International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 5 Sep-Oct 2021, pp: 578-592 www.ijprajournal.com ISSN: 2249-7781

NANOPARTICLES - Preparation, Polymer, Types, Applications , and Nano-toxicities in Novel Drug Delivery System:A Review.

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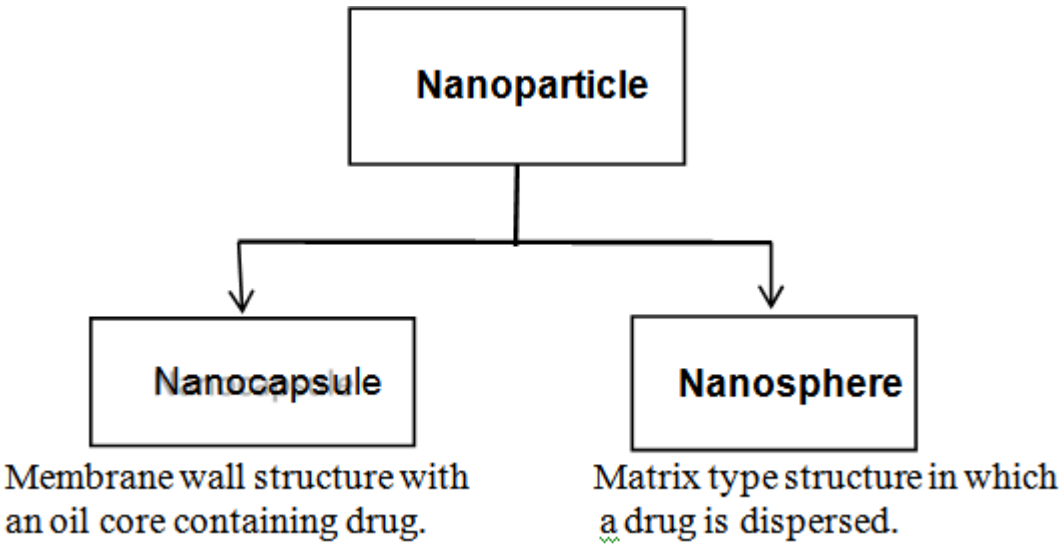
Date of Submission: 15-09-2021 Date of Acceptance: 28-09-2021

ABSTRACT :
Nanoparticles are at the leading edge of the rapidly developing field of the nanotechnology . A decade ago, nanoparticles were studied because of their size- dependent physical and chemical properties. In recent years , the development of nanoparticles has expanded into broad range of clinical applications. Nanoparticles have become an important area of research in the field of drug delivery because they have ability to deliver a wide range of drug varying areas of body. This review is provided a detail overview of the preparation, polymer , types and application of nanoparticles(NPs) exist in different form. As the safety of nanoparticles is a high priority, we also discuss the nanotoxicity and applications of nanoparticles .

Keywords : Nanoparticles , Nanotechnology , Novel drug delivery , Polymer, Nanoprecipitation , Nanocapsule , Solid-lipid nanoparticles(SLN) , Nanotoxicity.

I. INTRODUCTION

Nano derives from the Greek word ,'Nanos' which means dwarf or extremely small. It can be used as a prefix for any unit to mean a billionth of that unit. A nanometer is billionth of a meter or 10^{-9}m. Nanoparticles are solid colloidal particles ranging from 1 to 1000nm in size, they consist of macro-molecular materials in which the active ingredients (drug or biologically active material) is dissolved, entrapped, or encapsulated, or adsorbed. The term 'nanoparticles' stands for nanocapsules and nanospheres, which are distinguished by the structural morphology.



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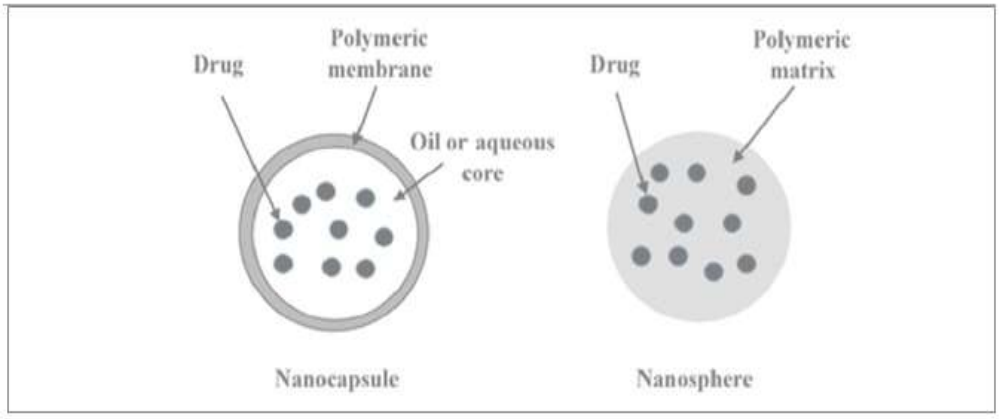
Volume 6, Issue 5 Sep-Oct 2021, pp: 546-556 www.ijprajournal.com ISSN: 2249-7781



For an increase in their activity, NPs can be coated with several coating agents, surface stabilizers, surfactants , polymers can be used as coating agents. These capping agents helps to stabilize the NPs against agglomeration.[1]. The material which are used for the preparation of NPs should be non-toxic, biodegradable, sterilizable, etc. NPs have been developed to overcomes limitations of free therapeutics and navigate biological barriers- systemic, micro-environmental and cellular- that are heterogeneous across patient populations and diseases.[2].

II. PREPARATION METHOD OF NANOPARTICLES

Preparation method of nanoparticles can be classified as follows :

1. Dispersion of performed polymer
2. Polymerization method

1) Dispersion of performed polymer

It includes-

A) Solvent evaporation method
B) Spontaneous emulsification / Solvent diffusion method C)Salting out / Emulsion diffusion
D)Non-aqueous phase separation E)Nanoprecipitation

A) Solvent evaporation method :

In this method, the drug is dissolved, dispersed or emulsified into an organic polymer solution, which is then emulsified into an external aqueous or oil phase.The **microsphere** are formed after solvent evaporation . This method allows the creation of nanospheres.[3].One of the strongest and highly directional field.[4].

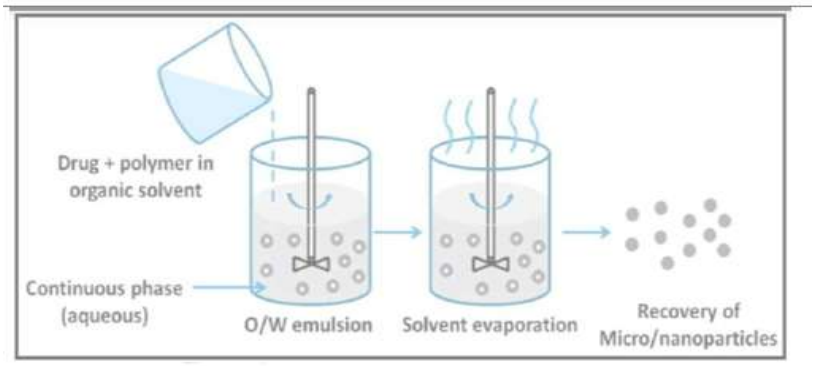


Fig: solvent evaporation method[5}

B) Spontaneous emulsification /solvent diffusion method :

This is modification of the solvent evaporation technique. In this method,water-miscible solvent such as methanol are used as the organic phase-I and water- immiscible solvent such as chloroform are used as the organic phase- II. When these two phases are mixed,then create the

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 5 Sep-Oct 2021, pp: 578-592 www.ijprajournal.com ISSN: 2249-7781

inter-facial turbulence that leads to formation of **Nps.**[6]

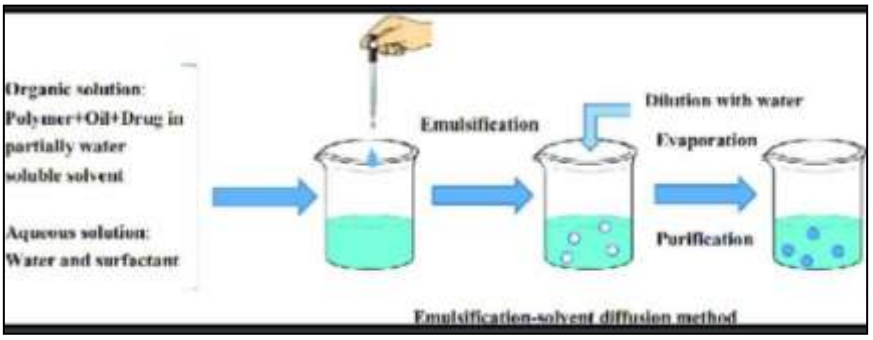


Fig: Spontaneous emulsification / Solvent diffusion method[7]

C) Salting out :

This method also known as emulsion diffusion method. In this method drug and polymer are dissolved in organic solvent miscible in water and the resultant solution is added to aqueous solution containing the salting out agent and stabilizer under constant stirring .[8]

Salting out agent- Isopropyl achohol ,acetonitrile, acetone, magnesium, sulphate, sodium chloride, calcium chloride, potassium carbonate.[9]

This salting out agents prevents the miscibility of organic solvents in aqueous phase resulting in formation of emulsion. The dilution of emulsion with access amount of water leads to reverse salting out effect and this effect leads to precipitation of polymer , which encapsulates the drug in polymer matrix results in the formation of **NPs** .[8]..The dimension of the nanospheres obtained by this method vary between 170 and 900nm.[10].

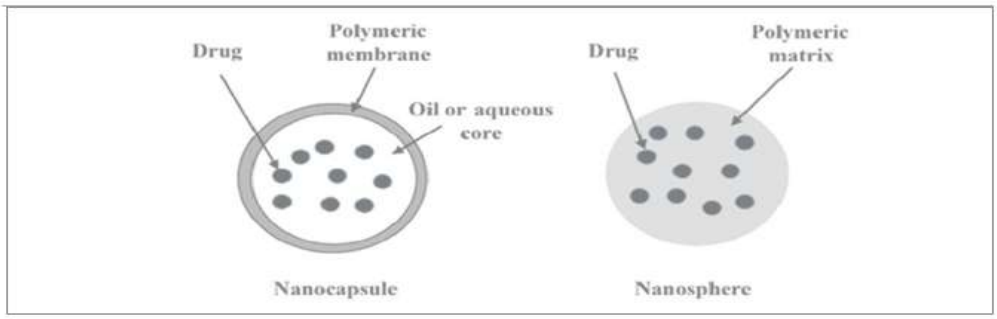


Fig : Salting out method[11]

D) Non-aqueous phase separation method :

This method is suitable for both water soluble(hydrophilic) and lipid soluble(lipophilic) drugs. Generally, the hydrophilic drugs are dissolved in water and then added to the organic phase on the other hand , the hydrophilic drugs are dissolved in a polymer solution . Once the aqueous phase and organic phase are mixed to form emulsion. Add silicon oil under vigorous stirring.(Note- Silicon oil is miscible with the first organic phase but does not dissolve the drug). This results in the extracting of the first organic solvent which causes the decrease in the solubility of polymer followed by phase separation and formation of polymer coacervate.This polymer coacervate adsorbs on to the drugs molecule to form drug loaded **NPs**[6]..

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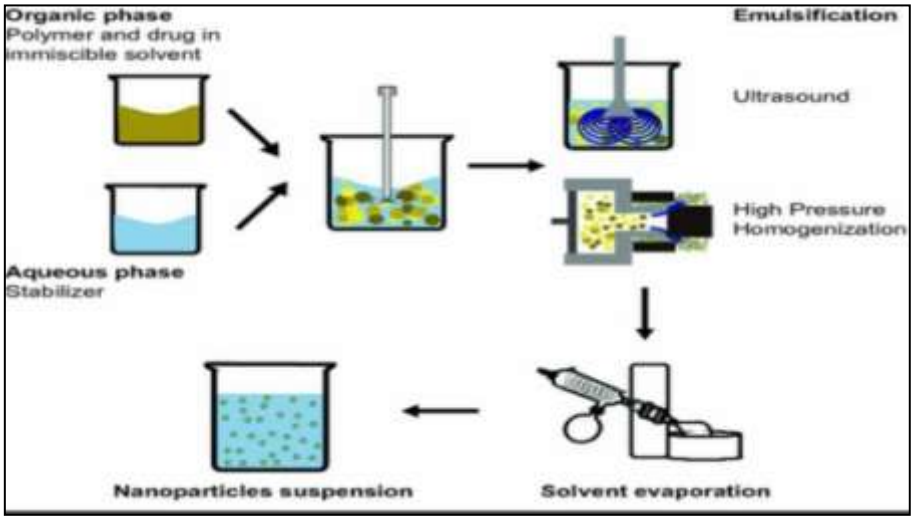

Fig: Non-Aqueous phase separation

E) Nanoprecipitation :

Nanoprecipitation method is also called as solvent displacement or inter-facial deposition method .Which was first developed and introduced by fessi's group.[12].

In nanoprecipitation method an organic solution of the polymer is emulsified in an aqueous solution(with or without surfactant). Then the organic solvent is removed by stirring(with or without vacuum) and this process allows **NPs** formation.[13].

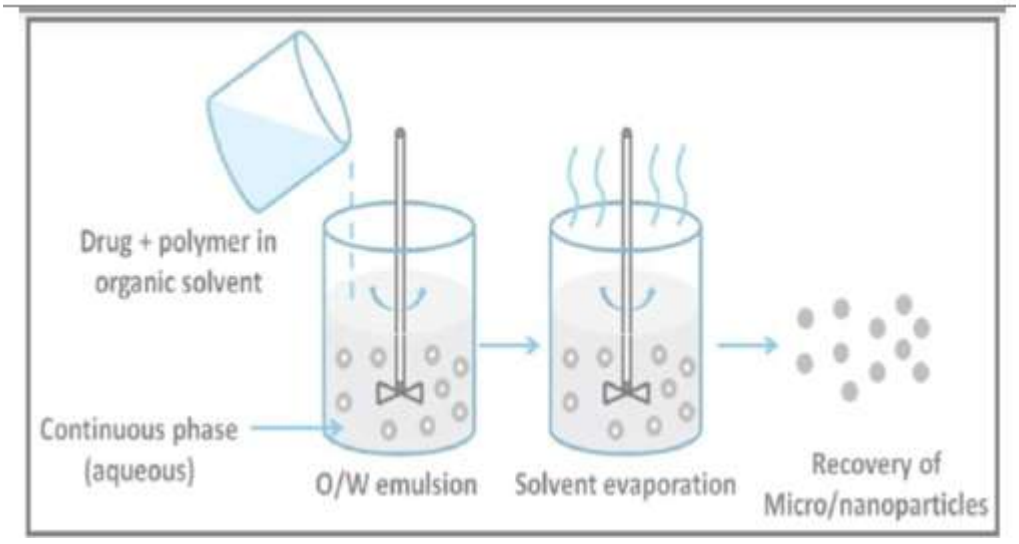

Fig: Nanoprecipitation[14]

2)Polymerization method :

A) Emulsion polymerization :

This method involves emulsification of monomer in non-solvent phase [15].It may be conventional or reverse depending upon nature of continuous phase.

❖ Conventional method = Aqueous phase in continuous.

❖ Reverse method = Organic phase in continuous

Monomer is emulsified in non- solvent partially soluble phase with stabilizer, leading to formation of monomer swollen micelles. Polymerization takes place in present of initiator (chemical or physical), which provides energy to

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monomer , so that in becomes free reactive radical .It colloids with the surrounding unreactive monomers , and initiates the polymerization reaction . It continues till concentration of monomer / initiator is consumed. Mechanism is micellar polymerization where swollen monomer micelles nucleation and polymerization. As monomer is slightly soluble in surrounding phase , it diffuses from monomer droplets and reach monomer micelles through continues phase , thus **polymerization** takes place in micelles .[16].

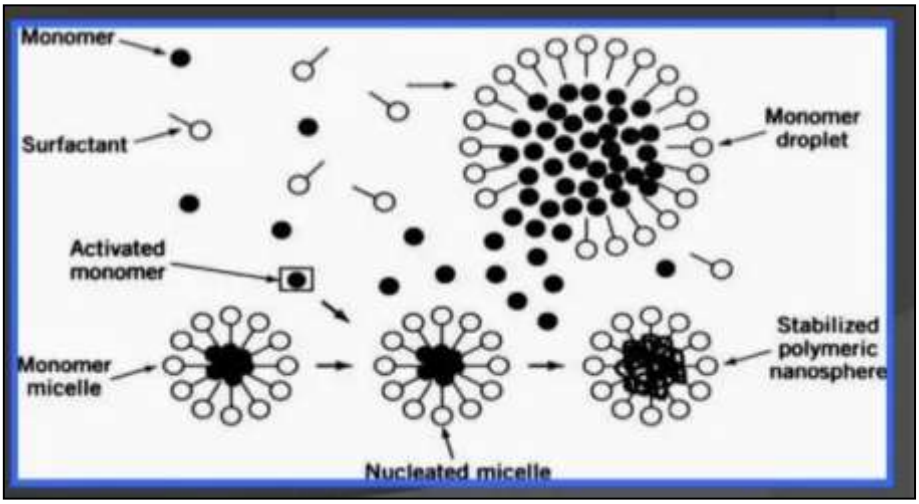

Fig : Emulsion polymerization

III. POLYMERS FOR NANOPARTICLES

Natural hydrophilic polymers

A) Proteins	B) Polysaccharides
-Gelatin	-Alginate
-Albumin	-Dextran
-Lectins	-Chitosan
-Legumin	-Agarose

A) Proteins **B) Polysaccharides**
-Gelatin -Alginate
-Albumin -Dextran
-Lectins -Chitosan
-Legumin -Agarose

A) Protein nanoparticles:

The first naturally occurring material used for the preparation of NPs consisted of albumin and gelatin . Among the colloidal system, those based on protein are very promising because they are biodegradable , less immunogenic and non-toxic .

- Gelatin nanoparticles (GNPs):

Gelatin NPs is a natural polymer derived from animal's collagen, which is more abundant available protein. The GNPs size obtained as particles with a typical size 5 to 40nm were produced .[17]. GNPs are very efficient in delivery and controlled release of drug , proteins and peptides.Gelatin is a poly-ampholyte consisting of both cationic and anionic groups along with a hydrophilic group.[18]. Its biomedical application including plasma expander, stabilizer in a no. of protein formulation, vaccines, and gelatin sponges.

- Albumin:

Albumin , a protein found in blood plasma , have always been a remarkable molecule owing to its manifold function and applications. These are

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bio-compatible, non-taxol, immnogenic and biodegradable protein. Transportation, metabolism and distribution of exogenous and endogenous ligands are the function of albumin circulatory system. It also has an ability to act as an important extracellular anti-oxidant and to impart protection from free radicals and other harmful chemical agents.[19].

B) Polysaccharides nanoparticles :

Polysaccharide based NPs have attracted considerable attention in broad range of application in recent years, because of their unique features such as biocompatability, biodegradability.[20]. NPs from naturally occurring polysaccharides were designed for the administration of peptides, proteins, and nucleic acid.[19].

-Alginate :

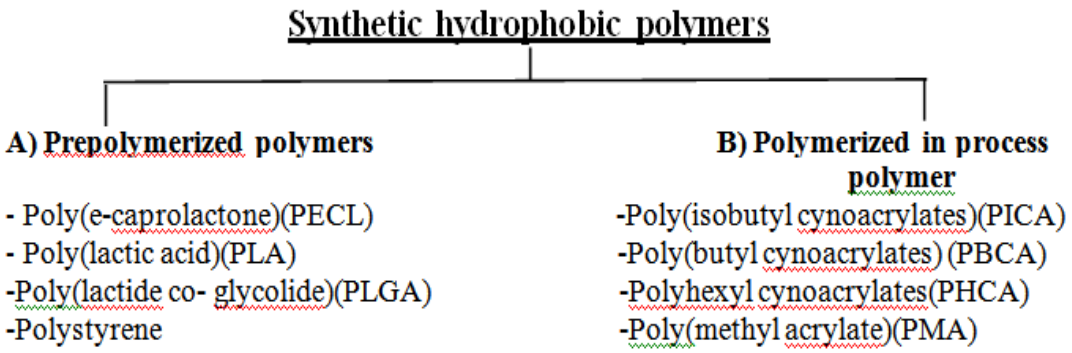
Alginate is a natural , biodegradable and mucoadhesive polymer that does not produce toxicity in administration.Alginate NPs as hydrophilic carriers prolong the antigen release and enhance the immunogenicity greater than traditional vaccine which is because of their adjuvant properties[21]. Also , alginate particles have not been observed agglomerate in any of the major organs. The solubility of alginate in water depends on the associated cations. Sodium alginate is soluble in water, whereas calcium induces the formation of gel.[19].

- Chitosan :

Chitosan is linear, hydrophilic , positively charged and has muco-adhesive property.It is an excellent bio-polymer for preparation of NPs owing to its excellent biocompatibilty and biodegradability .[19]. Chitosan show low toxicity and both in-vitro and some in-vivo models.[22]. Example will be given of chitosan-based NPs used for treatment of cancer , gastrointestinal diseases , pulmonary diseases, drug delivery to the brain and ocular infections.

Semi synthetic polymer :

Semi-synthetic polymer are the polymer made by modification of the properties of natural polymer.
Ex: Nitro-cellulose, cellulose-acetate etc. These are used in preparation of nanocapsules



A) Prepolymerized polymers:

This polymers are pre-polymerized from their monomers and therefore used for nanocarrier preparation.

-Poly(lactide co-glycoside)(PLGA):

Its is a biodegradable polymer and PLGA has been used for transdermal delivery of endomethacin , ketoprofen. PLGA is one of the best characterized biodegradable co- polymers that decomposes to non-toxic products(H_2O and CO_2), that are eliminated from the body.It has been approved the US-FDA to used in drug delivery system due to control and sustained release properties low toxicities and biocompatibilty with tissue and cells.[23].

- Poly(lactic acid)(PLA):

Poly lactic acid NPs (PLA) are a type of polymeric NP , frequently used a nonomedicines which have advantages over metallic NP such as ability to maintain therapeutic drug levels for sustained period of time.[24].PLA is a food and drug administration approved polymer that has proven to be a versatile material, with interesting properties such as biocompatibility and biodegradability.[25].

B) Polymerized in process:

These polymers synthesized from monomers during preparation of NPs.

-Poly(butyl cynoacrylates)(PBCA) :

PBCA NPs are ideal carriers for delivery of these

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drug due to biodegradability and ability to change bio distribution of drugs. Additionally , they are easy to prepare and need less of any sort of purification. PBCA NPs was widely distributed near injured sites together, our findings provide histological evidence that PBCA NPs can be used as an efficient delivery system for large molecule to overcome the barriers in brain with traumatic brain injury (TBI).[26].

IV. TYPES :

Various types of NPs applied in the drug delivery system.

Sr. No	Types of NPs	Material used	Application	Ref.
1.	Polymeric NPs	Biodegradable NPs	Controlled&Targeted drug delivery	**[27]**
2.	Liposomes	Phospolipid&cholesterol	Pharmaceutical and cosmoceutical application	**[28]**
3.	Lipid based NPs	Lipid and matrix containing soluble lipophilic molecule	Biomedical field as drug carrier and delivery and RNA release in cancer therapy.	**[29]**
4.	Nanosuspension and Nanocrystals	Drug powder is dispered in surfactant solution	Stable system for controlled delivery of poorly soluble drugs	**[30]**
5.	Solid-lipid Nanoparticles	Solvent liquid emulsifier and water/ solvent	Drug delivery, clinical medicines and research	**[31]**
6.	Polymeric micelles	Ampiphilic block co-polymers	Solubilization of poorly soluble molecules,sustained release and protection of encapsuled substance from degradation and metabolism	**[32]**
7.	Carbon Nanotubes	Metals , semiconductor	Gene and DNA delivery	**[27]**
8.	Nanoshells	Dielectric core covered by thin metallic shell	Target therapy, gene delivery, biomedical imaging, cancer imaging	**[33]**
9.	Metal NPs	Metals oxides/metals composites	Medical application such as drug delivery and antimicrobial activity.	**[34]**

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10.	Semiconductor particles	Core- shell material	Emerging technologies, energy conversion,imaging devices,detectors, photography.	**[35]**

V. ADVANTAGES OF NPS

- ✓ NPs are biodegradable, non-toxic and capable of being stored for longer periods.
- ✓ Active and passive drugs targeting can be achieved by manipulating the particle size and surface characteristics of NPs.
- ✓ Feasibility of incorporation of both hydrophilic and hydrophobic substances .
- ✓ NPs helps to achieve maximum therapeutic response with minimum adverse effects.
- ✓ NPs can be administered by parenteral, oral,nasal(or)ocular routes.
- ✓ Good protection of the encapsulated drugs.
- ✓ Increased bio-availability.
- ✓ Longer clearance time.
- ✓ NP drug carries have higher stabilities.
- ✓ Less toxicity.

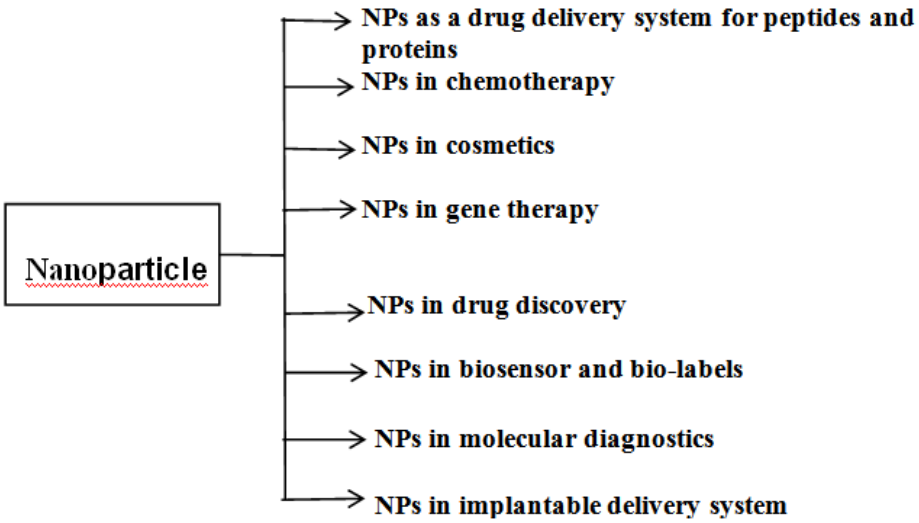
VI. DISADVANTAGES OF NPS

- ✓ Limited drug loading
- ✓ Susceptible to bursting and leakage of contents.
- ✓ Small size and and large surface area can be lead to particle aggregation.
- ✓ Extensive use of polyvinyl alcohol as a detergent- issues with toxicity.
- ✓ Cytotoxicity.
- ✓ The disturbance of autonomic imbalance by NPs having direct effect on heart and vascular function .
- ✓ Handling of NPs is difficult in liquid and dry forms
- ✓ Alveolar inflammation .
- ✓ Discontinuation of therapy is not possible .
- ✓ Pulmonary inflammation and pulmonary carcinogenicity.

VII. APPLICATIONS OF NANOPARTICLE TECHNOLOGY

Nanoparticles for pharmaceutical applications deals with emerging new technologies for developing customized solutions for drug delivery system. In addition , the drug delivery system should allow the drug to bind to its target receptor and influence that receptor's signaling and activity.[36].

-Applications of nanoparticle in Pharmaceutical field : [30]



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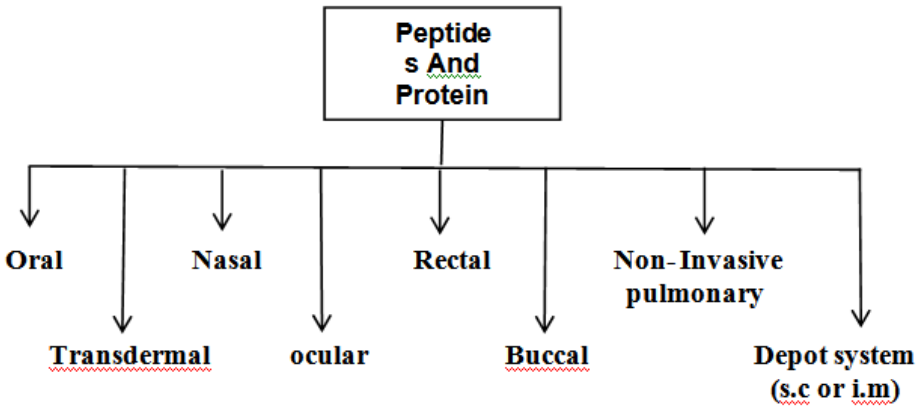
-NPs as a drug delivery system for peptides and proteins :

The proteins & peptides are increasingly seen as therapeutic drug ,as they are used for formulation in Solid- Lipid NPs confers improved protein stability, avoids proteolytic degradation as well as sustained release of the incorporated molecules . Important peptides such as cyclosporin A ,insulin, calcitonin & somatostatin have been incorporated into solid lipid particles.

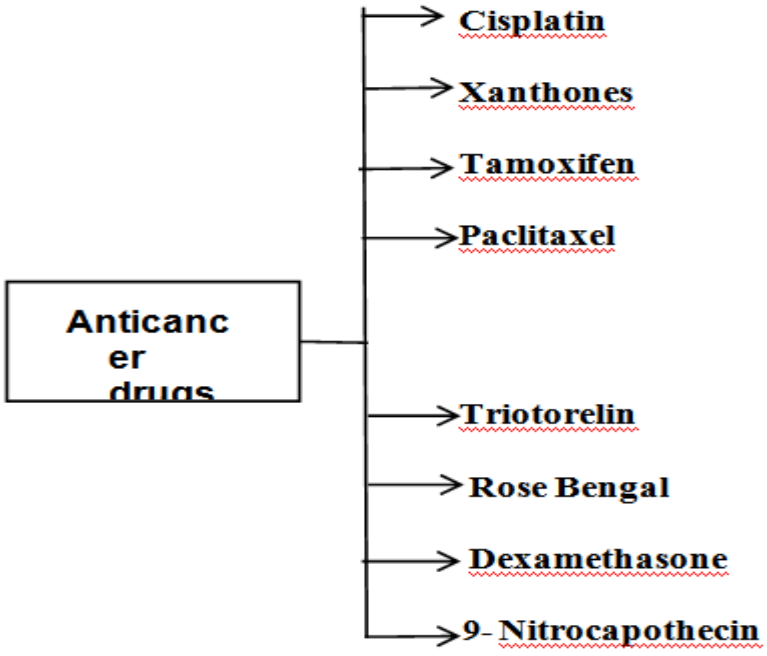
- delivery routes and novel technologies for therapeutic peptides and protein.[30].



-NPs in chemotherapy:

A new drug delivery technique may hold promise for efficient cancer therapies. The technique involves storing a cancer drug inside tiny object called NPs. Using this method we are able to shrink tumor in mice while using smaller doses of the drug to reduce harmful side effect.[37]..because of its smaller size, nanotechnology can detect changes in a very small no. of cell.It can tell the difference between normal and cancer cells.[38].The chemotherapy drug cisplatin is an effective killer.It used against half of the all human cancer.[37].

Encapsulation of various anticancer drugs in nanoparticles[30]:



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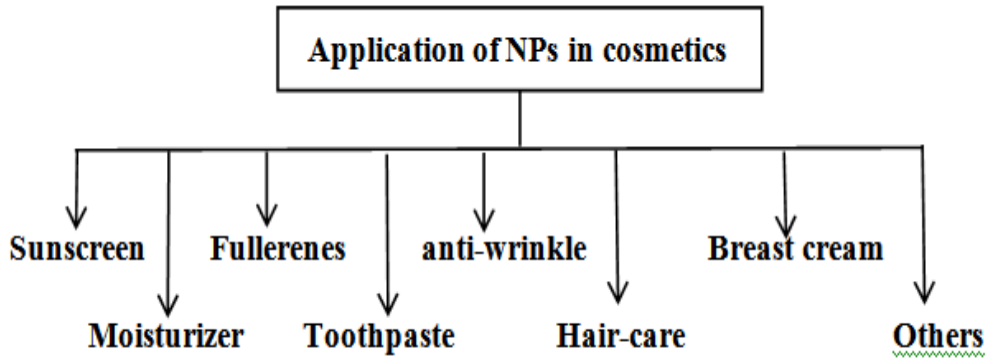
-NPs in cosmetics:

Nanotechnology in corporation in cosmetic formulation is considered as the hottest and emerging technology available. Cosmetics manufacturer use nanoscale size ingredients to provide better UV protection , deeper skin penetration , long lasting effect, increase colour , finish quality and many more.Micellar NPs is one of the latest field applied in cosmetic product. The most common type of nanomaterials that are use in personal care product are as follows:

-**Liposomes**(for their enhanced absorption by skin).
-**Nanoemulsions**(for their ability to prolong the shelf life of personal care products)
-**Nanocapsules**(for thier controlled release)
-**Solid-Lipid NPs**(for their enhanced UV blocking)
-**Nanocrystals**(for more effective passage through skin)
-**Nanosilver and nanogold**(for their enhanced anti-bacterial properties)
-**Dendrimers**(for better delivery of active agents)
-**Hydrogels**(for their prolonged effect on the place of application)
-**Buckminister fullerene, or buckyball**(for its potential to scavenge free radicals and slow down the aging process).
-**Cubosomes**(for their low cost and potential for controlled release)[38].



NPs keep natural sunscreen from leaving a white film on your skin. Zinc oxide and titanium dioxide work by reflecting UV rays away from the skin , shielding the skin from the sun.[39].

-Toothpaste-

Toothpaste may contain upto 3 different ingredients possibly present in the form of nano-size particles. Hydroxyapatite and titanium dioxides have been present in toothpaste for many decades to protect or whiten teeth. While the use of the third ingredient nanosilver is restricted to Asian countries .Several popular toothpaste brands do not contain NPs at all.[40].

-fullerenes-

Fullerene is a third form of carbon along with graphite & diamond. Fullerene are molecule with 60 atoms of carbon. Commonly denoted as C_{60} or.Carbon NPs (fullerene).Fullerene (also known as buckyball) exist as C_{60} or C_{70}. It can be used as anti-oxidant , anti-ageing. Anti-damage agent in cosmetic sector. They are investigated due to their capacity to absorb UV radiation and eliminate free radical.

Hair care-

Hair is a signal of youth, with hair quality being positively correlated with good health. Nanotechnology based innovations are aimed at improving the stability of cosmetic ingredients , enhancing the aesthetic appearance of products and targeting active ingredients to the focal structures with controlled release and sustained effects. NPs can be used to improve hair cosmesis- maintaining shine , silkiness, and health of the hair.Shampoo have have incorporated nanomaterial in order to optimize resident contact time with the scalp and the hair follicle, allowing active agents time to form a protective film, sealing moisture within the cuticles.[41].

Moisturizer-

SLNs, nanoemulsion , liposomes and niosomes are extensively used in moisturizing formulations as they form thin film of humectant and retain moisture for prolonged span.[42].

-Others-

Lip care- lip care products in nanocosmeceuticals comprise lipstick, lip balm, lip gloss, and lip volumizer.variety of NPs can be

International Journal of Pharmaceutical Research and Applications
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coalesced into lip gloss and lipstick to soften the lips by by impeding transepidermal water loss and also prevent the pigments to migrate from the lips and maintain colour for longer period of time. Lip volumizer containing liposomes increases lip volume , hydrates and outlines the lips and fills wrinkles in the contour.[42].

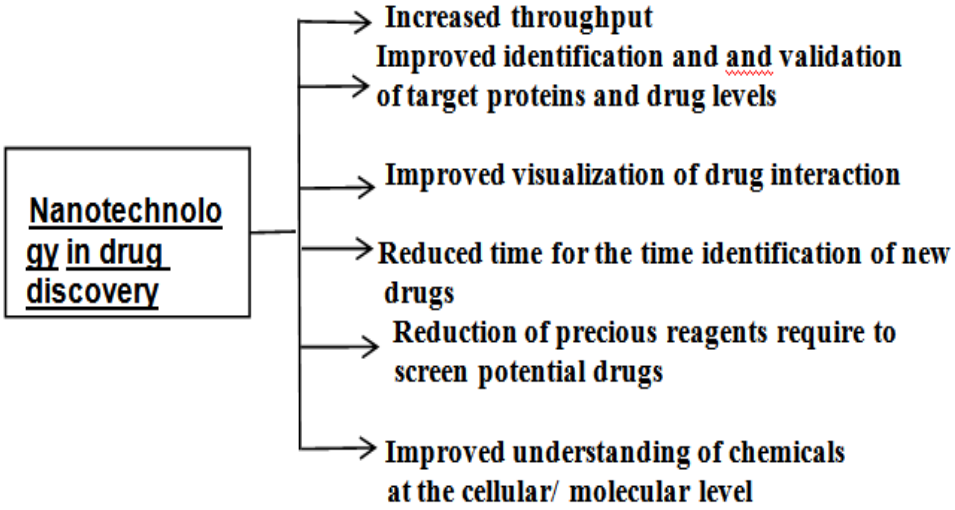
-NPs in biosensor:

A biosensor consists of four parts namely(1) bioreceptor,(2) a transducer, (3) a signal processor for converting electronic signal to a desired signal, and (4) an interface to display. A variety of samples and cells culture can be explored to analyze using Biosensor.[43].

Fig: Blood glucose Biosensor

NPs in Drug discovery :

In terms of drug discovery and development the role of Nanotechnology currently lies in improving diagnostic methods developing improved drug formulation and drug delivery system for disease therapy.



Segmentation of the nanotechnology market:

Nanotechnology can be broadly classified into 3 groups namely (Nano enabled tool, NPs , Nano enabled drug.) [44].

VIII. NANOTOXICITIES

Nanotoxicology is the study of the toxicity of nanomaterials. Because of quantum size effects and large surface area to volume ratio, nanomaterials have unique properties compare with their larger counterparts that affect their toxicity.Nanotoxicology is a sub-speciality of particle toxicology. Nanomaterial appear to have toxicity effect that are unusual and not seen with

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larger particles , and these smaller particles can pose more threat to the human body due to their ability to move with a much higher level of freedom.[45]

Composition:

- Metal-based NPs
- Carbon-based NPs
- Others- other class of nanomaterials include polymer such as nanocellulose and dendrimers.[45].

Mechanism of toxicity:

- Oxidative Stress
- Cytotoxicity
- Genotoxicity [45]

Routes of Administration:

- Respiratory
- Dermal
- GI[45]

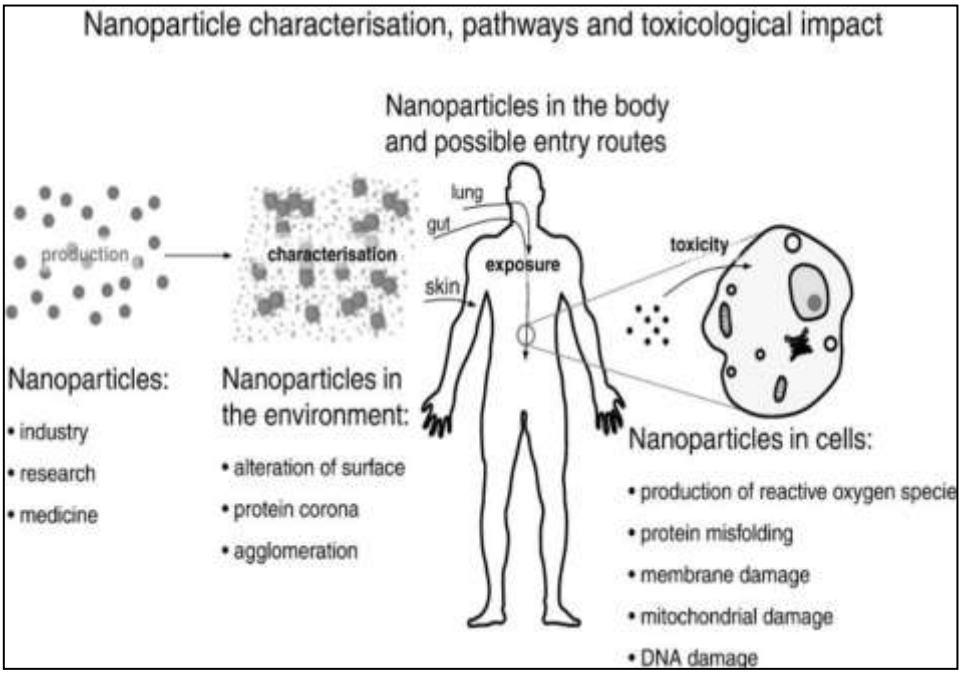

Fig: Routes of NPs in the body

Nanomaterials of different materials and their Toxicity:
NPs of metallic substances:

Substance	Use	Toxic effect
Aluminium oxide	Fuel cell, polymers,paints,coatings, textiles, biomaterials	Disturbs cell viability, alter mitochondrial function, increase oxidative stress, alter tight junctions, protein expression of BBB,cytotoxicity , and genotoxicity.
Copper oxide	Semiconductors, anti- microbial reagents heat transfer fluid, intrauterine contraceptive devices.	Impairment in Liver, kidney, spleen, genotoxicity, cytotoxicity, disturbing cell membranes,integrity and oxidative stress.

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Silver	Wound dressing, coating of surgical instruments and prostheses	Cytotoxicity, cell viabilty, generation of reactive oxygen species(ROS), and Lactate dehydrogenase leakage(LDL).
Zinc oxide	Paints, wave filter, UV detectors, gas sensors , sunscreen and many personal care products	Cytotoxicity, cellmembrane damage, oxidative stress, alteration in mitochondrial activity in human hepatocytes and embroynic kidney cells
Iron oxide	Biomedical, drug delivery diagnostic field	These NPs bioaccumulate in liver and other reticuloendothelial system organ, magnetic iron oxides have been observed to accumulate in liver,spleen, brain , and lungs alter inhalation
Titanium oxide	Food industries, UV filter in sunscreen,Paints, coating,Plastic, medicines	DNA damage, Genotoxicity, lung implantation,induce oxidative stress, they show toxic effect on kidney, spleen, liver, Glucose & Lipid homeostatis.

Nps of Non-Metallic substances:[46]

Carbon based Nanomaterial-

It posses size dependant cytotoxicity. Multiwalled carbon nano-tubes have produced carcinogenic effect. Single walled Carbon Nano-tubes in the liver has caused disturbance in certain biochemical parameters in the form of LDH.

Substance	Use	Toxic effects
Silica	Additive for the manufacturers of rubbers & plastics, medical imaging, drug delivery	NPs of silica cause the generation of ROS,and oxidative stress, alter the biochemical parameter along with hepatotoxic effects.

Others:

NPs of polymeric materials

It reported with least toxicity as it undergoes hydrolysis and produce biocompatible metabolities , lactic acid and glycolic acid .They are also consideres as Non- toxic , Non-immunologic .Non-Inflammatory & do not activate neutrophils.

Poly-(D,L-lactide -co-glycolide as nanosystem for targeted delivery of drugs and molecules.

It is used in Targed drug delivery in cancer chemotherapy, encapsulation of peptides, nucleic acid & proteins.[46]

IX .CONCLUSION

This review has discussed numerous NPs for therapeutic delivery and to overcome the toxicities found across patient populations and diseases.In the year to come, nanomaterials will innovate the world of technology due to their unique properties. The main approach of NPs is to make the novelty in the field of drug delivery. However , one important target area of NP research should be to reduce their toxic effect and enhance their bioavailability. NPs can clean up toxic chemical spills , as well as air-borne pollutants . Nanotechnolgy focuses on - to creating system, that can better deliver drug . to small areas within the

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body. Most of the Nano- based material commercially available in market are at the initial stage of the product life cycle.

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