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Colloidal dispersion systems in physical pharmaceuticals: Recent advances and applications

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Abstract

Colloidal dispersion systems play an important role in physical pharmaceuticals and modern drug delivery research. Colloids are heterogeneous systems in which one phase is dispersed uniformly into another phase with particle sizes generally ranging from 1 nm to 1000 nm. These systems improve drug stability, solubility, bioavailability, and therapeutic effectiveness. Pharmaceutical colloids include sols, gels, emulsions, suspensions, aerosols, foams, and nanosystems such as liposomes and nanoparticles. The physicochemical properties of colloids, including Brownian movement, zeta potential, electrophoresis, and electrical double layer, significantly influence formulation stability and performance. Recent advancements in colloidal drug delivery systems have enhanced targeted drug delivery, controlled release, and patient compliance. Colloidal dispersions are widely utilized in oral, topical, ophthalmic, pulmonary, and parenteral formulations. Nanotechnology-based colloidal carriers have also emerged as promising systems for anticancer therapy, vaccine delivery, and herbal drug formulations. This review discusses the classification, preparation methods, properties, stability, evaluation parameters, and pharmaceutical applications of colloidal dispersions along with recent innovations and future perspectives in physical pharmaceuticals.

Keywords: Colloidal Dispersion; Physical Pharmaceuticals; Drug Delivery System; Nanoparticles

1. Introduction

Physical pharmaceuticals is an important branch of pharmaceutical sciences that deals with the physicochemical principles involved in the formulation, development, and evaluation of dosage forms. Among the various systems used in pharmaceutical formulations, colloidal dispersions occupy a significant position due to their unique physicochemical properties and extensive applications in drug delivery. A colloidal dispersion is a heterogeneous system in which finely divided particles are distributed uniformly throughout another medium. The particle size of colloidal systems generally lies between true solutions and coarse dispersions, ranging from 1 nm to 1000 nm. Due to their small particle size and large surface area, colloidal systems exhibit unique characteristics such as Brownian movement, Tyndall effect, adsorption, and electrical charge.

Colloidal systems are widely used in pharmaceutical formulations because they improve the solubility and stability of poorly water-soluble drugs, enhance bioavailability, and allow controlled and targeted drug delivery. Different types of colloidal systems such as emulsions, suspensions, gels, liposomes, nanoparticles, microspheres, and aerosols are extensively employed in modern pharmaceuticals. Recent developments in nanotechnology and biotechnology have further expanded the applications of colloidal dispersions in advanced drug delivery systems.¹ Novel colloidal carriers provide site-specific delivery, prolonged drug release, reduced toxicity, and improved therapeutic efficacy. Colloidal systems are now used in cancer therapy, vaccine delivery, gene therapy, and herbal drug formulations. This review

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highlights the classification, properties, preparation methods, stability factors, pharmaceutical applications, and recent advancements in colloidal dispersion systems used in physical pharmaceuticals.²

A difficult issue in the creation of an appropriate pharmaceutical medication formulation is molecules that are poorly soluble in water. The majority of recently produced medications also show low solubility in organic environments, which further complicates this scenario. Consequently, poorly water-soluble medicines often have low systemic bioavailability and unpredictable absorption properties. Intravenous, intradermal, intramuscular, intraarterial, subcutaneous, and other parenteral routes of administration have a notably high absorption profile and hence improved bioavailability.³ Intravenous administration of solutions is both impracticable and harmful due to the limited solubility of medications, since they may precipitate and block the vessel.⁴ To address issues related to the parenteral administration of hydrophobic medicines, drug delivery experts have employed a variety of formulation techniques.³ The Greek words "para," which means beside, and "enteron," which means gut, are combined to form the phrase parenteral. Therefore, parenteral routes of medication delivery are those that avoid the gastrointestinal system. Simple oil-in-water (o/w) emulsions and various water-in-oil-in-water (w/o/w) formulations are popular heterogeneous systems for the intravenous (IV) route, which is the most important drug delivery mechanism.⁴ Complexation, solubilization of hydrophobic substances in micelles, and liposomes as drug carrier systems are some of the conventional and most popular methods for parenteral administration of poorly soluble medicines. Despite being utilized for hydrophobic drug delivery, the aforementioned methods have a number of drawbacks that prevent them from being fully utilized. In addition to the high expense of the liposome production method, cyclodextrins may show poor complexation with the medicine under consideration, limited micellar solubilization capability, and complexity.⁵ As a result, better formulation techniques are becoming more and more necessary to enhance the parenteral distribution of hydrophobic medications.

Emulsions and micro-emulsions are often used carriers in the pharmaceutical industry to transport lipophilic (hydrophobic) and lipophobic medicines, including those with limited permeability. Micro-nano-emulsions have recently drawn more attention in pharmaceutical applications as drug carriers, since they have the ability to address issues associated with the delivery of poorly water-soluble and lipid-soluble medicines.⁵

1.1. Biphasic Colloidal Carriers' Potential and Need for Parenteral Drug Administration

The challenges related to hydrophobic medications can be lessened by using an oil-in-water (o/w) emulsion and including the drug in the oil phase (dispersed phase). Additionally, a co-solvent-based formulation that often causes drug precipitation at the administration site can be replaced with a submicron emulsion.⁶ Submicron emulsions are potential drug carrier systems that have the following advantages over other dosage forms: (a) improved drug solubilization and bioavailability; (b) thermodynamically stable systems that require little energy to form; (c) targeted and controlled release colloidal drug delivery systems; (d) drug incorporation in non-polar phase in o/w micro-emulsion protects drugs that are vulnerable to hydrolysis and oxidation; and (e) aqueous dosage form for hydrophobic drugs.⁷ Micro-emulsions have shown promise as colloidal drug carrier technologies for parenteral administration that are economically viable. A parenteral micro-emulsion with desirable properties like prolonged circulation in blood and sustained release may be created with the right excipient selection.⁸ Depending on how hydrophobic the active ingredient is, drug loading into the dispersed phase may enable delayed or sustained release. Drugs that are hydrophilic or hydrophobic can be added to the dispersed phase of w/o and o/w emulsion systems, respectively [6]. An o/w parenteral micro-emulsion system containing itraconazole was created by Rhee et al. The dispersed (oil) phase was selected as a combination of benzyl alcohol and medium chain triglyceride. The micro-emulsion formulation's mean droplet size was less than 150 nm. The potential of the micro-emulsion system was demonstrated by comparing the pharmacokinetic profiles of itraconazole and its metabolite hydroxyitraconazole of itraconazole micro-emulsion with PEG 400 solution and cyclodextrin formulation.⁹ Nesamony et al. showed how to create a w/o emulsion with water, dioctyl sodium sulfosuccinate (DOSS), and ethyl oleate (EO). Additionally, rheology, electrical conductivity, dynamic light scattering, and (polarized) light microscopy were used to characterize the produced formulations. Furthermore, the potential of the developed submicron emulsion was demonstrated by in-vitro cell toxicity experiments and aseptic filtration as a method of sterilizing.¹⁰

For many years, coarse solid solutions have been produced for intramuscular (Bicillin® L-A) or subcutaneous (HUMULIN, LENTE) parenteral administration. Nanotechnology has recently been employed to solve issues with poor bioavailability and low solubility. Additionally, tailored (site-specific) medicine delivery is made possible by nanotechnology. Parenteral nanosuspensions can regulate the pace of medication delivery and lessen irritation. Scientist Norio Taniguchi of the University of Tokyo in Japan coined the term "nanotechnology," and the suffix "nano," which comes from a Greek word meaning "dwarf" or "small," was initially used to refer to any substance that falls inside the nanoscale size range.

Nanosuspensions have emerged as a potentially effective parenteral drug delivery method for hydrophobic medications. A new delivery method based on polycaprolactone nanoparticles stabilized with Pluronic F108 surfactant has been developed by Kolluru et al. for the delivery of difficult-to-solubilize docetaxel. In addition to improving the drug's solubility profile, this delivery method has demonstrated superior localization compared to free drug in targeted drug delivery to the tumor location. Furthermore, the medication's gradual release from the nanoparticles and the system's nanoscale will lessen negative effects and prevent the drug from being quickly eliminated from the body.¹¹ Etoposide-loaded bovine serum albumin (EPEG-BSA) nanosuspensions were also created and evaluated for the new nanosuspension system's safety both in vitro and in vivo. The prepared suspension displayed a prolonged drug release profile as opposed to Injection®. Additionally, in vivo research revealed less EPEG myelosuppression in mice [11]. Lastly, using a mix of precipitation and micro-fluidization techniques, Tian et al. created a p-terphenyl derivative (H2) nano-suspension, which they then lyophilized into dry powder. Reduced particle size was shown to significantly increase the rate of dissolution. Furthermore, following the decrease in particle size, the crystalline form of H2 was preserved. The promise of the H2 nanosuspension method was also demonstrated by longer residence times and higher AUC.¹²

1.2. Lipid-Based Biphasic Colloidal Systems' Structure

Since its creation by Schulman and associates, the term "micro-emulsion" has undergone revisions. Optically transparent, isotropic, low viscosity, thermodynamically stable dispersions of polar and non-polar phases stabilized by a mixture of a co-surfactant and a surfactant are known as micro-emulsions. However, structural microemulsions are more than just dispersions; they are a single percolated phase made up of micelles or reverse micelles, water or oil droplets, and bi-continuous structures that lack an internal or exterior phase.¹³

A dispersion of two immiscible liquids in which one liquid is distributed as droplets or globules in the continuous phase of the other liquid is known as an emulsion. The emulsion is referred to as a micro/nano-emulsion when the droplets or globules are smaller than microns. Water and oil are the two immiscible fluids most frequently utilized.¹⁴ A submicron emulsion, which seems to be a transparent system but is really made up of submicroscopic dispersed areas that are either oleic or aqueous in character, may include significant amounts of both oil and water phases.¹⁵ The interface of a micellar emulsion is a dynamic system that constantly and spontaneously changes. Structural micro-emulsions are divided into three categories: o/w systems, in which oil globules are dispersed in a continuous polar (aqueous) phase, w/o systems, in which water droplets are dispersed in a continuous non-polar (oil) phase, and bicontinuous structures with comparable concentrations of aqueous and oil phases. There is extremely little reciprocal solubility between the aqueous and oil phases. But when an amphiphile (surfactant) is added, the solubility rises until the amphiphile concentration is high enough to make the mixture homogenous.¹⁶ Sub-micron emulsion formulation is crucial for pharmaceutical acceptability of excipients depending on their toxicity.

Table 1 Classification of Colloidal Dispersions

Basis of Classification	Type of Colloidal Dispersion	Description	Examples
Based on Physical State of Dispersed Phase and Dispersion Medium	Sol (Solid in Liquid)	Solid particles dispersed in a liquid medium	Paints, starch solution, gold sol
	Gel (Liquid in Solid)	Liquid dispersed in a solid continuous phase	Jelly, cheese, butter
	Emulsion (Liquid in Liquid)	One liquid dispersed in another immiscible liquid	Milk, cream, mayonnaise
	Foam (Gas in Liquid)	Gas bubbles dispersed in a liquid	Shaving cream, whipped cream
	Solid Foam (Gas in Solid)	Gas dispersed in a solid matrix	Pumice stone, foam rubber
	Aerosol (Solid/Liquid in Gas)	Fine particles or droplets dispersed in gas	Smoke, fog, mist, sprays

	Solid Sol (Solid in Solid)	Solid particles dispersed in a solid medium	Colored glass, alloys
Based on Interaction with Dispersion Medium	Lyophilic Colloids	Strong attraction between dispersed phase and medium; highly stable	Starch, gelatin, proteins
	Lyophobic Colloids	Weak attraction between dispersed phase and medium; less stable	Metal sols, sulfur sol
Based on Nature of Particles	Multimolecular Colloids	Formed by aggregation of many small molecules or atoms	Gold sol, sulfur sol
	Macromolecular Colloids	Consist of large molecular weight substances	Proteins, polymers, starch
	Associated (Micellar) Colloids	Behave as normal molecules at low concentration and form colloids at higher concentration	Soap solution, detergents
Based on Charge on Colloidal Particles	Positively Charged Colloids	Colloidal particles carry positive charge	Ferric hydroxide sol, aluminum hydroxide sol
	Negatively Charged Colloids	Colloidal particles carry negative charge	Gold sol, sulfur sol, starch solution

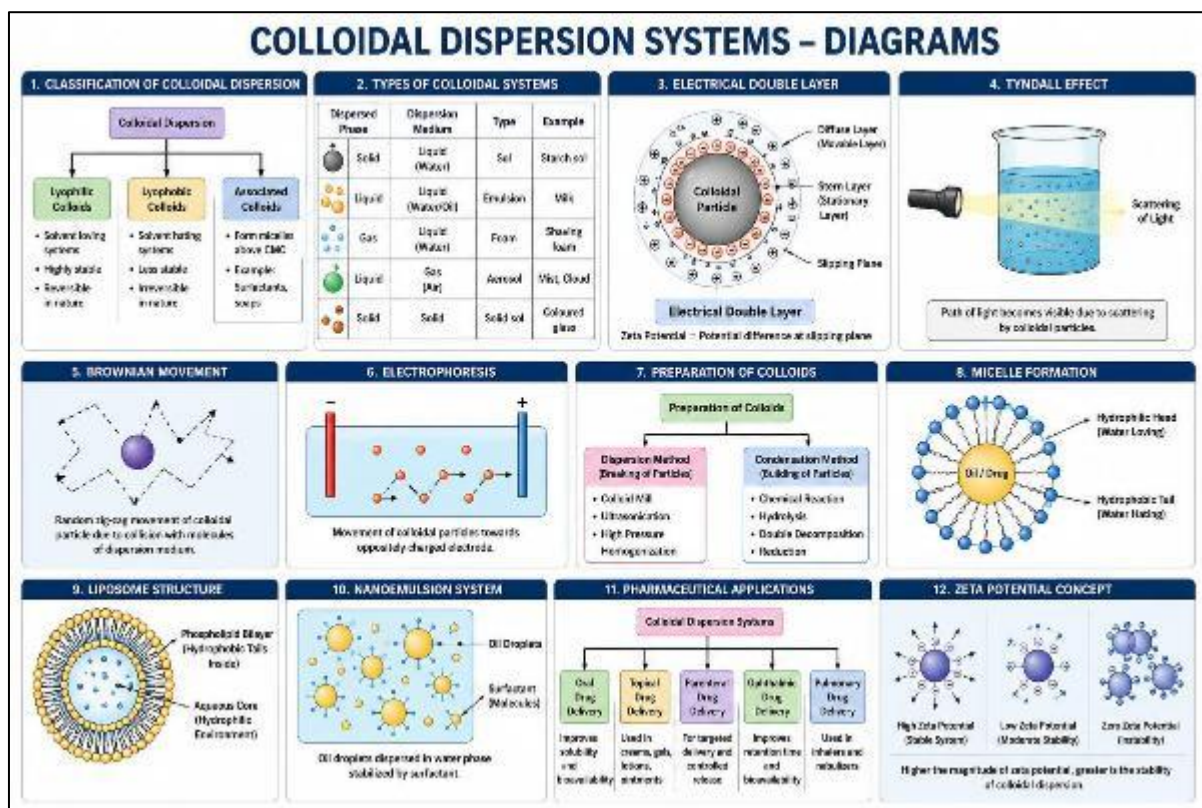


Figure 1 Illustrations of various Colloidal dispersion systems

2. Crucial Characteristics of Colloidal Drug Delivery Systems

2.1. Distribution of Particle Sizes

The physical, chemical, and biological characteristics of nanomedicines as well as their clinical results are determined by their particle size distribution (PSD). IV emulsions must adhere to pharmacopeial requirements, such as all parenteral dose forms. Parenteral emulsions need to be physically and chemically stable, sterile, non-pyrogenic, biodegradable, isotonic, and non-toxic. Additionally, the droplet size is usually between 100 and 500 nm and must be less than 1 μm .¹⁷ The FDA has not determined which of the several PSD procedures is best for PSD characterisation. Particle size is determined using "single particle" and "ensemble" approaches. A signal produced by many size ranges is detected using ensemble techniques. The signal is assumed to have a gaussian particle distribution after being deconvoluted, or inverted. Single particle techniques identify a reaction provided by a single particle, as contrast to ensemble approaches. While ensemble techniques require less dilution, single-particle methods need enough dilution to allow a single particle to pass through the equipment's optic area. Response is produced by several PSD methods according to volume, quantity, surface area, weight, or intensity. While laser diffraction produces a signal based on volume, dynamic light scattering (DLS), a popular method for measuring particle size, produces a signal based on intensity. The regulatory body data on D10, D50, and D90 provide detailed descriptions of both small and coarse particles. For particles falling within a given size, D10 denotes the 10th percentile, D50 the median, and D90 the 90th percentile.¹⁸ $(D90-D10)/D50$ yields the distribution's width, or SPAN value. The polydispersity index, which ranges from 0.0 to 1.0, provides further insight into the distribution's homogeneity and heterogeneity. The heterogeneity of the particle dispersion increases with the number. Additionally, the sponsor must present data from several batches to prove the method's repeatability.¹⁹

2.1.1. Dissolution Test in Vitro

The sponsor must create and confirm a discriminating in-vitro dissolution test to guarantee the product's quality and, consequently, its efficacy and safety. When clinical investigations are not practical, the FDA frequently suggests an in-vitro method for generic approval between test and brand goods. A selective in-vitro release test is one of the assays used in the in-vitro method. Complex nanomedicine release is influenced by temperature, agitation, equipment, volume, and release media selection. The in-vitro release test has been described using membrane diffusion, continuous flow, and sample and separation techniques. To comprehend the drug release processes, the drug release data are analyzed using a variety of models, including the zero-order model, first-order model, Higuchi model, Korsmeyer–Peppas model, etc.²⁰

2.2. Crystalline/Amorphous Content

Nanomedicines should maintain their amorphous/crystalline composition throughout their shelf life in order to maintain clinical settings. Regulations should include the amorphous/crystalline ratio. It is necessary to create and validate a method that can quantify the least quantity of crystalline or amorphous material. Thermal and X-ray diffraction, as well as solid-state NMR, are among the techniques described.²¹ *In vivo* performance is also influenced by other physical factors including charge and shape. Any drug delivery system's charge is an essential feature that controls both its efficacy in vivo and its stability in suspension because of electrostatic interactions.²²

2.3. Sterility and Rheology

Measuring viscosity gives information on how colloidal systems affect drug release. Additionally, non-uniform drug distributions might result in overdosage failure, therefore sedimentation properties during storage are crucial. Syringeability is another important consideration for nanosystem intravenous administration, in addition to the previously listed variables. The syringeability is a measure of the pressure associated with injection using a needle of certain gauge and length. Furthermore, a formulation must be sterile in order to be used safely in therapy. It has been shown that bacterial spores are resistant to chemical, dry, and wet sterilization and can become stuck throughout the crystallization process. Because they require higher temperature and pressure settings, moist heat sterilization methods like autoclaving are inappropriate for submicron biphasic systems. Aseptic sterilization methods are typically used to sanitize sub-micron biphasic systems without changing their physico-chemical characteristics.

3. Colloidal Carrier Applications

3.1. Complete Parenteral Nutrition

ICU patients frequently struggle with an energy shortage. Whether administered temporarily or over an extended period of time, parenteral nutrition (PN) can enhance the supply of calories to critically sick patients. Lipids are a significant source of calories in artificial nutrition. Intravenous lipid emulsions, or ILEs, are a crucial part of the PN regimen because they offer necessary and conditionally essential fatty acids as well as a rich source of energy. ILEs that are sold commercially are complicated oil-in-water mixes. As a uniform dispersion of fat globules in water, emulsification permits the lipid phase and aqueous phase to coexist at a reduced surface tension. ILEs have a typical diameter of $\approx 0.25\text{--}0.5\ \mu\text{m}$ and contain hundreds of fat globules per milliliter. In terms of oil supply, fatty acid content, lipid concentration, and other components like vitamins, ILEs vary from one another. The 2-in-1 system, which contains two macronutrients (glucose, amino acids) and all micronutrients in a single bag (ILE separate), and the 3-in-1 system (total nutrient admixture), which contains three macronutrients and all micronutrients in a single bag, are two popular ILE formulation delivery methods. Therefore, PN can enhance the supply of calories to all critically sick patients, either by itself or in conjunction with enteral nutrition (EN).

3.2. Administration of Vaccines

Vaccination is a fantastic way to avoid infectious illnesses, which greatly extends life expectancy. Even with these remarkable successes, vaccine delivery still has to be improved in order to fight infectious illnesses. Nowadays, the majority of immunizations are given using intrusive methods. Vaccines administered parenterally may cause a systemic immune response. Vaccine development fails when vaccine candidates are unable to elicit appropriate immune responses. To administer new generations of vaccinations against infectious (like pneumonia) and non-infectious (like cancer) illnesses, strong and safe adjuvants must be developed. The formulation and techniques for stimulating immune responses utilizing nanoemulsion and an inactivated pathogen via mucosal distribution are provided by Baker et al.'s invention. In 1997, Italy authorized squalene o/w emulsion containing influenza vaccine.

3.3. Therapy with Long-Acting Injectables (LAI)

Long-acting injectable formulations aid in maintaining medications' therapeutic effects in the body for the intended periods of time. Drugs that are prone to quick in vivo clearance are administered more often, which results in low patient compliance. Therefore, the creation of controlled release techniques enables prolonged systemic exposure following the delivery of a single dosage [34]. Variability in tissue shape, recipient physiology, injection pace, and technological format are important variables influencing drug release kinetics. Drug exposure is directed over extended periods of time when LAIs are given close to the afflicted tissue. Microencapsulation, in-situ forming depots (gels/implants), and molecular and particle delivery systems are examples of LAI technology platforms. The sterile paliperidone palmitate nanosuspensions Invega Trinza® and Invega Sustenna® were first approved at doses of 150 mg/human monthly and 525 mg/human every three months, respectively.

3.4. Anticancer Medications and Diagnostic Tools

The non-specific targeting of tumor cells and healthy body cells by conventional chemotherapeutic drugs used to diagnose and treat cancer might have potentially fatal adverse effects. The precise targeting of anti-cancer medications and diagnostic agents for the targeting of cancer cells has demonstrated promising outcomes when these chemicals are encapsulated in the nanoparticle matrix as nanosuspensions. Furthermore, a lot of the anti-cancer medications that are now in use have poor aqueous solubility and necessitate the use of hazardous co-solvents like cremophor to improve solubility. The creation of anti-cancer medications as nanosuspensions eliminates the need for hazardous solvents to increase solubility, and the inclusion of biodegradable polymers significantly improves the safety profile of these drug-loaded nanoparticle systems.

4. Kinetic Properties of Colloids Brownian Motion:

When a sol is examined with an ultramicroscope, the suspended particles are seen as shining specks of light. By following an individual particle it is observed that the particle is undergoing a constant rapid motion. It moves in a series of short straight-line paths in the medium, changing directions abruptly. The continuous rapid zig-zag movement executed by a colloidal particle in the dispersion medium is called Brownian movement or motion. This phenomenon is so named after Sir Robert Brown who discovered it in 1827. Suspension and true solutions do not exhibit Brownian movement. Explanation of Brownian movement. The explanation of Brownian movement was advanced by Albert Einstein around 1955 by mathematical considerations based on the kinetic molecular theory. According to him, at any

instant a colloidal particle was being struck by several molecules of the dispersion medium. The movement of the particle was caused by unequal number of molecules of the medium striking it from opposite directions. When more molecules struck the particle on one side than on another, the direction of movement change. In a suspension, the suspended particles being very large the probability of unequal bombardments diminishes. The force of the molecules hitting the particle on one side is cancelled by the force of collisions occurring on the other side. Hence they do not exhibit Brownian movement. The phenomenon of Brownian movement is an excellent proof of the existence of molecules and their ceaseless motion in liquids. It also explains how the action of gravity, which would ordinarily cause the settling of colloidal particles, is counteracted. The constant pushing of the particles by the molecules of the dispersion medium has a stirring effect which does not permit the particles to settle.

4.1. Electrical Properties of Colloids

(i) Electrostatic nature of sols: The most important property of colloidal dispersions is that all the suspended particles possess either a positive or a negative charge. The mutual forces of repulsion between similarly charged particles prevent them from aggregating and settling under the action of gravity. This gives stability to the sol. The sol particles acquire positive or negative charge by preferential adsorption of positive or negative ions from the dispersion medium. For example, a ferric hydroxide sol particles are positively charged because these adsorb Fe^{3+} ions from ferric chloride (FeCl_3) used in the preparation of the sol. Since the sol as a whole is neutral, the charge on the particle is counterbalanced by oppositely charged ions termed counter-ions (in this case Cl^-) furnished by the electrolyte in medium. (ii) Electrical Double layer: The surface of colloidal particle acquires a positive charge by selective adsorption of a layer of positive ions around it. This layer attracts counter-ions from the medium which form a second layer of negative charges. The combination of the two layer of +ve and -ve charges around the sol particle was called Helmholtz Double layer. Helmholtz thought that positive charges next to the particle surface were fixed, while the layers of negative charges along with the medium were mobile. More recent considerations have shown that the double layer is made of: (a) Compact layer of positive and negative charges which are fixed firmly on the particle surface. (b) Diffuse layer of counterions (negative ions) diffused into the medium containing positive ions. The combination of the compact and diffuse layer is referred to as the Stern Double layer after the colloid chemist who first realized its significance. The diffuse layer is only loosely attached to the particle surface and moves in the opposite direction under an applied electric field. Because of the distribution of the charge around the particle, there is a difference in potential between the compact layer and the bulk of solution across the diffuse layer. This is called by Electrokinetic or Zeta potential. The presence of the double layer accounts for the electrical properties: (a) Cataphoresis; and (b) Electro-osmosis of colloids. It has been made possible to estimate the magnitude of the zeta potential with the help of these properties.

5. Conclusion

Colloids are heterogenous solutions that have large surface areas and surface energies and whose properties are sometimes different from those of the corresponding bulk matter, atoms or molecules. Its ability to scatter light (Tyndall effect), undergo Brownian motion, and possess a net charge are some of the reasons its principle is applied in industries such as; the food industry, the pharmaceutical industry, In hospitals and in water purification.

Colloidal dispersion systems have become an integral component of physical pharmaceuticals and advanced drug delivery research because of their ability to enhance drug solubility, stability, bioavailability, and therapeutic efficacy. Their unique physicochemical characteristics contribute significantly to formulation performance and controlled drug release behavior. With advancements in nanotechnology and pharmaceutical sciences, colloidal systems such as nanoparticles, liposomes, emulsions, and other nanoscale carriers have expanded their applications in targeted therapy, vaccine delivery, and personalized medicine. Furthermore, ongoing developments in formulation strategies and characterization techniques continue to improve the efficiency and safety of colloidal systems. Therefore, colloidal dispersions hold significant potential for future pharmaceutical innovations and are expected to play a crucial role in the development of more effective and patient-centered therapeutic approaches.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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