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Development, Optimization and Characterization of an *Allium sativum L.* Extract-Loaded Polymeric Microsponge Gel

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Abstract

The present study developed and optimized a polymeric microsponge gel containing an extract of *Allium sativum L.* for controlled topical delivery. Garlic was selected because its organosulfur constituents, particularly allicin and related thiosulfinates, have recognized antifungal potential, while direct topical use is limited by strong odour, chemical instability, rapid loss of activity and possible irritation. A dark-brown semisolid extract was prepared from dried garlic powder, giving an extraction yield of 18.6% w/w. Ethyl cellulose microsponges were produced by the quasi-emulsion solvent-diffusion method. Six batches were prepared by varying the drug-to-polymer ratio from 1:1 to 1:3 and polyvinyl alcohol concentration from 0.5% to 1.0% w/v. The preparations were evaluated for production yield, drug content, entrapment efficiency, particle size, morphology and *in-vitro* release. The optimized batch, ASMS-3, showed a production yield of 82 ± 1.4%, entrapment efficiency of 88 ± 1.1%, mean particle size of approximately 45 µm, spherical porous morphology and 86 ± 1.2% release over eight hours. Particle-size analysis gave a Z-average of 45.3 ± 1.2 µm and a polydispersity index of 0.246. The optimized microsponges were incorporated into a 1% Carbopol 934 gel. The resulting gel was smooth and homogeneous, with pH 5.8 ± 0.2, viscosity 2850 ± 120 cP, good spreadability and 89 ± 1.2% drug content. During 90-day stability testing, the formulation retained acceptable appearance, pH, viscosity and more than 90% of its initial drug content. These findings demonstrate that ethyl-cellulose microsponges can convert garlic extract into a stable, cosmetically acceptable and controlled-release topical gel.

1. Introduction

Superficial fungal infections are commonly treated through the topical route because the causative organisms are frequently located in the stratum corneum, skin folds or other superficial tissues. A successful topical dosage form must do more than carry an active substance. It must remain at the

application site, release the active at an appropriate rate, spread easily, possess a skin-compatible pH and remain physically stable throughout storage. Conventional gels are non-greasy and acceptable to patients, but a freely dissolved active may be released rapidly and may not remain protected from environmental degradation. These limitations become more important when the active material is a chemically complex herbal extract.

Allium sativum L., commonly known as garlic, has a long history of use against microbial infections. Crushing garlic initiates the alliin-alliinase reaction and produces allicin, a reactive sulfur-containing compound that can interact with thiol groups in microbial proteins. Allicin and related organosulfur compounds have been associated with disruption of cellular enzymes, membrane integrity, oxidative balance and biofilm development (Ankri and Mirelman, 1999; Borlinghaus et al., 2014). These properties provide a pharmacological basis for selecting garlic as a herbal antifungal candidate. Nevertheless, its translation into a practical topical dosage form is challenging. Allicin is unstable, garlic has a strong pungent odour, and concentrated preparations may irritate sensitive skin. Direct incorporation of a crude extract into a conventional gel can also produce variable release, chemical degradation and poor sensory acceptance.

Microsponges are highly porous polymeric particles that act as microscopic reservoirs for active substances. The internal cavities can entrap a drug or herbal extract, while interconnected pores allow gradual diffusion into a surrounding vehicle. In dermatological formulations, this approach may reduce an initial burst, improve active-material stability, decrease direct exposure of irritant compounds and extend residence at the application site. Ethyl cellulose is frequently used as a microsponge-forming polymer because it is compatible with many actives, forms stable matrices and provides diffusion-controlled release. Polyvinyl alcohol can stabilize droplets during quasi-emulsion solvent diffusion, while a Carbopol gel can provide a smooth and washable final vehicle (Maiti et al., 2011; Mahant et al., 2020).

The properties of a microsponge formulation depend strongly on the ratio of active material to polymer and on the concentration of the stabilizer. Insufficient polymer may result in incomplete entrapment, irregular particles and rapid release. Excessive polymer can enlarge or harden the matrix and may retard release beyond the desired range. Stabilizer concentration affects droplet integrity, aggregation and particle-size distribution. Optimization must therefore consider several responses simultaneously rather than select a formulation only because it has the highest value for

one parameter. A practical topical microsponge should show adequate production yield, high entrapment efficiency, a particle size that does not produce grittiness, spherical porous morphology and sustained but substantially complete release.

The final dosage form adds a second optimization layer. A well-formed particle can still perform poorly if the gel base is too fluid, too rigid, incompatible with normal skin pH or unable to disperse the particles uniformly. Viscosity and spreadability are interdependent: sufficient viscosity improves residence, whereas adequate spreadability permits a thin and uniform dose. Content uniformity confirms that microsponges are evenly distributed, and stability testing determines whether the system resists separation, active loss and viscosity drift. For a herbal formulation, these measurements are central to reproducibility because composition and physical behaviour can vary more than for a single purified drug.

The present paper isolates the *Allium sativum* component of a wider formulation study. It focuses specifically on selection of garlic as a herbal antifungal active; preparation and optimization of ethyl-cellulose microsponges; incorporation of the optimized particles into a Carbopol gel; and characterization of the resulting microsponge and gel system. Antifungal bioassay outcomes and the comparative performance of the second plant are outside the main scope. The objective was to determine whether formulation variables could be adjusted to produce a reproducible garlic microsponge gel with appropriate particle characteristics, controlled release, topical consistency, spreadability and storage stability.

2. Materials and Methods

2.1 Plant material and extract preparation

Fresh, healthy *Allium sativum L.* bulbs were selected and inspected to exclude visible contamination, fungal growth or deterioration. The cloves were separated, cleaned and peeled, and then subjected to controlled drying to reduce moisture without unnecessary heat exposure. The dried material was ground mechanically and passed through a suitable sieve to obtain a homogeneous pale off-white powder. The powder was stored in an airtight container until extraction. From 100 g of dried garlic powder, a dark-brown, thick semisolid extract was obtained after extraction and solvent removal. The crude extract was protected from light in an amber container at 4 ± 2°C.

2.2 Preformulation assessment

The extract was examined for colour, odour, physical state, pH and solvent compatibility. A 10% w/v aqueous dispersion had a pH of 5.8 ± 0.2. The extract was highly soluble in ethanol and methanol, soluble in chloroform and acetone, moderately soluble in dichloromethane, propylene glycol and polyethylene glycol 400, and poorly soluble in water and phosphate buffer pH 5.5. Its moisture loss was 7.0% after drying to constant weight. Preliminary screening indicated strong sulfur compounds and carbohydrates, moderate flavonoids and proteins, and weak saponins, tannins and glycosides. These findings supported the use of an organic internal phase and confirmed the presence of chemical classes relevant to garlic's antimicrobial activity.

2.3 Formulation design

Six microsponge batches, ASMS-1 to ASMS-6, were designed. Each batch contained 100 mg of garlic extract. Ethyl cellulose was used at 100, 200 or 300 mg, corresponding to drug-to-polymer ratios of 1:1, 1:2 and 1:3. The stabilizer was polyvinyl alcohol at either 0.5% or 1.0% w/v in a 100 mL aqueous external phase. The internal organic phase was maintained at 10 mL and consisted of 5 mL dichloromethane and 5 mL ethanol. Stirring speed, addition time, stirring duration and temperature were held constant so that the effects of polymer amount and stabilizer concentration could be evaluated.

Table 1. Formulation design for *Allium sativum* microsponges

Batch	Drug:polymer	Ethyl cellulose	PVA
ASMS-1	1:1	100 mg	0.5% w/v
ASMS-2	1:2	200 mg	0.5% w/v
ASMS-3	1:3	300 mg	0.5% w/v
ASMS-4	1:1	100 mg	1.0% w/v
ASMS-5	1:2	200 mg	1.0% w/v
ASMS-6	1:3	300 mg	1.0% w/v

2.4 Preparation of microsponges

The required quantities of garlic extract and ethyl cellulose were dissolved in the organic solvent mixture. The internal phase was sonicated for five minutes to obtain uniform dispersion. Polyvinyl alcohol solution was prepared separately in distilled water. The internal phase was added dropwise to 100 mL of the aqueous phase during continuous mechanical stirring at 1000 rpm. Addition was completed within ten minutes, and stirring continued for three hours at 25 ± 2°C to permit diffusion and evaporation of the organic solvents. The formed particles were collected through Whatman No. 1 filter paper, washed three times with 20 mL portions of distilled water and dried in a hot-air oven at 40 ± 2°C for 24 hours. Dried microsponges were stored in amber glass containers at 4 ± 2°C.

2.5 Optimization criteria

Every batch was examined for physical appearance, flow, aggregation, production yield, drug content, entrapment efficiency, particle size, morphology and release. Predefined criteria included a production yield and entrapment efficiency of at least 70%, particle size within the general topical range of 10-100 µm, spherical porous morphology, no visible aggregation and sustained release for six to eight hours. Although individual responses were considered, the selected batch was required to provide the best overall balance for incorporation into a gel.

2.6 Microsponge characterization

Production yield was determined from the practical weight of dried microsponges relative to the theoretical combined weight of extract and polymer. For drug-content analysis, 100 mg of dried particles was crushed, transferred to a 100 mL volumetric flask, dispersed in ethanol and sonicated for 15 minutes. After filtration, the active content was measured by UV-visible spectrophotometry at the selected wavelength and calculated from a calibration curve. Entrapment efficiency was expressed as actual drug content divided by theoretical drug content multiplied by 100.

For particle-size assessment, dried microsponges were dispersed in water and deaggregated by short sonication. Preliminary sizing involved measurement of randomly selected particles, while the optimized batch was examined using a particle-size analyser. Z-average size, polydispersity index and distribution percentiles were recorded. Surface morphology was examined by scanning electron microscopy after mounting on aluminium stubs and gold coating. Spherical particles with

visible pores and without cracks or aggregation were considered evidence of successful microsponge formation.

Compatibility was assessed by Fourier-transform infrared spectroscopy. Spectra of garlic extract, ethyl cellulose and the optimized microsponge were compared over 4000-400 cm-1. Retention of characteristic bands without major new peaks or unexplained shifts was interpreted as absence of chemical incompatibility. Differential scanning calorimetry was also used to examine thermal transitions and dispersion of the extract within the matrix.

2.7 *In-vitro* release

Release from the optimized formulation was evaluated over eight hours using a diffusion-based method. Samples were analysed at 0.5, 1, 2, 3, 4, 6 and 8 hours, and cumulative release was expressed as percentage of loaded active. A gradual profile without an excessive early burst was considered desirable for controlled topical delivery.

2.8 Preparation and evaluation of the microsponge gel

The optimized microsponges were incorporated into a 1% w/w Carbopol 934 gel. For 100 g of base, 1 g of Carbopol 934 was dispersed in 70 mL distilled water and hydrated for 24 hours. Methyl paraben 0.18 g and propyl paraben 0.02 g were dissolved in 5 mL propylene glycol and added to the dispersion. Glycerin 5 g was incorporated as a humectant, and the base was mixed at 500 rpm for 20 minutes. Microsponges equivalent to 1% w/w garlic active were added by gentle stirring at 500 rpm for 30 minutes. Triethanolamine was added dropwise to neutralize the polymer and adjust the pH, and the final mass was brought to 100 g with distilled water.

The gel was assessed for appearance, odour, homogeneity, pH, viscosity, spreadability, extrudability, washability and content uniformity. Viscosity was measured with a Brookfield viscometer using spindle 64 at 20 rpm and 25 ± 2°C. Spreadability was assessed between glass slides using the relation $S = M \times L/T$. Drug content was measured after extracting 1 g of gel into ethanol and analysing the filtrate spectrophotometrically. All quantitative measurements were performed in triplicate and expressed as mean ± standard deviation.

2.9 Stability assessment

The optimized gel was packed in an airtight topical container and stored for 90 days under room and accelerated conditions. Samples were assessed initially and at 30, 60 and 90 days for colour, odour, consistency, homogeneity, phase separation, pH, viscosity and drug-content retention. Stability was accepted when physical changes were absent, pH remained in the dermal range of 5.5-6.5 and retained content remained above 90% of the initial value.

2.10 Statistical and quality considerations

Experimental measurements were repeated three times and reported as mean ± standard deviation. Optimization was interpreted through the combined behaviour of independent variables and responses. The active quantity, solvent volumes, stirring speed and duration were fixed to reduce process variability. Glassware and instruments were cleaned and calibrated before use, batches were coded prospectively, and samples were protected from excessive heat and light. These controls were used to ensure that differences among ASMS batches reflected formulation variables rather than avoidable handling differences.

3. Results

3.1 Extraction and preformulation performance

The garlic material produced a uniform powder and a dark-brown semisolid extract with the expected pungent odour. The recovery of 18.6 g from 100 g of dried powder corresponded to an extraction yield of 18.6% w/w. The acidic-to-near-neutral pH, low aqueous solubility and better solubility in the selected organic solvents supported the formulation approach. No visible instability or incompatibility was observed during preliminary mixing with ethyl cellulose, PVA, Carbopol 934 or the preservative system.

Figure 1: A) Fresh Garlic B) Garlic Powder C) Garlic Extract

3.2 Optimization of microsponge batches

Polymer concentration had a clear effect on the physical and quantitative properties of the particles. At a 0.5% PVA concentration, increasing the drug-to-polymer ratio from 1:1 to 1:3 increased production yield from 65 ± 1.2% to 82 ± 1.4%, entrapment efficiency from 60 ± 1.5% to 88 ± 1.1%, and drug content from 62 ± 1.5% to 88 ± 1.1%. Mean particle size decreased from 58 ± 2.1 µm to 45 ± 1.5 µm, while morphology improved from irregular to spherical. Similar trends occurred at 1.0% PVA. The 1:3 batches produced the highest yield and entrapment, whereas lower ratios were associated with irregular or semispherical particles.

ASMS-3 was carried forward as the optimized batch because it met all predefined criteria while using 0.5% PVA. It exhibited a production yield of 82 ± 1.4%, entrapment efficiency of 88 ± 1.1%, drug content of 88 ± 1.1%, particle size of 45 ± 1.5 µm and spherical morphology. The corresponding particle-size analyser result was 45.3 ± 1.2 µm, with a PDI of 0.246. D10, D50 and D90 were 18.7, 44.6 and 92.3 µm, respectively, confirming a relatively narrow distribution within the intended topical range.

Table 2. Optimization results for *Allium sativum* microsponge batches

Batch	Yield (%)	Entrapment (%)	Size (µm)	Morphology	Status
ASMS-1	65 ± 1.2	60 ± 1.5	58 ± 2.1	Irregular	Not selected
ASMS-2	72 ± 1.0	75 ± 1.3	52 ± 1.8	Semi-spherical	Not selected
ASMS-3	82 ± 1.4	88 ± 1.1	45 ± 1.5	Spherical	Optimized
ASMS-4	68 ± 1.3	62 ± 1.4	57 ± 2.0	Irregular	Not selected
ASMS-5	74 ± 1.1	76 ± 1.2	51 ± 1.6	Semi-spherical	Not selected
ASMS-6	81 ± 1.3	87 ± 1.0	46 ± 1.4	Spherical	Acceptable

3.3 Morphology and compatibility

Scanning electron microscopy showed predominantly spherical particles with a porous, sponge-like surface. The particles were discrete and did not show cracking, irregular crystallization or marked aggregation. FTIR retained the major garlic-related and polymer bands, including C-H stretching around 2920 and 2850 cm-1, a broad O-H region near 3400 cm-1 and bands associated with garlic constituents in the fingerprint region. No new major peak or disappearance of characteristic bands was detected. DSC similarly indicated physical encapsulation and thermal compatibility rather than chemical degradation.

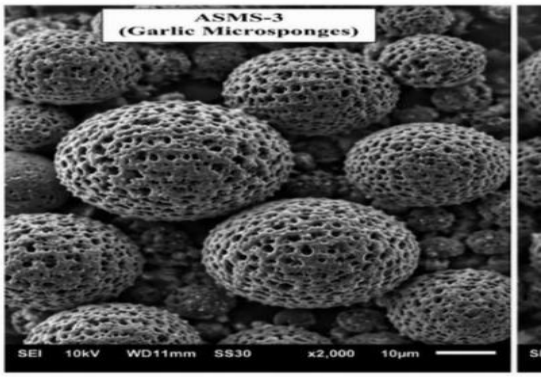

Figure 2: SEM morphology

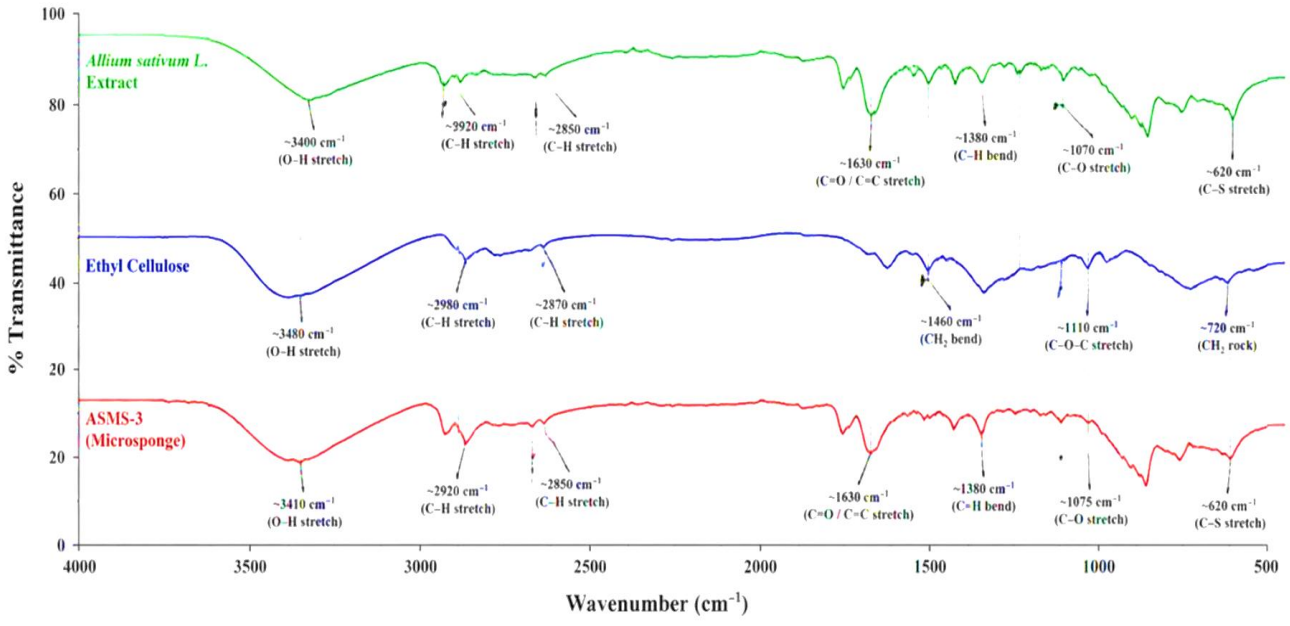

Figure 3: FTIR analysis

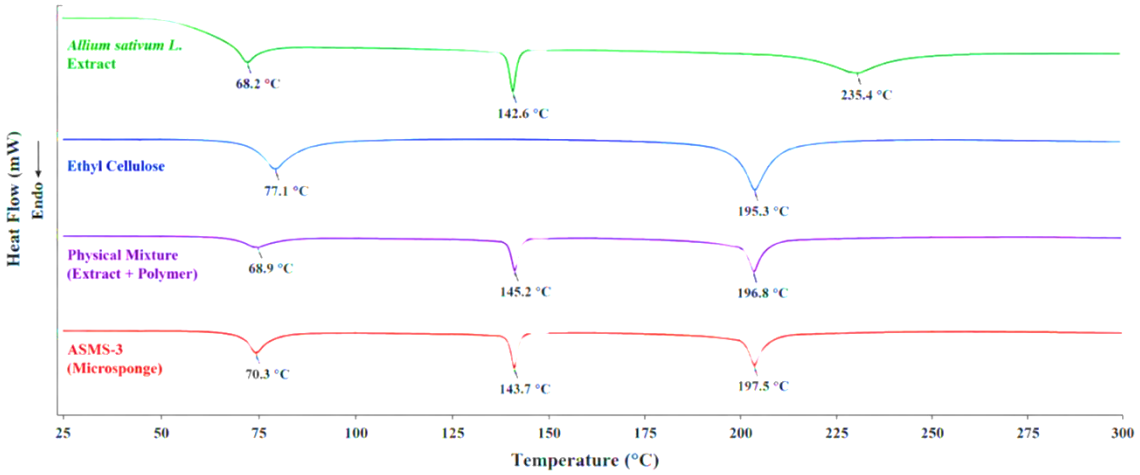

Figure 4: DSC Thermogram

3.4 Release behaviour

The optimized microsponges showed progressive release: 12 ± 0.8% at 0.5 hour, 22 ± 1.0% at 1 hour, 35 ± 1.2% at 2 hours, 48 ± 1.3% at 3 hours, 60 ± 1.5% at 4 hours, 75 ± 1.6% at 6 hours and 86 ± 1.8% at 8 hours. The profile demonstrated controlled delivery with no disproportionately high initial burst and substantial release by the end of the study.

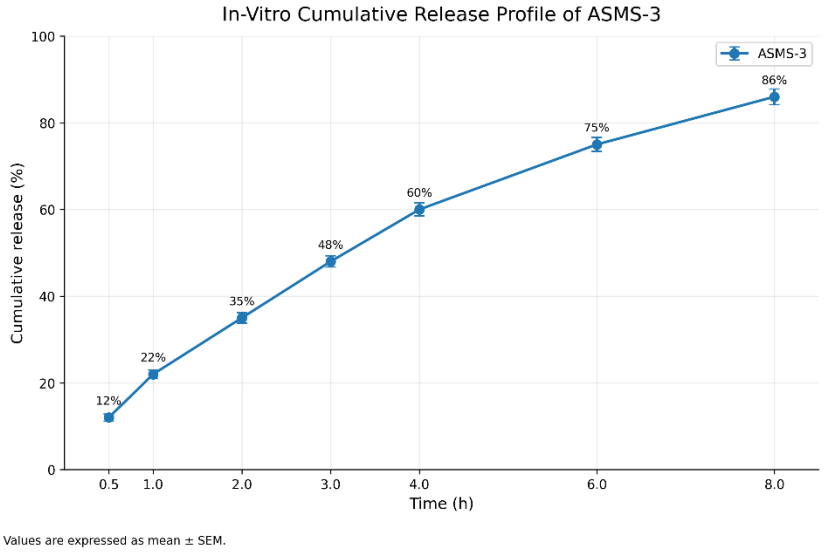

Figure 5. *In-vitro* release profile of optimized ASMS-3

3.5 Gel properties and stability

The ASMG formulation was smooth, homogeneous and off-white, with a milder garlic odour than the crude extract. It showed no grittiness, phase separation or visible particulate matter. The pH was 5.8 ± 0.2, viscosity was 2850 ± 120 cP, drug content was 89 ± 1.2%, and spreadability, extrudability and washability were rated good. These properties indicated adequate consistency for retention on the skin while allowing easy distribution.

Over 90 days, the gel retained its colour, odour, homogeneity and absence of phase separation. pH changed only from 5.8 to 5.6, and viscosity decreased from 2850 to 2720 cP. Drug-content retention was 97.8% at 30 days, 95.2% at 60 days and 92.6% at 90 days. All values remained within the predefined acceptance limits.

Table 3. Optimized gel characteristics and 90-day stability

Parameter	Initial	Day 90
Appearance	Smooth, homogeneous, off-white	No change
pH	5.8 ± 0.2	5.6
Viscosity	2850 ± 120 cP	2720 cP
Drug content/retention	89 ± 1.2% / 100%	92.6% retained
Spreadability	Good	Maintained
Phase separation	Absent	Absent

4. Discussion

The study demonstrates that a porous ethyl-cellulose carrier can address several formulation problems associated with garlic extract. Direct garlic preparations are difficult to standardize because the extract is viscous, strongly odorous and chemically sensitive. The recovery of 18.6% crude extract provided sufficient material for formulation, while the solubility profile justified the dichloromethane-ethanol internal phase. The absence of obvious incompatibility with the selected

excipients was important because reactive sulfur compounds could otherwise be altered during processing.

The progressive improvement in yield and entrapment as the ethyl-cellulose concentration increased is consistent with the role of polymer in forming a coherent matrix. A more viscous internal phase can limit movement of dissolved active into the aqueous phase during emulsification, thereby reducing processing loss. It can also provide sufficient structural material for spherical particle formation. Kaity et al. (2010) and Maiti et al. (2011) similarly describe polymer concentration as a major determinant of microsponge recovery, loading and release. In the present data, the 1:1 formulation was unable to provide the same structural control, and its particles remained irregular with lower yield and entrapment. At a ratio of 1:3, the polymer quantity was adequate to produce discrete, spherical and porous particles.

The stabilizer findings require interpretation alongside the polymer effect. Batches prepared with 1.0% PVA showed marginally higher yield or entrapment at some ratios, but the thesis carried ASMS-3 forward. This selection reflects the practical principle that optimization should not depend only on the largest numerical value. ASMS-3 met the yield and entrapment thresholds, had a slightly smaller particle size, spherical morphology and a sustained release profile while using less stabilizer. Excess PVA can be difficult to remove completely and may influence surface characteristics, so a lower concentration that produces stable particles can be preferable.

The mean particle size of about 45 μm is suitable for incorporation into a topical gel because it is sufficiently small to avoid a gritty sensation but remains within the microsponge range. The PDI below 0.3 and the close agreement between microscopy and instrumental sizing support a reasonably uniform preparation. The broad D10-D90 interval is expected for a formulation produced through emulsion diffusion rather than precision microfluidics, yet the absence of large aggregates and the smooth gel texture indicate that the distribution was pharmaceutically acceptable. SEM evidence of surface pores is particularly important: porosity distinguishes a microsponge from a simple solid microsphere and provides diffusion channels for release (Nokhodchi et al., 2005; Mahant et al., 2020).

The eight-hour release profile showed a gradual increase rather than an abrupt liberation of most of the payload. Approximately one eighth was released during the first 30 minutes and 60% by four hours, followed by continued release to 86% at eight hours. Such a profile can provide early

availability of active constituents while preserving a reservoir for prolonged delivery. The remaining fraction may reflect active retained within deeper pores or stronger association with the ethyl-cellulose matrix. This pattern is consistent with diffusion through a porous hydrophobic polymer and agrees with reports that ethyl-cellulose microsponges can moderate percutaneous release (Maiti et al., 2011; Mehta et al., 2012).

Conversion of the particles into a Carbopol gel was successful. The gel pH was within the normal dermal compatibility range, while the viscosity provided a balance between application and residence. A formulation that is too fluid may run from the application site, whereas excessive viscosity can reduce spreadability and active diffusion. The observed viscosity of approximately 2850 cP, together with good spreadability and extrudability, indicates that the 1% Carbopol system achieved a useful semisolid structure. The mild residual garlic odour suggests partial sensory masking, although complete odour elimination was not expected because characteristic volatile constituents remain part of the active material.

The stability results provide further support for the protective function of the microsponge-gel system. There was no phase separation or visible deterioration, and the 90-day changes in pH and viscosity were small. Retention of 92.6% active content at day 90 met the predetermined requirement and suggests that the polymer matrix and amber, airtight storage reduced degradation. Stability cannot be regarded as fully established from a three-month study, and detailed chemical marker analysis would be required to confirm preservation of allicin or specific thiosulfinates. Nevertheless, the physical and content-retention data demonstrate that the optimized system was sufficiently robust for preclinical topical formulation work.

The formulation strategy also has practical manufacturing implications. The process used moderate temperature, standard stirring equipment and conventional pharmaceutical excipients. These features support laboratory reproducibility and possible scale-up, although solvent-removal efficiency would become more critical at a larger scale. Dichloromethane is useful for particle formation but requires strict residual-solvent control. Future development should quantify residual solvent according to pharmacopeial limits and evaluate whether less hazardous solvent systems can reproduce the same porosity and loading.

The principal strength of the study is the direct connection between formulation variables and multiple performance outcomes. Polymer concentration, loading, particle size, morphology,

release, gel consistency and storage behaviour were considered as an integrated system. Limitations include reliance on a crude extract rather than a standardized allicin assay, use of a limited optimization design rather than a formal factorial model, and qualitative reporting of spreadability. Future work should quantify individual organosulfur markers, model release kinetics, measure residual solvent, apply design-of-experiments methods and conduct longer stability testing. Even with these limitations, the study establishes a reproducible foundation for topical delivery of *Allium sativum* through polymeric microsponges.

5. Conclusion

Allium sativum L. extract was successfully formulated into ethyl-cellulose microsponges and incorporated into a Carbopol 934 gel. A 1:3 drug-to-polymer ratio produced the most suitable balance of yield, entrapment, particle size, morphology and controlled release. The optimized ASMS-3 batch consisted of uniform porous particles of approximately 45 μm, released 86% of the active over eight hours and produced a smooth, skin-compatible gel with acceptable viscosity, spreadability and content uniformity. The formulation retained more than 90% of its initial content after 90 days. Polymeric microsponge technology therefore provides a practical means of improving the handling, stability and release characteristics of garlic extract for controlled topical application.

6. Declarations

Competing interests: The author(s) declare no competing interests.

Author contributions: Ayushi Srivastava contributed to conceptualization, methodology, investigation, formulation development, data collection, analysis, and preparation of the original manuscript. Sushila Kaura supervised the study, validated the methodology and results, and critically reviewed and edited the manuscript. Both authors approved the final version.

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