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AQUASOMES: A UNIQUE INNOVATION IN DRUG DELIVERY

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ABSTRACT

Aquasomes are novel approach for delivery of drugs in conventional dosage form. There are mainly two ways to administer aquasomes: - 1. Oral 2. Parenteral. It is spherical in shape with particle size 60-300 nm. It is composed of three layers, assembled with ceramic core coated stabilized by active biomolecules are absorbed without modification. Carbohydrate coating provides structural stability or protects against dehydration and maintaining the property of surface exposure in targeted delivery of molecules. Aquasomes can be easily delivered variety of bioactives like proteins, peptides, hemoglobin, antigens, enzymes and poorly water-soluble drugs. This article provides brief introduction to aquasomes, their advantages and composition, method of preparation, its characterization techniques and applications.

INTRODUCTION

Aquasome word is deriverd from two words: One is ‘aqua’ means water, and the second is ‘some’ means body. Aquasomes are three-layered nanoparticulate delivery systems comprising a solid phase nanocrystalline core coated with carbohydrate film (such as cellulose, sucrose, trehalose etc.) onto which bioactive molecules are adsorbed with or without modification. Moreover, calcium phosphate is present in the bones it makes it a good biomaterial with good biocompatibility, biodegradability, non-toxicity and stability to use it as a drug carrier. Calcium phosphate and hydroxyapatite are used as the backbone of ceramic in aquasomes.

STRUCTURE OF AQUASOMES

Core

The central core of the aquasome is made up of ceramics and polymeric materials. Various materials are available and are utilized as polymeric materials like gelatine, acrylates and albumin.[2,4] Ceramic materials are crystalline, have structural frequencies and an abundance of order, which gives excessive surface energy and demonstrates the effective binding of carbohydrates.[2] They used ceramic materials for aquasome because of their biodegradability, low cost, biocompatibility and ease of preparation. Therefore, they worked for drug delivery. Various ceramic materials, like nano-crystalline (diamond), calcium phosphate (brushite) and tin oxide are applicable for preparation.[10] Calcium phosphate is a naturally occurring inorganic material in the body, so it has advantages over other materials. Calcium phosphate is extensively used as a core, nanoparticles, nanorods, scaffolds, in stem cell technology, tissue engineering and coatings.[2,4]

Coating materials

Various coating materials, such as sucrose, trehalose, chitosan, citrate and cellobiose are used for preparing aquasome.[2,10] The carbohydrate acts as a coating material, which prevents changing the shape of drugs. It acts as a natural stabilizer and dehydrator by preserving its structural integrity and three-dimensional confirmation in water.[2]

Bioactive materials/Drugs

The bioactive molecules such as drugs, proteins, peptides, genes and antigens are adsorbed on the surface of coating materials via non-covalent bonding and ionic interaction.[2,4] They have the property of interfacing with film through non covalent and ionic association.[1]

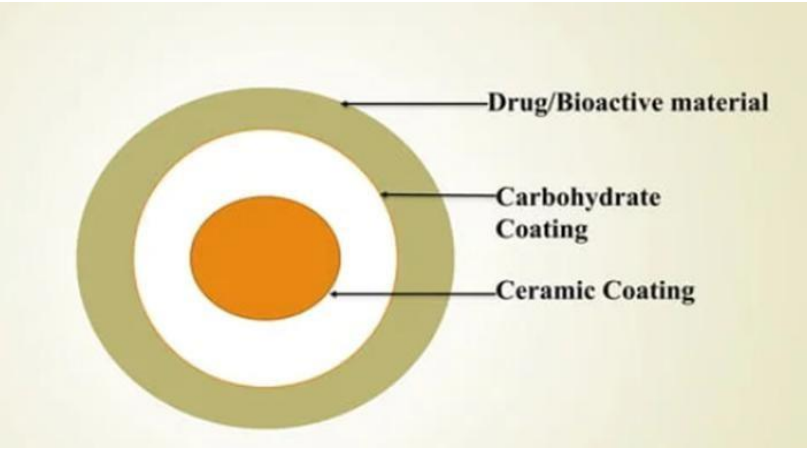
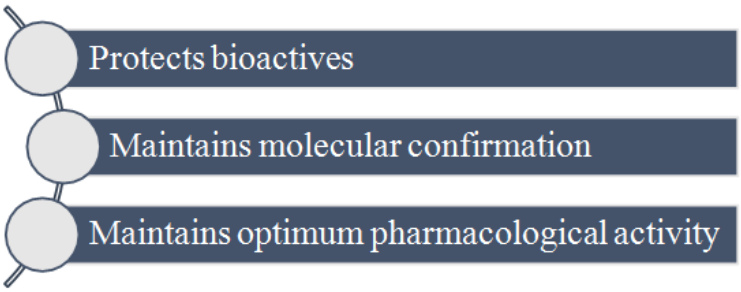


Figure 1: Structure of Aquasomes.[9]

OBJECTIVES[1,3]



PROPERTIES OF AQUASOMES

- Aquasome have a large size and larger active surface area, which provides loading enough active molecules.[2,3,7]
- The mechanism of action of the aquasomes is regulated by their surface chemistry. Aquasomes provide content by incorporating precise targeting, molecular shielding, and the mechanism of gradual and sustained release.[1]
- Aquasome restricts the degradation from the (RES) Reticuloendothelial System and provides structural stability.[2,7]
- The water-like properties of aquasomes provide a medium to maintain the conformational integrity and biochemical stability of bio-actives.[1,2,3,8]
- Calcium phosphate is biodegradable in nature it achieved by monocytes and multicellular cells.[3,7,8]
- It should have stable in environmental condition.[7]

ADVANTAGES[2,8]

- It enhanced the stability of formulation.[8]
- They are improved bioavailability of drug like BCS Class 2.[8]
- Aquasome works as a reservoir, which releases the drug molecule in a continuous and controlled manner.[2]
- It has overcome the difficulties of the drug insolubility or rapid degradation.
- The aquasome preparation hydrophilic and lipophilic drug can be incorporated.
- It reduces side effect and drug toxicity.
- In systemic circulation prolonged existence of the drug.
- Acts as a vaccine delivery system.[2,8]

DISADVANTAGES[2]

- Preparation of aquasomes is time-consuming method.

- Poorly soluble drugs cause toxicity due to burst release.
- Expensive
- Transfer efficiency is low.
- It causes leaching and aggregation on long-term storage.

METHOD OF PREPARATION

❖ Based on self-assembly techniques, the aquasome is prepared in three steps:[2,3,4]

1. Formation of an inorganic core
2. Coating of core with carbohydrate
3. Immobilization or Adsorption of Bioactive Material

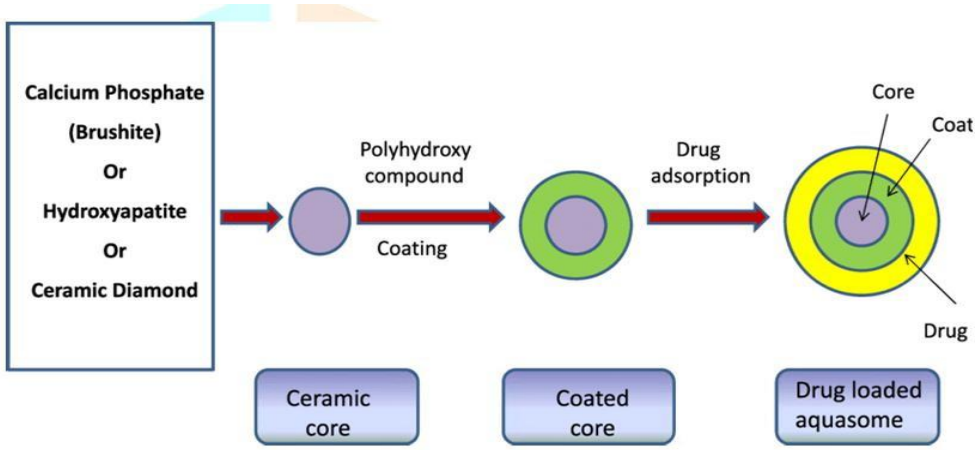


Figure 2: Method of preparation.[10]

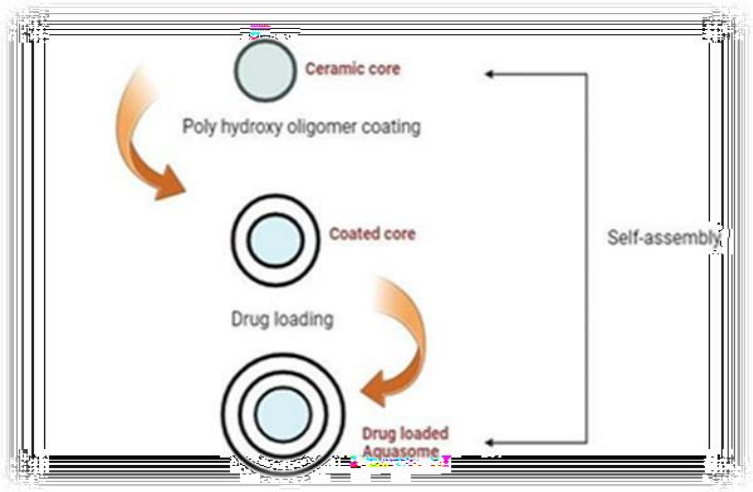


Figure 3: Steps involved in preparation of aquasome[4] Step-1 Fabrication of an inorganic core.

For the aquasome preparation, the initial step is the formation of core which is depends on

material selected.[2] Preparation of core is done by sonication method. In this method weigh, accurately quantity of disodium hydrogen phosphate and calcium chloride mixed well in 50 ml distilled water. After mixing using ultrasonic bath for sonication for 22 minutes and temperature was maintained 4°C. The ceramic core is prepared and separated by centrifugation in 15 minutes, the core material is prepared and the washed with some distilled water and then filtered pass in fine particles. The solution is filtered after collect the particles on the surface and then dried in hot air oven under 70°C temperature. The ceramic core often used in calcium phosphate and diamond particles.[8]

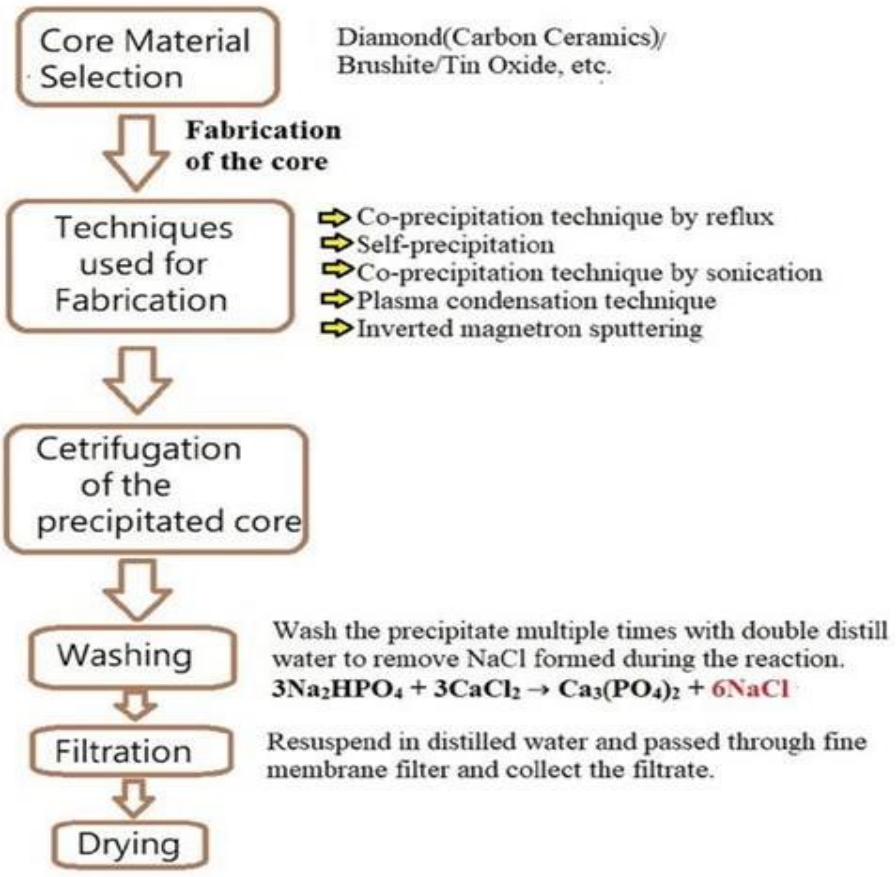


Figure 4: Schematic representation of the phenomenon of aquasomal core formation.[4]

Step 2: Coating of core with carbohydrate

In the second step, ceramic cores are coated with carbohydrate (polyhydroxyl oligomer).[6] The coating is carried out by addition of carbohydrate into an aqueous dispersion of the cores under sonication. These are then subjected to lyophilization to promote an irreversible adsorption of carbohydrate onto the ceramic surface. The unabsorbed carbohydrate is removed by centrifugation. The commonly used coating materials are cellobiose, citrate, pyridoxal-5-phosphate, trehalose and sucrose.[7]

Step 3: Immobilization or Adsorption of Bioactive Material

The final stage involves the loading of drug to the coated particles by adsorption. For that, a solution of known concentration of drug is prepared in suitable pH buffer, and coated particles are dispersed into it. The dispersion is then either kept overnight at low temperature for drug loading or lyophilized after some time so as to obtain the drug-loaded formulation (i.e., aquasomes).[3,7]

CHARACTERIZATION OF AQUASOMES

- The characterization of aquasome is conducted based on their structural properties, size, morphological properties, distribution and drug loading.[3]

1. Size distribution
2. Structural analysis
3. Crystallinity
4. Glass transition temperature
5. Mean particle size and Zeta potential
6. Drug loading efficiency
7. In vitro drug release study

1. Size distribution[4,5,7,8]

The morphological analysis or size distribution of aquasomes technique used by scanning electron microscope (SEM) and transmission electron microscope. The coated core is analyzed by these two techniques; The SEM particle size is placed on to the surface of gold coated sample with two sided can be observed under magnification and zeta potential is also determined by using electron photon spectroscopy. The TEM transmission electron microscope the particle is determining negative staining in 1% phosphotungstic acid and images is carried in both clear and dark mode as photographic film by adobe soft wares.

2. Structural analysis[4,5,7,8]

The structural analysis of aquasomes can use FT-IR Fourier transform infrared spectroscopy to determine core material on the sample using potassium bromide disk method. The identification and conformation of coating material is analysis by FTIR, their recording wave number range 200-400 nm; the particles are shift towards lower to higher wavelength is observed hydrogen bond formed in molecules.

3. Crystallinity[4,5,7,8]

The ceramic core is analyzed by X-ray diffraction (XRD) study it evaluated for it crystalline or amorphous characteristic. It based on interpretations of diffractogram, in this method observed that calcium phosphate core is identical it coated core is crystalline when it observed. After coating core is polysaccharide contains sucrose, lactose, trehalose, pyridoxyl-5 phosphate peak reduced intensity into amorphous. Polysaccharide is hydrolyzed in monosaccharide in addition of anthrone.

4. Glass Transition Tempreture[4,5,7,8]

The carbohydrate on drug-loaded aquasomes is determine or analyzed (DSC) Differential scanning calorimetry used in glass transition temperature. Glass to rubber transition is measure in DSC for change in temperature and melting point of glass. The formulation is filled in sample cell and buffer is packed in reference cell for analyzer in differential scanning calorimetry.

5. Mean particle size and Zeta potential[8]

The drug loaded aquasomes or its particle size is determined by zeta potential, (Zetasizer) is particle size analyzer. The sample is dissolved in distilled water or other solvent for zeta potential measurement. The formulation is deep into zeta dip cell, The study indicate saturation in carbohydrate containing lactose process in zeta potential decrease value.

6. Drug loading efficiency[8]

The drug loading is carried out in aquasome formulation in known concentration of solution of drug. Weigh the properly of drug is incubating for 24 hours at 4°C, after supernatant liquid is centrifuge for 30 minutes at low temperature and kept the solution in refrigerator. The clear solution is filtered and study under the UV spectrophotometer and drug loading formula is below.

% Drug loading = Weight of total drug added - Weight of an entrapped drug /Weight of aquasomes * 100

7. In vitro drug release study[8]

The in vitro release study in drug loaded aquasome formulation it utilizes the phosphate buffer pH 6.5 and dissolution media is 900 ml in USP type 1 dissolution test apparatus. Weigh the aquasome powder 50 mg fill in gelatine capsule into dissolution basket and media stirred at speed 100-rpm 37°C. Sample are 100 ml intervals at various time, then 10 ml sample

are withdrawn into basket aside for few minutes for centrifugation in 15 minutes. Filtered the solution and precipitate are examined content 340 nm using UV spectrophotometer and maintained with 10 ml fresh dissolution medium.

Table 1: Characterization of aquasomes.[2]

Sl. No.	Composition	Characterization Parameter	Instrument/Techniques
1.	Characterization of core.	Particle size	Transmission Electron Microscope (TEM).
			Scanning Electron Microscope (SEM).
2.		Crystallinity	X-ray Diffraction (XRD).
3.		Chemical structural analysis.	Fourier Transformed Infra-Red (FTIR).
4.		Zeta potential	Zeta Sizer.
5.		Glass transition temperature.	Differential Scanning Colorimetry (DSC).
6.	Characterization of coating material.	Measurement of coating.	Anthrone reaction.
			Concanavalin A-induced aggregation method.
			Phenol sulphuric acid method.
7.	Characterization of loaded bioactive.	Measurement of drug loading and release.	Drug loading capacity.
			In vitro Drug Release Study.
			In process stability study.

ROUTE OF ADMINISTRATION[2]

Various routes are used to deliver an aquasome to work as a carrier. Such as…

1. **Topical Route**: Aquasome are self-assembled three-layered nanoparticles which act as bodies of water. Their stable conformation and water-absorbent properties permit the aquasome to cross the aqueous layer of the skin and bind with molecules present in the skin as well as improve the permeability of bioactive substances.
2. **Parenteral Route**: It is the easiest route which provides higher bioavailability with reduced side effects. An Aquasome with a small particle size of less than 1000 nm is applicable for parenteral delivery because this size of aquasome prevents the obstruction to blood capillaries. Various proteins and peptides are delivered through aquasome via this route.
3. **Oral Route**: The oral route is the most common, easy and conventional route for delivering various therapeutic molecules. Unique structure of aquasome offers hydrophilic properties along with the facility of non-covalent linking of numerous molecules and prevents them from denaturation. It has been reported that enzymes serratiopeptidase and bromelain are delivered through aquasome via the oral route.

APPLICATIONS

1. Gene delivery[2,8]

Aquasome can effectively target intracellular gene delivery. Some research findings describe the capabilities of aquasome for effective gene delivery. Gene delivery through aquasome has five layers, a ceramic central core, a film of polyhydroxy oligomeric layer, part of an applied gene, carbohydrate coating and protein of viral membrane that works as a layer of targeting. This shows that the aquasome preserves and ensures the genes. The aquasome has the potential for targeting or delivering genes or viral vectors.

2. Antigen delivery[7]

The adjuvants generally used to enhance the immunity to antigens have a tendency either to alter the conformation of the antigen through surface adsorption or to shield the functional groups. In some studies, the aquasomes were proposed to have superior surface immutability, in that they protect the conformation of protein structure and present it in such a way to immune cells that it triggers a better immunological response.

3. Vaccine delivery[2,8]

The viral antigen or vaccine delivery in aquasome usually boost the immunity system against viral infection, the stimulation of B- cell in protein antigen for conformation state. The size range of aquasome is 5- 600 nm is protecting the high degree of antigen delivery; ceramic core coated is with disaccharide cellobiose for viral protein in drug delivery vehicle. The hydroxyapatite core contains antigen for hepatitis B development of immunity system against T helper cells. In case of Epstein- Barr virus aquasome is produce specific antibodies for targeting molecules for viral antigen or immune deficiency virus. as antigen.

4. An oxygen carrier[2,7]

The oxygen-binding properties of the aquasomes were studied and compared to those of fresh blood and hemoglobin solution. The aquasome formulations neither induced hemolysis of the red blood cells nor altered the blood coagulation time.

CONCLUSION

Aquasomes, the self-assembling surface-modified nanocrystalline ceramic cores, seem to have potential and promising carriers capable of preserving the structural integrity of protein pharmaceuticals and carrier for delivery of broad range of molecules including viral antigens, hemoglobin and insulin, thus promoting a better therapeutic effect. Also, these formulations

have been found to evoke a better immunological response and could be used as immunoadjuvants for proteinaceous antigens. This approach thus provides pharmaceutical scientists with new hope for the delivery of bioactive molecules.

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