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Review Article

Polymeric Nanoparticles for Drug Delivery: A Comprehensive Review

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ABSTRACT

Innovations in polymeric nanoparticles (PNPs) have become an efficient nanocarrier system of advanced drug delivery because of their capacity to increase therapeutic effect, enhance bioavailability and decrease systemic toxicity. These nanoscale systems, usually ranging from 10-1000nm, are prepared by using biodegradable and biocompatible polymers that allows precise control of physicochemical characteristics, such as particle size, shape, surface charge, surface architecture and surface functionalization. These characteristics enable targeted, stimuli-responsive, and controlled delivery of varied therapeutic agents, which renders polymeric nanoparticles an excellent system to be utilized in the current drug delivery methodologies. This review summarizes the fundamental aspects of polymeric nanoparticles including their advantages, limitations, types of polymers used, preparation techniques, and marketed products.

INTRODUCTION

Nanotechnology has now become a revolution in science as it has a broad application in medicine, pharmaceuticals, electronics, and material sciences [1,2]. Nanoparticles are defined as solid colloidal systems characterized by size of at least 1-1000nm in at least one dimension, which also displays unique physicochemical behaviour because of high surface-volume ratio and quantum effects that are not present in bulk materials [3,4]. Richard Feynman in 1959 gave the ground little thought process to the field that today constitutes nanotechnology in his farsighted lecture on the possibility of manipulating atoms and molecules on an atomic scale, and the term nanotechnology was coined later by Norio Taniguchi in 1974. The pharmaceutical interest of nanoparticles began in 1970s with the invention of early colloidal drug delivery systems like liposomes [5].Increasing issues concerning low aqueous solubility of drugs and systemic toxicity, especially in cancer treatment, drove the evolution of many

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nanoparticle systems including metallic nanoparticles, lipid-based systems, carbon nanotubes, and polymeric nanoparticles (PNPs) throughout the 1980s and 1990s [4,5].

Among these systems, Polymeric nanoparticles have received considerable interest due to their high levels of biocompatibility, biodegradation and formulation flexibility. PNPs exist in the form of nanospheres, in which the drug is dispersed uniformly in the polymeric matrix, or in the form of nanocapsules, which are made up of a liquid core surrounded by a polymeric shell [3,6]. These polymeric Nanoparticles are usually prepared by using FDA-approved biodegradable polymers that include poly (lactic-co-glycolic acid) (PLGA), polylactic acid (PLA) and polycaprolactone (PCL), which allow the drug release in controlled and sustained manner. Moreover, PNPs have the ability to take advantage of enhanced permeability and retention (EPR) effect, which enhances preferential retention in tumor tissues, and thus is especially useful to deliver hydrophobic drugs [5,7]. Although they have promising benefits, the issues are still present in the way of possible reproducible formulation, scalability, and clinical translation, which indicates the necessity to optimize the methods of its preparation [6].

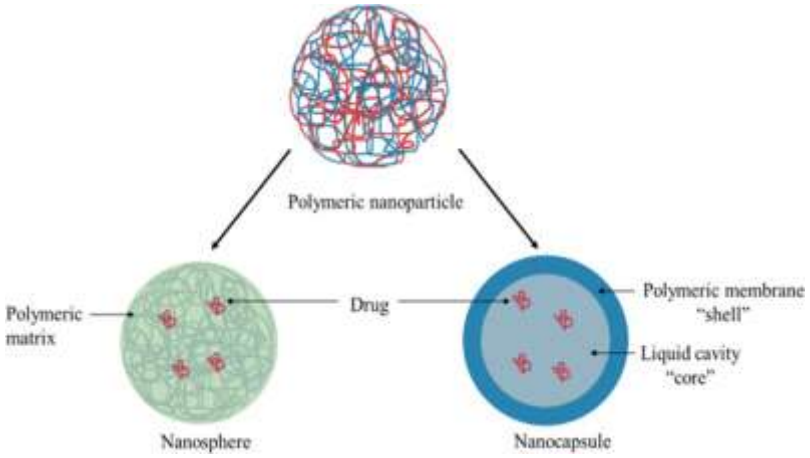

Figure1: Types of polymeric nanoparticles

Advantages of Polymeric Nanoparticles

- **Enhancement of Solubility and Bioavailability:** Many therapeutic agents belong to Biopharmaceutical classification system (BCS) Class II and Class IV that exhibit poor aqueous solubility which cause the limited absorption and low oral bioavailability Polymeric nanoparticles enhance aqueous solubility of BCS Class II/IV drugs by 2-12 fold by nano size reduction (10-200 nm) and amorphous molecular dispersion to overcome poor dissolution limitations.
- **Controlled & Sustained Release**: PLGA/PCL matrices have zero-order release kinetics that can sustain therapeutic plasma levels up to 7-30 days, allowing once-weekly dosing and increase patient compliance by >70%.
- **Biopharmaceutical Protection**: Encapsulation maintains peptides, proteins and siRNA (>85) bioactivity against GI pH (1.2-7.4) proteases, and CYP450 metabolism during transit.
- **Targeted Delivery:** Targeted delivery of drugs reduces the systemic toxicity and improves therapeutic outcomes. EPR

(Enhanced permeability and retention) effect is a passive targeting technique that allows the selective accumulation of nanoparticles in the tumor tissues. Active targeting involves the use of ligands such as peptides, antibodies, and folic acid improves the cellular uptake in specific site.

- **Optimal Cellular Penetration**: The cellular uptake and intra cellular delivery where improved by the polymeric nanoparticles which is important for gene therapy and anticancer drugs. 80-150 nm size is maximizes clathrin or caveolar endocytosis; PEGylation extends circulation half-life by 30 minutes to 48 hrs [8-13].

Limitations of Polymeric Nanoparticles

- **Formulation & Scale-up Complexity:** Polymeric nanoparticles preparation methods such as Nanoprecipitation, solvent evaporation, emulsification needs precise control of formulation and process parameters. small change can lead to variations in particle size, drug loading, stability and makes the large scale manufacturing difficulty. The high sensitivity in parameters of nanoprecipitation and emulsion techniques leads to 10% processing changes resulting in 50- 200 nm size differences and PDI more than 0.3 leading to GMP manufacturing difficulties.

- **Residual Organic Solvents Preparation:** various organic solvents used in the PNPs preparation. these organic solvents cause residual solvent toxicity if they are not completely evaporated during the preparation process. Solvents like dichloromethane, acetone, ethyl acetate can pose safety concerns and regulatory challenges mainly for parenteral formulations. DCM (>10 ppm residual) and ethyl acetate (>5000 ppm) pose the risk of haemolysis/cytotoxicity; complete removal reduces yields decline by 20-35%.

- **Initial Burst Release:** Surface-adsorbed drug results in 25-50% release in first 4 hours, which results in dose-dumping, and toxicity risks to narrow therapeutic index drugs.

- **Physical Instability:** Polymeric nanoparticles cause the particles aggregation, sedimentation and particle growth during the storage and effects the shelf life.40-70% aggregation occurs in 3 months unless zeta potential maintained at ±30mV when there exists a high surface energy; be lyophilized in the event of 1-5% cryoprotectants.

- **High Production Costs and Regulatory challenges:** strict quality control, reproducibility, safety assessments must be full filled before the clinical approval that makes the product development time consuming and expensive. 60% IND rejections due to batch reproducibility failures and stringent ICH Q3C solvent limits [14-17]

Components and formulation attributes

The major components of polymeric nanoparticles are polymers, surfactants (stabilizers), organic solvent, and aqueous phase. From these components Polymers are very important since they serve as the structure of the nanoparticle system. The polymers are macromolecules which are composed of repetitive monomers and have a profound effect on the physicochemical and biological characteristics of the formulation. The organic solvent is important in the dissolution of the polymer and the drug and the formation of nanoparticles during the emulsification process and solvent evaporation or diffusion processes; the

commonly used solvents are dichloromethane, ethyl acetate, acetone, and acetyl nitrile [18,19].

The surfactants maintain the droplets of emulsion and inhibit particles aggregation and consequently regulate the size and surface properties of the particles [20]. Polymeric nanoparticles use in drug delivery has achieved impressive gains of solubility, stability, controlled release, targeting efficiency, pharmacodynamics, and pharmacokinetics to drugs [19,21]. Polymer choice is one of the most important steps in the formulation development, and such properties of polymers like biocompatibility, biodegradability, chemical and physical stability, permeability, safety, glass transition temperature, and drug-polymer compatibility should be considered [20,22]. In order to further tune the properties of polymeric nanoparticles, polymer functionalization methodologies such as chemical modification, surface attachment with targeting ligands, and incorporation of lipid molecules are common place providing the ability to regulate drug release, targeting and enhance biocompatibility [21,23].

Polymers

Polymers to be used in nanoparticle formulation are broadly categorized into natural polymers and synthetic polymers basing on their origin.

Table 1: List of polymers used in the preparation of Polymeric Nanoparticles

Polymer	Type	Properties	Applications
PLGA	Synthetic	Biodegradable, controlled release, FDA approved	Cancer therapy, vaccines, sustained delivery
PLA	Synthetic	Biodegradable, prolonged release	Implants, long term drug delivery
PCL	Synthetic	Slow degradation, high permeability	Sustained and controlled delivery
PEG	Synthetic	Stealth effect, prolonged circulation	Surface modification, targeted delivery
Chitosan	Natural	Muchoadhesive, permeation enhancer	Oral, nasal, ocular and gene delivery
Alginates	Natural	Gel forming, biocompatible	Controlled release systems
Gelatin	Natural	Biodegradable, Non-toxic	Protein and gene delivery
Albumin	Natural	Tumor targeting, biodegradable	Anticancer drug delivery
Hyaluronic acid	Natural	Targeted-specific binding,biodegradable	Tumor-targeted delivery

Importance of Polymer Selection in Nanoparticles

The choice of polymer significantly influences:

- Particle size and surface charge
- Drug loading and encapsulation efficiency
- Drug release kinetics
- Stability and shelf-life
- Biocompatibility and biodegradation

By selecting appropriate polymers or their combinations, nanoparticles can be engineered to achieve site-specific targeting, controlled release, enhanced bioavailability, and reduced toxicity, leading to improved therapeutic outcomes[24,25]

Methods for Polymeric Nanoparticles preparation

Figure: 2 Polymeric nanoparticles preparation methods

1.Solvent Evaporation method

In this method of preparation of polymeric nanoparticles the selected polymer and Drug (if Hydrophobic) are dissolved in the organic solvents like DCM, Ethyl acetate, acetone, It forms organic phase. Aqueous phase is prepared by dissolving the surfactant or emulsifying agent in the distilled water. The organic phase is emulsified in an aqueous phase to form a stable oil in water (o/w) emulsion. Then the organic solvent is evaporated by continuous stirring or by reducing the pressure. Type and concentration of surfactant, polymer concentration, and homogenizer speed influence the particle size of polymeric nanoparticles. High speed homogenization and ultrasonication employed to obtain small particle size. Ultracentrifugation and cleaning with distilled water helps in the removal of additives like surfactants and to obtain solidified nanoparticles. The product is lyophilized in the end.[26].

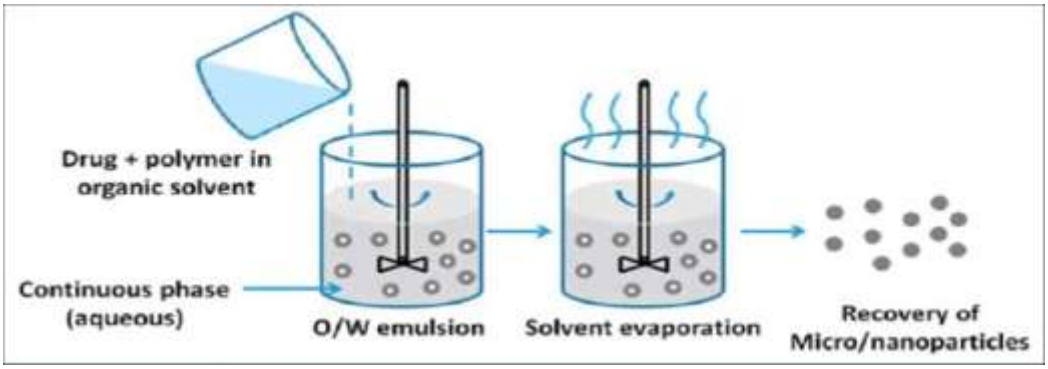

FIGURE 3: Schematic illustration of the solvent evaporation method

2. Salting out method

It is the modified method of emulsification/ solvent diffusion.it involves the separation of water miscible solvent from aqueous solution by a salting out effect. Organic phase prepared by dissolving the drug and polymer in acetone. The organic phase is emulsified into an aqueous phase that containing a salting out agents like (electrolytes, such as magnesium chloride, calcium chloride, and magnesium acetate, or non-electrolytes such as sucrose) and a colloidal stabilizer like polyvinylpyrrolidone or hydroxyethylcellulose to form oil in water(o/w) emulsion. For this o/w type emulsion is diluted with water for enhancing the diffusion of acetone into aqueous phase that leads to the formation of nanospheres [27]. Proper salting agent has to be selected as it plays a key role in drug entrapment efficiency. the organic solvent and the salting out agent are removed by cross-flow filtration.

Advantages – minimize the stress to protein encapsulants [28], useful for encapsulation of heat sensitive substances as it does not require high temperature conditions

This method is useful for the preparation PLA, poly (methacrylic) acid, nanospheres leads to high efficiency and is easily scaled up

Disadvantage- More applicable to lipophilic drugs and require extensive nanoparticles washing step[29]

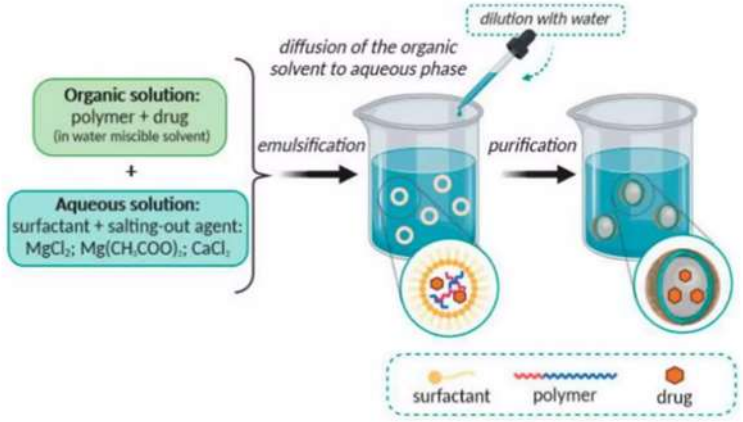

Figure4: Schematic illustration of the salting out method

3. Nanoprecipitation

This method is invented by Fessi et al, it is also referred as solvent displacement, solvent shifting, desolvation, antisolvent precipitation method in 1989. It is based on interfacial deposition phenomenon in which the polymer is dissolved by transport of a solvent into a non- solvent that cause the nuclei growth, crystal growth and nanoprecipitation.

During nanoprecipitation organic phase is introduced into the aqueous phase. For this the organic phase is prepared by dissolving the polymer and the hydrophobic drug in the water miscible organic solvent that has diffusion effect. The aqueous phase contain a stabilizer like surfactant ,the polymer must be insoluble in aqueous phase to slow aggregation process. To produce polymeric nanoparticles, organic phase is added to the aqueous phase drop wisely with moderate stirring. formed nanoparticles are ultracentrifuged and washed with water to remove surfactant ,as the organic solvent evaporates leaves the hardened nanoparticles which are collected by filtering, spinning and freeze-drying.

For nanoparticles preparation easily evaporated solvents such as acetone, ethanol, hexane, methylene chloride are selected. combination of solvents also used. The particle size is influenced by polymer concentration, types and ratios of solvent to non-solvent, stirring speed, rate of addition solvent to non-solvent, type of surfactant used. An increase in polymer concentration, increase in viscosity that prevents the diffusion of solvent into non-solvent that leads to production large size particles. Smaller size nanoparticles are obtained by using solvents with high diffusion coefficients like acetone, acetonitrile and also by decreasing the solvent to non-solvent volume ratio. Higher stirring rates also produce smaller particles. Use of surfactant (Pluronic)reduce the

interfacial intension ,there by reduces the nanoparticles size.

Figure5: Schematic illustration of the nanoprecipitation method

4. Emulsification solvent diffusion

First proposed by Leroux et al. The organic phase is generated by dissolving polymer in organic solvent and then saturated with water as it helps for polymer precipitation and improves its diffusion. The organic solvent is emulsified into aqueous phase containing stabilizer leads to solvent diffusion and nanoparticles production. The solvent is eliminated by distillation or crossflow filtration.

It has benefits like excellent reproducibility, no use of homogenizer, and simple to scale up. Drawback is require large amount of water to be eliminated from suspension[30].

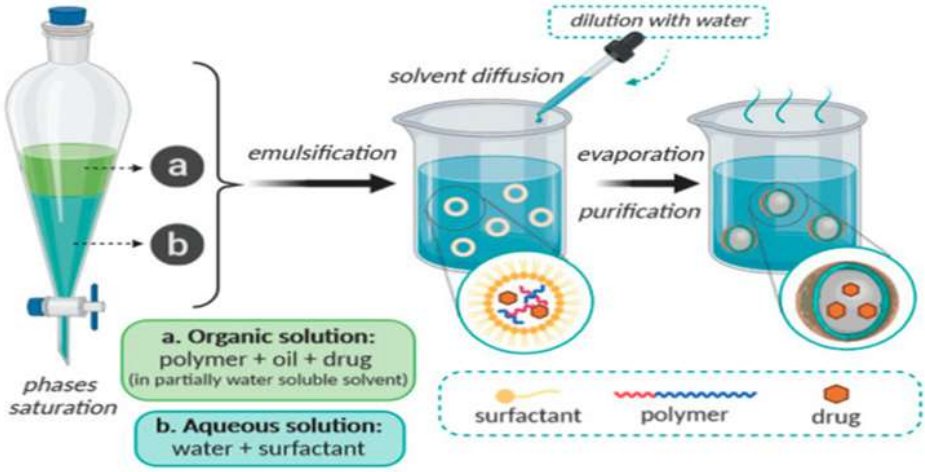

Figure6: Schematic illustration of the Emulsification solvent diffusion method

5. Coacervation or ionic gelation method

The use of biodegradable water soluble polymers such as sodium alginates, chitosan, gelatin for the production of nanoparticles has been investigated in several research [32].

In this method a mixture of two aqueous phases are used, of which one is the chitosan polymer, and a di-block co-polymer ethylene oxide or propylene oxide(PEO-PPO) and the other aqueous phase is a polyanion sodium tripolyphosphate. coacervates

in nano meter size are formed when a positively charged amino group of chitosan interacts with negatively charged tripolyphosphate. the electrostatic interaction between the two aqueous phases leads to the formation of coacervates, whereas, ionic gelation involves the material undergoing transition from liquid to gel due to ionic interaction conditions at room temperature [32].

6. Spray drying method

The first step involved in this method is dissolving the chitosan in acetic acid and then the drug is dispersed or dissolve in the solution. for this solution a suitable cross linking agent is added as it forms a solution or dispersion which is then atomised in a stream of hot air. during the atomisation step the solvent evaporates from small droplets which leaves free flowing powders. Particle size influenced by spray flow rate, size of the nozzle, atomisation pressure and inlet air temperature and extent of cross linking [33].

7. Supercritical fluid technology

Conventional methods used

This technology emerging as a ecofriendly method for the production of polymeric nanoparticles as it involves the use of environmental friendly solvents and produce highly pure polymeric nanoparticles without the use organic solvents that gains immense popularity.

Principles:

- Rapid expansion of supercritical solution (RESS)
- Rapid expansion of supercritical solution into liquid solvent (RESOLV).

Rapid expansion of supercritical solution (RESS)

In this method, the solute is dissolved in a supercritical fluid (CO2) to form a solution. the formed solution is subjected to rapid expansion through an orifice or a capillary nozzle into the surrounding ambient air. with higher supersaturation levels and the rapid reduction of pressure during the expansion leads to the generation of well dispersed particles.

The RESS experimental setup contain 3 primary components

1. A high pressure stainless steel mixing cell
2. A syringe pump
3. A pre expansion unit

Polymer concentration and degree of saturation affects the particle size and morphology.

Rapid expansion of supercritical solution into liquid solvent (RESOLV).

It is a modified method of RESS. Sun et al.in 2002 describes the supercritical solution is expanded into a liquid solvent. The liquid solvent supress the particle growth within the expansion jet and produce the nanosized particles .[34]

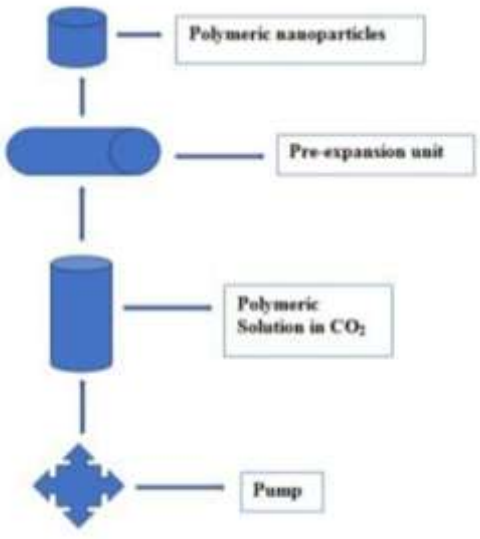

Figure7: Schematic illustration of the Supercritical fluid technology

8. Polymerization of monomers

Emulsion polymerization

It is most widely used, fastest and readily scalable method for producing polymeric nanoparticles.

Types- Based on type of continuous phase

1. Organic continuous phase method-organic solvents used as continuous phase in which the monomer dispersed, and monomer should be insoluble in the organic continuous phase. The monomer forms droplets and polymerization occur in these droplets.

2. Aqueous continuous phase method- in this water used as continuous phase in which the monomer dispersed or dissolved without the use of surfactants or emulsifiers.

This Aqueous continuous phase method can be divided into 2 types based on use of surfactants.

1) Traditional emulsion polymerization
2) surfactant free emulsion polymerization

1) Traditional emulsion polymerization

In Traditional method a water soluble initiator ,water ,somewhat water soluble monomer ,and a surfactant are used. The monomer is dissolved in the continuous phase (water) and a initiator is added to this. The initiating agent forms the monomeric radicles that interact with the monomers and initiate the polymerization reaction. The radicles propagate until they reach a critical chain length, at a point where their aqueous solubility is redused.at this stage the surfactants involves in stabilization process and form polymeric nanoparticles. This reaction is continued until no new particles are nucleated. when there is decrease in polymerization rate the process is terminated.

Limitations

Surfactant removal is a time consuming process that raises manufacturing cost.

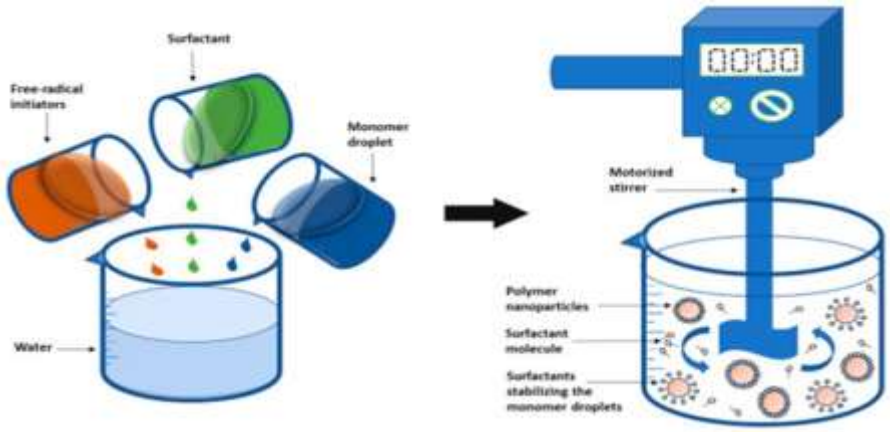

Figure8: Schematic illustration of the Emulsification polymerization method

Surfactant free emulsion polymerization

This method is invented to overcome the limitation of traditional emulsion polymerization method. In this method there is no use of stabilizing agent. A water soluble initiator, monomer, and water are used. The stabilization of polymeric nanoparticles is achieved by the use ionic co-monomers or ionizable initiators.

Mini emulsion polymerization

The components used for production of polymeric nanoparticles by this method include a co-

stabilizer, initiator, surfactant, monomer mixture and water. The use of a low-molecular mass co-stabilizer and a high shear device such as ultrasonicator forms the fundamental difference between the emulsion polymerization and mini emulsion polymerization. This method is used to produce a variety of polymeric nanoparticles. This method used to produce polyacrylonitrile NPs in the size range of 100 to 180 nm using HD and SDS as the co-stabilizer and surfactant.

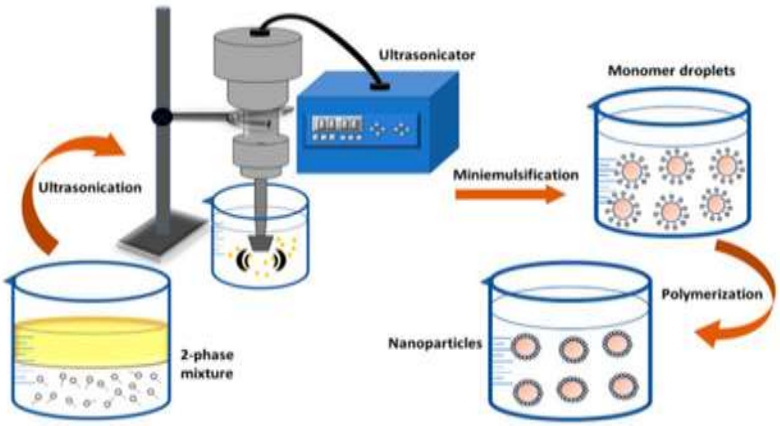

Figure9: Schematic illustration of the mini emulsion polymerization method

Micro emulsion polymerization

Emulsion polymerization and micro-emulsion polymerization are similar processes that form polymers with high molar mass, with different kinetics. This method is used to produce particles with smaller sizes and fewer chains per particle. A water soluble initiator is added to aqueous phase that containing high concentration of surfactants. The polymerization does not initiate simultaneously in all microdroplets, chain growth begins only within a fraction of them. Elastic force and osmatic pressure cause the microdroplets collapse leads to the formation of larger size particles along with empty micelles. This process depends upon the polymerization kinetics, physicochemical properties of polymeric nanoparticles, concentration and nature of the initiator, surfactant, and monomer.[35]

10. Dialysis method

Dialysis is a fast and easy method to prepare small, narrowly distributed polymeric nanoparticles [36]. The polymer solution is prepared by dissolving polymer in a organic solvent is placed inside a dialysis membrane with an appropriate molecular weight cut-off. The system is dialysed against a non-solvent, it leads to gradual replacement of the organic solvent across dialysis membrane. The polymer looses its solubility as the solvent diffuses out and start aggregation results in the generation of nanoparticles. Various studies have reported the synthesis of polymeric and copolymeric nanoparticles by using this method. The solvent selection for polymer dissolution influence the particle size distribution and morphology. Chronopoulou et al.(2009) introduce a novel osmosis based method for the preparation of natural and synthetic polymeric nanoparticles. In this method a physiological barrier, such as dialysis membrane or conventional semipermeable membrane is used that allows the passive transport of solvent and there by slow the mixing of the polymer solution with a non-solvent [37]

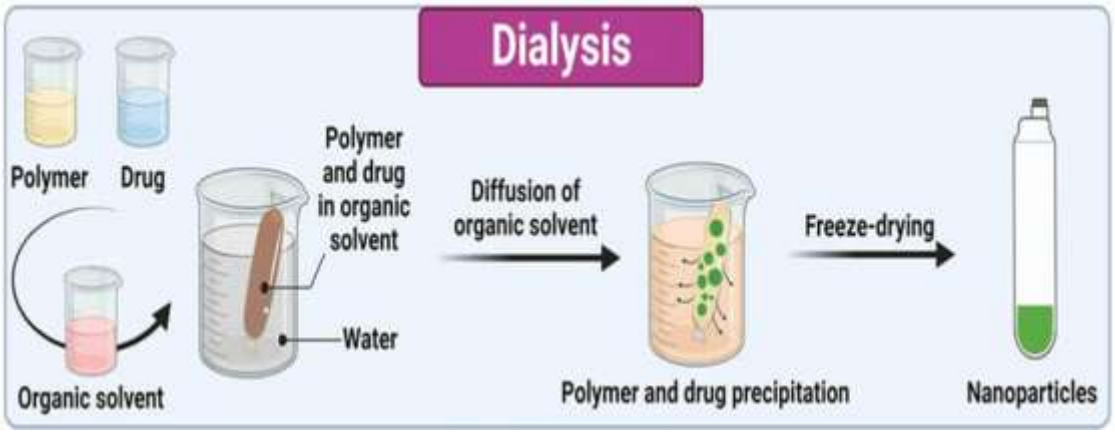

Figure10: Schematic illustration of the Dialysis method

Marketed products of polymeric nanoparticles

Table2 : Marketed products of polymeric nanoparticles

Product name (Brand name)	Drug	Polymer/ carrier system	Nanoparticle type	Indication	Approval/ market status	Reference
Abraxane®	Paclitaxel	Human serum albumin (protein polymer)	Albumin-bound polymeric nanoparticles	Breast cancer, NSCLC, pancreatic cancer	FDA approved (2005)	38,41,42
Genexol-PM®	Paclitaxel	PEG–PDLLA block copolymer	Polymeric micelle nanoparticles	Breast, lung, pancreatic cancer	Approved in south korea	38-40,43,44
Apealea® (Paclical®)	Paclitaxel	Retinoic-acid derived polymeric surfactant (XR-17)	Polymeric micelle nanoparticles	Ovarian cancer	EMA approved (2018)	38-40,45
Eligard®	Leuprolode acetate	PLGA (poly-lactic-co-glycolic acid)	PLGA polymeric nanoparticles	Prostate cancer	FDA approved (2002)	38-40
Zilretta®	Triamcinolone acetonide	PLGA-based polymer matrix	Long acting polymeric nanoparticles	Osteoarthritis, knees pain	FDA approved (2017)	38-40,46
Apretude®	Cabotegravir	PLGA-based polymeric nanoparticles	Long acting injectable nanoparticles	HIV prevention (PrEP)	FDA approved (2021)	38-40,47

CONCLUSION

Polymeric nanoparticles can be used in a highly promising and diverse manner in field of advanced drug delivery systems that offers numerous advantages in drug solubility, bioavailability, therapeutic efficacy and drug stability with reduced systemic toxicity. These polymeric nanoparticles have the ability to precisely control the particle size particle surface characteristics and drug release behaviour enables the targeted and controlled delivery of a wide range of therapeutic

agents. Polymeric nanoparticles were prepared with tailored physicochemical and biological properties by using various biodegradable and biocompatible polymers along with well established preparation techniques. Along with this, the commercialization of certain polymeric nanoparticle based products has been successful, which proves that they are relevant to the clinical field and translatable products.

Along with widespread clinical application these polymeric nanoparticles offers several challenges related to large-scale manufacturing, formulation reproducibility, regulatory approval, long-term safety and cost effectiveness. This is due to the fact that by solving these drawbacks with superior formulation approaches, scalable techniques of production and extensive in vivo experiments will be required in their future development. Finally to further extend the clinical applications of polymeric nanoparticles, continuous research and technological advancements are expected which makes the polymeric nanoparticles as a key component for next generation drug delivery systems.

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