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Nanosponges-Based Topical Delivery System: A Comprehensive Review on Formulation Strategies and Evaluation with Reference to Sulindac for Arthritis Treatment

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ABSTRACT
Nanosponges are a fascinating class of nanoparticulate systems that have revolutionized the field of controlled and targeted drug delivery. Their unique porous, cross-linked polymeric structures allow encapsulation of a broad spectrum of bioactive molecules, including poorly soluble drugs, proteins, and nucleic acids. This review discusses the evolution of nanosponge technology with emphasis on synthesis methods, materials used, characterization techniques, and evaluation parameters. The potential of nanosponges as drug delivery carriers, especially for anti-inflammatory drugs like Sulindac in arthritis therapy, is comprehensively explored. Furthermore, critical assessment of various characterization tools such as FTIR, SEM, Zeta potential, particle size analysis, and drug release studies are highlighted. This review also evaluates the challenges and prospects of nanosponge-loaded gels as a novel topical delivery system for enhancing therapeutic efficacy and reducing systemic side effects.
Keywords: Nanosponges, Drug Delivery System, Sulindac, Topical Gel, Nanotechnology, Arthritis, NSAIDs, Controlled Release, Ethyl Cellulose, Eudragit RS100, Carbopol 934.

I. INTRODUCTION

Over the past decades, nanotechnology has transformed pharmaceutical sciences by offering advanced delivery carriers capable of overcoming limitations of conventional drug formulations. Among these, **nanosponges** have emerged as versatile and promising carriers with exceptional drug encapsulation efficiency and controlled release capabilities.

These three-dimensional cross-linked polymeric structures possess an inner hydrophobic cavity and outer hydrophilic surface, making them suitable for both lipophilic and hydrophilic drugs. Applications span across oncology, infectious diseases, dermal therapy, and anti-inflammatory treatments. Specifically, NSAIDs like **Sulindac**, commonly prescribed for arthritis, suffer from low solubility and gastrointestinal toxicity—problems nanosponges can potentially overcome via topical administration.

II. NANOSPONGE TECHNOLOGY: FUNDAMENTALS AND DRUG LOADING MECHANISMS

2.1 Composition of Nanosponges

- **Polymers**: Ethyl Cellulose, Eudragit RS100, β-Cyclodextrins.
- **Crosslinking agents**: Dibasic agents that create stable 3D networks.
- **Drug Substances**: Molecules with <400 Da MW, low aqueous solubility, and suitable thermal stability.

2.2 Methods of Preparation

- **Hyper Cross-Linked β-Cyclodextrins**: Forms networked polymer matrices.
- **Quasi Emulsion-Solvent Diffusion**: Utilizes organic and aqueous phases for nanosponge formation.
- **Ultrasound-Assisted Synthesis**: Enhances cross-linking efficiency.
- **Polymerization Techniques**: Produces uniform and tunable nanosponge sizes.

III. CHARACTERIZATION TECHNIQUES FOR NANOSPONGES

3.1 Preformulation Studies

Evaluation of Sulindac indicated appropriate physicochemical characteristics (melting point ~183°C, insolubility in water, solubility in DMSO & Methanol) suitable for nanosponge incorporation.

3.2 Particle Size & Surface Morphology

- Average diameter: **58.48 nm**, conducive for enhanced skin permeability.

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- **SEM analysis** revealed distinct spherical morphology and porosity.
- **Eudragit-based nanosponges** showed superior size control (80–95 nm) over Ethyl Cellulose types.

3.3 Spectral Analysis (FTIR)

FTIR confirmed absence of significant chemical interaction between Sulindac and polymer matrix, indicating physical entrapment rather than complexation.

3.4 Zeta Potential

Negative zeta potential values confirmed colloidal stability and dispersibility of nanosponges in aqueous media.

IV. ADVANTAGES AND LIMITATIONS

4.1 Merits

- Targeted, sustained drug release.
- Improved drug solubility and bioavailability.
- Versatile carrier for both hydrophilic and hydrophobic drugs.
- Reduced systemic side effects.
- Adjustable particle size.

4.2 Demerits

- Limited encapsulation of extremely small molecules.
- Need for precise optimization to prevent premature drug leakage.
- Scale-up challenges in industrial production.

V. TOPICAL GEL FORMULATION: INTEGRATION WITH NANOSPONGES

Carbopol 934-based gels were utilized as carriers for Sulindac nanosponges:

- Maintained physiological pH (6.2–6.8).
- Enhanced viscosity for topical retention.
- Propylene glycol addition ensured smooth skin application.

G2 formulation (Eudragit-based nanosponges) demonstrated superior drug release (~77.11% at 30 hrs) compared to G1 (Ethyl cellulose-based, ~58.43%).

In-vitro Release & Kinetics

- Sustained release profile observed for both gels via **dialysis membrane assay** in PBS buffer (pH 7.4).
- Eudragit-based nanosponge gel outperformed Ethyl cellulose counterpart in release efficiency.
- Controlled release attributed to nanosponge's porous architecture and gel matrix stabilization.

Future Prospects

- Clinical translation for arthritis and other dermal conditions.
- Nanosponges as carriers for dual/multi-drug delivery.
- Integration with stimuli-responsive polymers for intelligent drug release.
- Industrial scale-up and regulatory standardization for commercial use.

VI. CONCLUSION

Nanosponges represent a potent nanocarrier system capable of addressing the shortcomings of conventional drug delivery, particularly for NSAIDs like Sulindac in arthritis management. This review underscores the critical role of polymer selection, cross-linking method, and nanosponge characterization in ensuring optimal drug encapsulation, release, and clinical efficacy. The integration into gel formulations offers a viable route for enhancing topical delivery, minimizing systemic exposure, and improving patient compliance.

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