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GREEN NANOEMULSIONS FOR ORAL DRUG DELIVERY: FORMULATION STRATEGIES, CHARACTERIZATION, THERAPEUTIC APPLICATIONS, CHALLENGES, AND FUTURE PERSPECTIVES

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ABSTRACT

Green nanoemulsions have become a viable delivery method for enhancing the oral administration of naturally occurring bioactive substances and medications that are poorly soluble in water. While green techniques focus on renewable, biodegradable, and biocompatible materials as well as more sustainable production, conventional nanoemulsions tend to depend on synthetic surfactants, petroleum-derived excipients, organic solvents, and energy-intensive processing. Their wide interfacial area and small droplet size can enhance gastrointestinal behavior, drug solubilization, dispersion, and, for appropriate lipophilic drugs, systemic exposure. The basic concepts of green nanoemulsions, the selection of sustainable oils and emulsifiers, preparation techniques, important physicochemical characterization parameters, mechanisms of oral bioavailability enhancement, representative therapeutic applications, safety considerations, and Quality-by-Design approaches are all summarized in this review. The limited availability of natural raw materials, oxidative instability, surfactant-related issues, gastrointestinal changes, scale-up, reproducibility, regulatory ambiguity, and the paucity of relevant clinical evidence are all given special consideration. There is also discussion of emerging directions such as gut-nanoemulsion interactions, life-cycle evaluation, enhanced natural emulsifiers, continuous

production, artificial intelligence-assisted formulation, and the integration of sustainability with pharmaceutical quality. Green nanoemulsions offer a lot of potential overall, but effective translation necessitates striking a balance between pharmacological performance, safety, reproducibility, manufacturability, clinical relevance, and observable environmental impact.

KEYWORDS: sustainable formulation, natural oils, biosurfactants, bioavailability, green chemistry, oral drug delivery, green nanoemulsion, nanotechnology, and quality by design.

1. INTRODUCTION

Because of its ease of use, patient acceptability, affordability, and well-established manufacturing infrastructure, oral drug delivery is still the recommended method. However, many therapeutic drugs have limited oral efficacy due to poor aqueous solubility, insufficient gastrointestinal permeability, chemical instability, significant first-pass metabolism, and unpredictable absorption. These issues are especially significant for molecules that are poorly soluble in water, as the drug's ability to dissolve and remain in an absorbable condition can play a significant role in determining its bioavailability.

Kinetically stable dispersions of two immiscible liquids, usually water and oil, stabilized by surfactants and, if necessary, co-surfactants, are called nanoemulsions. Their tiny droplets can enhance the dispersion and solubilization of lipophilic substances by offering a broad interfacial surface. The incorporation of green chemistry principles to nanoemulsion design has been prompted by the increasing emphasis on sustainable pharmaceutical development.

Green nanoemulsions aim to minimize waste and harmful solvents, employ renewable or biodegradable materials, and, whenever feasible, use less energy during production.

Because digestible lipid phases can interact with bile components and digestive processes to preserve poorly soluble drugs in solubilized forms and promote intestinal absorption, green nanoemulsions are especially appealing for oral delivery. However, a formulation's natural origin does not prove that it is safer or more sustainable. It is also necessary to take into account raw-material variability, oxidation, surfactant exposure, manufacturing energy, packaging, and end-of-life effects. Thus, the advantages and disadvantages of using green nanoemulsions as oral drug delivery methods are the main topics of this review.[1]

2. Foundations and Green Formulations principles

2.1 Green Nanoemulsions and Nanoemulsions

Colloidal oil-water dispersions containing nanoscale droplets are known as nanoemulsions. Instead of being thermodynamically stable, they are kinetically stable systems. Because oil droplets can disperse in gastrointestinal fluids and offer a carrier environment for lipophilic medicines, oil-in-water (O/W) nanoemulsions are especially pertinent to oral delivery.

Multiple nanoemulsions and water-in-oil systems have specific uses, although they typically increase formulation complexity.

It takes more than just switching out one excipient to convert ordinary nanoemulsions to green ones. Renewable feedstocks, biodegradability, toxicity, solvent selection, energy consumption, waste production, and the product's entire life cycle should all be considered in a green formulation. Therefore, a formulation that uses natural oil but depends on energy-intensive processing and non-sustainable auxiliary ingredients shouldn't be regarded as completely green.[2]

2.2 Green Nanoemulsion Components

Drug loading, droplet formation, digestion, oxidative stability, and absorption are all significantly impacted by the oil phase, which serves as the main reservoir for lipophilic drugs. Because they are renewable and suitable for oral delivery, plant-derived oils and food-compatible lipids such coconut oil, olive oil, sunflower oil, soybean oil, sesame oil, flaxseed oil, rice bran oil, and medium-chain triglycerides have been studied. However, as their fatty acid content influences both oxidative stability and formulation performance, it must be taken into account.[1,3]

Lecithin, proteins, phospholipids, saponins, gum-based compounds, and microbial biosurfactants including rhamnolipids and sophorolipids are examples of natural emulsifiers. These substances may lessen reliance on traditional synthetic surfactants while offering interfacial stabilization. On the other hand, natural emulsifiers may show biological effects that depend on concentration, unpredictability, and difficulties with purification. Co-surfactants that promote interfacial flexibility and droplet formation include glycerol, ethanol where applicable, propylene glycol, and other relevant polyols. The continuous phase of oral

O/W systems is typically formed by purified water, while stability can be affected by pH and ionic strength.

Therefore, a comprehensive approach that takes into account drug solubility, digestibility, oxidative stability, oral safety, regulatory status, environmental impact, cost, commercial availability, and scalability should be used when choosing excipients. Without adding needless toxicity, instability, or manufacturing complexity, the ideal green excipient should enhance drug performance.[3]

2.3 Green Chemistry in the Creation of Nanoemulsions

A significant conceptual foundation for the development of sustainable nanoemulsions is provided by green chemistry. Preventing waste, using cleaner solvents and auxiliaries, using renewable feedstocks, energy efficiency, and designing for degradation are the principles that are most immediately applicable to pharmaceutical nanoemulsions. These ideas can be put into effect by using fewer solvents, using renewable lipid phases, employing biodegradable emulsifiers where necessary, cutting down on pointless processing, and assessing the formulation's whole life cycle.

Crucially, rather than being viewed as a distinct goal, green chemistry should be linked with pharmaceutical requirements. Only when sustainability is attained without sacrificing drug stability, dose homogeneity, safety, manufacturability, and therapeutic efficacy is a formulation considered useful.[4]

3. Preparation and Physicochemical Characterization

3.1 Preparation Methods

Nanoemulsion preparation methods can be broadly divided into high-energy and low-energy approaches. High-energy techniques use mechanical forces to disrupt larger droplets, whereas low-energy methods exploit formulation composition and interfacial behavior to generate nanosized droplets. The appropriate method depends on the drug, lipid and emulsifier system, required droplet characteristics, scalability, energy demand, and sensitivity of the formulation to heat or shear.

3.1.1 High-Energy Methods

High-pressure homogenization produces nanosized droplets by forcing a coarse emulsion through a narrow valve under high pressure. It is reproducible and scalable, but equipment and energy requirements can be substantial, and processing may increase temperature.

Ultrasonication uses acoustic cavitation to break droplets and is convenient for laboratory-scale preparation, although prolonged sonication can generate heat and potentially accelerate oxidation of unsaturated oils. Microfluidization produces droplets through high-velocity interaction of fluid streams and can provide good uniformity and reproducibility, but it also requires specialized equipment.

3.1.2 Low-Energy Methods

Phase inversion temperature relies on temperature-dependent changes in nonionic surfactant behavior. Phase inversion composition produces inversion through controlled changes in composition and is attractive for heat-sensitive materials. Spontaneous emulsification or self-emulsification can form nanosized droplets with relatively low mechanical input and is therefore particularly relevant to sustainable oral delivery. Low-energy methods may reduce energy consumption, but successful application depends strongly on component ratios and interfacial properties.

Emerging manufacturing strategies include continuous processing, microfluidic systems, membrane emulsification, and process analytical technologies. These approaches may improve reproducibility and facilitate scale-up, but their suitability must be demonstrated for each formulation rather than assumed from laboratory performance.[4]

3.2 Physicochemical Characterization

Comprehensive characterization is required to establish product quality, stability, and performance. Droplet size is a major quality attribute because it influences interfacial area, physical stability, and drug dispersion. Dynamic light scattering is widely used to determine hydrodynamic droplet size and polydispersity index (PDI). A lower PDI generally indicates a more uniform droplet population, although the interpretation should consider the measurement method and formulation characteristics.

Zeta potential provides information about interfacial charge and potential electrostatic repulsion between droplets. High absolute values may support electrostatic stability, although sterically stabilized systems can remain stable at lower values. The measured value depends on pH, ionic strength, surfactant type, and the measurement medium. Morphological techniques such as transmission or scanning electron microscopy provide complementary structural information.

Additional evaluations include pH, viscosity, drug content, encapsulation or loading efficiency where applicable, in vitro release, and stability. Drug content may be quantified using a validated chromatographic or spectrophotometric method. Stability studies should monitor droplet size, PDI, zeta potential, pH, viscosity, drug content, appearance, and relevant degradation or oxidation markers. Accelerated and long-term studies, together with stress testing where appropriate, help establish formulation robustness and shelf life.[5]

Table 1: Physicochemical characterization.

Parameter	Typical method	Purpose
Droplet size	Dynamic light scattering	Assesses size distribution and formulation performance
PDI	Dynamic light scattering	Assesses droplet-size uniformity
Zeta potential	Electrophoretic light scattering	Provides information on interfacial charge/stability
Morphology	TEM/SEM	Visualizes droplet structure and aggregation
pH	Calibrated pH meter	Assesses chemical stability and compatibility
Viscosity	Rotational viscometer	Evaluates flow and physical stability
Drug content	HPLC/UV–Vis	Confirms dose uniformity
In vitro release	Dialysis/dissolution method	Compares release behavior
Stability	Accelerated/long-term studies	Establishes robustness and shelf life

4. Mechanisms of Oral Bioavailability Enhancement

Green nanoemulsions can improve oral delivery through several complementary mechanisms rather than through droplet-size reduction alone. First, poorly soluble lipophilic drugs can be incorporated into the oil phase in a pre-solubilized state, reducing dependence on dissolution after administration. The large interfacial area of small droplets can also promote interaction with gastrointestinal fluids and facilitate lipid digestion.

During gastrointestinal digestion, lipids are hydrolyzed and their products interact with bile salts and phospholipids to form mixed colloidal structures. These structures can maintain lipophilic drugs in solubilized or bioaccessible forms and may reduce precipitation. The extent of this benefit depends on the lipid type, drug properties, digestion rate, and composition of the interfacial layer.

Nanoemulsions may also protect susceptible compounds during gastrointestinal transit and can influence the interaction of the drug or formulation with the mucus and intestinal epithelial surface. Lipid digestion products may modify membrane interactions and facilitate

transcellular transport. For some formulations, cellular uptake or endocytic pathways may contribute to absorption, although the relevance of intact droplet uptake varies with formulation characteristics.

A further mechanism is intestinal lymphatic transport. Highly lipophilic drugs associated with digestible lipids may become incorporated into chylomicron-associated pathways and enter the lymphatic circulation, thereby reducing the extent of hepatic first-pass metabolism. This mechanism is dependent on drug lipophilicity and lipid composition and should be demonstrated experimentally rather than inferred solely from small droplet size.

Overall, bioavailability enhancement is determined by a combination of drug solubilization, lipid digestion, colloidal transformation, intestinal interaction, and, for suitable compounds, lymphatic transport. Important variables include droplet size and distribution, lipid type, surfactant composition, drug lipophilicity, loading, digestion behavior, and stability in gastrointestinal fluids.[6]

5. Therapeutic and Pharmaceutical Applications

Green nanoemulsions have been investigated for poorly water-soluble conventional drugs as well as phytochemicals, nutraceuticals, vitamins, and other lipophilic bioactives. The strongest rationale exists when the active compound is limited by aqueous solubility, chemical instability, or inefficient gastrointestinal absorption.[5,6]

5.1 Phytochemicals and Nutraceuticals

Phytochemicals such as curcumin, luteolin, flavonoids, carotenoids, and other polyphenols are frequent candidates because their biological activity is often accompanied by poor aqueous solubility and limited oral bioavailability. Nanoemulsification can improve aqueous dispersibility and bioaccessibility by maintaining these compounds within lipid-derived colloidal structures during digestion. However, improved bioaccessibility should not automatically be interpreted as improved clinical efficacy.[7]

5.2 Curcumin

Curcumin is a representative poorly water-soluble bioactive compound. Nanoemulsion systems can improve its dispersion and gastrointestinal bioaccessibility, but formulation design must balance physical dispersion against chemical stability. The use of naturally derived phospholipids or other biocompatible emulsifiers provides an attractive green-

formulation strategy, but the complete formulation must still be evaluated for stability and safety.[8]

5.3 Luteolin and Other Flavonoids

Luteolin provides an example of a flavonoid for which nanoemulsion formulation has been associated with improved oral exposure. An optimized luteolin nanoemulsion reported in the source manuscript showed approximately a three-fold increase in oral bioavailability compared with suspension and evidence that lymphatic transport contributed to absorption. Such findings support the mechanistic potential of lipid-based systems, but results remain formulation- and drug-specific.[9]

5.4 Conventional Poorly Water-Soluble Drugs

Green nanoemulsions can also be applied to synthetic drugs whose oral performance is limited primarily by poor dissolution. Incorporation into digestible lipids can maintain the drug in a solubilized environment and, for sufficiently lipophilic compounds, may support lymphatic transport. Nevertheless, the magnitude of benefit depends on drug log P, dose, lipid digestibility, formulation composition, and gastrointestinal conditions.[10]

5.5 Vitamins and Other Lipophilic Bioactives

Fat-soluble vitamins and other lipophilic compounds can benefit from nanoemulsification because their absorption is closely linked to lipid digestion and mixed-micelle formation. Natural oils can provide both a solubilizing environment and a physiologically digestible lipid source. Oxidation-sensitive compounds require particular attention to oil selection, antioxidant protection, packaging, and storage.[11]

5.6 Critical Evaluation of Therapeutic Applications

A substantial proportion of the literature remains at the in vitro or animal-study stage. Improvements in dissolution, bioaccessibility, cellular uptake, or plasma exposure do not necessarily demonstrate clinical superiority. Furthermore, the term green nanoemulsion is not used uniformly, and some formulations described as green still contain conventional synthetic surfactants. Therapeutic claims should therefore be linked to the actual formulation tested and supported by appropriate pharmacokinetic, pharmacodynamic, and safety evidence.[12]

6. Safety, Biocompatibility, and Environmental Considerations

Natural or biodegradable ingredients do not automatically make a nanoemulsion safe. Safety

depends on the active drug, oil, surfactant, co-surfactant, droplet characteristics, concentration, route, duration of exposure, and interactions among formulation components. Oral evaluation should consider gastrointestinal digestion, mucus and epithelial interactions, systemic exposure, and potential long-term effects.[13]

6.1 Natural Oils and Surfactants

Natural oils should be evaluated for fatty-acid composition, purity, oxidation state, peroxide value, contaminants, digestibility, and regulatory suitability. Unsaturated oils can undergo oxidation during processing and storage, potentially affecting formulation quality and generating undesirable degradation products. Natural surfactants can offer biocompatibility advantages, but their effects remain concentration-dependent. Excessive surfactant exposure may alter membrane permeability or produce irritation, making minimum effective concentrations preferable.[14,15]

6.2 Gastrointestinal and Cellular Safety

Because nanoemulsions undergo structural changes during gastrointestinal digestion, safety evaluation should consider their dynamic behavior rather than only the initial formulation. Simulated digestion can assess lipid hydrolysis, droplet changes, drug precipitation, bioaccessibility, and interactions with bile components. Intestinal models such as Caco-2 systems can provide preliminary information on cell viability and barrier integrity, while more advanced studies may evaluate tight-junction markers, inflammatory responses, oxidative stress, and histological changes.[16]

Long-term and repeated-dose safety requires a formulation-specific assessment. Depending on the active ingredient and excipients, investigations may include systemic toxicity, hematology, biochemical parameters, histopathology, genotoxicity, immunotoxicity, biodistribution, and other scientifically justified endpoints.[17]

6.3 Environmental Sustainability

The environmental claim of a green nanoemulsion should be assessed across its life cycle. Cultivation and extraction of natural ingredients, water and energy use, manufacturing, packaging, transportation, and disposal can all contribute to environmental impact. Life-cycle assessment can provide a more meaningful basis for determining whether a formulation is genuinely more sustainable than a conventional alternative. Natural origin should therefore be considered one component of sustainability rather than its sole definition.[18,19]

7. Regulatory and Quality-by-Design Considerations

Translation from laboratory research to pharmaceutical products requires reproducible quality, safety, efficacy, manufacturing, and stability. Regulatory evaluation depends on the active ingredients, excipients, dosage form, manufacturing process, route, and characteristics of the final product rather than simply the label 'green.' Naturally derived excipients still require appropriate identity, purity, quality, and safety control.[20]

7.1 Quality-by-Design Framework

Quality-by-Design provides a systematic approach for linking the desired product profile with critical quality attributes, material attributes, process parameters, risk assessment, experimental design, and a control strategy. For green nanoemulsions, the Quality Target Product Profile may include the intended oral dosage form, acceptable droplet characteristics, drug content, physical and chemical stability, microbiological quality, release performance, and shelf life.[20]

7.2 Critical Quality Attributes and Process Variables

Potential critical quality attributes include droplet size, PDI, zeta potential, viscosity, appearance, phase stability, drug content, degradation products, oxidation markers, release behavior, digestion behavior, bioaccessibility, and microbiological quality. Critical material attributes include oil type and composition, surfactant quality and concentration, drug solubility, co-surfactant properties, water quality, and antioxidant content. Critical process parameters may include homogenization pressure, sonication time and amplitude, temperature, mixing speed, addition rate, processing time, and cooling rate.[21]

7.3 DoE, Risk Assessment, and Control Strategy

Design of Experiments is valuable because oil, surfactant, co-surfactant, and process variables can interact. Factorial, response-surface, Box–Behnken, and mixture designs can identify influential variables and define an operating region with fewer experiments than one-factor-at-a-time approaches. Risk assessment can prioritize variables likely to affect CQAs, but risk rankings should be experimentally verified. A final control strategy should integrate raw-material specifications, process controls, analytical methods, and stability monitoring.

Scale-up should preserve the physical mechanisms responsible for droplet formation rather than simply increasing laboratory parameters. Changes in mixing geometry, shear

distribution, processing volume, temperature, and addition rate can change droplet size and PDI. Continuous manufacturing and in-line monitoring may improve consistency, but their suitability must be established for the specific formulation.[22]

7.4 Regulatory Challenges

Important regulatory challenges include variability of natural materials, novel excipients, control of contaminants and degradation products, nano-specific characterization, limited long-term clinical evidence, and the absence of a universally standardized definition of green nanoemulsion. Sustainability claims should be supported by objective evidence such as life-cycle or sustainability assessments rather than by natural origin alone.[22]

8. Current Challenges and Future Perspectives

The major limitations of green nanoemulsions are closely connected. Natural materials can vary between batches; unsaturated oils can oxidize; high surfactant concentrations can raise tolerability concerns; and laboratory-scale processing may not translate directly to industrial manufacture. Nanoemulsions are kinetically stable rather than thermodynamically stable and may undergo Ostwald ripening, coalescence, flocculation, creaming, or phase separation. In gastrointestinal fluids, additional transformations may alter droplet structure, drug release, supersaturation, precipitation, and bioaccessibility.

Reproducibility is also affected by differences in raw materials, equipment, processing energy, sample dilution, analytical conditions, and storage. Standardized reporting is therefore necessary for meaningful comparison among studies. Importantly, the literature still contains a substantial gap between improved formulation performance and demonstrated human therapeutic benefit. More rigorous pharmacokinetic, pharmacodynamic, repeated-dose safety, and comparative clinical studies are needed.[22,23]

8.1 Emerging Research Directions

Artificial intelligence and machine learning may help predict formulation responses and reduce trial-and-error optimization when sufficiently standardized datasets are available. Advanced natural emulsifiers, including phospholipids, lecithin, proteins, saponins, polysaccharides, and microbial biosurfactants, may provide additional opportunities for sustainable formulation. Continuous manufacturing and process analytical technology could improve scale-up and real-time control.

Future systems may also investigate personalized oral delivery, lymphatic transport, interactions with the gut microbiome, stimuli-responsive behavior, combination delivery, and hybrid lipid platforms. However, greater complexity should not be pursued for its own sake; a simpler formulation that meets the therapeutic objective may be preferable from pharmaceutical, regulatory, economic, and environmental perspectives.

A particularly important future direction is the integration of sustainability into QbD. Instead of optimizing only quality, safety, and efficacy, formulation development could also consider renewable content, energy use, water consumption, waste, carbon footprint, and biodegradability. This would support a more complete definition of pharmaceutical sustainability.[24]

8.2 Prospects for Future Development

Standardized renewable raw materials → QbD and DoE-assisted formulation → mechanistic gastrointestinal evaluation → pharmacokinetic and pharmacodynamic assessment → safety and long-term stability → life-cycle assessment → scalable manufacturing → regulatory evaluation → clinical translation can be summed up as a practical development pathway. Formulations that are both pharmaceutically beneficial and truly sustainable are more likely to be produced using this integrated method.[24]

Table 2: Major Challenges and Potential Strategies.

Challenge	Potential consequence	Potential strategy
Natural-material variability	Poor reproducibility	Raw-material specifications and standardization
Oxidation	Reduced stability	Stable oils, antioxidants, protective packaging
Surfactant exposure	Irritation or membrane effects	Use minimum effective concentration
GI transformation	Drug precipitation or variable absorption	Simulated digestion and bioaccessibility studies
Scale-up	Changes in droplet characteristics	Mechanistic process development
Analytical variability	Poor cross-study comparison	Standardized measurement/reporting
Limited clinical evidence	Uncertain therapeutic relevance	Human PK/PD and comparative studies
Uncertain sustainability	Unsupported green claims	Life-cycle assessment
Regulatory uncertainty	Delayed translation	Early regulatory strategy and QbD

9. CONCLUSION

Green nanoemulsions provide a promising intersection between advanced oral drug delivery and sustainable pharmaceutical formulation. Their small droplet size, large interfacial area, ability to solubilize lipophilic compounds, and compatibility with digestible lipid systems can address important barriers to oral delivery. The use of renewable oils and naturally derived emulsifiers may further reduce dependence on conventional materials, but these advantages must be demonstrated within a broader framework of pharmaceutical quality and environmental assessment.

Future development should move beyond optimization of droplet size alone. Raw-material standardization, oxidative stability, surfactant safety, gastrointestinal behavior, reproducible manufacturing, QbD, and appropriate regulatory control are all essential. Similarly, improved solubility or bioavailability should not be equated automatically with clinical benefit. Greater emphasis on physiologically relevant digestion, pharmacokinetic–pharmacodynamic relationships, long-term safety, scale-up, and clinical comparison is required.

Ultimately, the most successful green nanoemulsions are likely to be those that achieve an appropriate balance among efficacy, safety, stability, reproducibility, scalability, patient acceptability, cost, and environmental responsibility. Green nanoemulsions therefore have considerable potential as next-generation oral delivery systems, provided that future research addresses the current scientific, manufacturing, regulatory, and translational gaps through rigorous and standardized approaches.[25]

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