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Review Article

A Review On Novel Drug Delivery System (Liposome)

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ABSTRACT

In Recent times, understanding of pharmacokinetic & pharmacodynamic behaviour of the drug has offer a more rational approach to the development of optimal drug delivery system. Now it's appreciable that in the future success in Drug delivery research will largely to be the result of multi displinary efforts. If any therapeutic agent that can be the more effective and safe using and improved drug delivery system represent both good marketing opportunities for pharmaceutical company and advancement in the treatment of Many diseases of human being. An ideally design of the drug delivery system delivers a specified amount of drug to the target at the particular site at an appropriate time and rate is reached or desired by the physiological needs of the body. Conventional Pharmaceutical Dosage forms are incapable of controlling the rate of drug delivery towards the target site. As a result the distribution of drug in non-target tissue and body fluids necessitate therapeutic doses that could far exceed the amount required in target cells, the higher doses often lead to serious adverse reaction during treatment thus, the novel drug delivery systems (NDDS) are such carriers which maintain the drug concentration in therapeutic range for longer period of time and also, in addition may deliver the required amount to the specific site of action as per requirements.

INTRODUCTION

A Novel drugdelivery systems is the new system advances in the understanding of Pharmacokinetic & Pharmacodynamic behaviour of the drug which offer a more rational approach to the development of optimal drug delivery system.

The novel drug delivary system[NDDS]are carrier which maintain the drug concentration in thereapeutic ranger fort longer time.

There are several advantages of novel drug delivery systems over conventional drug delivery,as follows.

1. Optimum therapeutic- drug concentration in the blood system or in a tissue may be maintained over a prolonged period of time.
2. Pre- determined rate of the drug which helps to extend drug action.
3. Short half- life drug may be increased

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4. By targeting the site of action, side effects may be decreased.
5. Frequent dosing and wastage of the drug may be reduced.
6. Better patient compliance.

There are Various drug delivery systems have been developed and some of them under development with an aim to minimize drug loss, to prevent from harmful side effects and to incresed drug bioavailability and also to favour and facilitate the accumulation of the drug in the required bio- zone (site). There are number Of Novel carries which have been established and documented to be useful for controlled and Sustained drug delivery. It is important to evaluate different terms used under the different broad categories of Novel drug delivery system

- **Sustained-**

or controlled- drug delivery systems provides drug action at a pre-determined rate by providing a prolonged or constant (Zero-order) release respectively, at the therapeutically effective levels in the circulation.

- **Localized drug delivery**

devices provide drug action through rate limiting drug release in the vicinity of the target.

- Pre-deternine rate of drug delivery provide drug action by change the release of drug molecules by system design which control the molecular diffusion of drug molecules in systemic circulation

Targeted drug delivery provides drug action by using carries either for passive or active diffusion or one base or self programmed approach, usually used with suitable sensory devices, which recognize their receptor at the targeted site.

Advantages of novel drug delivery system:-

1. Protection from physical and chemical degradation.
2. Sustained delivery.
3. Improved tissue macrophages distribution.
4. Enhancement of stability.
5. Enhancement of pharmacological activity.
6. Protection from toxicity.
7. Increased bioavailability.
8. Enhancement of solubility .

CLASSIFICATION OF SUSTAINED OR CONTROLLED RELEASE SYSTEM BASED ON THEIR RATE:-

Type of System	Rate Control Mechanism
1. Diffusion Control	
Reservoir Systems	Diffusion through membrane
2. Water penetration controlled	
Osmotic Systems (oros, alzet, osmotic, pump)	Osmotic transport of water through semi-permeable membrane
3. Chemically controlled	
Ion exchange resins	Exchange of acidic or basic drug with the ion presents on resins

Carrier system for the targeted and sustained drug delivery purpose may be classified on the basis of their nature, mechanism of drug release and nature of the drug . Diffusion occurs when bioactive agent is hydrophilic(water loving) and passes through the polymer, the key building block and controlled release concept. Many environmentally – responsive system are also designed that retains their content until appropriately placed in biological by an environment and are activated by an external or internal stimulus for the release of drug. Show the mechanism of drug release from various drug – delivery systems.

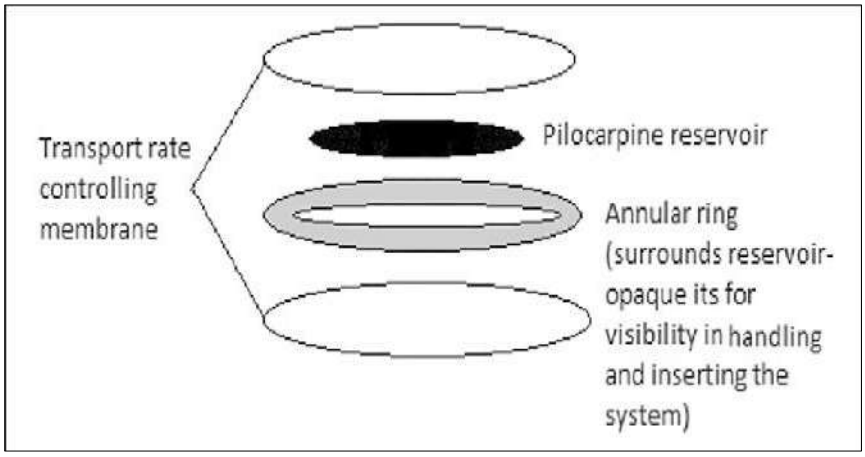
Reservoir :-

In the reservoir- type drug delivery systems, drug is encapsulated in the drug reservoir compartment

those drug – releasing surface is covered by a rate-controlling an embryonic polymer membrane. The drug in the reservoir compartments can be drug in liquid or solid type dispersion of drug in a liquid or solid type dispersion medium. The polymeric membrane can be fabricated from a homogeneous or heterogeneous non – porous polymeric material or semi- permeable membrane. The release of drug from this type of delivery system obtained at a nearly constant rate (Q/ t).

Ocusert:-

A truly continuous, controlled- release and zero – order kinetic release was achieved using ocusert. First marketed by Alza Corporation, California, the pilocarpine ocusert improved the non complience problems, low intra -ocular drug bioavailability and potential systemic side effect of pilocarpine. The systems consist of a pilocaroine-aliginate core of (drug) sandwiched between two transparent rate – controlling ethylene- venyl acetate co- polymerbased thin membrane. When this is placed under the upper eyelid, The pilocaroine molecules after getting dissolved in the lachrymal fluid are released through the rate controlling membranes at a pre determine rate. A mixture of pilocarpine and alginic acid in the drug reservoir releases the drug for up to one week. A thin membrane of ethylene venyl acetate (EVA) co polymer encloses the reservoir above and below. A retraining ring of the same material impregnated with titanium dioxide encloses the drug reservoir circumferentially.



DRUG DELIVERY NOVEL CARRIER FOR CONTROLLED & TARGETED:-

As per the knowledge of the molecular nature and pathophysiology of diseases has expanded, more therapeutically accurate and purpose specific drug are being developed. These newly prepared drug have high potency and required their localization of the particular site of their action. Most of the drugs are administrated by conventional immediate- release dosage forms. They distributed freely throughout the systemic circulation & accumulate the non – specific organs in an undesirable manner and hence produce adverse side effects. To reduce these slides and inhance their therapeutic benefits, they should be delivered to their respective site of action, and thus suitable carrier systems becomes mandatory requirement. Various novel carriers have been developed for the purpose Among these colloidal carriers such as liposomes, nano- particles & supra molecular system, i.e. micelles have gained more effect in the field of controlled and targeted drug delivery. Recently new carriers such as the inorganic particles, liquids crystal, aquasomes, carbon nano tubes, dendrimers etc. Are also investigated for the specialized purpose. In the following section, these carriers for the same purpose a brief. Mohd. Gayoor Khan2017

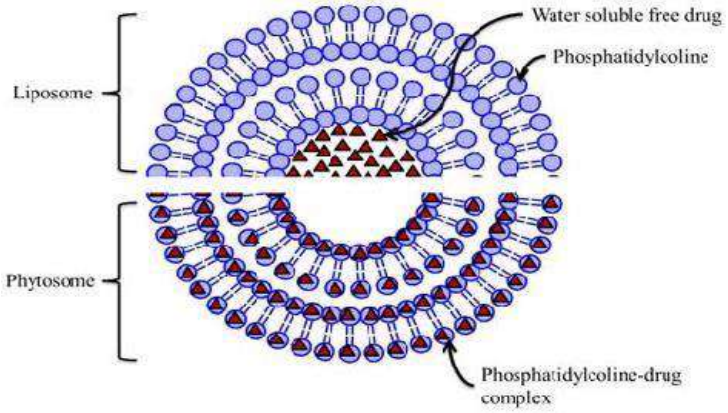
Recent developments in novel drug delivery system:-

1. Phytosome.
2. Liposome.
3. Nanoparticles.
4. Nanoemulsions.
5. Microsphere.
6. Ethosome.
7. Niosomes.
8. Proniosomes.
9. Solid liquid Nanoparticle.
10. Transdermal drug delivery system.
11. Dendrimers .
12. Liquid Crystal.
13. Hydrogels.

A. Phytosome:-

Phytosomes are phospholipids-primarily based totally drug delivery system has been determined promising for natural drug delivery. Complexing the polyphenolic phytoconstituents withinside the molar ratio with phosphatidyl choline consequences in a new natural drug delivery system, recognized as "Phytosome". The phytosome offer an envelope, like coating across the active constituent of drug and because of this the leader constituent of natural extract stays secure from degradation through digestive secretion and bacteria. Phytosome is correctly capable of absorb from a water loving environment into lipid loving environment of the cell membrane and finally achieving to blood circulation.It may be used with inside the treatment of various fatal diseases with out denaturing the active phyto compounds and improved bioavailability. Phytosomes show better pharmacokinetic and therapeutic profile than conventional herbal extracts.

Structure of phytosomes



Properties of phytosome: -

1. Chemical properties

A phytosomes is a complex between a natural product and natural phospholipids, like soya phospholipids. Such a complex consequences from the response of stoichiometric quantities of phospholipid with the chosen polyphenol (like easy flavonoids) in a nonpolar solvent. During the interaction there arise formation of hydrogen bonds between the polar groups of phospholipids and polarportion of the substrate molecule.

2. Biological properties

Pharmacokinetic and pharmacodynamic research in experimental animalsand in human topics have beenused to illustrate the biological behaviour of phytosomes.

Advantages of phytosomes :-

1. It enhances the absorption of lipid insoluble polar phytoconstituents via oral as well as topical path showing higher bioavailability, therefore significantly more therapeutic benefit.
2. Appreciable drug entrapment.
3. As the absorption of active constituent is improved, its dose requirement is also reduced.
4. Phosphatidyl choline utilized in preparation of phytosomes, except appearing as a provider

also acts as a hepatoprotective, therefore giving the synergistic impact while hepatoprotective materials are employed.

5. Chemical bonds are formed between phosphatidylcholine molecule and phytoconstituent, so the phytosomes show higher stability profile.

Phytosome Benefits :-

1. Improved phospholipid complex bioavailability.
2. Enhanced GIT absorption.
3. Improved therapeutic results are attributed to increased bioavailability.
4. High bioavailability requires less dosage.
5. Greater stability. More stability.
6. High lipophilicity causes high pene tration and is thus used over liposomes in cosmetics .

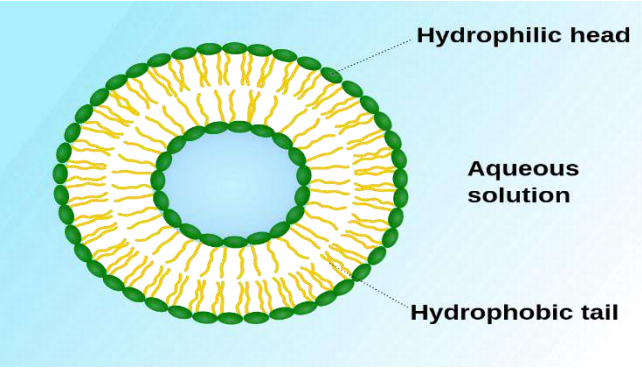
B. Liposomes:-

Liposomes are defined as shape consisting of one or greater concentric spheres of lipid bilayers separated by water or aqueous buffer compartments. Phospholipids are the main component of naturally occurring bilayers. These phospholipids include phosphatidylcholines (PC), phosphatidylethanolamines (PE) and phosphatidylserines (PS). Liposomes are composed of small vesicles of phospholipids encapsulating an aqueous space ranging from approximately 0.03 to 10 μm in diameter. Consisting of one or more concentric spheres of lipid bilayers enclosing aqueous compartments. Liposomes had been attracting growing attention as a drug provider for drug delivery systems due to the fact they could convey each hydrophilic compounds and lipophilic compounds. Liposomes are significantly used as carriers for numerous molecules in cosmetic and pharmaceutical industries. Additionally, meals and farming industries have significantly studied using liposome encapsulation to develop delivery systems that may entrap volatile compounds for example, antimicrobials, antioxidants, flavors and bioactive elements) and defend their functionality. Liposomes can trap each hydrophobic and hydrophilic compounds, keep away from decomposition of the entrapped combinations, and release then trapped at special targets .

Properties of liposomes:-

1. The system consists of structures of bimolecular sheets intercalated by aqueous space.
2. They are permeable to water.
3. They are osmotically sensitive.
4. Positively charged membranes are impermeable to cations and negative are highly permeable to anions.

Structure of liposome :-



Advantages of Liposome

1. Encapsulate each hydrophilic as well as lipophillic drug molecule.
2. Good solubilisation power.
3. Exhibit excellent colloidal, chemical and organic stability.
4. Reduce their uptake through macrophages.

5. Enhancing the therapeutic effectiveness of encapsulated drug.
6. Maintain therapeutic drug level into blood stream.
7. Provide safety of drug from environmental factors.
8. Promote the intracellular delivery of drug molecules.

C. Nanoparticles :-

Nanoparticles are described as particulate dispersions or solid particles with a length in the range of 10-1000nm.The drug dissolved, entrapped, encapsulated or connected to nanoparticles matrix. Nanoparticles (consisting of nanospheres and nanocapsules of size 10-200 nm) are withinside the solid state and are both amorphous or crystalline . Polymeric substances have been significantly used for the preparation of nanoparticles. Depending upon the method of preparation, nanoparticles, nanospheres or nanocapsules may be obtained. Nanocapsules are systems wherein the drug is confined to a hollow space surrounded by a completely unique polymer membrane, even as nanospheres are matrix systems wherein the drug is physically and uniformly dispersed. In current years, biodegradable polymeric nanoparticles, in particular those covered with hydrophilic polymer including poly (ethylene glycol) (PEG) called long-circulating debris, were used as cappotential drug delivery devices due to their ability to flow into for a extended duration time target a selected organ, as carrier of DNA in gene therapy, and their ability to supply proteins, peptides and genes.

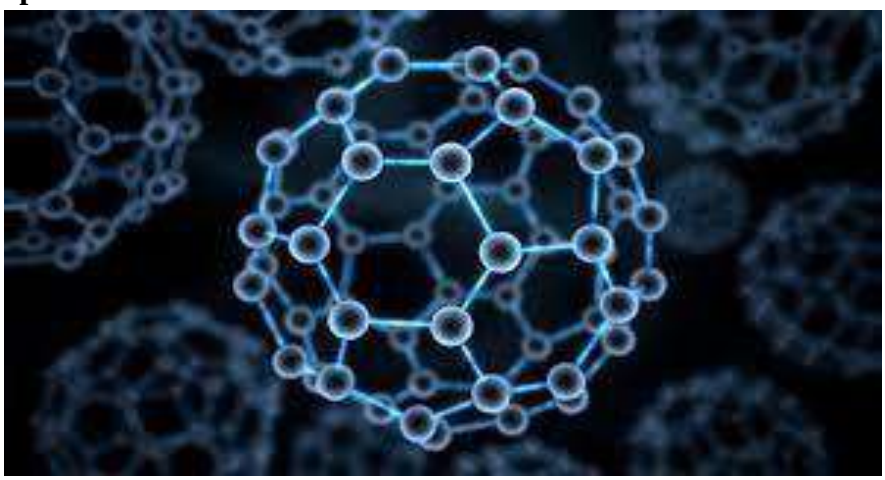
Advantages of nanoparticles :-

1. They are biodegradable,nontoxic, site precise and able to being saved for as a minimum one year.
2. They provide managed rate of drug release and particle degradation characteristics that may be comfortably modulated with the aid of using the selection of matrix constituents.
3. They provide higher therapeutic effectiveness and usual pharmacological response/unit dose.
4. Nanoparticles will increase balance of drug/proteins against enzymatic degradation.
5. They are able to concentrated on a drug to a particular site withinside the body by attaching targeted ligands to surface of particles.
6. Drug loading is excessive and drugs may be integrated into the systems with none chemical reaction; that is an essential issue for keeping the drug activity.

Properties of nanoparticles :-

1. The excessive surface region to extent ratio of nanoparticles offers a tremendous using pressure for diffusion, specially at increased temperatures. Sintering can take place at lower temperatures, over shorter time scales than for large particles.
2. Nanoparticles also regularly own unexpected optical properties as they're small sufficient to restrict their electrons and convey quantum effects. For example, gold nanoparticles seem deep red to black in solution.
3. Suspensions of nanoparticles are feasible because the interaction of the particle surface with the solvent is powerful enough to overcome density differences, which in any other case typically bring about a material both sinking or floating in a liquid.
4. Nanoparticles with one-half hydrophilic and the other half hydrophobic are termed Janus particles and are specifically powerful for stabilizing emulsion.[2] Miss Pranali P At all .2022

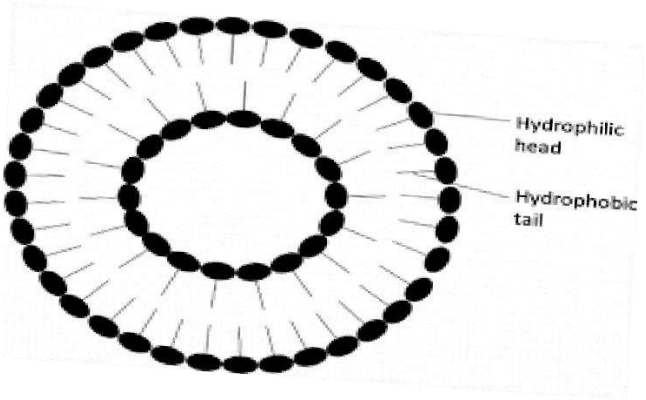
Structure of nanoparticle :-



D. Niosomes:-

Niosomes are multilameller vesicular shape of non-ionic surfactants, just like liposomes and are composed of non-ionic surfactant rather than phospholipids that are the additives of liposomes. Niosome or non-ionic surfactant vesicles at the moment are extensively studied as an opportunity tool to liposome. Various styles of surfactants were stated to form vesicles, and feature the potential to entrap and maintain the hydrophilic and hydrophobic solute particles.

structure of Niosomes



Advantages of niosomes:-

1. Niosomes have better patient compliance and higher therapeutic impact than conventional oily formulations.
2. Niosomes may be utilized withinside the delivery of huge range of medicine because it has functionality to entrap hydrophilic, lipophilic as well as amphiphilic drugs.
3. Niosomes show managed and sustained release of medicine because of depot formation.
4. Shape, size, composition, fluidity of niosomes drug may be controlled as and while required.
5. Niosomes show a more bioavailability than conventional dosage forms.
6. Niosomes were efficiently utilized in concentrated on drugs to numerous organs.

E. Nanoemulsions :-

Nanoemulsion are collidal particulate system withinside the submicron size range appearing as providers of drug molecules. Their size varies from 10 to 1,000 nm. These providers are stable spheres and their surface is amorphous and lipophilic with a negative as macroemulsions, are normally defined as immiscible phases dispersed inside another.There are charge. Magnetic

nanoparticles may be used to enhance site specificity. As a drug transport system they enhance the therapeutic efficacy of the drug and decrease adverse impact and poisonous reactions. Major utility consists of remedy of infection of the reticuloendothelial system (RES), enzyme substitute remedy withinside the liver, treatment of cancer, and vaccination.Emulsions, also known a primary variations between conventional emulsions and nanoemulsions which ends up from size and shape of the particles withinside the continuous phase. Firstly, particle sizes in nanoemulsions (5-200 nm) are very smaller than conventional emulsions (0.1-100 μm).

Advantages of Nanoemulsion:-

1. Provides aqueous dosage form for water insoluble drugs.
2. Eliminates variability in absorption.
3. Increases bioavailability.
4. They do not show the troubles of inherent creaming, flocculation, coalescence and sedimentation.
5. Increase the rate of absorption.
6. Helps in solubilizing lipophilic drug.

F. MICROSPHERE:-

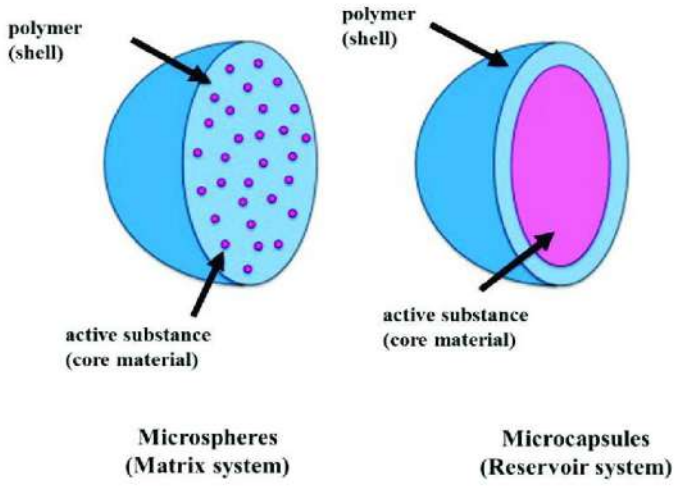
Microsphere comprises of small spherical particles, with diameters in the micrometer range, typically 1 μm to 1000 μm (1 mm). Microspheres are sometimes referred to as micro-particles.

Structure of microsphere:-

Microspheres can be manufactured from various natural and synthetic materials. Glass microspheres, polymer microspheres and ceramic microspheres are commercially available. Microspheres are classified as biodegradable or non-biodegradable. Biodegradable microspheres include albumin microspheres, modified starch microspheres, gelatin microspheres, polypropylene dextran microspheres, polylactic acid microspheres, etc. According to the current literature reports on non-biodegradable microspheres, polylactic acid is the only polymer approved to be used by people, and it is used as a controlled-release agent. Solid and hollow microspheres vary widely in density and therefore are used for different applications .

Advantage of microsphere :-

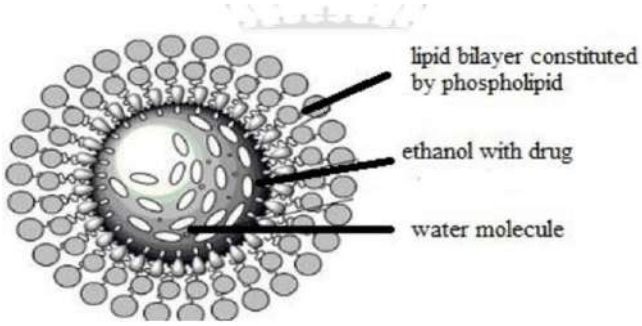
1. Administration of medication via micro-particulate system is advantageous because microspheres can be ingested or injected, and they can be tailored for desired release profiles and used for site-specific delivery of drugs and in some cases can even provide organtargeted release.
2. Drug can be easily released from the formulation.
3. It can protect the specific function of drugs, and can release the drugs into an outer phase for a long period.



G. Ethosomes :-

Ethosomes are developed by mixture of phospholipids and high concentration of ethanol. This carrier can penetrate through the skin deeply lead to improve drug delivery into deeper layer of skin and in blood circulation. These formulations are useful for topical delivery of alkaloids in form of gel and cream for patients comfort. They show increase in their permeability through the skin by fluidizing the lipid domain of the skin. Unstable nature and poor skin penetration are limits for Ethanosomes tropical delivery. The Ethosomes was developed and examined for their ability the topical absorption of Tetrandine through dermal delivery, and the relation of formulations to the pharmacological activity of Tetrandrine loaded in the formulation was also accessed. Result of the drug levels in rat plasma showed that when Tetrandrineloded Ethosomes were topically administered in rats the drug level was low to be detected in rat plasma. By providing fewer delivery of Tetrandrine into bloodstream, topical administration might offer favorable efficacy with reduced side effects, thus leading to improve patient's compliances. In conclusion, Ethosomes were demonstrated to be promising carrier for improving topical delivery of Tentrandrine via skin

Structure of Ethosome:-



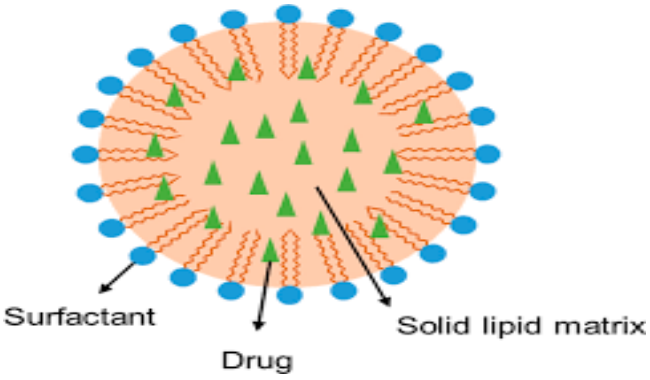
Advantages of ethosomal drug delivery:-

1. Ethosomes enhance transdermal permeation of drug through skin.
2. Ethosomes are a platform for the delivery of large amounts of diverse groups of drugs.

H. Solid Lipid Nanoparticles (SLN):-

It is a technique developed in the 1990s. It is a colloidal carrier used especially for the delivery of lipophilic compounds. The average mean size of solid lipid nanoparticles ranges from 50 nm to 1000 nm. Solid lipid nanoparticles are composed of lipid matrix, which becomes solid at room temperature and also at the body temperature . The main features of solid lipid nanoparticles (SLNs) with regard to parenteral application are the excellent physical stability, protection of incorporated labile drugs from degradation. To cross blood brain barrier, it should be made for selection of lipids and surfactants. The SLNs are prepared by different methods such as homogenization and the warm micro-emulsion high-speed stirring ultra sonication and solvent-diffusion method. Lipids show compatibility with lipophilic drugs and increase the entrapment efficiency and drug-loading into the SLN .

Structure of Solid lipid Nanoparticle



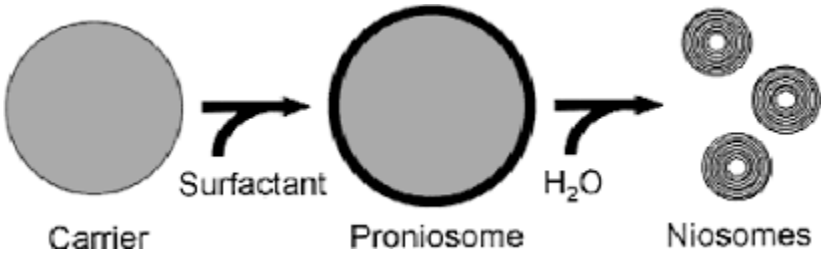
Advantages of solid lipid nanoparticle:-

1. It provides controlled release and site-specific drug targeting.
2. Large-scale production can be done.
3. In this formulation, both lipophilic and hydrophilic drugs can be loaded.

I. Proniosomes:-

Proniosomes gel system is step forward to niosome, which can be utilized for various applications in delivery of actives at desire site. Proniosomal gels are the formulations, which on in situ hydration with water from the skin are converted into niosomes .

Structure of proniosomes



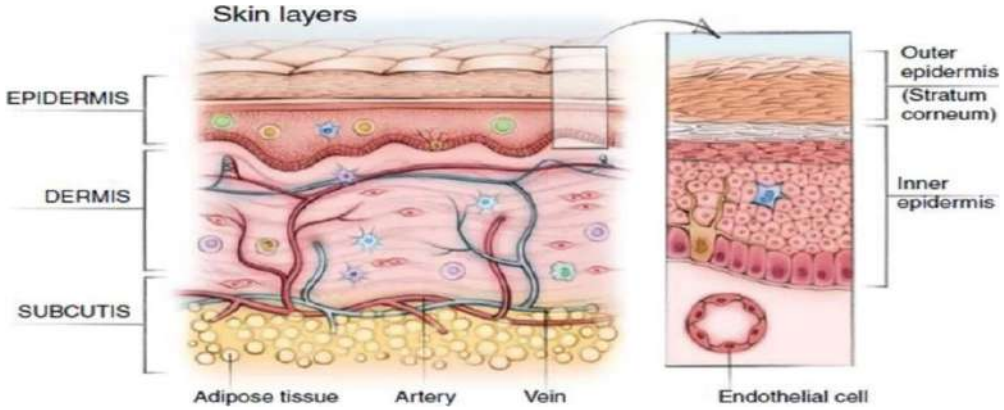
Advantages of Proniosomes :-

1. More stable during storage and sterilization.
2. Easy to transfer and distribution .

J. Transdermal Drug Delivery System:-

Transdermal drug delivery system has been an increased interest in the drug administration via the skin for both local therapeutic effects on diseased skin (topical delivery) as well as for systemic delivery of drugs. But immense potential lies in transdermal drug as future smart drug delivery devices . These are the devices in which drug present in the formulation permeates into the systemic circulation by diffusion to stratum corneum and further to the effected organ. These devices use polymer matrix, adhesive bandage and permeation enhancers.

Structure of TDDS:-



Advantages of Transdermal Drug Delivery System:-

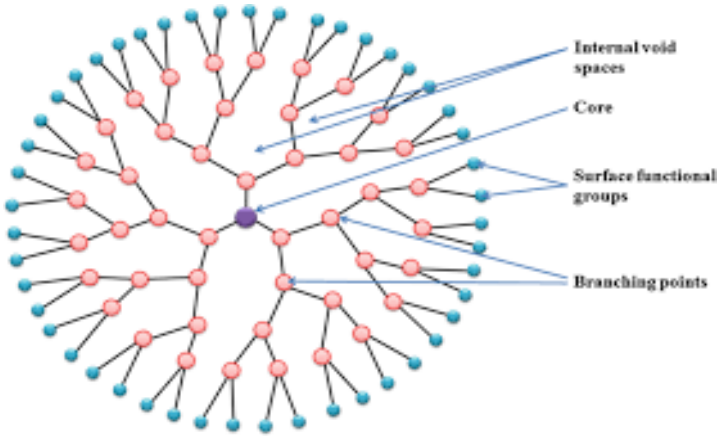
1. Controlled drug delivery, enhanced bioavailability, reduction in side effects and easy application.
2. Transdermal delivery of herbal drugs are to increase the penetration and sustained action.e.g.transdermal films containing boswellic acid (Boswellia serrate) and curcumin (Curcuma longa) were formulated for the treatment of inflammation (synergistic effect).
3. Limitations are hepatic first pass metabolism, increased herapeutic effect, and maintenance of steady state concentration in the serum .

K. Dendrimers :-

Dendrimers are nanometer-sized, highly branched and monodisperse macromolecules with

symmetrical architecture while their stability and protection from the Mononuclear Phagocyte System (MPS) is being achieved by functionalization of the dendrimers with polyethylene glycol chains (PEG) .

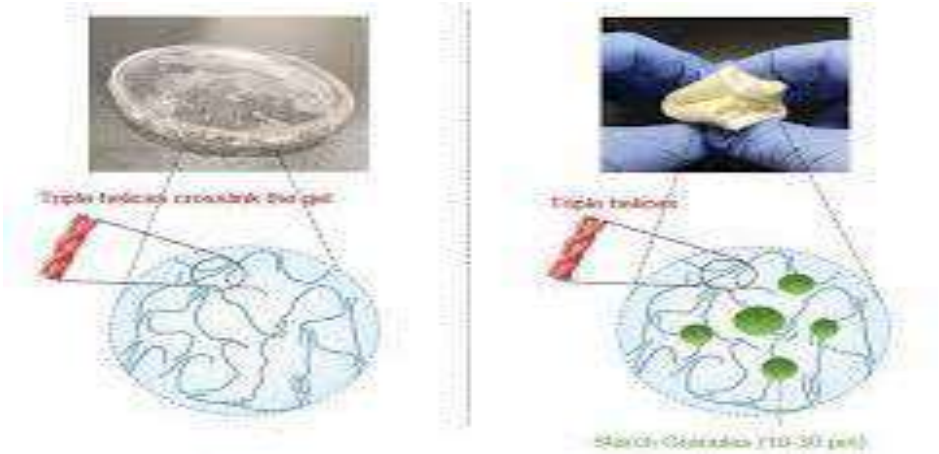
Structure of Dendrimers:-



L. Hydrogels:-

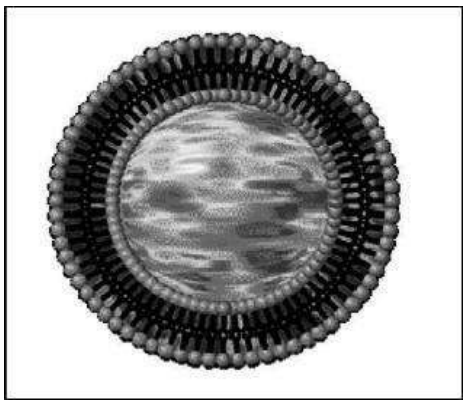
Hydrohgels are three-dimensional, hydrophilic, polymeric networks capable of imbibing large amounts of water or biological fluids. They are used to regulate drug release in reservoir-based, controlled release systems or as carriers in swellable and swelling-controlled release devices Shaktipal Patil at all 2016.

Structure of Hydrogels



A BRIEFLY DETAILS IN LIPOSOME:-

Liposomes have been receiving a lot of interest as a carrier for advanced drug delivery. Liposomes were first produced in England in 1961 by Alec D. Bangham, who was studying phospholipids and blood clotting. It was found that phospholipids combined with water immediately formed a sphere because one end of each molecule is water soluble, while the opposite end is water insoluble. Water soluble drugs added to the water were trapped inside the aggregation of hydrophobic ends; fat-soluble drugs were incorporated into the phospholipids layer. A liposome is a spherical vesicle with a membrane composed of a phospholipids bilayer used to deliver drug or genetic material into a cell. Liposomes can be composed of naturally-derived phospholipids with mixed lipid chain like egg phosphatidylethonalimine or of pure components like DOPE (dioleolylphosphatidylethanolamine).



There are several mechanism by which act within and outside the body which are as follows:

1. Liposomes attach to cellular membrane and appear to fuse with them, releasing their content in to the cell.
2. Sometimes they are taken up by the cells and their phospholipids are incorporated in to the cell membrane by which the drug trapped inside is release.
3. In the case of phagocyte cell, the liposomes are taken up, the phospholipids wall are acted upon by organelles called lysosomes and the active pharmaceutical ingredients are released.

Advantages of Liposome:-

Provides selective passive targeting to tumour tissue (liposomal doxorubicin).

1. Liposome are increased efficacy and therapeutic index of drug (Actinomycin-D).
2. Liposome is increased stability via encapsulation.
3. Liposomes are biocompatible, completely biodegradable, non-toxic, flexible and nonimmunogenic for systemic and non-systemic administrations.
4. Liposome are reduction in toxicity of the encapsulated agent (Amphotericin B, Taxol).
5. Liposomes help to reduce exposure of sensitive tissues to toxic drugs
6. Site avoidance effect.
7. Flexibility to couple with site-specific ligands to achieve active targeting.

Disadvantages of Liposome :-

1. Production cost is high.
2. Leakage and fusion of encapsulated drug / molecules.
3. Sometimes phospholipid undergoes oxidation and hydrolysis like reaction.
4. Short half-life.
5. Low solubility.
6. Fewer stables

Properties of liposomes

1. The system consists of structures of bimolecular sheets intercalated by aqueous space.
2. They are permeable to water.
3. They are osmotically sensitive.
4. Positively charged membranes are impermeable to cations and negative are highly permeable to anions.

Classification of Liposomes :-

Liposomes are classified on the basis of:

1. Structure.
2. Method of preparation.
3. Composition and application.
4. Conventional liposome.
5. Specialty liposome.

Classification of Liposomes :-

Liposomes are usually classified according to their lamellarity and size. The following categories show the major types of liposomes (New, 1990; Philippot and Schuber, 1995):

1. Multilamellar vesicles (MLV):

This population has a broad range of size distribution that occurs in a range of 100-1000 nm. The lipid composition may influence the lamellarity of these MLVs. However, the lamellarity typically varies between 5 and 20 concentric lamellae.

2. Large unilamellar vesicles (LUV):

The size of these vesicles is normally up to 1000 nm and the structure consists of a single lamellae.

3. Small unilamellar vesicles (SUV):

The structure normally consists of single lamellae and the diameter of this population is below 100 nm.

Method of Liposome Preparation :-

Various methods used for the preparation of liposome:-

1. Passive loading techniques: -

Passive loading techniques include three different methods:

A. Mechanical dispersion method

Lipid film hydration by hand shaking, no hand shaking or freeze drying

- Handshaking methods
- Sanitation
- French pressure cell
- Membrane extrusion
- Dried reconstituted vesicles
- Freeze-thawed liposome.

B. Solvent dispersion method

- Ether injection
- Ethanol injection
- Double emulsion vesicles
- Reverse phase evaporation vesicles
- Stable plurilamellar vesicles

C. Detergent removal method

- Detergent (cholate, alkylglycoside, Triton X-100) removal form mixed micelles
- Dialysis
- Column chromatography
- Dilution o Reconstituted sendai virus enveloped vesicles

D. Active loading technique

- Detergent Dialysis
- Microlluidization

a Proliposomes

b Lyophilization .

Method of Liposome Preparation: -

A. Mechanical dispersion method

1. Handshaking Method:-

In order to produce liposome lipid molecules must be introduced into an aqueous environment. When dry lipid layer film is hydrated the lamellae swell and grow into myelin figures. Only mechanical agitation provided by vortexing, shaking, swering or pippeting causes myelin figures to break and reseal the exposed hydrophobic edges resulting in the formation of liposomes can be made by hand shaken method.

a. Sonication Method :-

This method is probably the most widely used method for the preparation of small Unilamellar vesicles. There are two sonication techniques:

Probe Sonication :-

The tip of sonicator is directly immersed into the liposome dispersion is very high in this method. The dissipation of energy at the tip results in local overheating and therefore the vessel must be immersed into an ice bath. During the sonication up to one hour more than 5% of the lipids can be de-esterify. Also, with the probe sonicator, titanium will slough off and contaminate the solution.

Bath Sonicator:-

The liposome dispersion in a tube is placed into a bath sonicator. Controlling the temperature of the lipid dispersion is usually easier in this method compare to sonication the dispersion directly using tip. Material being sonicated can be kept in a sterile container, unlike the probe units, or under an inert atmosphere. The lipid bilayer of the liposomes can fuse with other bilayers, thus delivering the liposome contents. By making liposomes in a solution of DNA or drug they can be delivered past lipid bilayer.

b. Freeze Dried Rehydration Method :-

Freeze dried liposomes are formed from preformed liposomes. Very high encapsulation efficiencies even for macromolecules can be achieved using this method During the dehydration the lipid bilayers and the material to be encapsulated into the liposomes are brought into close contact. Upon reswelling the chances for encapsulation of the adhered molecules are much

higher. The rehydration is a very important step and is should be done very carefully. The aqueous phase should be added in very small portions with a micropippete to the dried materials. After each addition the tube should be vortexed thoroughly. As a general rule the total volume used for rehydration must be smaller than the starting volume of the liposome dispersion.

B. Solvent dispersion method:-

d. Ether Injection Method :-

A solution of lipids dissolved in diethyl ether or ether/methanol mixture is slowly injected to an aqueous solution of the material to be encapsulated at 55-65°C or under reduced pressure. The subsequent removal of ether under vacuum leads to the formation of liposomes. The main drawbacks of the method are that the population is heterogeneous (70-190 nm) and the exposure of compounds to be encapsulated to organic solvents or high temperature.

e. Ethanol Injection Method :-

A lipid solution of ethanol is rapidly injected to a vast excess of buffer. The MLVs are immediately formed. The drawbacks of the method are that the population is heterogeneous (30-110 nm), liposomes are very dilute, it is difficult to remove all ethanol because it forms azeotrope with water and the possibility of various biologically active macromolecules to inactivation in the presence of even low amounts of ethanol.

f. Reverse Phase:-

Evaporation Method Historically this method provided a breakthrough in liposome technology, since it allowed for the first time the preparation of liposomes with a high aqueous space-tolipid ratio and able to entrap a large percentage of the aqueous material presented. Reverse phase evaporation is based on the formation of inverted micelles. These inverted micelles are formed upon sonication of a mixture of a buffered aqueous phase, which contains the water soluble molecules to be encapsulated into the liposomes and an organic phase in which the amphiphilic molecules are solubilized.

C. Detergent removal method:-

g. Detergent (cholate, alkylglycoside, Triton X-100) removal form mixed micelles :-

The detergents at their critical micelles concentrations have been used to solubilize lipids. As the detergent is removed the micelles become progressively richer in phospholipid and finally combine to form LUVs. The detergents were removed by dialysis . The advantages of detergent dialysis method are excellent reproducibility and production of liposome populations which are homogenous in size. The main drawback of the method is the retention of traces of detergent(s) within the liposomes. A commercial device called LIPOPREP (Diachema AG, Switzerland) which is a version of dialysis system is available for the removal of detergents. Other techniques have been used for the removal of detergents:

a. by using Gel Chromatography involving a column of Sephadex G25,
b. by adsorption or binding of Triton X-100 (a detergent) to Bio-Beads SM-2.
c. by binding of octyl glucoside (a detergent) to Amberlite XAD-2 beads.

D. Active loading technique :-

h. Microfluldization Methods:-

Mayhew et al. (1984) suggested a technique of microfluidization/ microemulsification/ homogenization for the large scale manufacture of liposomes. The reduction in the size range can be achieved by recycling of the sample. The process is reproducible and yields liposomes with good aqueous phase encapsulation. Riaz and Weiner (1995) prepared liposomes consisting of egg yolk, cholesterol and brain phosphatidylserin diasodium salt (57:33:10) by this method. First MLV were prepared by these were passed through a Microluidizer (Microlluidics Corporation, Newton, MA, USA) at 40 psi inlet air pressure. The size range was 150-160 nm after 25 recylces.

In the Microluidizer, the interaction of fluid streams takes place at high velocities (pressures) in a precisely definedmicrochannels which are present in an interaction chamber. In the chamber pressure reaches up to 10,000 psi this can be cause partial degradation of lipids.

Storage of liposomes:-

Freeze-drying Liposome dispersions are potentially prone to hydrolytic degradation and leakage. Hence, it is desirable to freeze-dry the suspension to a powder and store in this dried form. The powder can be reconstituted to an aqueous suspension immediately before use. By doing so, SUVs may be converted to MLVs dispersion upon rehydration. Addition of a carbohydrate (trehalose) during freeze-drying prevents fusion and leakage of the vesicles.

Stability of Liposomes :-

a Physical and Chemical Stability:-

Cholesterol and phospholipids containing unsaturated fatty acids undergo oxidation. One solution to this problem is to use phospholipids which contain saturated fatty acids. Synthetic saturated lecithins provide a good alternative to egg or soybean lecithin. Lecithin undergoes hydrolysis to give lysolecithin and other degradation products. The presence of lysolecithin inlipid bilayers greatly enhance the permeability of liposomes. Therefore, it is important to start with phospholipids which are free of lysolecithin (also of any phospholipases). The rate of hydrolysis of distearoylphosphatidylcholine in aqueous solution at 70°C was found to be dependent on pH 6.5. Freeze drying (lyophilizalion) can be useful in some cases to solve long term stability problems of liposomes. On reconstitution (rehydration) most of drug remains within liposomes. It has been shown that liposomes when freeze dried in the presence of trehalose (a sugar) retained as such as a 100% of their contents.

b Stability in Biological Fluids:-

The stability of liposomes in the circulation is of great interest when they are to be applied as intravenous drug carriers. This is a well established fact that the liposomes are generally unable to retain their entraped substances when incubated with blood or plasma.Generally MLV are most stable since only a portion of the phospholipid is exposed to the attach and SUV are the least stable because of the stress imposed by their curvature. The incorporation of cholesterol sometimes increases the stability of liposomes in the presence of plasma.

APPLICATION OF LIPOSOME:-

The field of liposume research has expanded considerably over now possible to engineer a wide range of his The field of i last 30 years. liposome of varying size, phospholipids composition, cholesterol composition, surface morphology suitable for wide range of application . Liposomes interact with cells in many ways to cause liposomal components to be associated with target cella. The liposome carrier can be targeted to liver and spleen and distinction can be made between normal and tumors tissue using Tomography. In case of transdermal drug delive delivery system, liposome has a great application. Liposomal drug delivery system when used to target the tumor cells leads to reduction in the toxic effect and enhances the effectiveness of drags. The targeting of the liposame to the site place by by the attachment of amino acid fragment, such as antibody or proecin or appropriate fragments that target specific receptors cell. Liposomal DNA delivery vectors and of action takes,further enhancement in the form of LPDI - and LPD-II are some of the safest and potential most versatile transfer vectors which used to date, DNA vaccination and improved efficiency of gene therapy are just a few of the recent application of liposome. Several modes of drag delivery application have been purposed purposed for the liposomal drug delivery system, few of them are as follows:

- Enhance drug solablisation (Amphotericin-B, Minoxidil, Pacli- taxels, and Cyclosporins) .
- Protection of smsitive drug molecules (Cytosine arabinosa,DNA, RNA, Anti-sense oligo- nucleotides, Ribozymes).
- Enhance intracellular uptake (Anticancer, anti viral and antinti crobial drugs),.
- Altered pharmacokineties and bio-distribution (prolongod astained released drugs with short circulatory half life). Several recent applications of liposomal dmg delivery system. as followes.

1. Liposome for Respiratory Drug Delivary System.
2. Eye Disorder.
3. Liposome as Vaccine Adjuvent.
4. Liposome Of Brain Targeting .
5. Liposome of tumor therepy.

Liposame for Respiratory Drug Delivery System:_

Liposome is widely used in several types of respiratory disorder . Liposomal aerosol has several advantages over ordinary aerosol which are as follows:

- Sustained release
- Prevention of local irritation
- Raliced toxicity and
- Improved stability in the large aqueous core.

Several injectable liposome hased product the mar- ker including ambisome, Fungisome and Myocet. To be effective, Eposomal drug delivery system for the lung is dependent on the following parameters:

- Lipid composition.
- Size
- Charge
- Drug and Lipid
- Method of delivery

The recent use Jung the delivery of DNA to the means that a greater understanding of their use in macтomolecular delivery via inhalational is now emerging. Much of this new know lodge, including now lipids and analytical techniques, can be in the development of liposome based protein formulations. or dry form is taken and the For inhalation of liposome the liquid drag release occurs during nebulization. Drug powder liposome has been produced by milling or by spary drying. Drugs which are for- mulated in the form of liposame are presented in . Liposomal Farmulation for the Respiratury disorder.

Table no 1 Liposome formulation for the respiratory disorders

Active constituent	Effect
Insulin	Facilitated pulmonary adsorption and enhanced hypoglycemic effect
Catalase	Conferred resistance to pulmonary oxygen toxicity
Super oxide dismutase	Minimize toxicity to subsequent hyperoxia & improved survival
Cyclosporine	Preferentially adsorbed by lung & shows sustained release
Ricin vaccine	Improved safety profile for intra pulmonary vaccination
Inter leukin-2	The lung facilated bioactivity & reduce toxicity
Isoniazid and rifampicin	Improved the effect of drugs for the tuberculosis

Eye Disorders:-

Liposome has been widely used to treat disorder of both anterior and posterior segment. The disease

of eye include keratitis, corneal transplant rejection, uveitis, andopthelmitis and proliferative vitro retinopathy. Retinal diseases are loading cause of Windness in advanced countries. Liposome is used as vector for genetic transfection and monoclonal antibody directed vehicle. The recent techniques s of the treatment like applying of focal laser to heat in induced release of liposomal drugs and dyes are used in the treatment of selective tumour and non-vascular vessels occlusion, angiography, retinal and choroidal blood vessel stasis. Liposomal drug formulations have been approved for the two of patent drugs to date and several other products e under clinical trials. The liposome drugs currently approved are "verteporfin" for the use the eye, the banefit of the liposome will be applied in treatment. diagnostic and research aspect of phthalmology in feature .

Liposome as Vaccine Adjuvant :-

Liposome has hean fimily established as immuno-adjuvant,potentiating both cell mediated and non coll mediated (humoral) mmunity .plinesome acts as immuno-adjuvant by the following therapetic of view:

1. Liposomes as an immunological (vaccine) adiuvant.
2. Liposomal vaccines.
3. Liposomos as caricrof.
4. Liposomes immunomodulation for a tool in immuno diagnosticstion.

Liposomal immuno-adjuvant act by slowly releasing encapsulated antigen on intramuscular injection and also by passively accamulating within regional lymph node . The accumulation of liposome to lymphoid is done by the tar geting of liposome with the help of phosphatidyl sarine. Liposomal vaccine can be prepared by inoculating microbes, soluble antigen, cytokinesis of deoxyribonucleic acid with liposome. The latter stimadating gan immune response on on expression of antigenic protein.

Table No. 2 Some As Antigen As Liposomal And Preparation There Application .

Antigen as liposomal preparation	Application
Rabies glycoprotein	Interleukin-2 enhancement
Cholera toxin	Enhanced Ab* level
Diphtheria toxoids	Superior immunoadjuvant
Herpes simplex virus	Enhanced Ab level
Hepatitis B virus	Higher Ab response
Bacterial polysaccharides	Superior immunoadjuvant
Tetanus toxoids	Increased Ab titer
Influenza subunit antigen	Intranasal, protect animal from virus
Carbohydrate antigen	Increased Ab titer in salivary gland

Liposomes for Brain Targeting:-

The biocompatible and biodegradable behaviour of liposomes have recently led to their exploration as drug delivery system to brain Liposomes with a small diameter (100 nm) as well as large diameter undergo free diffusion through the Blood Brain Barrier (BBB). However it is possible that a small unilamellar vesicles (SUVS) coupled to brain drug transport vectors may be transported through the BBB by receptor mediated or absorptive mediated tran- scytosis. Similarly, cationic liposomes which were developed re- cently showed these structures to undergo absorptive mediated endocytosis into cells. Whether cationic liposomes successfully undergo absorptive mediated transcytosis through the BBB has not yet been determined.

LIPOSOME IN TUMOR THERAPY:-

The long term therapy of anticancer drug leads to several toxic side effect. The liposomal therapy for the targeting to the tumour cell have been

revolutionized the world of cancer therapy with least side effect. It has been said that the small and stable liposome are passively targeted to different tumour because they can circulate for longer time and they can extra vasate in tissue with enhanced vas- cular permeability . Liposome macrophage uptake by liver and spleen hampered the development of liposome as drug delivery for aver 20 years. Several formulations of liposomal anticancer drug which are in clinical use are given in Table[3]

Various intravrnous liposoime antibiotics & antineoplastic .

Preparation	Drug	Targeted site
Liposome [doxil]	Doxorubicin	Kaposi sarcoma
Liposome[EVACT]TM	Doxorubicin	Refractory tomor metastatics breast cancers
Liposome [dauno xome]	Daunosome	Advanced Kaposi sarcoma , breast ,small cell lung cancers, leukemias &solid tumors
Liposome	Nystatin	Systemic fungal infection
Liposome	Anamycin	Kaposi sarcoma ,refractory breast cancers
Liposome [vin-caxone]	Vincristin	Solid tumors
Liposome [mika-some]	Amikacin	Serious bacterial infection

Doxil is the liposomal formulation of doxorubicin, intravenous, chemotherapeutic agent. Doxil is prepared by the new technology called stealth technology, stealth liposome. These are the long cir- culatory liposome which is prepared by several means. Caelyx and myocet are the liposomal formulations of doxorubicin. Caelyx is used for treatment of metastatic ovarian cancer but now in now in advanced breast cancer. Myocet s approved for metastatic breas cancers. Abdus Samad at all 2007.

CONCLUSION:-

1. Novel Drug delivery System (NDDS) NDDS is a combination of advance technique and new dosage forms which are far better than conventional dosage forms
2. Advantages of Novel Drug Delivery System are: Optimum dose at the right time and right location, Efficient use of expensive drugs, excipients and reduction in production cost,
3. Beneficial to patients, better therapy, improved comfort and standard of living. Basic modes of novel drug delivery systems are: Targeted Drug Delivery System, Controlled Drug Delivery System etc.
4. Novel Drug delivery & drug targeting is new techniques which is used in pharmaceutical science. Like targeting drug delivery, vaccine delivery, Gene therapy, commercial development of novel carries.
5. Patient compliance .
6. Bioviability reduced.
7. Dosing frequency.
8. Poor absorption from target site.
9. Fluctuation in plasma drug level.

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