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Preparation and In-Vitro Evaluation of Itraconazole Loaded Nanosponges for Topical Drug Delivery

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Abstract: *Nanosponges are a novel class of hyper cross -linked polymer based colloidal structure made of sub -microscopic particle with cavities a few nanometers wide. Itraconazole is an Imidazole derivative and used for the treatment of local and systemic fungal infection. There has been significant progress in recent years in resolving the clinical and pharmacological limitations of hydro gel for drug delivery application. The Nano sponges are one of the effective drug carriers for drug having the low solubility and high permeability. Hydro gel is the 3D porous structure produced with hydrophobic polymer synthesized by cross linking water soluble polymer. Nanosponges are a type of nanoparticle, often a synthesized carbon-containing polymer. They are porous in structure, pores being about 1–2 nanometer in size, and can therefore be targeted to absorb small amounts of matter. Hydro-gels is natural/synthetic polymer chains that are connected to each other by cross-linkers to produce a hydrophilic material with the macro molecular structure of a gel. Besides hydro gel entrapment, directly using nanoparticle as cross-linkers to construct 3D hydro gel network offers another approach for nanoparticle assembly to acquire hydro gel-like properties (i.e., nanoparticle colloidal hydro-gel .Nanosponges, a recently created colloidal system, have the potential to overcome issues with medication toxicity, decreased bio-availability, and drug release over a wide area because they can be modified to work with both hydrophilic and hydrophobic types of drugs*

Keywords: Nanosponges, Hydrogel, Anti-fungal Drug

I. INTRODUCTION

The term "Nanosponge" refers to nanoparticles with a porous structure. To efficiently and effectively administer pharmaceuticals to their target locations, pharmaceutical professionals are currently searching for alternatives to oral or parenteral administration. The development of pharmaceutical technology is to blame for this. "Nano sponges" are specific kind of nanoparticles that have the drug enclosed in a polymer-based core. The word "nanosponge" was first coined in the 1990s due to its nanoporous, sponge-like structure and the need to overcome the limitations of native cyclodextrins (CDs), particularly, their water solubility and inability to properly encapsulate charged and large molecules. Like other azole antifungals, itraconazole works by inhibiting lanosterol 14α-demethylase, which stops fungi from producing ergosterol. To get to the point of action, they travel throughout the body andrelease the medication in a predictable way, but because other medications have a propensity to inhibit cytochrome P450 3A4 CC, care should be used while assessing drug interactions.- The antifungal drug itraconazole is the first of a class of triazole antifungals with a high lipophilicity. Ergosterol synthesis is hindered by the inhibition of the cytochrome P-450-dependent enzyme by itraconazole. Itraconazole has been used to treat aspergillosis, Cryptococci meningitis, and histoplasmosis blast mycosis. (et,al.Shrishail M. Ghurghure10.5281/zenodo.2659719)

Microscopic structures known as nanosponges, which mimic meshes and have a broad range of substance-holding capacity. According to early experiments, this method of administering medications for breast cancer is up to five times more effective than existing approaches. This could revolutionize the treatment of many diseases.

The delivery of topical medications can be controlled with a novel technique called nanospong. Nanosponge is a novel method of administering topical medication. Drug delivery systems that make use of nanosponge technology are employed to improve the effectiveness of drugs applied topically.

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Nanosponges are tiny sponges that mimic viruses in size and have the capacity to contain a variety of drugs. These minuscule sponges have the ability to travel throughout the body until they reach the exact location of the target, attach to the surface, and begin to release the medication in a controlled and predictable manner. One of the most promising areas of research is life science, thanks to the application of nanosponges in controlled drug delivery. Component entrapment is made possible via nanosponge technology, which is also said to help mitigate adverse effects. enhanced stability, more elegance, and more formulation freedom. Using nanosponges is safe, non-allergic, non-mutagenic, and non-toxic.

Nanosponges, which are small, mesh-like structures, have the potential to revolutionize the treatment of many diseases. With the use of technology, drug delivery is five times more effective.in comparison to breast cancer conventional procedures. The miniscule particles that make up nanosponges have cavities that are only a few nanometres across and can contain a wide range of chemicals. These particles have the ability to convey hydrophilic and lipophilic compounds, as well as to increase the solubility of molecules that are not very water soluble. The drug molecules are encapsulated within the core of nanosponges, a sort of encapsulating nanoparticle. In contrast to other nanoparticles, nanosponges are non-toxic, porous, insoluble in water and organic solvents, and stable at temperatures as high as 300 °C.

These microscopic sponges can move throughout the body until they come into contact with the precise target place, adhere to the surface, and start to release the medication in a predictable and regulated way. For a given dosage, the drug will work better since it can be released at the precise target place rather than circulating throughout the body. The aqueous solubility of these nanosponges is another noteworthy characteristic that makes it possible to use these systems efficiently for medicines with poor solubility. The solid nanosponges can be prepared in dose forms for oral, parenteral, topical, or inhalation. These can be mixed with lubricants, diluents, excipients, and anti-caking agents to create a tablet-making matrix for oral delivery.These can be easily combined with saline, sterile water, or other aqueous solutions for parenteral delivery. They can be efficiently added to topical hydrogel for topical delivery. (et.al. Shrishail M.2019)

Nanosponges

Nanosponges are tiny sponges with a size of about a virus (250nm-1um) which consist of cavities that can be filled with wide variety of drug. The sponges act as three dimensional networks. Which consist of backbone known as long length polyester? It is mixed in solution with cross-linkers to form the polymer Nano-sponges technology is a newer technology, Which uses the targeted drug delivery system to release the drug in controlled manner to the targeted site. These are able to carry both hydrophilic and lipophilic drug substance; they increase the solubility of poorly water soluble drug substance. This technology is considered to be a novel approach which offers controlled drug delivery system for topical use. Nano-sponge is type of encapsulating nano-partical which encapsulates the drug molecule with the core by different method.

Types of Nanosponge

There are many types of NS that are available and can be designed and formulated depending on the polymer added, its concentration, and the method of preparation used accordingly. The most common types of NS which are prepared and have been diversely used are beta CD-based NS. The formulation aspect for beta-CD NS is a relatively simple process and there are relatively multiple modifications that are possible

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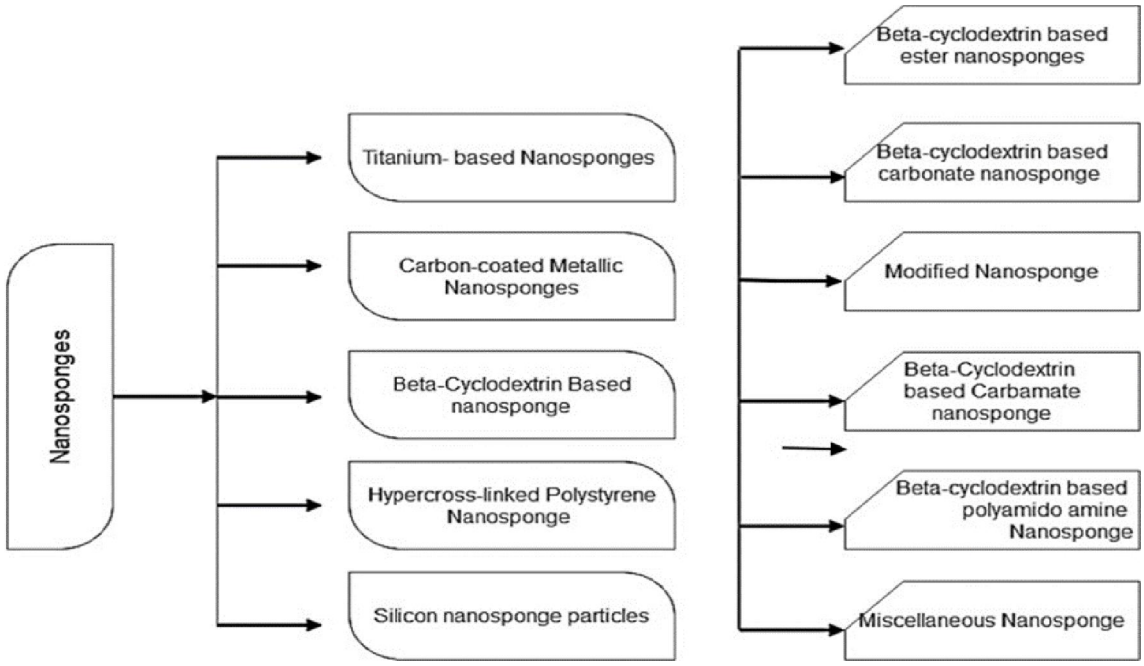

Importance of nanotechnology in drug delivery

1. **Enhancing solubility:** Nanoparticles can improve the solubility of poorly water-soluble drugs, like itraconazole, allowing for more effective absorption.
2. **Targeted delivery**: Nan carriers can be engineered to target specific sites, reducing side effects and improving therapeutic outcomes.
3. **Controlled release**: Nanoparticles can release drugs in a controlled manner, maintaining optimal drug levels and reducing dosing frequency.
4. **Improved bioavailability**: Nanotechnology can enhance drug bioavailability, ensuring more of the drug reaches the intended site.
5. **Minimizing toxicity**: Nanoparticles can reduce drug toxicity by delivering drugs directly to the target site, minimizing exposure to healthy tissues.
6. **Combination therapy**: Nanocarriers can co-deliver multiple drugs, enabling combination therapy and potentially improving treatment outcomes (et, al. Y,Liu.2012)

Polymers Used in Nanosponge Preparation

There are various polymers and cross linkers are used in the preparation of nanosponges, listed in table

Polymers	Copolymers	Cross linkers
Hyper cross linked Polystyrenes, Cyclodextrins and its derivatives like Alkyl oxycarbonyl Cyclodextrins, Methyl β-Cyclodextrin, Hydroxy Propyl β-Cyclodextrins.	Poly (valerolactoneallylvalerolactone), Poly (valerolactoneallylvalerolactone oxepanedione), Ethyl Cellulose, Poly vinyl alcohol.	Carbonyl diimidazoles, Carboxylic acid dianhydrides, Diarylcarbonates, Dichloromethane, Diisocyanates, Diphenyl Carbonate, Epichloridine, Gluteraldehyde, Pyromellitic anhydride, 2,2-bis (acrylamido) Acetic acid.

Table 1: Different polymers for nanosponge formulation

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Composition and structure of Nanosponges

Nanosponges are complex structures, normally built up from long linear molecules that are folded by cross linking into a more or less spherical structure, about the size of a protein. Typical nanosponges have been constructed from cyclodextrin cross linked with organic carbonates. Nanosponges mainly consists three components. They are,

A. Polymer

B. Cross linking agent

C. Drug substance.

A. Polymer: Type of polymer used can influence the formation as well as the performance of Nanosponges. For complexation, the cavity size of nanosponge should be suitable to accommodate a drug molecule of particular size.The ability of the polymer to be cross-linked depends on the functional groups and active groups to be substituted. The selection of polymer depends on the required release and the drug to be enclosed. The polymers can be used to enclose the drug or to interact with the drug substance. For the targeted drug release the polymer should have the property to attach with the specific ligands.

B. Crosslinking agent: Selection of crosslinking agent depends on the structure of polymer and the drug to be formulated. The list of polymers and crosslinking agents used for the synthesis of nanosponges are presented in Table

C. Drug substance: Drug molecules to be formulated as nanosponges should have certain characteristics mentioned below.

- Molecular weight between 100 and 400 Daltons.
- Drug molecule consists of less than five condensed rings.
- Solubility in water is less than 10 mg/ml
- Melting point of the substance is below 250

APLICATIONS OF NANOSPONGES

At low concentrations, cyclodextrin-based nanosponges have the ability to connect with organic molecules and extract them from water. Based on the same idea, grape fruit juice's bitter components can be reduced by combining a polymer with a cross-linker. For proteomic applications, the three-dimensional structure of nanosponges is crucial to the fractionalization of peptides. Microporous hyper cross linked polymers have been employed in size-exclusion chromatography for the separation of inorganic electrolytes. Certain biomarkers can be absorbed by nanosponges to aid in diagnosis. According to a study, blood can be used to extract a rare cancer marker using nanosponges. Gases such as carbon dioxide and oxygen can be carried by nanosponges. Such nanoparticles may find utility in the biomedical field. The oxygen-filled nanosponges might provide diverse tissues, including hypoxic tissues, with oxygen. In the field of biomedicine, nanosponge can serve as a carrier for the release and distribution of proteins, peptides, and enzymes. Nanosponges based on cyclodextrin are an appropriate carrier for the adsorption of proteins, macromolecules, enzymes, and antibodies. To connect the target linkers, the researchers created simple, high-yield nanosponge particles. Paclitaxel was the medication utilized in the animal studies.

Researchers observed the reaction of two distinct tumour types: fast-acting rat glioma and slow-growing human breast cancer. They administered a solitary shot to those tumours and noted the reaction. When compared to alternative chemotherapy techniques, they discovered that in both situations, the distribution via nanosponges accelerated the pace at which cancer cells died and slowed the growth of the tumour.(et,al. Francesco T. 2011.)

Limitations

- Poor solubility in water (<0.001 mg/mL)
- Low bioavailability (~55%)
- The GI tract exhibits variable and inadequate absorption; the tissue distribution is extensive and the lipophilicity is considerable, posing a potential hazard.
- First-pass metabolism: decreased availability throughout the body
- Absorption reliant on food (has to be administered with meals)
- Possible interactions between drugs (inhibits cytochrome P450 enzymes)

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- Insufficient water solubility (<0.001 mg/mL)
- Low bioavailability (~55%)

Advantages:

- The gastrointestinal tract shows uneven and insufficient absorption
- There is a large tissue distribution and significant lipophilicity
- which could be dangerous.
- First-pass metabolism reduced availability across the body
- Food-dependent absorption (must be taken with meals)
- Potential medication interactions (cytochrome P450 enzyme inhibition)Among the limitations are
- Insufficient water solubility (<0.001 mg/mL) Approximately 55% bioavailability
- The gastrointestinal tract has a wide tissue distribution, high lipophilicity, and insufficient and uneven absorption—all of which have the potential to be hazardous.
- First-pass metabolism: reduced availability throughout the body Food-dependent absorption (must be taken with meals)
- Potential interactions between drugs (cytochrome P450 enzyme inhibition)

Disadvantages

- The only molecules on nanosponges are tiny ones.
- There could be a dose dump.
- Could postpone the release the only molecules on nanosponges are tiny ones.
- Rely only on loading capacity
- There could be a dose dump.
- could postpone the release

Nanotechnology's significance for medication distribution

1. Improving solubility: By making weakly water-soluble medications like itraconazole more soluble, nanoparticles can facilitate more efficient absorption.
2. Targeted delivery: By designing nanocarriers to target particular locations, adverse effects can be minimized and therapeutic results can be enhanced.
3. Controlled release: Nanoparticles can release medications in a controlled manner, preserving optimal drug levels and minimizing dose frequency.
4. Increased bioavailability: By using nanotechnology to increase a drug's bioavailability, more of the medication will reach its intended location.
5. Reducing toxicity: By delivering medications directly to the target region and reducing exposure to healthy tissues, nanoparticles can minimize the toxicity of drugs.
6. Combination therapy: Nanocarriers can co-deliver multiple drugs, enabling combination therapy and potentially improving treatment outcomes(et, al. Y, Liu.2012)

MECHANISUM OF DRUG RELEASE FROM NANOSPONGES

The sponge particles have an open structure and the active is free to move in and out from the particles and into the vehicle until equilibrium is reached. In case of topical delivery, once the finished product is applied to the skin, the active that is already in the vehicle will be absorbed into the skin, depleting the vehicle, which will become unsaturated, therefore disturbing the equilibrium. This will start a flow of the active from the sponge particle into the vehicle and from it to the skin until the vehicle is either dried or absorbed. Even after that the sponge particles retained on the surface of stratumcorneum will continue to gradually release the active to the skin, providing prolonged release over time .(et.al.Rogers C, Vallero R. 2007)

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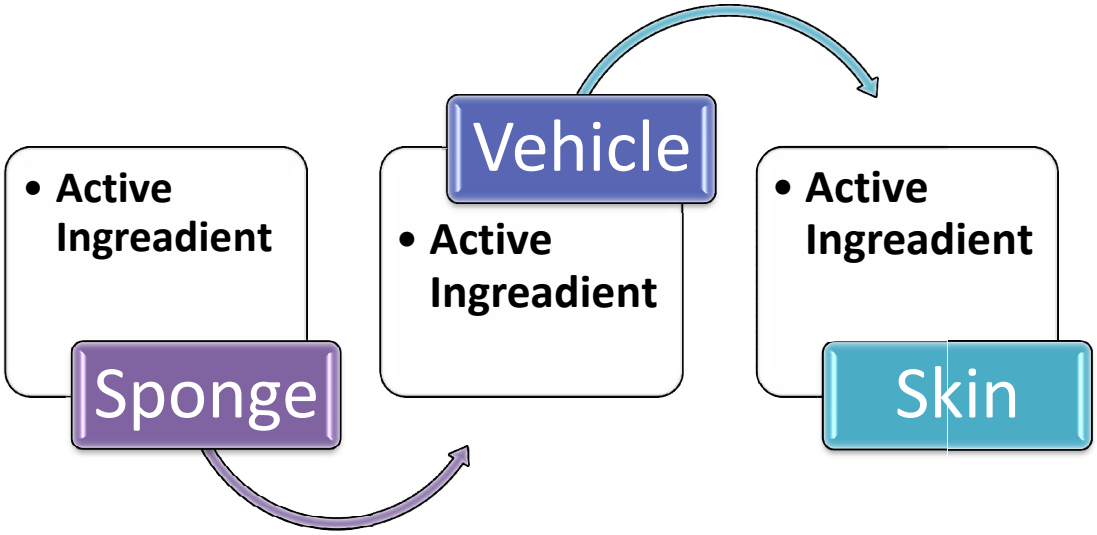

Figure: Mechanisum of Action of Nanosponges

Materials

Itraconazole (99.79%) was donated by Hetero Biopharma Limited, Hyderabad. Ethylcellulose, Polymethyl methacrylate was purchased from Nice Chemicals, Ernakulam. Hydroxypropyl Methyl Cellulose was purchased from Yarrow Chemicals, Mumbai. Microcrystalline Cellulose, Magnesium stearate was purchased from Ozone International, Mumbai. Ultra-pure grade water used throughout the study was prepared from deionizedwater, Wation DB 100, Labsol Enterprises, India. The chemicals used for the experiment were of analytical grade and not purified further.

1. Itraconazole: Active pharmaceutical ingredient (API)
2. Polymers:
   - Polyvinylpyrrolidone (PVP)
   - Polyethylene glycol (PEG)
   - Poly (lactic-co-glycolic acid) (PLGA)
   - Chitosan
3. Solvents:
   - Dichloromethane (DCM)
   - Ethanol
   - Acetone
   - Water
4. Cross-linking agents:
   - Glutaraldehyde
   - Formaldehyde
5. Surfactants:
   - Polysorbate 80 (Tween 80)
   - Sodium lauryl sulfate (SLS)
6. Other additives:

- pH adjusters (e.g., HCl, NaOH)
- Antifoaming agents (e.g., silicone oil)

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Purpose of the study: to formulate and evaluate itraconazole nanosponges

The primary objective of this study is to formulate and evaluate itraconazole-loaded nanosponges as a novel drug delivery system, aiming to:

1. Improve solubility: Enhance the aqueous solubility of itraconazole, thereby increasing its bioavailability.
2. Optimize drug release: Achieve controlled and sustained release of itraconazole from the nanosponges.
3. Enhance therapeutic efficacy: Improve the antifungal activity of itraconazole against various fungal pathogens.
4. Reduce side effects: Minimize the toxicity and adverse effects associated with itraconazole therapy.
5. Develop a patient-friendly formulation: Create a nanosponge-based formulation that is easy to administer and improves patient compliance.

II. CONCLUSION

Nanosponge are nano sized colloidalcarrier so they easily penetrate throughskin. Due to their small size and porous nature they can bind poorly- soluble drugs within the matrix and improve their bioavailability of drug and they also increase the solubility of poorly soluble drugs. The nanosponges have the ability to incorporate many drugs and release them in a controlled and predictable manner at the target site. Topical nanosponge can be more patien tcompliant and provide sufficient patient benefits by reducing repeated doses and side effects. Nanosponge can be effectively incorporated into topical drugn delivery system for retention of dosage form on skin. Nanosponges are tiny meshlike structures that may revolutionize then treatment of many diseases and this technology is five times more effective at delivering drugs for cancer than conventional methods. These are sell sterilizing where bacteria cannot penetrate.

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