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From Suspensions to Gummies: A Comprehensive Review of Simethicone Dosage Form Evaluation and Stability

Rahul. R[1], P. K. Kulkarni[1], Salman. M[1], Venkatesh. K[2], K Hanumanthachar Joshi[3]

[1,2]Dept of Pharmaceutics, Sarada Vilas College of Pharmacy, Mysore, India.
[3]Dept of Pharmacognosy, Sarada Vilas College of Pharmacy, Mysore, India.

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ABSTRACT

Simethicone is a widely used antiflatulent agent employed for the management of gastrointestinal discomfort caused by excess gas. Although the active ingredient is chemically inert and pharmacologically simple, formulation development of simethicone presents multiple challenges due to its hydrophobic nature, high viscosity, and sensitivity of dosage forms to stability and patient acceptability issues. This systematic review critically evaluates the formulation strategies of simethicone across conventional and novel dosage forms, highlighting excipient selection, manufacturing techniques, stability concerns, and emerging patient-centric approaches.

Keywords : Simethicone, antiflatulent, pharmaceutical formulation, suspensions, emulsions, chewable tablets, gummies, stability, patient-centric dosage forms

I. INTRODUCTION

Simethicone is a mixture of polydimethylsiloxane and silica gel, acting as a surface-active agent that reduces surface tension of gas bubbles in the gastrointestinal tract, facilitating their coalescence and elimination. It is not absorbed systemically and is considered pharmacologically inert, making it suitable for use across pediatric, adult, and geriatric populations.[1]

Despite its therapeutic simplicity, simethicone poses considerable formulation challenges. Its hydrophobic, viscous, and non-crystalline nature complicates uniform dispersion, dose uniformity, and long-term stability. Consequently, formulation design plays a critical role in ensuring product quality, efficacy, and patient compliance.[2]

The objective of this systematic review is to analyze existing literature on simethicone formulations, evaluate formulation approaches across dosage forms, identify stability and manufacturing challenges, and highlight research gaps and future directions.[3]

II. Physicochemical Properties Relevant to Formulation

Key formulation-relevant properties include:

- High viscosity and low surface tension
- Insolubility in water
- Chemical inertness and non-reactivity
- Tendency to adsorb onto container surfaces

These properties necessitate the use of suitable emulsifiers, suspending agents, and processing techniques.[4]

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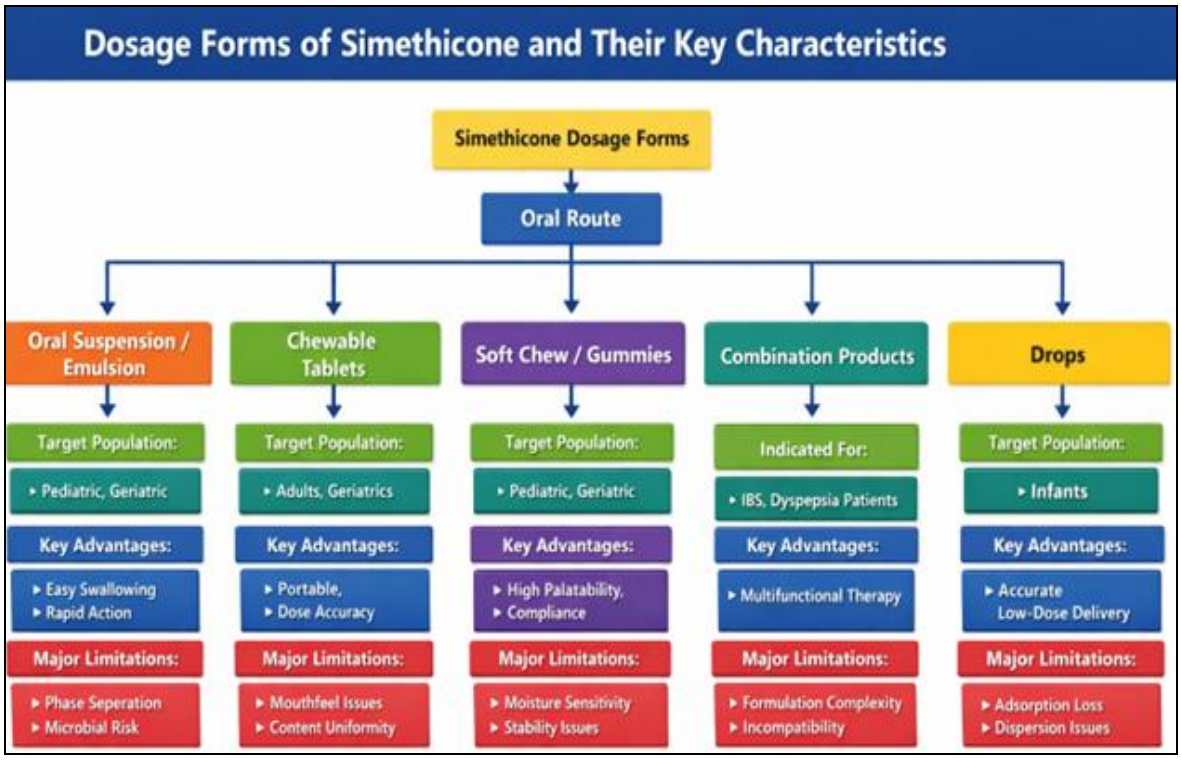
III. Conventional Dosage Forms of Simethicone [5]



IV. Oral Suspensions and Emulsions

Oral suspensions are the most common dosage form for simethicone, especially in pediatric use. Formulation typically involves dispersing simethicone in an aqueous medium using emulsifying agents such as polysorbates and suspending agents like xanthan gum or carboxymethyl cellulose.[6]

Challenges:

- Phase separation and creaming
- Poor redispersibility
- Microbial growth due to aqueous base [7]

Strategies:

- Use of optimized emulsifier combinations
- Addition of preservatives
- Controlled viscosity adjustment [8]

V. Chewable Tablets

Chewable tablets are an important solid oral dosage form of simethicone designed to improve patient convenience, portability, and compliance, particularly in adults and geriatric populations. Formulation of simethicone chewable tablets is challenging due to the liquid, hydrophobic, and viscous nature of the drug. [9] To overcome this, simethicone is typically adsorbed onto suitable carriers such as colloidal silicon dioxide, microcrystalline cellulose, or magnesium aluminum silicate to convert it into a free-flowing, compressible powder. This adsorption step is critical for achieving content uniformity and consistent dosing.[10]

Excipients such as mannitol, sorbitol, or xylitol are commonly used as diluents to provide a pleasant mouthfeel and cooling sensation during chewing. Flavoring agents and sweeteners are incorporated to mask any unpleasant taste.[11] The selection of binders and lubricants must be carefully optimized, as excessive lubrication can interfere with tablet integrity and drug distribution. Manufacturing is generally carried out using direct compression or dry granulation techniques to avoid moisture-related instability. [12]

Quality control parameters for simethicone chewable tablets include hardness, friability, content uniformity, disintegration time, and organoleptic properties. Stability concerns mainly involve adsorption loss, changes in hardness, and moisture uptake. Overall, chewable tablets offer a patient-friendly alternative to liquid formulations when designed with appropriate excipients and processing controls.[13]

VI. Novel and Patient-Centric Dosage Forms

Table 1: Comparative Evaluation of Simethicone Dosage Forms (Gummies vs Chewable Tablets vs Oral Suspensions) [14]

Parameter	Gummies	Chewable Tablets	Oral Suspensions
Physical nature	Semi-solid	Solid	Liquid
Patient population	Pediatric, geriatric, dysphagic	Adults, geriatrics	Pediatric, infants, geriatrics
Palatability	Excellent	Good	Moderate
Ease of administration	Very high	High	Moderate
Dose accuracy	Moderate	High	High (with proper measuring device)
Key excipients	Gelling agents, plasticizers, sweeteners	Adsorbents, diluents, sweeteners	Emulsifiers, suspending agents, preservatives
Major formulation challenge	Moisture sensitivity, dispersion	Content uniformity, mouthfeel	Phase separation, microbial stability
Stability concerns	Texture changes, stickiness	Hardness variation, adsorption loss	Creaming, sedimentation
Manufacturing complexity	Moderate to high	Moderate	Moderate
Patient compliance	Very high	High	Moderate

Table 2: Common Excipients Used in Simethicone Formulations [15]

Excipient Category	Examples	Functional Role
Emulsifiers	Polysorbate 80, sorbitan monooleate	Dispersion of hydrophobic simethicone
Suspending agents	Xanthan gum, CMC, HPMC	Physical stability, redispersibility
Adsorbents	Colloidal silicon dioxide, MCC	Convert liquid simethicone to free-flowing powder
Gelling agents	Gelatin, pectin, agar	Structure formation in gummies
Sweeteners	Sorbitol, sucralose, xylitol	Palatability improvement
Preservatives	Sodium benzoate, parabens	Microbial control
Flavoring agents	Fruit flavors, menthol	Taste masking

VII. Simethicone Gummies

Simethicone gummy formulations represent an emerging, patient-centric dosage form designed to enhance palatability and compliance, particularly among pediatric, geriatric, and dysphagic patients. Gummies are typically prepared using gelatin or plant-based alternatives such as pectin, agar, or starch, making them suitable for vegan and halal requirements.[16] The major formulation challenge in simethicone gummies arises from the hydrophobic and viscous nature of simethicone, which complicates its uniform dispersion within the aqueous gel matrix. To address this, simethicone is often pre-emulsified using suitable surfactants or incorporated as an adsorbed form before being mixed into the gummy mass.[17]

Plasticizers such as glycerin or sorbitol are added to impart elasticity and prevent brittleness, while sweeteners and flavoring agents improve taste masking. Moisture control is a critical consideration, as excessive water content can lead to stickiness, microbial growth, and texture instability during storage. Preservatives may be required to ensure microbial safety, especially in sugar-based formulations.[18]

Manufacturing involves controlled heating, mixing, molding, and curing steps, with strict control over temperature to avoid degradation of excipients. Stability concerns in gummy formulations include moisture uptake, texture changes, and phase separation.[19] Despite these challenges, simethicone gummies offer a highly acceptable and innovative alternative to conventional dosage forms when developed with optimized formulation strategies.[20]

VIII. Stability Considerations

Table 3: ICH Stability Study Design for Simethicone Formulations [21]

Study Type	ICH Guideline	Storage Conditions	Duration	Sampling Points	Parameters Evaluated
Accelerated stability study	ICH Q1A(R2)	40°C ± 2°C / 75% RH ± 5% RH	6 months	0, 1, 2, 3, 6 months	Appearance, assay/content uniformity, viscosity, pH, phase separation, microbial limits
Intermediate stability study	ICH Q1A(R2)	30°C ± 2°C / 65% RH ± 5% RH	6–12 months	0, 3, 6, 9, 12 months	Physical stability, assay, moisture content
Long-term stability study	ICH Q1A(R2)	25°C ± 2°C / 60% RH ± 5% RH	12–24 months	0, 3, 6, 9, 12, 18, 24 months	Assay, appearance, redispersibility, packaging interaction
In-use stability study	ICH Q1A(R2)	Room temperature after opening	30–60 days	0, 7, 15, 30, 60 days	Microbial limits, physical changes
Photostability study	ICH Q1B	Light exposure as per guideline	As specified	Initial and final	Color change, physical integrity

Explanation of ICH Stability Studies

Accelerated Stability Study

Accelerated stability studies are conducted to predict the long-term stability of simethicone formulations within a shorter time frame. As per ICH Q1A(R2), products are stored at 40°C ± 2°C and 75% RH ± 5% RH for six months. This study is particularly important for simethicone formulations because, although the active ingredient is chemically inert, the dosage forms are prone to physical instability. Under accelerated conditions, oral suspensions may exhibit phase separation, creaming, or viscosity changes, while gummies may show texture softening, stickiness, or moisture uptake. Chewable tablets may undergo changes in hardness or friability.[22] The data generated help identify potential degradation pathways of excipients, packaging interactions, and formulation weaknesses. Accelerated studies also assist in selecting suitable excipients, optimizing viscosity modifiers, and determining moisture-protective packaging. Any significant change observed during this study signals the need for reformulation or additional testing. Thus, accelerated stability testing serves as a rapid and cost-effective tool to assess formulation robustness and to support provisional shelf-life assignment.[23]

Intermediate Stability Study

Intermediate stability studies are performed when accelerated stability studies show significant changes or when products are intended for markets with climatic conditions between long-term and accelerated zones. According to ICH Q1A(R2), simethicone formulations are stored at 30°C ± 2°C and 65% RH ± 5% RH for a period of 6 to 12 months. This study bridges the gap between accelerated and long-term testing and provides supportive data for shelf-life estimation.[24] For simethicone products, intermediate conditions are useful in evaluating gradual physical changes such as slow phase separation in suspensions, moisture-induced softening of gummies, or minor assay variability due to adsorption losses. The results help confirm whether the formulation can withstand moderately stressful conditions without compromising quality. Intermediate stability data are particularly valuable for products marketed in tropical and subtropical regions, including India. Overall, this study strengthens regulatory submissions and ensures that the formulation maintains acceptable quality attributes under realistic storage environments.[25]

Long-Term Stability Study

Long-term stability studies are the most critical component of stability testing and are used to establish the actual shelf life of simethicone formulations. As per ICH Q1A(R2), products are stored at 25°C ± 2°C and 60% RH ± 5% RH for a duration of 12 to 24 months. These conditions simulate normal storage environments encountered during product distribution and patient use.[26] For simethicone dosage forms, long-term studies focus primarily on physical stability parameters, as the drug itself is chemically stable. Oral suspensions are evaluated for redispersibility, viscosity consistency, and absence of phase separation, while chewable tablets are assessed for hardness, friability, and content uniformity. Gummies are monitored for texture, moisture content, and

microbial limits. Data from long-term studies form the basis for expiry date assignment and label storage conditions. Regulatory authorities rely heavily on these results to ensure that the product remains safe, effective, and acceptable throughout its intended shelf life.[27]

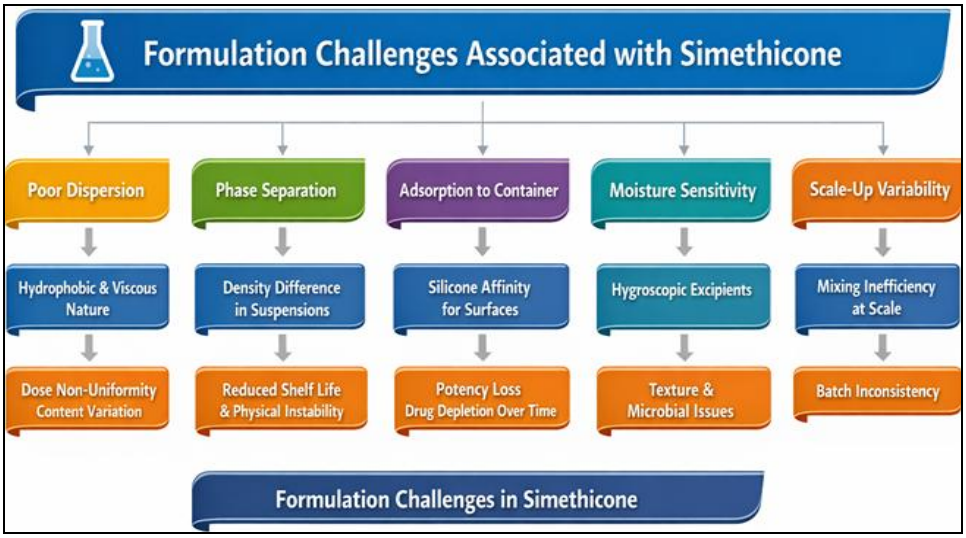
In-Use Stability Study

In-use stability studies evaluate the stability of simethicone formulations after the product has been opened and used by the patient. This study is particularly relevant for multidose liquid preparations such as suspensions and drops. After opening, products are stored at room temperature and tested over 30 to 60 days, simulating real-world usage conditions. For simethicone suspensions, repeated opening and closing of containers may introduce moisture, air, and microbial contamination, potentially affecting physical stability and preservative efficacy.[28] Parameters such as appearance, odor, viscosity, redispersibility, and microbial limits are closely monitored. In-use stability studies help confirm that the formulation remains safe and effective throughout the recommended usage period after opening. The results guide labeling instructions such as "use within 30 days after opening." This study enhances patient safety and ensures compliance with regulatory expectations for multidose pharmaceutical products.[29]

Photostability Study

Photostability studies are conducted in accordance with ICH Q1B to evaluate the effect of light exposure on simethicone formulations. Although simethicone itself is not photosensitive, excipients such as flavors, colors, and polymeric materials may degrade or undergo physical changes when exposed to light. In this study, the product is exposed to defined light sources and compared with protected samples. For simethicone formulations, photostability testing helps identify potential color changes, packaging interactions, or degradation of flavoring agents that may affect product acceptability. Liquid formulations may show slight turbidity changes, while gummies and chewable tablets may exhibit discoloration. Based on the outcomes, appropriate packaging such as amber bottles or light-resistant blisters can be selected. Photostability studies ensure that the product maintains its quality throughout storage and use, even when exposed to light during handling or dispensing.[30]

Formulation challenges associated with simethicone



Simethicone is chemically stable; however, formulations are susceptible to physical instability. Common stability issues include:

- Phase separation in suspensions
- Texture changes in gummies
- Moisture-induced degradation of excipients

Accelerated stability studies highlight the importance of moisture-protective packaging and controlled storage conditions.[31]

IX. Manufacturing and Scale-Up Challenges

Table 4: Strategies and Solutions for Simethicone Formulation Challenges [32]

Identified Problem	Formulation/Process Strategy	Outcome
Non-uniform dispersion0	High-shear mixing, emulsifier blends	Improved homogeneity
Content uniformity failure	Use of adsorbents and granulation	Consistent dosing
Physical instability	Optimized viscosity and stabilizers	Enhanced shelf life
Moisture-related degradation	Moisture-barrier packaging	Improved stability
Scale-up issues	QbD-based process optimization	Batch-to-batch reproducibility

Key manufacturing challenges include achieving uniform dispersion, preventing adsorption losses, and ensuring batch-to-batch consistency. High-shear mixing, Consistent dosing controlled addition of simethicone, and in-process quality control are critical.[33]

X. Regulatory and Quality Considerations

Simethicone is included in major pharmacopeias, with specifications for identification, viscosity, and microbial limits. Quality by Design (QbD) approaches are increasingly recommended for robust formulation development.[34]

XI. Research Gaps and Future Perspectives

- Limited published data on vegan and sugar-free gummy formulations
- Insufficient long-term stability studies
- Lack of comparative studies between dosage forms

Future research should focus on advanced dispersion technologies, novel polymers, and patient-centric design supported by robust stability data.[35]

XII. Conclusion

Although simethicone is pharmacologically simple, its formulation is complex and highly dependent on excipient selection and processing conditions. Advances in patient-centric dosage forms have expanded its application, but stability and manufacturing challenges remain. A systematic and QbD-driven approach is essential to develop robust, effective, and patient-friendly simethicone formulations.

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The authors have no conflicts of interest to declare.