IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 11, May 2025
Impact Factor: 7.67

Nanosponges : Formulation and Evaluation of Miconazole Loaded Nanosponges

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Abstract: *This review aims that the study of to formulate and evaluate nonosponges as a Novel drug delivery systems, exploiting their potential to improve the biological availability of drug with long half lives. Nanosponges, tiny mesh structure with enhanced ability to encapsulate water and lipid soluble drug , have gained significant attention in the field of pharmaceuticals. These spherical colloidal particles possess a hydrophobic core, allowing for the transport of therapeutic molecules with both hydrophilic and hydrophobic properties composed of 3D network with long -chain polyester backbones and cross -linkers , nonosponges can be synthesized through the treatment of cyclodextrins with appropriate cross-linkers.The study will investigate the physicochemical properties, in-vitro release profile and biological efficiency of nonosponges, providing insights into their potential applications in pharmaceutical technology.*

Keywords: Biological efficacy, Cyclodextrin, crosslinkers, 3D Network, Nanosponges

I. INTRODUCTION

Nanosponges are tiny mesh structures that can encapsulate a large number of substances and drug molecules[1, 2]. They have enhanced ability to dissolve water- and lipid-soluble drugs and also possess spherical colloidal properties [3]. They increase the biological ability of drugs with long drugs.[4] Inside the hydrophobic room. In addition, due to the nature of external pepidation branches and nanopion's parents, therapeutic molecules, which are both dopply and hydrophobic, can be transported. [5] They resemble 3D networks with long-chain polyester backbones present in solution and cross-linkers connecting different parts of the polymer [6].It has been shown that treatment of cyclodextrins (cyclic oligosaccharides) with appropriate cross-linkers can result in nanosponges, unique nanostructured materials composed of hyperlinked cyclodextrins [7].

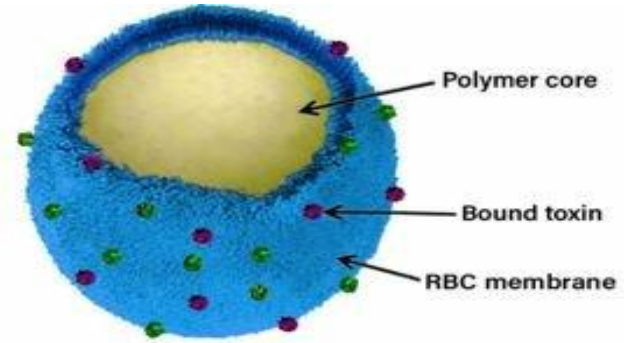

Fig.no 1 : NANOSPONGE

According to the agent used as a cross-linking agent, nanosponges can be synthesized as neutral or acidic materials and swell [8]. The result is hollow spheres with voids that can hold drug molecules . During preparation, the proportion of

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cyclodextrin crosslinking can be modified to improve drug loading and provide a customized release profile. Theirhighly permeable nanomeric nature, compared to that of parent cyclodextrin molecules, allows drug molecules to organize into nanospongy inclusions and interact with each other in a non-inclusion modeand provide efficient drug loading . Compared to other nano particles, they can be easily reproduced using various treatments, so there are several advantages.Wash with environmentally friendly solvent, stripped, relatively harmless heat gas, delicate heating, or change Strong. They are used in different areas [9]. The technical potential of nanosponges stems from the relatively simple principle the chemistry of their cross-linking peptides and polyesters. Being water-soluble, they do not chemically disintegrate in water . Nano humans are composed of several voids in major structures and provide free movement of drug components. Partially Atc he can move freely in the vehicle, reduce the concentration of drugs in the vehicle, create abundant United Nations, and increase the slim balance. This procedure continues until the body has absorbed all of the drug. Once the liquid is prepared, the solubility of the drug molecules increases, reducing the benefit of gradual release and making the drug fragments behave as if they were administered in a free rather than entrapped form [10]. They mix it with water and use the resulting liquid as a means of transportation. They are a valuable tool for converting liquid materials into solid forms. Nanosponges are able to selectively bind to the target through chemical linkers . They are safe for oral and invasive routes, making them a viable drug delivery vehicle .Nanosponges can be delivered through the lungs,and due to their minute size, veins can be seen [11]. To produce capsules or tablets for oral administration, the complex can be dispersed in a solution of:a matrix containing diluents, lubricants, adjuvants and anti-caking agents. This step is required for the production process. Non –oral the introduction of substances can be obtained by dissolving sterilized water, physiological solutions, or one of many other aqueous solutions. They can effectively include them in the local hydrogel [12].

II. CHARACTERISTIC FEATURES OF NANOSPONGES

Nanosponge particles have a certain size, and their polarity can be changed using different ratios of crosslinking agents and polymers. When the polarity of the voids changes, nanosponges can have diameters of less than 1 μm[13]. They can be quasicrystalline or crystalline. The crystal structure of nanosponges is important for drug complexation because the level of crystallization significantly affects the stacking performance of nanosponges. Paracrystallinenanosponges have been proven to possess a range of drug loading capabilities according to the literature . They are stable up to temperatures of 130 °C and pHs from 1 to 11. They are porous, biodegradable, and essentially non-toxic [14]. They can do it for their three -dimensional structure Capsules,transport, and guarantee that drugs and other compounds have been observed. Underwater, nanosping provides transparency An unclear coloid suspension that can be extracted from extraction of solvent or thermal detachment and extracted from microwave and heat detachment Ultrasound . They show the targeted release of various compounds from the possibility of interaction with several functional Groups that can be improved using synthetic linkers that are aimed at sites. External magnetic field can be used for targeted the category by adding magnetic qualities to the configuration of nanoponses during the production process by expanding ferrite and other Magnetic materials .Nanosponges have been selected as the material of choice for providing sustained release due to their desirable properties: They allow for 24-hour dosing and can be used to encapsulate immiscible liquids, resulting in less irritation and improved flexibility and stability. Although nanosponges have many advantages, they also have some disadvantages. Essentially, small drug molecules are incorporated into the nanosponges, but they can also contain macromolecules and oligonucleotides . The degree of cross-linking affects the ability to load drugs, as it controls the amount of free space within the nanosponge available for loading. Premature degradation of the cross-linker increases the likelihood of dose reset.

III. MATERIALS USED TO MAKE NANOSPONGES

Many substances have shown promising results and can be used to make the desired type of nanosponge. It depends on the material used, the type of nanosponge and the degree of cross-linking required. From his influence on the release of the drug and the encapsulation of the drug, The quantity of sewing is an important component of nanospognes and depends on the concentration of seams. Various components are used ,In the preparation of Nanoponge, is discussed below (Table 1). Polymers and copolymers The development and performance of nanosponges is influenced by the type

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of polymer used in their formulation. In the case of , the cavities of the nanosponges developed must be such that they can accommodate a particular drug for complexation.

Table 1 : Materials used within the framework of nanosponges

Sr..no	Ingredients used in nanosponges	Examples
1	Polymers	Cyclodextrin and its derivatives, hypercrosslinked polystyrene, Eudragit RS100, acrylic polymers, etc.
2	Copolymers	Polyvinyl alcohol, polyvalerolactone, allyl valerolactone, ethyl cellulose, etc.
3	Crosslinkers	carboxylic acid dianhydrides, carbonyldiimidazole, dichloromethane, diphenyl carbonate, Glutaraldehyde, etc.

The polymer also depends on the type of drug to be entrapped and the desired release profile [15]. Some polymers used are cyclodextrin and its derivatives, hypercrosslinked polystyrenes, Eudragit RS100, acrylic polymers, etc. [16]. prepared ferulic acid nanosponges to improve water solubility. Nanosponges were formulated using cyclodextrin as a polymer. Cyclodextrins are a suitable wall material to trap both hydrophilic and hydrophobic molecules due to their hydrophobic central chamber and hydrophilic surface. Due to the porous structure of the cyclodextrin polymer, the solubility of ferulic acid is enhanced after encapsulation in nanosponges[17]. Lamy et al. developed Temoporfin loaded nanosponges for neck and head cancer.Nanosponges were prepared using hypercrosslinked β-cyclodextrin polymers. The use of crosslinked β-cyclodextrin polymers improves drug permeation [18]. Desai et al. Synthetic neuropeptide Y nanosponges cross-linked using β-cyclodextrin. Nanosponges crosslinked with β-cyclodextrin enhance drug release and stability. They are useful for drug administration [19]. Hafez et al. Carboplatin hydrogel was formulated using nanosponges as a carrier. Nanosponges were formulated using ethyl cellulose using the evaporation method of a double emulsion solvent. Formulated hydrogels containing nanosponge have shown an improvement The effectiveness of the drug in the target zone with prolonged release and biodhesion[20]. Hao et al. used polylactic acid-glycolic acid-polyethylene glycol copolymer to neutralize tumor acidity and prepared calcium carbonate nanosponges to act as proton nanosponges[21]. Abemaciclib-loaded nanosponges prepared by Anver et al. using ethyl cellulose and Kolliphor P-188 showed that the amount of ethyl cellulose and Kolliphor P-188 used as copolymers influenced the drug entrapment efficiency. The results showed that a higher amount of ethyl cellulose and a lower amount of Coryphore P-188 could increase the encapsulation efficiency and prevent drug leakage from the nanosponges.[22]

Sewing agent (crosslinking agent)

The type of sewing depends on the structure of the polymer and drug that needs to be nanopant. Dian Hidridokarboxylic acid, CarbonyylJitomaidazole, Jiflman, Ziphenyl, Glutardogyde, etc. Used sewing agent . The number of crosslinks is the most important component of nanosponges, as it affects the drug release and encapsulation behavior, and depends on the concentration of the crosslinker. (new11) Balancing hydrophilicity and hydrophobicity Nanosponges can be prepared to deliver active drug molecules by varying the concentration of the crosslinker. Depending on the type of crosslinker used, water-soluble or insoluble nanosponge structures can be developed.In addition, different crosslinkers can significantly alter important properties such as the swelling ability and hydrophilicity or hydrophobicity of the polymer.[23] Ansari et al. To improve solubility and stability, resveratrol nanosponges were formulated using cyclodextrin as a polymer and carbonyldiimidazole as a cross-linking agent, which forms an inclusion complex with the drug, increasing its solubility [24]. Taleb et al. prepared quercitrin-loaded nanosponges using β-cyclodextrin and 2-hydroxypropyl-β-cyclodextrin separately as polymers and diphenyl carbonate as a cross-linking agent. The results of particle size depicted that the amount of crosslinker used affects the particle size of nanosponges. For the two types of used Cyclodextrins, it was shown that formulations with greater molar ratios of crosslinker had Particle size that was larger than those with lower molar ratios of crosslinker [25]. To improve the binding properties of conventional cyclodextrin nanosponges, Massaro et al. proposed the synthesis of cyclodextrin-calixarene copolymers using triazole as a binding agent. Quercetin and silibinin, two polyphenol bioactive chemicals,

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have been used to fabricate composite materials using this combination of cyclodextrin-calixarene nanosponge materials [26].

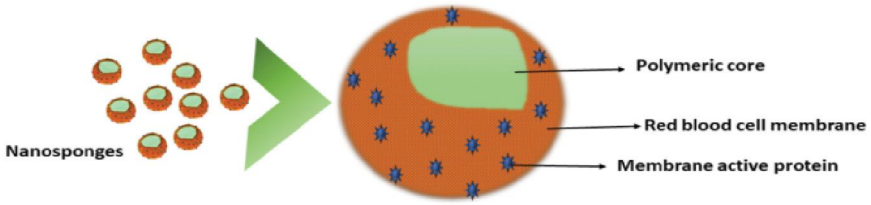

Fig no 02 : Nanosponges

IV. LITERATURE REVIEW

1] Himanshu bhowmik et al (2018) :Recent advances in nanotechnology have led to the development of targeted drug delivery systems. However, to effectively deliver a molecule to a specific location using a drug delivery system, a specialized drug delivery system is required. The discovery of nanosponges has been a significant step forward in overcoming certain issues such as drug toxicity, poor bioavailability, and drug release in a predictable manner as they can accommodate both hydrophilic and hydrophobic drugs. Nanosponges exhibit an inherently porous structure and have the unique ability to entrap drug molecules and achieve the desired release. Nanosponges are tiny sponges that can travel through the body to reach specific locations, bind to surfaces, and release drugs in a controlled and predictable manner. Nanosponges can be prepared by cross-linking cyclodextrins with carbonyl or dicarboxylate (cross-linking agents). Nanosponge technology has been widely investigated for drug delivery for oral, topical, and parenteral administration. Nanosponges also act as effective carriers for enzymes, proteins, vaccines, and antibodies.

2] Rahul Salunke et al (2019) : Objective: The aim of this study was to develop and characterize optimal stable gliclazide (GLZ) nanosponges using emulsion solvent diffusion method with the aim to enhance its bioavailability and drug release in a sustained and controlled manner.Methods: GLZ nanosponges were prepared by emulsion solvent diffusion method using different drug to polymer ratios (1:1 to 1:5). The polymer used is Eudragit S100. The compatibility of GLZ with the polymer was evaluated by differential scanningcalorimetry (DSC) and Fourier transform infrared spectroscopy (FTIR).All formulations were evaluated for product yield, entrapment efficiency, in vitro drug release, scanning electron microscopy (SEM), and stability studies. Results: DSC and FTIR studies showed no interaction between the drug and polymer. The product yields for all batches ranged from 73.8±0.30 to 85.6±0.32. The highest yield of products was shown by batch F3, the collection efficiency of batch F3 was 70.6±0.77. The average particle size is from 303±2.36 to 680±2.50 nm. At the end of 10 h, formulation F3 showed the highest drug release of 94.40 ± 1.12%.The release kinetics of the optimized formulation shows zero-order drug release. Stability studies show that there is no significant change in the in vitro dissolution profile of the optimized formulation

3] Abdul waris khan et al (2021)

Nanotechnology mediated drug delivery has been reported to enhance the drug efficacy, bioavailability, reduced toxicity and improve patient compliance by targeting the cells and tissues to elicit the desired pharmacological action. The main aim of the study was to formulate lovastatin loaded nanosponges and to evaluate them. Lovastatin charged with nanopons It was prepared by diffusion of emulsion solvent using various polymers (ethylcellulose, polyvinyl alcohol, β-cyclodestrin, page F68, propyl hydroxy β-cyclodestrin). The Ftir test is carried out as a preliminary test, because of this There was no interaction between the drug and the polymers. Next, the Namp Spage was estimated by the particle size and PDI. Zeta is the possibility of SEM, which is the effectiveness of capture and release of Invitro drugs. The particle size has changed from 295.5 to 578.8 nm. The PDI changed from 0.189 to 0.465, and the bunker potential was -35.96 MV from -17.3, and the capture efficiency has changed. 78.38-95.77 %. The cumulative release percentage from all nanosponges varied from 66.86 to 96.60% after 12 h depending on the drug-to-polymer ratio, with the F6 formulation showing the highest drug release percentage (96.60%).Release kinetic studies showed that the release was first-order diffusion controlled, and the n value (0.6017) of the Korsmeyer-Peppa model indicated that the release mechanism was of non-Fikian type

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4] Dalia a. gaber et al (2023)

Cyclodextrin nanosponges are solid nanoparticles developed by crosslinking cyclodextrin polymers. They have been widely used as excellent delivery systems for water-insoluble drugs. The aim of this study is to improve the solubility of piroxicam (PXM) using a β-cyclodextrin-based nanosponge formulation. PXM nanosponge (PXM-NS) formulations were prepared using β-cyclodextrin and carbonyldiimidazole as crosslinkers, and three drug/nanosponge ratios as well as three β-cyclodextrin/crosslinker ratios were tested. Piroxicam nanosponge formulations were characterized for particle size, zeta potential, physical compatibility, and in vitro releaseTo obtain the optimal formulation, stability studies were performed at three temperatures (4°C, 25°C, and 40°C).Finally, the in vivo analgesic activity and pharmacokinetic parameters of the optimal formulation were performed. The optimized formulation of PXM-NS (PXM-NS10) showed particle size (362 ± 14.06 nm), polydispersity index (0.0518), zeta potential (17 ± 1.05 mV) and %EE (79.13 ± 4.33). The dissolution study showed a significant increase in the amount of PXM dissolved compared to the unformulated drug.Research on stability has shown that nanospon has been accepted for 90 days at 4 ° C and 25 ° C for 90 days. It has been confirmed that in Vivo's analgesic research has increased in PXM in the mouse's analgesic reaction. 1.42 times with relative bio -availability of PXM -NS10 compared to over -the -counter drugs. Nanosponges prepared under optimal conditions are promising formulations to enhance the solubility and hence bioavailability of piroxicam

5] Akash Garg et al (2024): NanospongesThe complex chemical reactions related to the production of new drug administration systems have hindered the efforts to create a targeted drug delivery system for a long time. Nano Spunation, a recently created coloid system, can overcome drug toxicity, decrease in biopailability, and release drugs in a wide area. Nanosponges are tiny sponges consisting of a three-dimensional network with porous cavities. They can be easily prepared by cross-linking cyclodextrins with various compounds. Due to the excellent biocompatibility, stability, and safety of cyclodextrin, numerous cyclodextrin-based drug delivery systems have been rapidly developed. Nanosponge-based drug delivery systems have various applications in various diseases, including cancer, autoimmune diseases, therapeutic applications, enhanced bioavailability, and stability. This review details the advantages and disadvantages, preparation methods, factors affecting their preparation, characterization methods, applications and the latest developments in the field of.nanosponges.

V. AIM AND OBJECTIVES

AIM :

To review and study nanosponge as a novel and targeted drug delivery system and to formulate and evaluate nonsponges .

Nanosponges are an innovative drug delivery system that has recently emerged due to the rapid development of nanotechnology and the need for precise and targeted drug delivery systems.

These are very small, microscopic spongy particles,roughly the same size as a virus, that consist of a series of cavities that can be filled with drugs.

Objectives :

1.To discuss nanosponges.
2. Advantages and disadvantages .
3. Factor influencing their formation.
4. Method of preparation .
5. Characterization.
6. Applications.

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VI. DRUG PROFILE

MICONAZOLE { MICONAZOLE NITRATE }

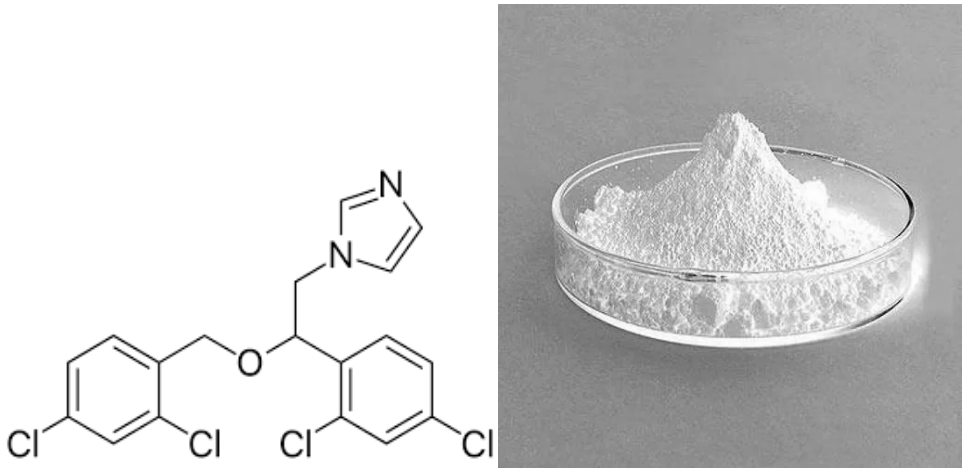

Fig : Miconazole

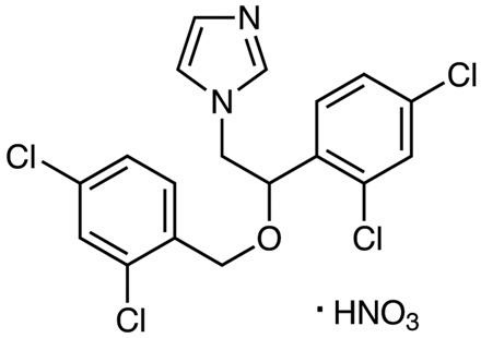

Fig : Miconazole nitrate

Miconazole nitrate is an antifungal medication primarily used topically to treat superficial fungal infections of the skin, like athlete's foot, jock itch, and ringworm, as well as pityriasis versicolor. It works by interfering with the fungal cell membrane, inhibiting fungal growth. Miconazole is also available in vaginal formulations for treating vaginal yeast infections.

Mechanism of Action:

Miconazole disrupts the integrity of fungal cell membranes by inhibiting ergosterol synthesis, a vital component of fungal cell walls.

It also inhibits the enzyme CYP450 14α-lanosterol demethylase, which is involved in the production of ergosterol.

Uses:

Topical: Athlete's foot, jock itch, ringworm, tinea versicolor, and other fungal skin infections.

Vaginal: Vaginal yeast infections (candidiasis).

Administration:

Topical: Usually applied topically as a cream, ointment, or powder to the affected skin area.

DOI: 10.48175/IJARSCT-27255

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Vaginal: Available as suppositories or creams for insertion into the vagina.
Side Effects:
Topical: May cause local irritation, burning, itching, or stinging at the application site in some individuals.
Vaginal: May cause vaginal burning or itching in some individuals.

Contraindications:
Allergy:
Individuals with a known allergy to miconazole or other azole antifungal medications should not use miconazole.
Co-administration:
Miconazole should be used with caution when co-administered with certain medications that are metabolized by the CYP3A4 enzyme, as it can potentially increase the blood levels of those medications.
Warnings:
Do not use on mucous membranes or open wounds:
Miconazole is intended for external use only and should not be taken orally.
Avoid occlusive dressings:
Do not apply occlusive dressings (airtight coverings) over miconazole unless specifically directed by a healthcare professional, as this can increase the risk of skin irritation.
Consult a healthcare professional:
If symptoms worsen or do not improve after 2-4 weeks of treatment, consult a healthcare provider.

Drug Interactions:
Miconazole can interact with certain medications metabolized by CYP3A4, such as statins, certain sedatives (triazolam and oral midazolam), and some drugs that prolong the QT interval.

IUPAC Name
1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole

Chemical Formula
$C_{18}H_{14}Cl_4N_2O$

Brand Names
Aloe Vesta Antifungal, Baza, Critic-aid Clear, Desenex, Fungoid, Inzo,etc.

Generic Name
Miconazole

Background
Miconazole is a broad-spectrum azole antifungal with some activity against Gram-positive bacteria as well. It is widely used to treat mucosal yeast infections, including both oral and vaginal infections; although intravenous miconazole is no longer available, a wide variety of suppositories, creams, gels, and tablet-based products are available.Miconazole is thought to act primarily through the inhibition of fungal CYP450 14α-lanosterol demethylase activity.
Miconazole was first synthesized in 1969 and first granted FDA approval on January 8, 1974, for sale by INSIGHT Pharmaceuticals as a topical cream. It is currently available as a variety of prescription and over the counter products. Despite having been in clinical use for an extended period, resistance to miconazole among susceptible organisms is relatively low.

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Indication

Miconazole is indicated for the local treatment of oropharyngeal candidiasis in adult patients and for the adjunctive treatment of diaper dermatitis complicated by candidiasis in immunocompetent patients aged four weeks and older.Miconazole is available as both a suppository and cream for the treatment of vaginal yeast infections and the relief of associated vulvar itching and irritation. Lastly, miconazole cream is effective in treating athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm infections (tinea corporis), pityriasis (formerly tinea) versicolor,and cutaneous candidiasis.

Pharmacodynamics

Miconazole is an azole antifungal that functions primarily through inhibition of a specific demethylase within the CYP450 complex.As miconazole is typically applied topically and is minimally absorbed into the systemic circulation following application, the majority of patient reactions are limited to hypersensitivity and cases of anaphylaxis.Patients using intravaginal miconazole products are advised not to rely on contraceptives to prevent pregnancy and sexually transmitted infections, as well as not to use tampons concurrently.

Mechanism of action

Miconazole is an azole antifungal used to treat a variety of conditions, including those caused by *Candida* overgrowth. Unique among the azoles, miconazole is thought to act through three main mechanisms.The primary mechanism of action is through inhibition of the CYP450 14α-lanosterol demethylase enzyme, which results in altered ergosterol production and impaired cell membrane composition and permeability, which in turn leads to cation, phosphate, and low molecular weight protein leakage.

In addition, miconazole inhibits fungal peroxidase and catalase while not affecting NADH oxidase activity, leading to increased production of reactive oxygen species (ROS). Increased intracellular ROS leads to downstream pleiotropic effects and eventual apoptosis

Lastly, likely as a result of lanosterol demethylation inhibition, miconazole causes a rise in intracellular levels of farnesol. This molecule participates in quorum sensing in *Candida*, preventing the transition from yeast to mycelial forms and thereby the formation of biofilms, which are more resistant to antibiotics.In addition, farnesol is an inhibitor of drug efflux ABC transporters, namely *Candida* CaCdr1p and CaCdr2p, which may additionally contribute to increased effectiveness of azole drugs.

Absorption

Miconazole given to healthy volunteers as a single 50 mg oral tablet produced a mean C_{max} of 15.1 ± 16.2 mcg/mL, a mean AUC_{0-24} of 55.2 ± 35.1 mcg*h/mL, and a median T_{max} of 7 hours (range 2.0-24.1). In these patients measurable plasma concentrations ranged from 0.5 to 0.83 mcg/mL.

Topical miconazole is absorbed poorly into the systemic circulation.In pediatric patients aged 1-21 months given multiple topical applications of miconazole ointment for seven days, the plasma miconazole concentration was less than 0.5 ng/mL in 88% of the patients, with the remaining patients having a concentration of 0.57 and 0.58 ng/mL, respectively.Similarly, patients. administered with a vaginal 1200 mg ovule had a mean C_{max} of 10.71 ng/mL, mean T_{max} of 18.4 hours, and mean AUC_{0-96} of 477.3 ng*h/mL.

Protein binding

In vitro data suggests that miconazole binds human serum albumin, however, the clinical significance of this observation is unclear.

Metabolism

Miconazole is metabolized in the liver and does not give rise to any active metabolites.

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Half-life
Miconazole has a terminal half-life of 24 hours

Route of elimination
Miconazole is excreted through both urine and feces; less than 1% of unchanged miconazole is recovered in urine.

Summary
Miconazole is an azole antifungal with broad-spectrum activity used to treat fungal infections affecting the vagina, mouth and skin, including candidiasis.

VI. FORMULATIONS OF MICONAZOLE

Miconazole is available in various topical formulations, including creams, ointments, powders, gels, and solutions. It can also be found in tablet and vaginal suppository forms. These formulations are used for treating fungal infections of the skin, nails, and mucous membranes.

Topical Formulations:

- **Creams:** Commonly used for various fungal skin infections.
- **Ointments:** Similar to creams, often used for deeper or more severe skin infections.
- **Powders:** Used to treat fungal infections on the feet or in other areas prone to sweating.
- **Gels:** Can be used for localized infections or in areas where creams or ointments may not be as effective.
- **Solutions:** Typically used for larger areas or to facilitate penetration into the skin.
- Other Formulations:
- **Tablets:** Miconazole can be taken orally for certain types of fungal infections, but topical application is more common for localized skin and nail infections.
- **Vaginal Suppositories:** Used to treat vaginal yeast infections.

Example Formulations:

- **Micatin (Desenex):** A topical powder containing miconazole, used for treating athlete's foot and other fungal skin infections.
- **Micogel:** A miconazole-containing gel used for vaginal yeast infections.
- **Micofact:** A miconazole nitrate vaginal cream.
- **Monistat:** A variety of over-the-counter products containing miconazole for treating vaginal yeast infections, including creams, suppositories, and one-day or three-day regimens.
- **Oravig:** A miconazole buccal tablet for localized treatment of oropharyngeal candidiasis (thrush).

Factors Affecting Formulation Choice:

- **Location of Infection:** Different formulations are better suited for different areas of the body.
- **Severity of Infection:** More potent formulations may be needed for severe infections.
- **Patient Preference:** Some patients prefer creams, while others may prefer gels or powders.
- **Accessibility and Cost:** Over-the-counter formulations are readily available and more affordable than prescription-strength products.

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VII. MATERIALS AND EQUIPMENTS

Chemicals	**Uses**	**Quantity**
Ethyl cellulose	Coating agents it has sustained release properties.	
Polyvinyl alcohol	Water-souble , non-toxic and biodegradable polymer.	
Beta - cyclodextrin	For increasing the bioavaiability of poorly water - soluble drugs.	
Dichloromethane	Use to dissolve a particular quantity of loaded drug containing nanosponges.	
Miconazole Nitrate(drug)	Antifungal agent.	
Apparatus	**Uses**	**Principle**
Butter paper	It is used as weighing paper.	-
Filter paper	Use for filtration.	Separation of solid particles from liquids.
Syringe	Use to form nanosponges droplets.	-
Beakers	Use to hold liquid samples.	-
Stirrer	Use for stirring or mixing of solution.	-
Measuring cylinder	Use to measure the volume of liquids.	-
Funnel	Use for transferring liuids in small containers.	-
Instruments	**Uses**	**Principle**
Magnetic stirrer	Use for stirring or mixing a solution.	A magnetic stirrer uses a rotating magnetic field to stir a non-magnetic liquid in a container
Hot air oven	Use to sterilize lab objects and samples.	A hot air oven uses dry heat and conduction to sterilize or dry heat-resistant materials.
Weighing balance	Use to determine the weight or mass of the object.	Weighing balances work on the principle of equilibrium, balancing an unknown weight against a known weight until a state of equilibrium is reached.

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Fig: Magnetic sterrier

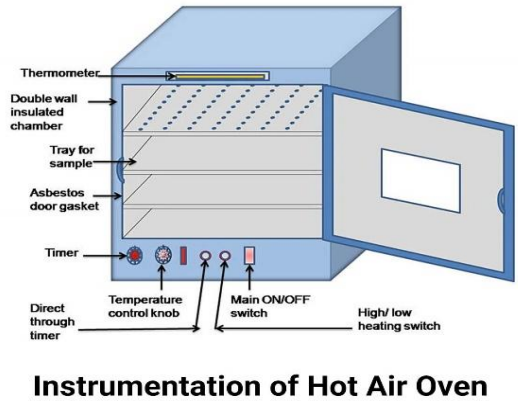

Fig: Hot air oven

Fig : Weighing balance

METHODS OF FORMULATION OF NANOSPONGES

Methods of preparation of Nanosponges :
Quasi emulsion solvent diffusion
Ultrasound-assisted synthesis
Solvent method
Hyper crosslinked method
Microwave irradiation method
Polymerization

1] Emulsion Solvent Diffusion Method

In this method, nanosponges are prepared using different proportions or amounts of ethyl cellulose.And polyvinyl alcohol. This method uses twophases – dispersed and continuous. The dispersed phase consists of ethyl cellulose and the drug, which is dissolved in 20 ml of dichloromethane, and a small amount of polyvinyl alcohol (PVA) is added to 150 ml of the continuous (aqueous) phase. The mixture is then stirred at 1000 rpm for approximately 2 hours. Product, It is assembled by filtering. Finally, the product is dry with Innoanon Temperature 400 ° C [28]

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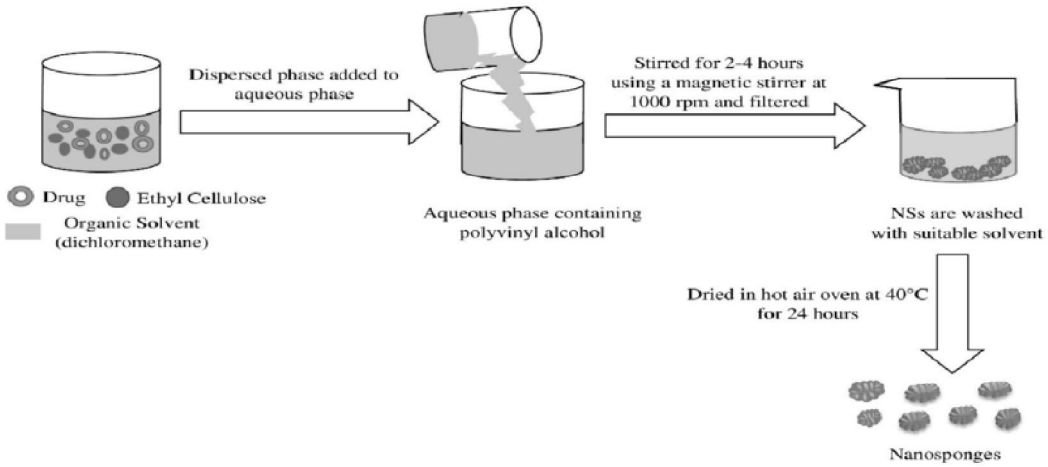

Fig.no.3: Emulsion solvent diffusion method

In this method , nanosponges are preapared using different amount of ethyl cellulose / cellulose powder and poly vinyl alcohol .

In this method two phases used :

1) Dispersed phase.

2) Continous phase.

Dispersed phase : Drug + cellulose powder dissolved in dichloromethane.

Continous phase : Poly – vinyl alcohol is added to 150 ml of distilled water .

Dispersed phase added to continuous phase.

Stirred for 2-4 hours using magnetic stirrer at 1000 rpm and fitered.

Nanosponges are washed with suitable solvent.

Dried in hot air oven at 40 degree celcieus for 24 hrs.

Add Carbapol / Beta –cyclodextrien.

LAB WORK

Continuous phase

DOI: 10.48175/IJARSCT-27255

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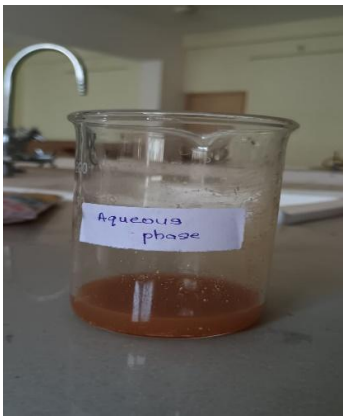
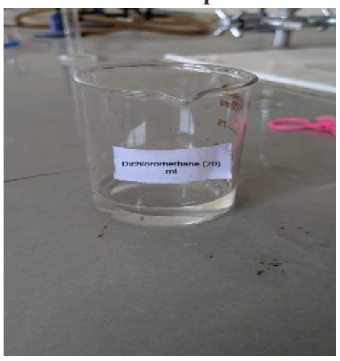


Dispersed phase

Drug + cellulose powder dissolved in dichloromethane.

Continuous phase



Dichloromethane

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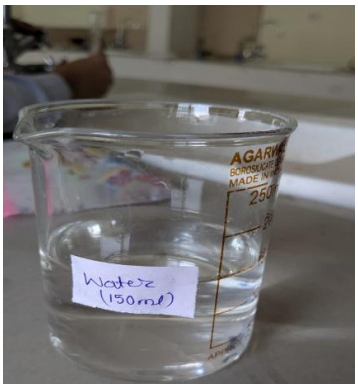

Distilled water

Continous phase + Dispersed phase

Filtered the filtrate (Nanosponges)

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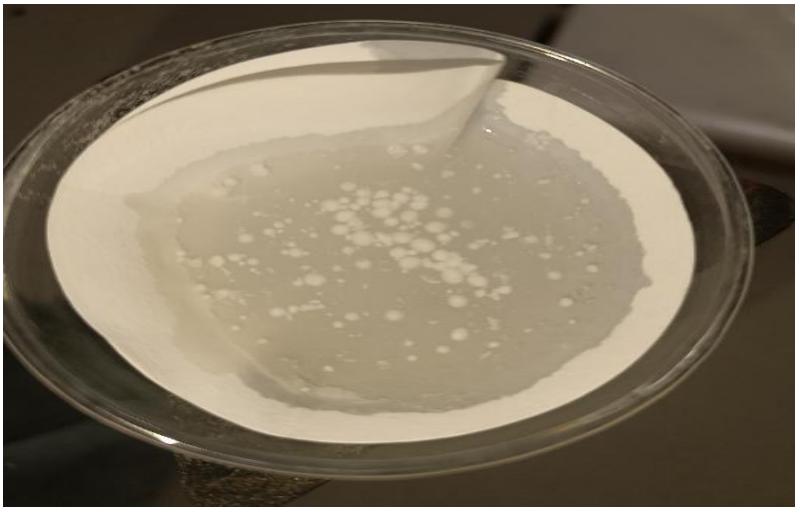
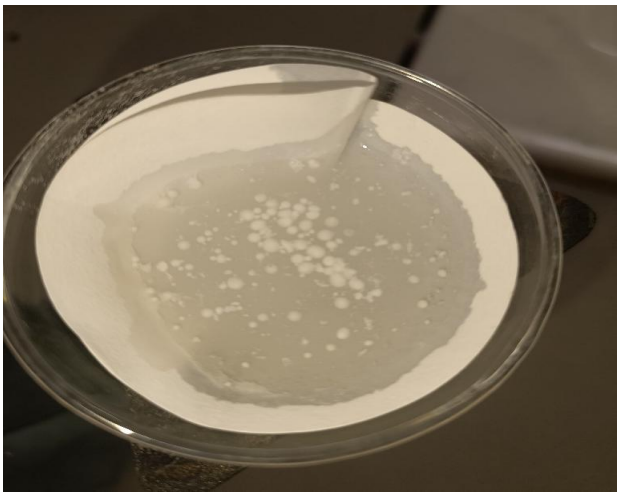
Nanosponges loaded with Iprazole



NANOSPONGES LOADED WITH MICONAZOLE NITRATE



Formulate at P.Wadhawani college of Pharmacy Girija Nagar , Yavatmal.

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RESULTS

Nanosponges is formed by Emulsion Solvent Method

Loading Of Drug into Nanosponges:

Pretreatment of nanosponges is necessary to achieve a mean particle size of less than 500 nm for drug delivery. To avoid the formation of aggregates, sonicate the nanosponges in water, then centrifuge the suspension to separate out the colloidal fraction. Freeze-dry the sample after separating the supernatant.

Prepare the Nanosponge aqueous suspension, disperse any extra medication, and keep the suspension constantly stirred for the precise amount of time needed for complexation. After complexation, centrifuge the complexed drug to separate it from the uncomplexed (undissolved) drug. The solid nanosponges crystals can then be obtained by freeze drying or solvent evaporation.nanosponges and crystalline nanosponges have distinct loading capabilities. Crystalline nanosponges have a higher drug loading than paracrystalline ones. Drug loading takes place as a mechanical mixture rather than an inclusion complex in poorly crystalline nanosponges.

The nanosponge's crystal structure is crucial for the complexation of drugs. According to a study, paracrystalline.

Mechanism of drug release from nanosponges

Since nanosponges have an open structure (they do not have a continuous membrane in the surrounding nanosponges), the active substance is added to the carrier in an encapsulated form. The encapsulated active substance can freely move from the particles into the carrier until the carrier is saturated and equilibrium is reached. As soon as the product is applied to the skin The ingredients of the actor become immersive and cause violations I have a balance. Therefore, the flow of active substances in nanospongeThe particles in the vehicle start with the epidermis toward the car Absorption or drying. The release of active substances into the skin continues for a long time even after the nanosponge particles are retained on the surface of the skin, i.e. in the stratum corneum..[Nanosponge : A Review by Himangshu Bhowmik]

FACTORS AFFECTING NANOSPONGES

Factors that affect the preparation of nanosponges :

1] Nature of polymer

The polymer used in the preparation of nanosponges can influence its formation and can also affect the pre-formulation. The size of the cavity of a nanosponge should be big enough to entrap a drug molecule of a particular size into it for complexation .

Type of polymer influence the performance and formation of nanosponge(cavity size should be suitable to accomodate a drug molecule).[33]

2] Drug

To be complex with nanosponges, the drug molecules should have some specific characteristics as mentioned below:

- The molecular weight of the drug molecule should be in range ranging from 100-400 Daltons.
- Structure of drug molecule should not consist of more than 5 condensed ring.
- The solubility of thedrug in water should be<10 mg/ml.
- The melting point of the drug should be <250 ˚ C.

Molecular weight = 100 - 400 Da.
Solubility = (water < 10 mg/ml)
Melting point = 250 Degree
Drug Molecule = less than 5 condensed rings

3] Temperature

Changes in the temperature can affect the complexation of drug ornanosponges. Increasing the temperature generally decreases theextent of the stability constant of the drug or the nanospongecomplex which may be due to the reduction

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of interaction forcessuch as hydrophobic forces and Van der Waal forces ofdrug/nanosponges with an increase in the temperature .
Increase in the temperature, decrease in the stability of nanosponge.[34]

4] Degree of substitution
The number, position, and type of the substituent of the parentmolecule can affect the ability of complexation of the nanosponges toa greater extent .
Complexation ability of nanosponge affected by number and position of substituent of parent molecule.[Nanosponge : A Review by Himangshu Bhowmik]

EVALUATION OF NANOSPONGES
1. Loading Efficiency/Entrapment Efficiency / Drug content
2. Solubility Study
3. Particle size analysis
4. Porosity
5. Zeta potential
6. Polydispersity index
7. Scanning Electron Microscopy
8. Swelling and Water Uptake

1] Loading Efficiency/Entrapment Efficiency / Drug content
Loading Efficiency
Loading efficiency(%)of nanosponge can be determined by ,
Loading Efficiency = Actual drug content
---------- * 100
Therotical drug content

Entrapment Efficiency
Weigh accurate quantity of nanosponge + Suitable solvent in a volumetric flask + Flask was shaken for 1 minute(vortex mixer) + Volume made up upto 10 ml with solvent + Solution was filtered and diluted with the concentration of drug(UV Spectrometer) + Yield of nano particles determined by initial weight of nanosponge.
Drug Content
An accurately weighed amount of 20 mg of lovastatin nanosponge was added to 20 ml of methanol and placed in a container. The thermoshaker was operated at 100 rpm and 25°C for 45 min followed by vertexing for 10 min. The solution was filtered through a 45 µm membrane filter and the drug was measured spectrophotometrically at λmax 237 nm. Based on a previously prepared standard curve. The medication content of the formulated nanospons has been calculated on the base of the following equation

SR.NO	CONC (mcg/ml)	ABSORBANCE
1.	0	0
2.	2	0.036
3.	4	0.068
4.	6	0.101

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5.	8	0.134
6.	10	0.165

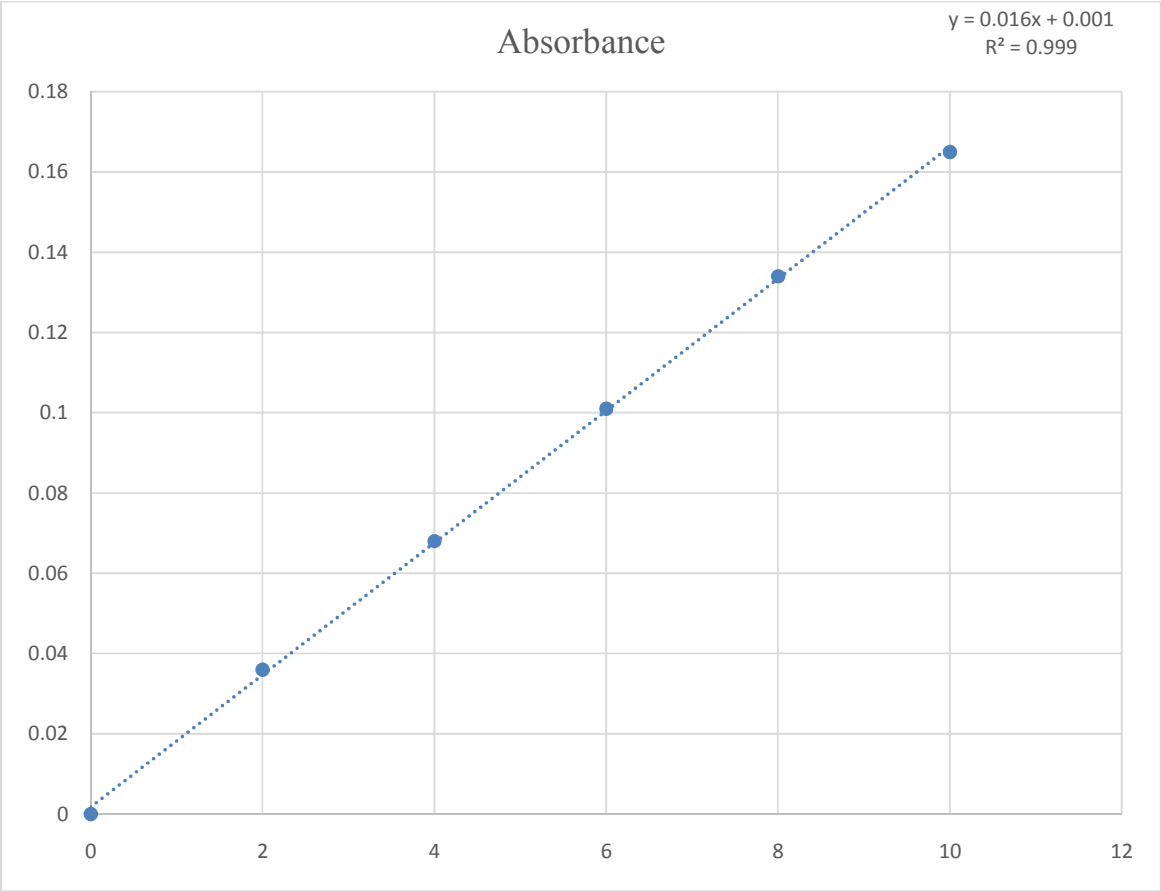

Fig : Callibration Curve Miconazole nitrate

2] Solubility Study

The most widely used approach to study inclusion complexation in the phase solubility method described by Higuchi and connors model, which examines the effect of a nanosponge on the solubility of drug.

3] Particle size analysis

The particle size was determined by dynamic light scattering, using a Malvern system, with vertically polarized light supplied by an argon-ion laser (Cyonics) operated at 40 mW. Experiments were performed at a temperature of 25.0 ± 0.1ºC at a measuring angle of 90º to the incident beam. Laser diffraction technology is based on the principle that particles passing through a laser beam scatter light at angles that are directly related to their size. When particle size decreases, the observed scattering angle increases logarithmically. The observed scattering intensity also depends on the particle size and decreases, to a good approximation, with respect to the particle cross-sectional area. Therefore, large particles scatter light at narrow angles with high intensity, while small particles scatter at wider angles but with low intensity.

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4] Porosity

Percent porosity is given by equation ,

$$\% \text{ Porosity (E)} = \frac{\text{Bulk volume} - \text{True Volume}}{\text{Bulk Volume}} * 100$$

5] Zeta potential

Zeta potential analysis was performed to evaluate the stability of the nanosponges. Zeta potential is a measure of the influence of electrostatic charge. It is the main force that causes repulsion between neighboring particles. The net results are attraction or repulsion depends on the magnitude of the two forces. The empirical rule describes the relationship between the responses of determining the zeta potential of nanosponges.Zeta potential of any system under investigation is a measure of the surface charge.

6] Polydispersity index

In light scattering, the terms polydispersity and % polydispersity are derived from a parameter, the polydispersity index. It is calculated from a cumulant analysis of the intensity autocorrelation function measured by DLS. In the cumulant analysis, a single particle size mode is assumed and a single exponential fit is applied to the autocorrelation function, and the polydispersity describes the width of the assumed Gaussian distribution. The Polydispersity Index is dimensionless and scaled such that values smaller than 0.05 are rarely seen other than with highly mono disperses standards. Values greater than 0.7 indicate that the sample has a very broad size distribution and is probably not suitable for the dynamic light scattering (DLS) technique. Different size distribution algorithms work with data that fall between these two extremes. Particle size, zeta potential and polydispersity index were determined with the same instrument, the Malvern zeta meter [35,36].

7] Scanning Electron Microscopy

To evaluate the surface morphology of the nanosponges, the sample was analyzed under a scanning electron microscope after preparing the sample by lightly spraying it onto double-sided adhesive tape adhered to an aluminum plug. The stumps were then coated with platinum. The stump containing the coated sample was placed in a scanning electron microscope. The samples were then scanned randomly and photomicrographs were taken at an accelerating voltage of 20 kV. From the resulting image, the average particle size was determined [37]

8]Swelling and Water Uptake

$$\text{Percentage of swelling} = \frac{\text{Marking of the cylinder at a specified time point}}{\text{Initial marking before soaking}} * 100$$

$$\text{Percentage of Water Uptake} = \frac{\text{Mass of the hydrogel after 72 hrs}}{\text{Initial mass of dry polymer}} * 100$$

VIII. SUMMARY AND CONCLUSION

Nanosponge-basedsystems feature considerable porosity, simple functionalization procedures, unique topology, environmental friendliness, and cost-effectiveness, and have been shown to be an attractive alternative for targeted drug delivery.

Cyclodextrin-based nanosponges stand out from other nanosponges for their unique qualities, excellent biocompatibility, low toxicity, and ease of surface modification, making them the most commonly tested nanosponges in nanomedicine.

By adjusting the concentration of polymers and other materials and the ratio of crosslinkers, the right size can be achieved, which can improve the solubility of various poorly soluble drugs and prevent their degradation.

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Nanosponges have found applications in various areas that cannot be achieved by other nanocarriers, such as targeting, improving stability and solubility, preventing drug photodegradation, increasing formulation flexibility, gas administration, blood purification, etc.

It is important to note that although nanosponges have shown promising results in various areas such as drug delivery, oncology, and COVID-19, further research and development is required to determine their properties, optimize their performance, and ensure their safety.

Ethical considerations, regulatory approvals, and scalability will also play a role in determining the practical applications and widespread adoption of nanosponges in future.

Despite the applications discussed above, nanosponges have various other applications like environmental clean-up (absorption of pollutants and other contaminants) and industrial applications (absorb and recover valuable materials from waste during the manufacturing process

Nanosponges offer a promising approach for drug delivery and other applications due to their ability to improve drug solubility, enable controlled release, and target specific sites. However, careful optimization of formulation parameters and consideration of potential limitations are necessary for successful implementation of this technology.

IX. RESULT AND DICUSSION

Nanosponges, a type of drug delivery system, have been shown to enhance drug solubility, improve stability, and enable controlled release of both hydrophilic and lipophilic drugs. Their porous structure allows for encapsulation of various substances and can be used in diverse applications, including targeted drug delivery, cosmetics, and bioremediation.

Advantages and Applications:

Enhanced Solubility and Bioavailability:

Nanosponges can increase the solubility and bioavailability of poorly water-soluble drugs, making them more effective.

Controlled Drug Release:

They can be designed to release drugs in a controlled and sustained manner, extending the duration of drug action and reducing dosing frequency.

Targeted Drug Delivery:

Nanosponges can be designed to target specific sites in the body, minimizing side effects and maximizing therapeutic efficacy.

Improved Formulation Stability:

Nanosponges can help stabilize drug formulations, particularly in the case of drugs that are susceptible to degradation.

Versatile Applications:

Nanosponges have applications in various fields, including drug delivery, cosmetics, biomedicine, bioremediation, agrochemistry, and catalysis.

Limitations and Considerations:

Potential for Drug Dumping:

If the cross-linking in nanosponges is not optimized, there is a risk of premature drug release (dumping).

Drug Loading and Encapsulation Efficiency:

The ability of nanosponges to load and encapsulate drugs can be affected by factors such as the degree of cross-linking.

Scale-Up Challenges:

While nanosponges are relatively easy to prepare, scaling up their production for industrial purposes can present challenges.

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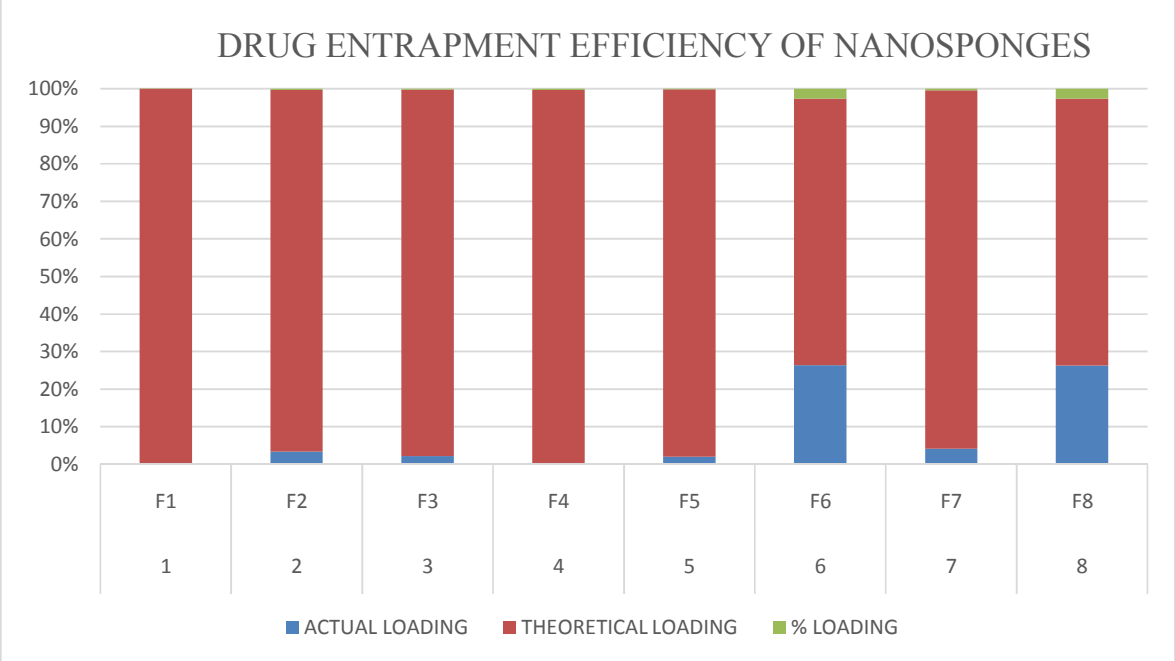
EVALUATION OF NANOSPONGES

1]Loading Efficiency/Entrapment Efficiency / Drug content

SR.NO	RATIO / BATCH CODE	ACTUAL LOADING	THEORETICAL LOADING	% LOADING
1.	F1	3.327	1000	0.3327
2.	F2	34.962	1000	3.4962
3.	F3	22.236	1000	2.2236
4.	F4	2.9145	1000	2.9145
5.	F5	20.29	1000	2.029
6.	F6	372.39	1000	37.239
7.	F7	42.963	1000	4.2963
8.	F8	370.5	1000	37.05



According to this graph ,

F6 batch shows optimum loading capacity.(% loading capacity : 37.239)

SR.NO	RATIO / BATCH CODE	ACTUAL LOADING	THEORETICAL LOADING	% LOADING
1.	F6	372.39	1000	37.239

(F6) batch contains ,

1.Dichloromethane (20 ml)

2.Poly vinyl alcohol (3g)

3.Ethyl cellulose (2g)

4.Miconazole Nitrate (1g)

So that, for the further formulation of nanosponges we refer batch F6.

DOI: 10.48175/IJARSCT-27255

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2. Solubility test

Solubility test of formulated nanosponges takes place.

SOLUBILITY TEST

SR.NO	SOLVENT	SOLUBILITY
1.	Alcohol	Soluble
2.	Chloroform	Sparingly Soluble
3.	NaOH	Sparingly Soluble
4.	Dimethyl Formamide	Soluble
5.	Water	Insoluble

RESULT

Nanosponges are a promising drug delivery system that can encapsulate both hydrophilic and lipophilic drugs, enhancing their solubility and bioavailability. They offer controlled drug release at specific target sites, reducing side effects and improving patient compliance. Nanosponge technology is also being explored in other areas like cosmetics, biomedicine, bioremediation, and catalysis.

Here's a more detailed look at the results and benefits of using nanosponges:

Enhanced Drug Delivery and Solubility:

Improved Bioavailability:

Nanosponges increase the solubility of poorly water-soluble drugs, making them more readily available for absorption by the body.

Targeted Delivery:

They can be designed to deliver drugs to specific locations, such as tumors or specific areas on the skin, minimizing side effects.

Controlled Release:

Nanosponges allow for sustained and controlled release of drugs over time, reducing the need for frequent dosing.

Reduced Toxicity:

By encapsulating drugs, nanosponges can help reduce their toxicity and potential side effects.

Applications Beyond Drug Delivery:

Cosmetics: Nanosponges can be used in cosmetics to enhance the delivery of active ingredients to the skin.

Biomedicine: They are being explored for various biomedical applications, including treating neurological illnesses and targeting cancer cells.

Bioremediation: Nanosponges can be used to remove pollutants from water and soil.

Catalysis: They can be used as catalysts in various chemical reactions.

Advantages of Nanosponges:

Improved stability:

Nanosponges can enhance the stability of drug formulations, especially for drugs that are prone to degradation.

Enhanced flexibility:

They offer greater flexibility in formulation design, allowing for various drug combinations and dosage forms.

Better patient compliance:

Controlled release and reduced side effects can improve patient compliance with treatment.

Self-sterilization:

Nanosponges have a tiny pore structure that prevents bacteria from penetrating, acting as a self-sterilizer.

Reduced side effects:

By targeting specific sites and controlling drug release, nanosponges can minimize unwanted side effects.

Reduced dosing frequency:

Sustained release from nanosponges can reduce the need for frequent dosing, improving patient convenience.

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IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 5, Issue 11, May 2025 Impact Factor: 7.67

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