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Review Article

Polymeric Nanoparticles: An Overview

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ABSTRACT

For the past few decades, there has been a considerable research interest in the field of drug administration that uses particle delivery devices to transport both big and small compounds. Particulate systems like Polymeric nanoparticles which are defined as particulate dispersions or solid particles with size in the range of 10-1000nm and have been used as a physical approach to alter and improve the pharmacokinetic and pharmacodynamic properties of various types of drug molecules. They have been utilized in vivo to transport the drug, limit access to specific areas, and check that the drug entity in the systemic circulation at a controlled and sustained rate to the site of action. Various polymers have been used in the formulation of nanoparticles for drug delivery research and to minimize adverse effects and maximize therapeutic benefit. And we studied the various characterization such as particle size, Zeta potential, PDI values and Drug entrapment efficiency and drug release.

INTRODUCTION

Polymeric nanoparticles may be defined as being colloidal system which are usually around 5-10nm and are formulated from biocompatible and biodegradable polymers in size between 10-1000 nm where the drug is enclosed, trapped, dissolved, or joined to a matrix of nanoparticles. Depending upon the method of preparation of nanoparticles, nanospheres or nanocapsules can be obtained. The medicine is contained within a cavity that is encircled by a special polymer membrane in nanocapsule systems. while nanospheres are matrix systems in which the drug is physically and uniformly dispersed [1,2]. and polymer nanotechnologies are an important part of the more promising future to overcome obstacles in medication delivery, such as those pertaining to drug targeting and the delivery of undeliverable molecules such as oligonucleotides or RNA interfering effectors [3-9]. and they have attracted considerable interest over the last few years due to

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their unique properties and behaviours resulting from their small size [10]. In comparison to nanospheres, nanocapsules are reservoir-shaped structures with a solid outer shell enclosing a liquid or semisolid center at ambient temperature (15–25°C) and able to encapsulate water-soluble compounds which were developed more recently.[77]Drugs, proteins, and DNA are efficiently transported to target cells and organs via polymer-based nanoparticles. Their stability in the bloodstream and efficient penetration through cell membranes are facilitated by their nanoscale size. Polymers are incredibly practical materials that may be used to create a wide variety of molecular designs that can be integrated into unique nanoparticle constructs with many potential medical applications [11]. Polymeric nano-revolution in medicine is an exciting prospect as it boasts the potential to transform the conceivable solutions of current therapeutic, diagnostic, prophylactic, and biological challenges to options that are more effective and reliable [12]. Thus, natural polymers are preferred for the preparation of polymer nanoparticles as in vivo drug delivery systems. Starch, polypeptides, albumin, sodium alginate, chitin, gelatin, cellulose, and polyhydroxyalkanoates (PHAs) are common natural polymers used to make polymer nanoparticles, whereas polyethylene glycol (PEG), poly-lactic acid-co-glycolic acid (PLGA), polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), polyethylene (PE), polyanhydrides, and polyorthoesters are common synthesis polymer materials [13]. It has been observed that a variety of polymer nanoparticles with high densities and positive charges can pass across the blood-brain barrier. A naturally occurring biodegradable and biocompatible carbohydrate, chitosan can effectively form nanoparticles [14]. Early work demonstrated that intranasal delivery of estradiol-loaded chitosan nanoparticles leads to significant amounts of estradiol within the CNS [15].

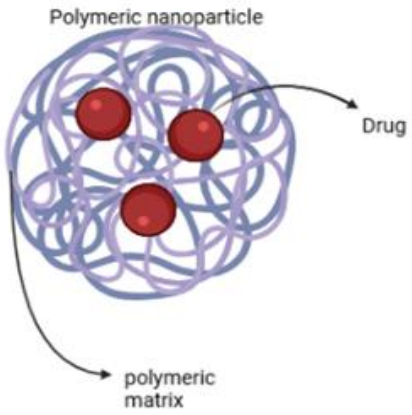


Fig no.1 Polymeric nanoparticles

Characteristics of polymeric nanoparticles: [16].

1. They are stable and allow high drug loading.
2. They provide control over drug release kinetics,
3. They can be readily modified to display a variety of surface-attached ligands, and a lot of polymers have been used safely by people for a long time.
4. Polymer nanoparticles are an important part of the more promising future to overcome obstacles in drug delivery, such as those based on drug targeting and the delivery of undeliverable molecules such as oligonucleotides or RNA interfering effectors [17,18].

Polymeric nanoparticles are stable and allow high loading of many agents, they provide control over drug release kinetics, they can be readily modified to display a variety of surface-attached ligands, and many polymers have a long history of safe use in humans[19]. 6. They have prolonged plasma half-life and a different biodistribution profile compared to conventional drugs [20].

With the help of polymeric nanoparticles, fragile molecules are better preserved from enzymatic degradation occurring in biological medium when they are entrapped in the nanocarrier [21, 22].

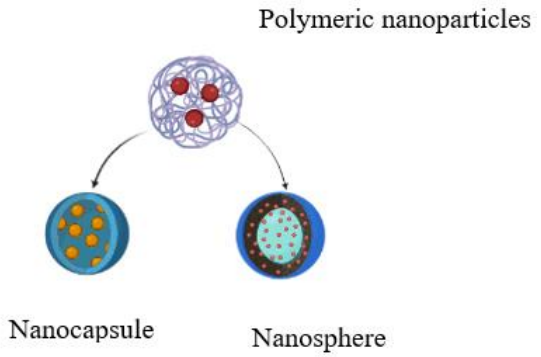


Fig no.2: Structure of Nanocapsule and Nanosphere

Advantages of polymeric NPs as drug carriers

1. Polymeric nanoparticles have a potential use for control or sustain release.

2. They have the ability to protect drug and other molecules with biological activity against the GI environment.

3. They improve the bioavailability and therapeutic index of drugs [23,24].

4. In terms of efficacy and bioavailability, they show a remarkable enhancement over intravenous and oral administration routes.

5. Also, in relation to drug delivery, PNPs can be easily integrated into other activities such as tissue engineering.

6. Apart from above advantages, they transport active ingredients to a targeted tissue or organ with the designated concentration and give volatile active components stability and extended activity period.

7. PNPs can be considered as an ideal candidates for vaccines delivery, cancer therapy, and targeted antibiotics delivery in accordance with the polymer choice and capacity to adjust drug release from PNPs [25].

8. Polymer nanoparticles like micelles, vesicles or star polymers allow for the efficient encapsulation of cargo molecules that can be released at targeted sites [26].

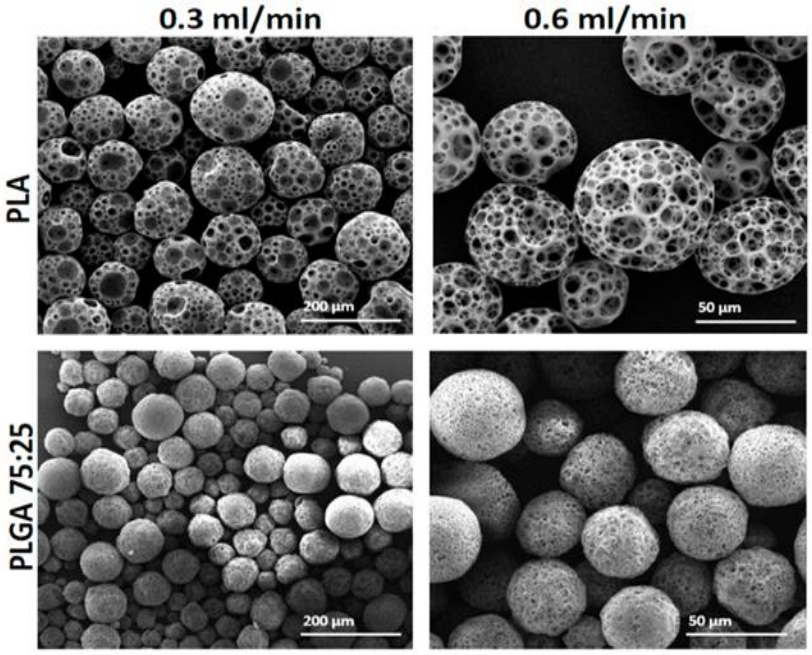
Disadvantages of polymeric nanoparticles [27,28].

1. Nonbiodegradability, fragility, increased production costs, and the usage of hazardous solvent residues are some of the disadvantages of polymeric nanoparticles.

2. It is imperative to have a better understanding of basic principles involved in designing and using polymer nanoparticles for therapeutic treatment, diagnostics, or a mix of therapy and imaging in many clinical settings.

3. Many factors need to be optimized to design advanced polymer nanoparticles for molecular imaging of drug delivery, including pharmacokinetics, cost effectiveness, in vivo targeting effectiveness, and biocompatibility.

4. They are nonbiodegradability, fragileness, higher manufacturing costs, toxic solvent residuals [29,30].



Microscopic view of Polymeric nanoparticles

The polymers which are used in the formulation of polymeric nanoparticles:

1. The polymers should be compatible with the body in the terms of adaptability (non-toxicity) and (non-antigenicity) and should be biodegradable and biocompatible

2. Natural polymers such as chitosan, gelatin, sodium alginate, albumin and synthetic polymers such as polylactides, polyglycolides, polyanhydrides and polycaprolactone.

3. The polymer needs to fulfil several requirements to be used in such an application. Firstly, it needs to be biodegradable or at least totally eliminated from the body in a short period of time allowing to repeat administration without any risk of uncontrolled buildup.

4. Secondly, it must be non- toxic and non-immunogenic. It must also be non-toxic and non-immunogenic, if it degrades. The next step is to formulate it into polymer nanoparticles with appropriate characteristics regarding the drug delivery goal for which the nanoparticles are designed [34].

5. Some of the colloidal stabilizers are used in the formulation of polymeric nanoparticles such as Dextran, Pluronic F-68, Tween 20 or Tween 80 and some of the co-polymers such as polylactide-polyethylene glycol and poly(epsilon-caprolactone)-poly ethylene glycol [36,37].

6. Biodegradable polymers such as poly lactide-co-glycolide (PLGA) have been utilized for many years to encapsulate medications for targeted administration and controlled release. They break down rather quickly into innocuous by products, have little inherent toxicity, and easily form enclosing matrices [38].

7. Nanoparticles made of PLGA and modified PLGA polymers have been employed to improve the bioavailability and dissolution of

substances that are not very soluble in water [39].

8. Chitosan is one of the biodegradable and biocompatible polymer that due to its cationic nature has good mucoadhesive and membrane permeability–enhancing properties. And Hence, it has been extensively investigated for its potential as an absorption enhancer across intestinal epithelium for peptides and proteins [47]. and it has shown potential as a biocompatible and biodegradable API nanocarrier. Chitosan degradation in vivo occurs through an enzymatic degradation, with a degradation rate proportional to the degree of deacetylation [80].

9. Another natural polymer that is Arabic gum (acacia), also a biocompatible and biodegradable polymer, is mainly used in oral and topical pharmaceutical formulations as a suspending and emulsifying agent. And also used in the preparation of lozenges and as a tablet binder. It has also been evaluated as a bioadhesive in novel tablet formulations and modified-release tablets [48].

10. Most of the polymers used are approved by the US FDA and EMA and have been extensively employed in biomedical applications due to their simple removal by physiological processes, biodegradability, biocompatibility and nontoxicity [67].

Mechanism of drug release from the polymeric nanoparticles: [31]

1. By the swelling of the polymer nanoparticles by hydration followed by release through diffusion.

2. By an enzymatic reaction resulting in rupture or cleavage or degradation of the polymer at point of delivery, allowing the medication to be released from the inner core that has been confined.

3. Dissociation of the drug from the polymer and its deadsorption/release from the swelled nanoparticles.

❖ **Methods of preparation of Polymeric nanoparticles:**

Polymer nanoparticles can be conveniently prepared either from dispersion of preformed polymers or by direct polymerization of monomers using classical polymerization. Numerous techniques have been proposed to create biodegradable polymers for the dispersion of premade polymeric nanoparticles made of PLA, PLG, PLGA, and poly(e-caprolactone) [82].

1. Solvent evaporation method:

- This process involves the creation of emulsions by preparing polymer solutions in volatile solvents.

- Early, dichloromethane and chloroform preformed polymer were widely used, but are now a days they are replaced with ethyl acetate which has a better toxicological profile.

- Further, emulsion is converted into a nanoparticle suspension on evaporation of the solvent for the polymer, which is allowed to diffuse through the continuous phase of the emulsion. In the conventional methods, two main strategies are being used for the formation of emulsions, the preparation of single emulsions. e.g., oil-in-water (o/w) or double-emulsions, e.g., (water-in-oil)-in-water, (w/o)/w.

- These techniques use high-speed homogenization or ultrasonication, and then

the solvent is evaporated, either under reduced pressure or by continuous magnetic stirring at ambient temperature. To get rid of additives like surfactants, the solidified nanoparticles can then be recovered by ultracentrifugation and cleaned with distilled water. The product is lyophilized in the end. It was discovered that the kind and amounts of stabilizer, the speed of the homogenizer, and the concentration of the polymer all affected particle size. High-speed homogenization or ultrasonication are frequently used to create tiny particle sizes.

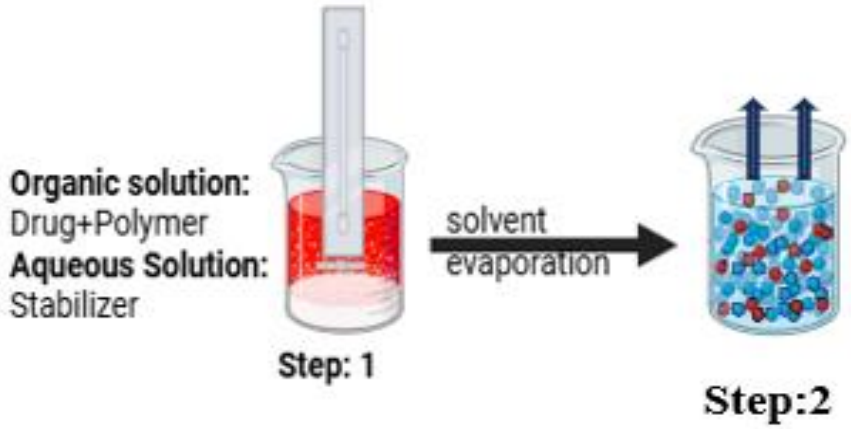


Fig no. 3: Structure of Solvent evaporation method

2. Coacervation or ionic gelation method: [40,41]

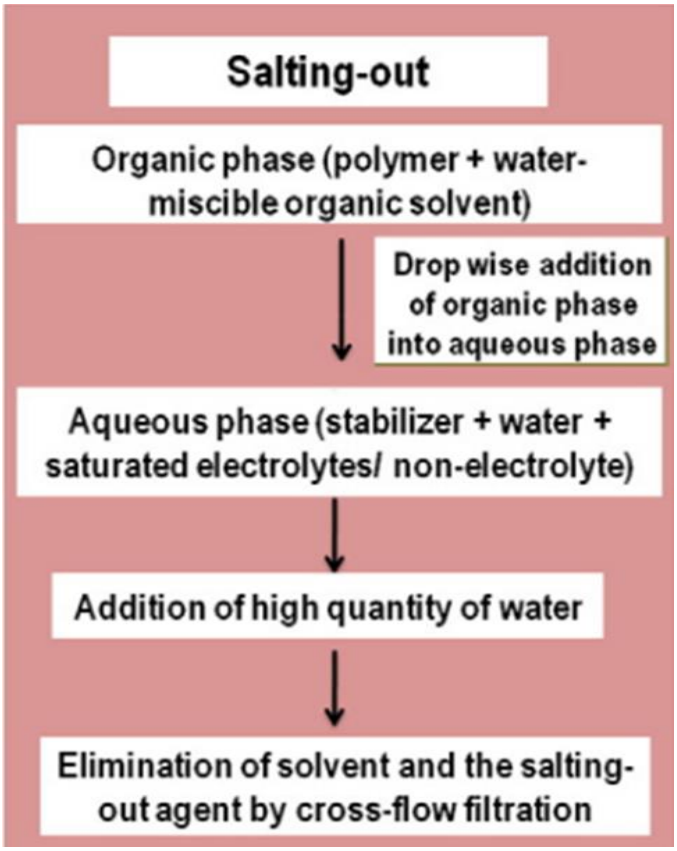
This method involves a mixture of two aqueous phases, of which one is the polymer Chitosan, a diblock co-polymer ethylene oxide or propylene oxide and the other is a polyanion sodium tripolyphosphate. In this method, positively charged amino group of Chitosan interacts with negative charged tripolyphosphate to form coacervates with a size in the range of electrostatic interaction between two aqueous phases, However, in ionic gelation, the substance changes from a liquid to a gel due to ionic interaction conditions at room temperature.

It is a method for the encapsulation of macro-molecules such as insulin.[42] using natural polysaccharides;chitosan (CS) and gum arabic (GA). Naturally occurring polysaccharides, chitosan and gum Arabic, are essentially polycationic and polyanionic, respectively, and are biodegradable, biocompatibleand less toxic [43-45]

3. Emulsification Diffusion method :

- This method utilizes a partially water-soluble solvent like acetone or propylene carbonate. The polymer and the drug are dissolved in the solvent and it is emulsified in the aqueous phase containing the stabilizer. The stabilizer was added because it prevents the aggregation of emulsion droplets by adsorbing of the of the droplets.
- Addition of water to the emulsion, allow the diffusion of the solvent into the water. The solution is stirred leading to the nano precipitation of the particles. Further it can be collected by centrifugation, or the solvent can be removed effectively by dialysis.
- The main disadvantage with this method is that the water soluble drugs tend to escape the polymer phase throughout the diffusion

process. Therefore, the dispersing medium was modified from an aqueous medium to avoid this issue. to medium chain triglycerides and a small amount of surfactant is added to it. The nanoparticles are collected by centrifugation [46].



Salting out method:

Salting out method: It is based on the separation of a water miscible solvent from aqueous solution via a salting out effect. The salting out procedure can be considered as a modification of the emulsification/solvent diffusion. Initially polymer and drug are dissolved in a solvent such as acetone, which is subsequently emulsified into an aqueous gel containing the salting-out agent (electrolytes, such as magnesium chloride, calcium chloride, and magnesium acetate, or non- electrolytes such as sucrose) and a colloidal stabilizer such as polyvinylpyrrolidone or hydroxyethylcellulose.

This oil/water emulsion is diluted with a sufficient volume of water or aqueous solution to enhance the diffusion of acetone into the aqueous phase, thus inducing the formation of nanospheres [49].

The selection of the salting out agent is important, because it can play an important role in the encapsulation efficiency of the drug. Both the solvent and the salting out agent are then eliminated by cross-flow filtration. This technique used in the preparation of PLA, poly (methacrylic) acid, nanospheres leads to high efficiency and is easily scaled up. The main advantage of salting out is that it minimizes stress to protein encapsulants [50]. Salting out does not require an increase of temperature and therefore, may be useful when heat sensitive substances have to be processed. The greatest disadvantages are exclusive application to lipophilic drugs and the extensive nanoparticle washing steps [51].

5. Supercritical fluid technology:

- Traditional techniques including solvent diffusion, solvent extraction-evaporation, and organic phase separation procedures need the use of enormous amounts of organic solvents which are hazardous to the environment as well as to human beings.

- Therefore, the synthesis of biodegradable micro- and nono nanoparticles has been explored using supercritical fluid technology as an alternative.

- Supercritical fluids are environmentally safe. [30]. A supercritical fluid can be generally defined as a solvent at a C temperature above its critical temperature, at which the fluid remains a single phase regardless of pressure. The most popular supercritical fluid is supercritical CO2 (SC CO2) because of its mild critical conditions (Tc = 31.1 °C, Pc = 1 as 73.8 bars), nontoxicity, non-flammability and low price. The most common processing techniques involving supercritical for fluids are supercritical anti-solvent (SAS) and rapid expansion of critical solution (RESS).

- The process of SAS employs a liquid solvent, e.g. Methanol can dissolve because it is totally miscible with the supercritical fluid (SC CO2). this solute to be micronized; at the process conditions, because the solute is insoluble in the supercritical fluid, the extract of the the liquid solvent by supercritical fluid leads to the or instantaneous precipitation of the solute, resulting the formation of nanoparticles. The solvent power of supercritical fluids dramatically decreases and the solute on eventually precipitates. Since there is essentially no solvent in the precipitate, this method is clean, RESS and its modified process have been used for the product of polymeric nanoparticles [52].

❖ **Characterization of Polymeric nanoparticles:**

Successful preclinical development depends on these nanomaterials being thoroughly characterized. The physicochemical characteristics of the particles affect physiological interactions, therefore predicting how well the PNPs will function in the body requires a thorough understanding of them.

❖ **SEM:**

It is used as a surface imaging technique to study nanoparticles. SEM involves an electron beam interacting with the sample, generating signals that reflect the sample's atomic composition and surface morphology. Backscattered and secondary electrons are used to create a 3D image of the sample. Because organic nanoparticles do not deflect electron beam sufficiently, they are not easily visible to electron microscopy. To overcome this, coating the nanoparticles with a thin layer of metal to make them conductive while preparing the sample, which improves imaging quality. SEM provides valuable information about the size, size distribution, and morphology of nanoparticles. However, it has limitations, such as destructive sample preparation and potential bias in statistics due to heterogeneous samples.[53]

❖ **TEM:**

It is a 2D imaging technique that uses electrons transmitted through the sample to form an image. It offers sub-nanometre resolution, allowing for the observation of the nanocarrier's internal structure and for evaluating the thickness of the polymeric wall of nanocapsules.[54] In a study, using TEM, The membrane thickness of the emulsion-

diffusion method produced PCL nanocapsules that ranged in size from one to two nanometers. Organic materials may sustain structural damage as a result of local heating brought on by the kinetic energy absorbed during imaging, and the ideal specimen thickness for TEM is approximately 100 nm. Cryo-TEM, which enables the investigation of frozen-hydrated nanoparticle structures with These problems can be fixed with very minor sample changes, making it a useful technique for researching organic nanoparticles [55].

❖ **FT-IR**:

To examine the structural attributes of nanoparticles (PNPs) and the molecular interactions between drugs and encapsulating polymers, Fourier Transform Infrared (FT-IR) and Raman spectroscopy are utilized as vibrational spectroscopies. FT-IR relies on periodic variations of dipole moments, while Raman spectroscopy is based on periodic shift in the polarizabilities due to specific molecular vibrations within molecules or atomic groups [56]. These methods complement each other, with FT-IR capturing strong vibrations and Raman offering weaker signals. FT-IR and Raman spectroscopy are beneficial for confirming the presence of established compounds in the fingerprint range and detecting impurities or unexpected interactions based on characteristic functional groups [57].

❖ **Particle Size, Particle Size Distribution, and Zeta Potential [58-61]**

The particle size and particle size distribution of the nanoparticle formulation was determined by photo correlation spectroscopy with a zeta master, in which every sample was diluted with distilled water. The surface charge (Zeta potential) was determined by measuring the electrophoretic mobility of the nanoparticles using a Malvern zeta sizer. Samples were prepared by diluting with distilled water.

❖ **Polydispersity Index:**

It is a parameter to define the particle size distribution of nanoparticles obtained from photon correlation spectroscopic analysis. The autocorrelation function is used to extrapolate this dimensionless number, which varies from 0.01 for monodispersed particles to 0.5-0.7 Samples with very broad size distribution have polydispersity index values > 0.7.

❖ **Entrapment Efficiency:**

A UV spectrophotometer set to 254 nm was used to measure the amount of drug in the clear supernatant following centrifugation in order to evaluate drug entrapment. This was accomplished by producing a standard medication calibration curve. Subtracting the amount of drug in the supernatant from the total amount of drug added during preparation (W) was the next step. Effectively, the amount of medication trapped in the particles may be determined using (W-w).

Then percentage entrapment of a drug was calculated according to Equation i,e

$$\% \text{ Drug Entrapment} = (W-w/W) \times 100$$

❖ **Loading Efficiency:**

By using 0.1 M hydrochloric acid to remove the drug from the nanoparticles, the preparation's drug content was ascertained. The drug content was ascertained by filtering the 50 mg of nanoparticles through a Millipore filter after they had been agitated in 50 ml of 0.1 M hydrochloric acid until they had dissolved, after suitable dilution, at 254 nm by UV spectrophotometry. The loading

efficiency (L) of the nanoparticles was calculated according to Equation i.e

$$L\ (\%) = \times 100\ (Qn / WN)$$

Where Wn is the weight of the nanoparticles and Qn is the amount of drug present in the nanoparticles.

❖ **In vitro release profile: [62-64].**

Franz diffusion cells that had been modified were used for in vitro release experiments. Before being mounted in a Franz diffusion cell, the dialysis membrane was soaked in double-distilled water for 12 hours. It had a pore size of 2.4 nm and a molecular weight cut off of 12,000–14,000. The donor compartment was filled with a volume equal to 6 mg of the practically estimated rivastigmine-loaded PNPs formulation, while the receptor compartment was filled with 10 ml of PBS. A magnetic stirrer was used to agitate the cell's contents at 370C. Using a side tube, aliquots were taken out of the receiver compartment every hour for a total of twelve hours. To maintain a steady volume, fresh PBS media was substituted each time. UV visible spectroscopy was used to evaluate the samples at 263 nm.

❖ **Drug-release kinetics [65,66]**

The drug release data was subjected to various analyses like Zero-order, First-order, Higuchi, Hixson Crowell model and Korsmeyer-Peppas.

Applications of Polymeric nanoparticles:

1. Biodegradable PNPs have exhibited therapeutic potential for precise drug delivery applications for the cure of cancer and advanced diagnosis. Targeted PNPs have been utilized for efficient transfer of chemotherapies to tumor cells with less damage to the healthy tissues. They are utilized to deliver a variety of medicines in a constrained way, such as antihypertensive agents, anticancer agents, hormones, immunomodulatory drugs and vitamins [68].

2. The polymer-based nanocarriers may enhance the bioavailability of poorly water-soluble drugs and provide their sustained release [69, 70].

3. The polymeric nanoparticle is an approach to improve insulin absorption from the gastrointestinal tract. Synthetic or natural polymeric materials modulate insulin release and consequent pharmacological activity. Insulin-loaded nanoparticles, which are prepared by using biodegradable polymers such as poly(lactide-co-glycolide), polyanhydride, and polyalkyl cyanoacrylate are absorbed from the intestinal epithelial cells and transport insulin through the intestinal mucosa [71].

4. The enteric coating technique has been applied to insulin oral delivery in which the enteric coating polymers possess a pH dependent property . Polyacrylic polymers (e.g., Eudragit L100-55 and Eudragit S100) and cellulosic polymers (e.g., hydroxypropyl methyl cellulose phthalate) have been widely used for this purpose [72, 73].

5. Polymeric nanoparticles stand out due to their high encapsulation efficiency of lipophilic drugs, protection against drug degradation and low irritation due to its polymeric coating. The polymeric nanoparticles may also be capable to generate sustained drug release, possibly leading to the increase of drug residence time and numbers doses necessary for treatment [74].

6. The polymers such as polylactic acid (PLA), polyglycolic acid (PGA), poly-e-caprolactone (PCL) are biodegradable and biocompatible which has the ability to control the drug release, promote high drug encapsulation efficiency, and improve the bioavailability. Among three above mentioned

polymers, the polymer polycaprolactone (PCL) which has been extensively used to obtain control drug release and it can be used for intravenous administration [75, 76].

7. The Polymeric Nanoparticles as Nutraceutical Agents: Polymeric nanoparticles are mostly referred to as pharma-foods, a powerful toolbox to be used as a complement to the diet and before prescribing drugs, in order to improve health and prevent and/or treat pathologic conditions. Subjects could be people who may not yet be eligible for conventional pharmaceutical therapy [79].

8. Polymeric nanoparticles are also used in the treatment of eye diseases, for example: Montmorillonite-based Polymeric nanoparticles were created to treat glaucoma by releasing drugs in a regulated manner.

Future perspective:

Applications for polymer-based nanomedicine are numerous and have a long history. The shift from lab-scale proof of concept research to reproducible, precisely physicochemical, and high-yielding manufacture of usable nanomaterials is arguably one of the most significant difficulties related to nanoparticles. Furthermore, some nanomaterials are never going to make it to clinical testing. If the regulatory standards for clinical trials and the essential characteristics that make a polymer appropriate for biological application (biodegradable, stable, non-cytotoxic, and well defined) are met, this could be somewhat circumvented and they were taken into account. Nanomedicine offers a great opportunity for improvement of current therapies and development of novel therapeutic approaches for illnesses that were previously seen as incurable or difficult to cure. Even though there has been a lot of research on therapeutic nanoparticles recently, An important drawback of nanoparticle-based drug delivery systems is the rapid initial or burst release, which is frequently explained by the drug component being adsorbed or only loosely attached to the surface of the nanoparticle.[35] First, the number of polymeric materials currently available for their utilization as DDS is still limited although the R&D has been moved in the last decade, exceeding expectations, from the micro- to the nanosize scale [78].

CONCLUSION:

This review's primary objective was to outline the many accessible preparation methods for production of polymeric nanoparticles. It was noted that PNP preparation is a cutting-edge technology that calls for an appropriate approach from the range of potential approaches. Nowadays, it is possible to create drug-loaded nanospheres or nanocapsules using straightforward, secure, and repeatable methods. The optimum preparation technique and polymer to create nanoparticles with the necessary size range and good drug entrapment effectiveness can be chosen based on the physicochemical properties of the drug.

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Abbreviations:

1	%	Percentage
2	°C	Degree of celsius
3	ΔH	Change in temperature
4	Λmax	Absorption maxima
5	±SD	Standard deviation
6	%CDR	Cumulative drug release
7	Mgm	microgram

8	µm	micrometer
9	%w/w	Percentage weight by weight
10	BCS	Biopharmaceutical classification system
11	Cm	Centimeter
12	DEE	Drug entrapment efficiency
13	DLS	Dynamic light scattering
14	DMF	Dimethyl formamide
15	DSC	Differential scanning calorimetry
16	FE-SEM	Field emission scanning electron microscopy
17	FC	Fenoprofen calcium
18	FNP	Fenoprofen nanoparticles
19	FT-IR	Fourier transform infrared radiation
20	g/cc	Gram per cubic centimeter
21	g/cm^3	Gram per cubic centimeter
22	HCL	Hydrochloric acid
23	Hrs	Hours
24	IR	Infrared radiation

Conflicts Of Interest:

The authors declare no conflict of interest

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Not Applicable

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