effective drug delivery system that releases active pharmaceutical ingredients gradually over an extended period to maintain therapeutic drug levels in the body.
2. These beads improve patient adherence by reducing the frequency of drug administration due to their ability to sustain drug release.
3. Commonly utilized in oral formulations, they enhance the bioavailability of drugs with short half-lives and limited absorption windows.
4. The beads can be engineered using various natural or synthetic polymers, such as sodium alginate,

which control the drug release rate through gelation and diffusion mechanisms.
5. sustained release beads find applications in targeted drug delivery, including passive targeting of tumor sites and localized therapies, thereby improving therapeutic efficacy and minimizing side effects.
6. Their ability to float in gastric fluids further prolongs gastric residence time for drugs that require localized stomach absorption.

CONCLUSION

Sodium alginate beads as drug delivery systems provide several advantages, including greater flexibility and adaptability of dosage forms. alginate beads were easily and successfully formulated by employing the ionotropic gelation technique**.**

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