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A Comprehensive Review: Nanosponges as Novel Carriers in Antifungal Therapy

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ABSTRACT:
The recent advance in nanotechnology has led to the development of targeted drug delivery system. However, targeting a molecule to a particular Site using a drug delivery system effectively requires a specialized drug delivery system. The discovery of Nano sponge has become a significant step in overcoming certain problems such as drug toxicity, poor bioavailability and release of drug in a predictable fashion as they can accommodate both hydrophilic and hydrophobic drug. Nanosponges are minute, sponge-like carriers characterized by their porous architecture, which enables them to encapsulate active drug molecules efficiently. Their distinctive structure allows for a controlled and sustained release of therapeutic agents. These nanoscale systems can circulate throughout the body, navigate to the targeted site, adhere to the surface, and gradually dispense the drug in a regulated and site-specific manner. Nano sponges can be formulated by crosslinking of cyclohexatriene with carbonyl or decarboxylase (Cross linkers). Nanosponges have been widely studied for delivering medicines through different routes, including by mouth (oral), on the skin (topical), and by injection (parenteral).Nano sponges can also serve as an effective carrier for enzyme, proteins, vaccine and antibodies. The Present review highlights the method of preparation, characterization and their potential application in drug delivery system.

Keywords: - Targeted drug delivery system, Nanosponges, Hydrophilic and Hydrophobic drug

INTRODUCTION: -

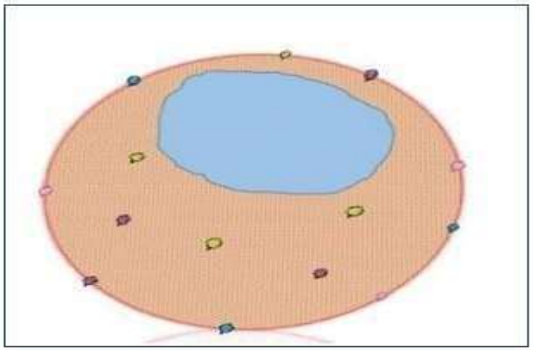


Fig No.01 Nanosponges have a special structure with tiny hollow spaces that can hold and carry drugs.

For a long time, scientists have aimed to develop drug delivery systems that can accurately reach the desired target in the body.In the beginning, Nano sponge drug delivery system appeared only as a topical delivery system, but in the 21st century, Nano sponges can be administered by oral as well as intravenous (IV) route [1]. Nano sponge is a modern category of material and is made up of tiny particles with a narrow cavity of few nanometers. The mixture is then stirred at 1000 rpm for approximately 2 hours These tiny particles are having a capability due to which it is able to carry both hydrophilic and lipophilic drug substance and can increase the stability of poorly water-soluble drug substance or molecules [2]. The Nano sponges are a three-dimensional scaffold (backbone) or network of polyester that are capable of degrading naturally. These polyesters are mixed with across linker in solution to form Nanosponges. Here, the polyester is generally biodegradable, so it breaks down in the body moderately. Once the scaffold of Nano sponge's breaks down it releases the drug molecules which is loaded, in a derogatory fashion.

Advantages of Nano sponges:-

1. Increase aqueous solubility of the poorly water-soluble drug.
2. Nano sponges can release the drug molecules in a predictable
3. Fashion.
4. Because of their tiny pore size (0.25 μm), bacteria cannot Penetrate the Nano sponges and they act like a self-sterilizer.
5. Nano sponge's drug delivery system are non-irritating, nonmutagenic and non-toxic.
6. Nano sponges help to remove the toxic and venom substance from the body.
7. Nano sponges drug delivery system minimize side effect.
8. Increase formulation stability and enhance the flexibility of the formulation.
9. Reduce dosing frequency.
10. Better patient compliance.

Disadvantages of Nano sponges:-

1. Nano sponges have the capacity of encapsulating small Molecules
2. not suitable for larger molecules.
3. Dose dumping may occur at time.

Methods of Preparation:

1. **Solvent Method: -** Using solvent method, Nano sponges are prepared by mixing polar aprotic solvents like Dimethyl sulfoxide (DMSO), Dimethylformamide (DMF) with the polymer. A cross linker is then added to this mixture in the ratio of 1:4. The above reaction should be proceeded at temperature 10˚C to reflux the temperature of the solvent for the time ranging from 1 to 48 h. Once the reaction has completed , the solution is cooled down at room temperature and then obtained a product is added to bi-distilled water. The product is recovered by filtering the product under vacuum and refining by soxhlet extraction with ethanol followed by drying.
2. **Emulsion solvent diffusion**:- In this method, different proportion or amount of ethyl cellulose and polyvinyl alcohol are used to prepare Nano sponges. This method uses two phases: a dispersed phase and a continuous phase. The dispersed phase contains ethyl cellulose and the drug, which are dissolved in 20 ml of dichloromethane. Meanwhile, a small amount of polyvinyl alcohol (PVA) is

added to 150 ml of the continuous (water-based) phase. The entire mixture is then stirred at 1000 rpm for about 2 hours. Finally, the formed nanosponges are separated using filtration.

3. **Mechanism of drug release from Nano sponges:-** Since the Nano sponges have an open structure (in the surrounding of Nano sponges they do not have any continuous membrane), the The active ingredient is first added to the base (vehicle) in a protected, encapsulated form. It gradually moves from the nanosponges into the base until both are balanced, or in equilibrium. When the product is applied to the skin, this balance is disrupted as the base becomes unsaturated. This triggers the release of the active ingredient from the nanosponges into the skin. The release continues as long as the base remains on the skin, either until it is absorbed or dries. Nanosponges remain on the outer layer of the skin (stratum corneum) and continue to gradually release the active ingredient over an extended period

Factors influencing in the formulation of Nano sponges:-

1. **Nature of polymer:-** The polymer used in the preparation of Nano sponges can influence its formation and can also affect the pre-formulation. The size of the Cavity of a Nano sponge should be big enough to entrap a drug Molecule of a particular size into it for complexation.
2. **Drug:-** To be complex with Nano sponges, the drug molecules should have some specific characteristics as mentioned below:
    1. The molecular weight of the drug molecule should be in range ranging from 100-400 Daltons.
    2. Structure of drug molecule should not consist of more than 5 Condensed ring.
    3. The solubility of the drug in water should be<10 mg/ml.
3. **Temperature: -** Changes in the temperature can affect the complexation of drug or Nano sponges. Increasing the temperature generally decreases the extent of the stability constant of the drug or the Nano sponge complex which may be due to the reduction of interaction forces such as hydrophobic forces and Van der Waal forces of drug/Nano sponges with an increase in the temperature.
4. **Method of preparation: -** The method of drug loading into the Nano sponges can cause a change in the complexation of drug and the Nano sponges. Although, the success of a method mainly depends on the nature or the characteristics of the drug and polymer; in some cases, freeze drying has also been known to affect the drug and Nano sponge complexation.

Characteristics of Nano sponges:-

1. Nano sponges are porous particles, used mainly to encapsulate the poorly soluble drugs
2. These Nano sponges have high aqueous solubility and are capable of carrying both lipophilic and Hydrophilic drugs.
3. Nano sponge's formulations are stable over the pH range of 1 to 11 and temperature up to 300 ℃
4. Nano sponges are non-irritating and non mutagenic, non-allergic and non-toxic and protect the drugfrom physiological degradation.

Particle size determination: The particle size of Nano sponge is an important criterion in the optimization process of nanosponge. The particle Size of the drug can affect the drug release as well as the solubility of the drug. Particle size can be determined by Using the instrument, laser light

diffractometric or Zeta sizer. Cumulative percentage drug release from Nano sponges of different particle size can be plotted against time to study the effect of particle size on drug release. Particle size larger than 30 µm can show gritty feeling and particle size range from 10 –25 µm can be preferred for topical drug delivery.

Solubility studies:- Higuchi and Connors explained the method to study the inclusion complexation known as phase solubility method. This method used to explain the effect of Nanosponge on the solubility of the drug, which indicates the degree of complexation.

Microscopy studies:- Scanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM) can be used to study the microscopic aspects of the drug and nanosponge formulation. SEM are used for the study morphology of the nanosponges. The difference in crystallization state of the raw materials used for the preparation of nanosponge and the final formulation seen under electron microscope indicates the formation of the inclusion complexes.

Applications of Nanosponges: -

1. **Solubility Enhancement:**

$$LE = \frac{\text{Actual drug content in nanosponges}}{\text{Theoretical drug content}} X\ 100$$

Nanosponges can improve the wettability and solubility of molecules with poor solubility in water. The drug can be molecularly dispersed in the nanosponge structure and then released as a molecule, avoiding the dissolution step. Therefore, the apparent solubility of the drug can be increased. Many formulations and bioavailability problems

2. **Nanosponges for Drug Delivery:** Nanosponges Are solid in nature and can be formulated into oral, Parenteral, topical or inhalation dosage forms. For oral administration, the complex can be dispersed in a matrix suitable for the preparation of Capsules or tablets with excipients, diluents, Lubricants, and anti-caking agents. For parenteral Administration, the complex can simply be carried in sterile water, saline or other aqueous solutions. For topical administration, they can be effectively incorporated into topical hydrogels.
3. **Topical Agents:-** The nanosponge delivery system is a unique technology used to control the release of topical drugs that extend drug release and retention of drug form on the skin Local anesthetics, antifungals, and antibiotics belong to the category of drugs that can be easily formulated into topical Nano sponges. When the active ingredient penetrates into the skin, a rash or more serious side effects may occur.
4. **Nanosponges as a Carrier for Delivery of Gases:-** Gas plays an important role in medicine, whether it is used for diagnostic or therapeutic purposes. The Lack of an adequate supply of oxygen, called Hypoxia, is associated with various pathologies, from inflammation to cancer. In clinical practice, it is sometimes difficult to deliver oxygen in an appropriate form and dose. Cavalli et al. develop nanosponge formula as an oxygen delivery system for topical application, with the ability to store and release oxygen slowly over time.

Role of nanosponges for treatment of fungal: -

1. **Fungal Infection: -** Fungal infections, or mycosis, are diseases caused by a fungus (yeast or mold). Fungal infections are most common on your skin or nails, but fungi (plural of fungus) can also cause infections in your mouth, throat, lungs, urinary tract and many other parts of your body.

Type of fungal infection: -

1. **Superficial: -** Affect skin – mucous membrane. E.g. tinea versicolor dermatophytes: Fungi that affect keratin layer of skin, hair, nail. E.g. tinea pedis, ring worm infection Candidiasis: Yeast- like, oral thrush, vulvo-vaginitis, nail infections.
2. **Deep infections: -** Affect internal organs as: lung, heart, brain leading to pneumonia, endocarditis, and meningitis

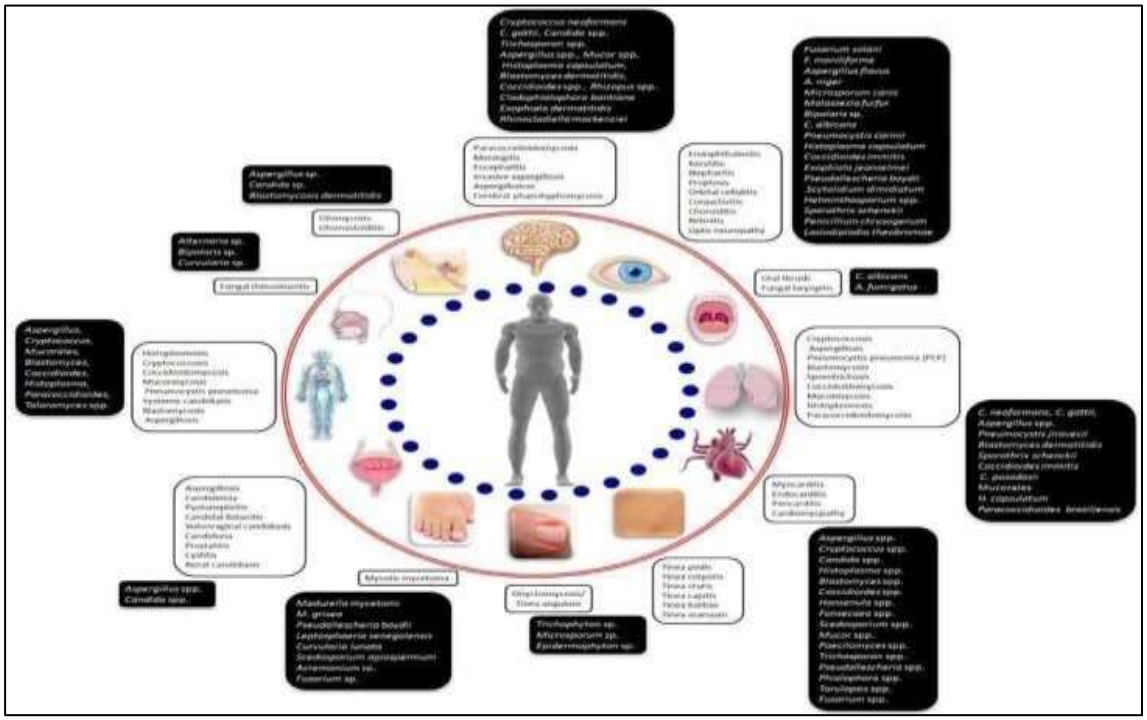


Fig No:-02 Types of fungal infection

Overview of Fungal Skin Infections: - Physiology of normal skin

- The skin is composed of three layers,

1. Epidermis (50–100 µm)
2. Dermis (1–2 mm)
3. Hypodermis (1–2 mm)

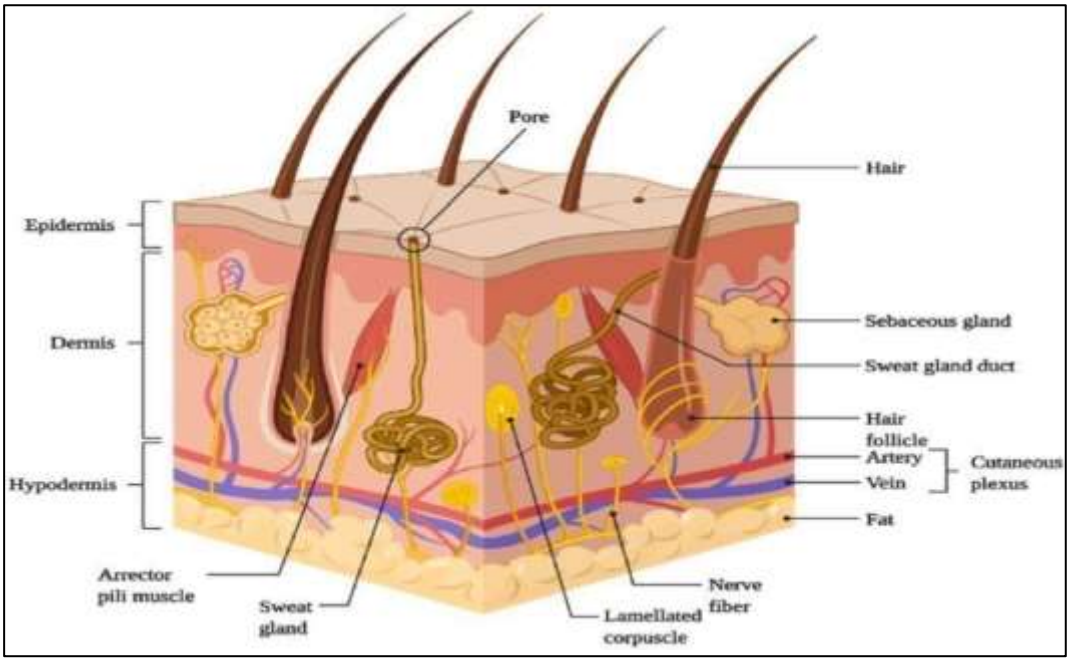


Fig.No.03 Internal structure of skin

Fungi usually make their homes in moist areas of the body where skin surfaces meet between the toes, in the genital area, and under the breasts. Common fungal skin infections are caused by yeasts (such as Candida or Malassezia furfur) or dermatophytes, such as Epidermophyton, Microsporum, and Trichophyton. Many such fungi live only in the top most Layer of the epidermis (stratum cornea) and do not penetrate deeper. Obese people are more likely to get these infections because they have excessive skinfolds, especially if the skin within skinfold becomes irritated and broken down (intertrigo). People with diabetes tend to be more susceptible to fungal infections as well. Strangely, fungal infections on one part of the body can cause rashes on other parts of the body that are not infected. For example, a fungal infection on the foot may cause an itchy, bumpy rash on the fingers. These eruptions (dermatophytids, or identity or id reactions) are allergic reactions to the fungus. They do not result from touching the infected area.

Symptoms:-

1. Skin changes
2. red and possibly cracking Peeling skin.
3. Itching
4. Causes of fungal skin infection:-

Imbalance of bacteria is due to following reasons:-

1. Due to use of antibiotics
2. Hormone imbalance
3. Poor eating habbits

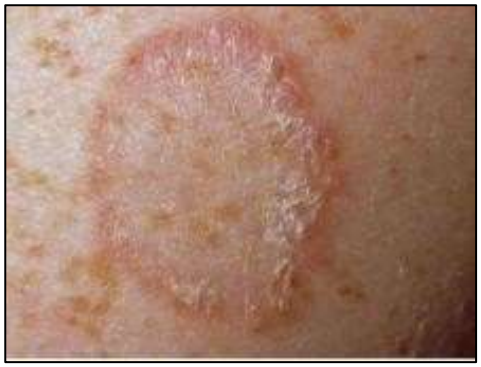


Fig no:-04 Fungal infection on skin

Diagnosis:- Doctors may suspect a fungal infection when they see a red, irritated, or scaly rash in one ofthe commonly affected areas. They can usually confirm the diagnosis of a fungal skin Infection by scraping off a small amount of skin and having it examined under a microscope Or placed in a culture medium where the specific fungus can grow and be identified.

Treatment:

1. Antifungal drugs
2. Measures to prevent moisture
3. Fungal infections are typically treated with antifungal drugs, usually with antifungal
4. Drugs that are applied directly to the affected area (called topical drugs).
5. Topical drugs May include creams, gels, lotions, solutions, or shampoos. Antifungal drugs may also be taken by mouth.
6. In addition to drugs, people may use measures to keep the affected areas dry, such as Applying powders or wearing open-toed shoes.
7. For some infections, doctors give corticosteroids to relieve inflammation and itching. Introduction to Nanoemulgel:-

Plant profile:-

Pongamia Pinnata:-*Pongamia pinnata (L.)* Pierre belongs to the Fabaceae family, a medium-sized perennial tree commonly known in Hindi as Karanja and in English as Indian beech. *Pongamia pinnata* has been documented in a number of traditional medicinal systems for the cure of various human diseases and foods. It includes alkaloids, flavonoids, tannins, hormones, glycosides, karangin, glabrin, kanugin, and fixed oils, as well as other phytoconstituents. Historically, P. pinnata has been used as a folk medicinal plant, mostly in the Indian medicine systems of Ayurveda and Siddha. The anti-inflammatory, anti-nonciceptive, antioxidant, anti-diarrhoeal, anti- fungal, anti-plasmodial, anti-ulcer, anti-hyperglycemic, anti-lip oxidative, anti- hyper ammonic and analgesic functions are available in plant extracts. The tree is known for its multipurpose advantages and as a potential biodiesel source.

Synonyms:-

Pongamia pinnata is sometimes referred to by different synonyms, such as *Millettia pinnata (L.) Panigrahi Derris indica (Lam.), Pongamia glabra Vent. , Pongamia pinnata Merr. Bennett Millettia novo-guineensis Kane. & Hat*

Taxonomical Classification of Pongamia pinnata (L.)

1. Kingdom - Plantae

2. Subkingdom - Tracheobionta
3. Super division - Spermatophyta
4. Division - Magnoliophyta
5. Class - Magnoliopsida
6. Subclass – Rosidae
7. Order – Fabales
8. Family – Fabaceae
9. Genus – Pongamia
10. Species – Pinnata
11. Vernicular names – Different vernacular names of P.pinnata have been reported as follows
12. Telugu-Kanuga
13. Hindi-Karanj,pongam oil
14. Bengali-Karach

Phyto-chemistry:-

Fig No:-05 Pongamia pinnata

[A] The whole plant [B] Leaves [C] Fruits [D] Seeds

1. Contents of Leaves: Alkaloid,Carbohydrates,Flavonoids-Kaempferol, Quercetin, Rutin,Tannin, Saponin, Phytosterol.
2. Contents of seeds:- Karangin,Kaempferol,Kanugin,Kankone,Alkaloids dimethoxy-kanugin,Glabrin,Gamatay,Glabrosaphonin,Tannin,β-sitosterol,Saponin, Quercetin , Pongapin ,Pinnatin ,Pongamol ,Neoglabrin.

3. Contents of seed oil: - Karanjin (S18H22O4), Pongamol, Glabrachalcone, Kanjone, Pongapin
4. Content of bark: - Resin, Contains a bitter alkaloid, Sugar, Mucilage.

NEEM:-

Azadirachta indica commonly known as neem, is native of India and naturalized in most of tropical and subtropical countries are of great medicinal value and distributed widespread in the world. The chemical constituents contain many biologically active compounds that can be extracted from neem, including alkaloids, lavonoids, triterpenoids, phenolic compounds, carotenoids, steroids and ketones, biologically most active compound is azadirachtin, it is actually a mixture of seven isomeric compounds labelled as azadirachtin A-G and azadirachtin E is more effective1. Other compounds that have a biological activity are salannin, volatile oils, meliantriol and nimbin.

Taxonomical classification: -

The taxonomic classification of neem is as follows:

1. Kingdom: Plantae,
2. Order: Rutales,
3. Suborder: Rutinae,
4. Family: Meliaceae,
5. Subfamily: Melioideae,
6. Tribe: Melieae,
7. Genus: Azadirachta,
8. Species: A.indica

The antifungal activity of neem leaves against pathogenic fungi like-*Aspergillus flavus, Alternaria solani and Cladosporium*. 5% aqueous leaf extract of neem was shown to cause inhibition in growth of six tested fungal pathogens *(Aspergillus fumigatus, Aspergillus Niger, Aspergillus terreus, candida albicans and microsporum gypserum*)

Fig No :- 06 Neem :- [A]Tree [B]Leaves [C]Fruits [D]Seeds

Active compounds of Azadirachta Indica L. (Neem)

Azadirachta indica L. (neem) shows therapeutics role in health management due to rich source of

various types of ingredients. The most important active constituent is azadirachtin and the others are *nimbolinin, nimbin, nimbidin, nimbidol, sodium nimbinate, gedunin, salannin, and quercetin*. Leaves contain ingredients such as *nimbin, nimbanene, 6-desacetylnimbinene, nimbandiol,nimbolide,ascorbicacid,n-hexacosanol and aminoacid, 7-desacetyl-7-benzoylazadiradione,7-desacetyl-7-benzoylgedunin,17-hydroxyazadiradione, and nimbiol.*

***Peppermint (Mentha piperita L.*):-**

One of the popular Type of medicinal herb is p*eppermint* (*Mentha piperita L.*), which is known as pudina in India. This is mainly grown in hilly areas and mainly in cold climatic regions. It is widely known to the world for its cooling and calming effects. It is mentioned in Ayurveda as it is used to maintain the balance of 'vata dosha' whereas is used to decrease the 'pitta' and 'kapha doshas'. *Peppermint (Mentha piperita. L.)* is actually a crossed-hybrid mint of watermint *(M. aquatica L.)* and *spearmint (M. spicata L.)* It belongs to the family of *'Lamiaceae'*. In Sanskrit it is known as 'rochani', which means taste perception improver].There are found many significant uses of *peppermint* in various industrial purposes, as well as it is used to prepare tisane. Leaves of this plant are mainly used to made tisane. Peppermint *(Mentha piperita L.)* is among the renowned mainly single component herbal teas. India stands at the topmost producer and exporter country of mint oil among all over the world, which is produced from the leaves of it after extraction. Mint oil and its constituent's and derivatives can be used in different types of industrial purposes including food, pharmaceutical, perfumery and flavouring industry. Therapeutic phytochemical compounds present in peppermint has a number of bioactive phytochemicals that have well defined and proven chemical structures and possess significant physiological roles.

Chemical Components of Peppermint:-

1. Polyphenols Rosmaric acid, eriocitrin, cinnamic acid, caffeic acid etc.
2. Flavonoids glycosides –Narirutin, luteolin-7-o-rutinoside,isorhoifolin, hesperidin
3. Limonene 1-methyl-4-(1-methylethenyl)-cyclohexen
4. Cineole – 1,3,3 -Trimethyl-2-oxabicyclo [2.2,2] octane
5. Methone (2S,5R)-2-isopropyl-5-methylcyclohexanone
6. Menthofuran 3,6-Dimethyl-4,5,6,7-tetrahydro-1-benzofuran

Fig.no.07:- Peppermint

Emulgel:-

Emulgel is combination of emulsion and gel. Which is new approach for topical delivery of drug. It has a double control release like emulsion and gel. It is a new class of formulation, it release the drug faster in comparison ointment, cream & lotion. Incorporation of drug in emulgel formulation is suitable to treat

skin disorders. Emulgel having advantage of both gel & emulsion act as a control drug delivery system for topically applied drugs.

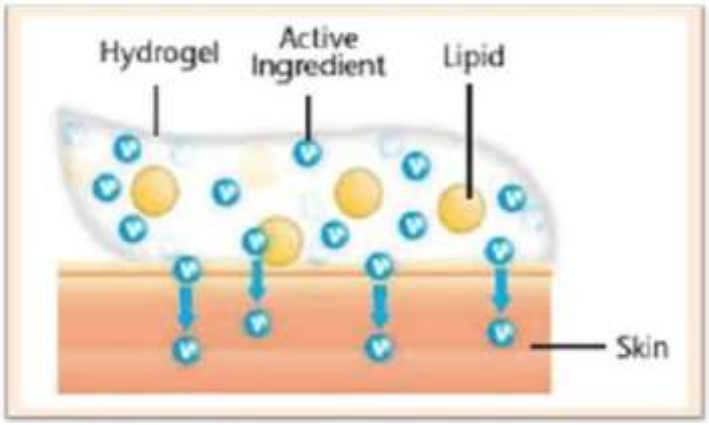


Fig no:-08 Structure of Emulgel

They are emulsion of either oil in water or water in oil type which are gelled by mixing with a gelling agent Emulgel is prepared both in oil-in-water & water-in-oil type of emulsion mixed with gel Oil-in-water is used for lipophilic drug & water–in- oil type is used for hydrophobic drug delivery.

ADVANTAGES:-

1. Incorporation of hydrophobic drugs
2. Better loading capacity
3. Better stability
4. Controlled release
5. No intensive sonication
6. Avoiding first pass metabolism
7. Avoiding gastrointestinal incompatibility
8. More selective for a specific site
9. Improved patient compliance

DISADVANTAGES:-

1. Skin irritation on contact dermatitis.
2. The possibility of allergenic reactions.
3. The poor permeability of some drugs through the skin.
4. Drugs of large particle size are not easy to absorb through the skin.
5. The occurrence of the bubble during formulation of emulgel.

Formulation Of Emulgel:-

For the preparation of emulgel some constituents are used including drug, which are:

1. **Vehicle**:- Vehicle should follow the ideal characters given in the Pharmacopeias
2. **Aqueous material:-** The aqueous phases used are water, alcohol, etc.
3. **Oil** :-Oils are used for preparation of emulsion. Mineral oils and paraffin are used either alone or in combination
4. **Emulsifiers**:-Emulsifiers used for preparation of emulsion. Some examples are span 80, tween 80,

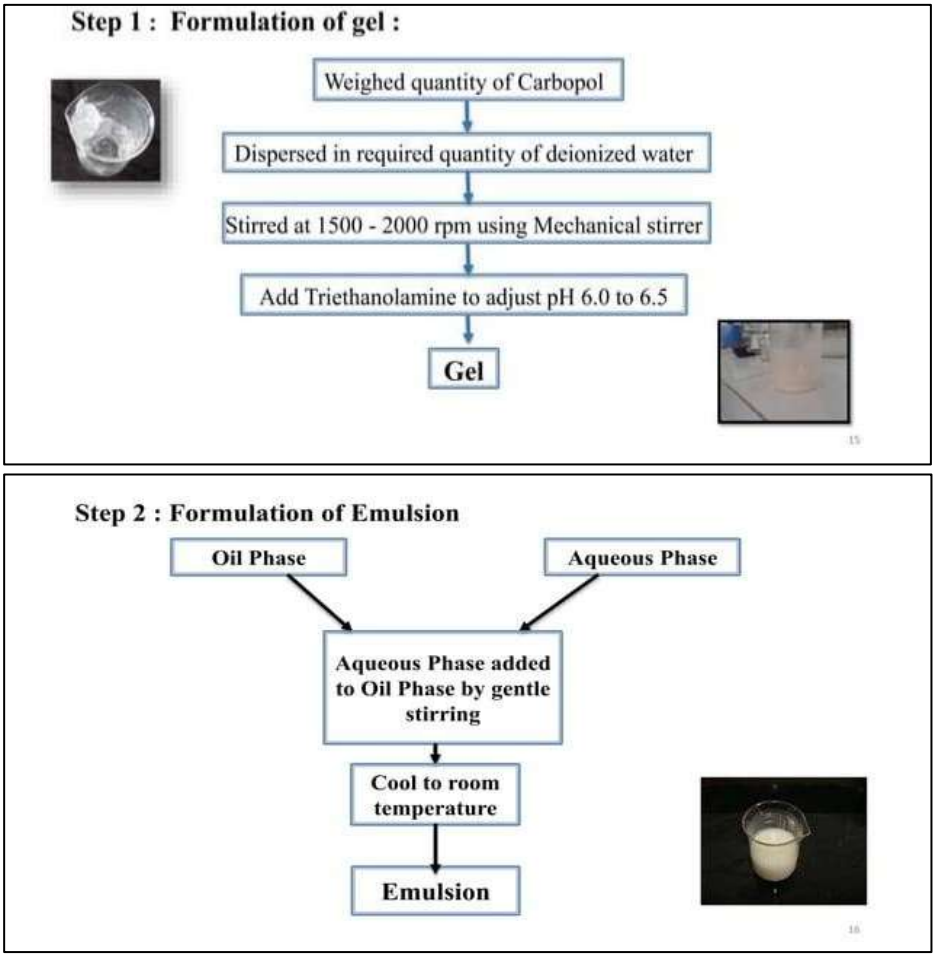
stearic acid, sodium stearate.

5. **Gelling agents:-** Gelling agents are used for prepare gels, which enhance consistency of preparation.
6. **Penetration enhancers:-** Penetration enhancers help to absorb drug to the skin.

Ideal Properties Of Additives:-

1. They should be nontoxic.
2. They should be easily available.
3. They should be cheap.
4. They do not be contraindicated.
5. They should physically be stable.

Preparation Of Emulgel:-



Emulgel are prepared by incorporating gel and emulsion. The emulsion and gel are prepared separately and mixed together. For preparing emulsion, aqueous phase and oil phase are taken separately and mixed together. Then the gel is prepared by using gelling agent. After preparing gel and emulsion, they are mixed with gentle stirring. The chemicals are used as oil phase are castor oil, clove oil, liquid paraffin, etc. Water and alcohol are used as aqueous phase.

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