REVIEW PAPER

Review on Self Micro-Emulsifying Drug Delivery System

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ABSTRACT

Poor aqueous solubility, dissolution-limited absorption and variable oral bioavailability remain important obstacles in the development of many modern drug molecules. Self micro-emulsifying drug delivery systems (SMEDDS) are isotropic mixtures of drug, oil, surfactant and co-surfactant that disperse spontaneously in gastrointestinal fluid to form fine oil-in-water microemulsions. This review summarizes the pharmaceutical basis, formulation components, development strategy, characterization requirements, advantages, limitations and recent advances of SMEDDS, with special emphasis on solid SMEDDS, supersaturable SMEDDS and the rational selection of newly approved drugs for future formulation screening. A literature-oriented approach was used to organize information from published work on lipid-based oral formulations, self-emulsifying systems and official novel drug approval lists from 2023 to 2026. The review identifies oil solubilization capacity, surfactant/co-surfactant compatibility, self-emulsification time, globule size, polydispersity index, zeta potential, dilution robustness, precipitation resistance, dissolution behavior and thermodynamic stability as critical variables for successful SMEDDS development. The recent approval of several orally relevant anticancer, anti-inflammatory, metabolic, CNS, antibacterial and antiviral molecules provides opportunities for formulation scientists to screen SMEDDS as a bioavailability-enhancing platform. However, suitability must be established by experimental solubility, dose loading, drug-excipient compatibility, digestion and stability studies. Overall, SMEDDS represents a practical and adaptable lipid-based technology for improving the oral delivery of poorly soluble drugs when developed with systematic excipient screening, quality-by-design principles and careful regulatory control.

Keywords: Self micro-emulsifying drug delivery system, SMEDDS, SEDDS, lipid-based formulation, oral bioavailability.

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INTRODUCTION

Oral drug administration is preferred in pharmaceutical therapy because it is convenient, economical and acceptable to patients. Nevertheless, many active pharmaceutical ingredients have limited aqueous solubility and incomplete dissolution in gastrointestinal fluid. Poor solubility may cause low exposure, high intersubject variability, food effects and delayed onset of action, especially when permeability is adequate but dissolution is the rate-limiting step.[1,2]

Lipid-based formulation is a well-established approach for improving the delivery of lipophilic drugs. Lipid excipients can maintain the drug in solubilized form, improve wetting, promote dispersion in gastrointestinal fluid, support mixed micelle formation after digestion and, in selected cases, contribute to intestinal lymphatic transport.[2,3]

SMEDDS are an important class of lipid-based systems. They are clear or slightly opalescent isotropic mixtures containing oil, surfactant, co-surfactant or co-solvent and the drug. After dilution with aqueous gastrointestinal fluid under mild agitation, they form microemulsions or fine emulsions without the requirement of high-energy homogenization.[3,4]

The scientific importance of SMEDDS has increased because a large proportion of new chemical entities are poorly water soluble. Recent advances have expanded the technology from liquid-filled capsules to solid SMEDDS, supersaturable SMEDDS, pelletized systems, adsorbed powders, tablets, hot-melt extruded systems and hybrid lipid-solid formulations.[5,6]

Despite numerous reports on SMEDDS, there is a need to connect classical formulation principles with newly approved drug molecules from 2023 to 2026. These approvals include several small molecules in oncology, infectious disease, metabolic disorders, central nervous system disorders and inflammatory conditions. Such drugs can be screened for SMEDDS only after confirming dose, solubility, lipophilicity, stability and route of administration from experimental data and regulatory labels.[12–15]

MATERIAL AND METHODS

This review was prepared by organizing information from the attached topic guideline, published reviews and official drug approval sources. The search terms considered for manuscript development included SMEDDS, SEDDS, self micro-emulsifying drug delivery system, lipid-based formulation, solid SMEDDS, supersaturable SMEDDS, BCS class II drugs, oral bioavailability, pseudo-ternary phase diagram, droplet size, precipitation inhibitor and FDA novel drug approvals 2023-2026. Relevant literature was selected for formulation principles, excipient selection, characterization parameters, challenges and recent approved drug examples. Duplicate, non-pharmaceutical and non-relevant sources were excluded. Recent FDA novel drug approval lists were used only to identify approved molecules for formulation screening discussion and not to claim that these products are approved as SMEDDS.[12–15]

NEED OF SMEDDS IN MODERN PHARMACEUTICS

The need for SMEDDS arises from the increasing number of drugs that show poor aqueous solubility, dissolution-limited absorption and unpredictable oral exposure. For BCS class II drugs, permeability is usually adequate but dissolution is insufficient; for BCS class IV drugs, both solubility and permeability may be problematic. In such conditions, conventional tablets may not provide reproducible drug absorption unless formulation strategies improve solubilization and maintain the drug in a dissolved state.[1,4]

SMEDDS can improve bioavailability through multiple mechanisms: enhanced drug solubilization in lipidic droplets,

increased interfacial surface area after emulsification, improved wetting, reduced effect of gastric emptying variability, protection from hydrolysis in the lumen and possible alteration of efflux or first-pass effects depending on excipient and drug properties.[2,3]

The technology is particularly suitable for low-to-moderate dose drugs with high lipophilicity and adequate solubility in pharmaceutical oils or surfactant mixtures. However, the system must be optimized carefully because excessive surfactant concentration, precipitation after dilution, drug leakage from capsules and stability problems can limit its clinical translation.[6,7]

Table 1. Difference between SEDDS, SMEDDS and SNEDDS

System	Approximate dispersion character	Typical feature	Pharmaceutical relevance
SEDDS	Coarse to fine emulsion after dilution	Self-emulsifies under mild gastrointestinal agitation	Useful for lipophilic drugs where rapid dispersion is required
SMEDDS	Microemulsion or very fine emulsion	Usually transparent or translucent dispersion with smaller globules than conventional SEDDS	Improves dissolution and maintains drug in solubilized state
SNEDDS	Nano-sized emulsion droplets after dilution	Very small droplet size and high surface area	May enhance dissolution rate and uniformity of oral absorption
Solid SMEDDS	Solid dosage form that disperses as SMEDDS	Liquid preconcentrate adsorbed or solidified using carrier/processing technology	Improves handling, stability and patient acceptability

BASIC PRINCIPLE AND MECHANISM OF BIOAVAILABILITY ENHANCEMENT

SMEDDS works as a preconcentrate. The drug is first dissolved in a lipidic blend. After oral administration, the system contacts gastrointestinal fluid and rapidly disperses into fine droplets. The surfactant reduces interfacial tension, the co-surfactant improves flexibility of the interfacial film and the oil phase provides a solubilization reservoir for the drug.[3,8]

The main biopharmaceutical goal is to maintain a higher apparent concentration of dissolved drug in the intestinal lumen. When the dispersion is stable, the drug remains available for partitioning across the intestinal membrane. If precipitation occurs after dilution or digestion, the benefit of SMEDDS may be lost. Therefore, precipitation testing under dilution and digestion-relevant conditions is a critical part of development.[7,9]

Long-chain lipid systems can sometimes promote lymphatic transport of highly lipophilic molecules. This route can reduce first-pass hepatic metabolism for selected drugs, but it is not universal and depends on log P, triglyceride solubility, drug dose and the type of lipid excipient used.[2,3]

COMPOSITION OF SMEDDS

The formulation contains four major elements: oil, surfactant, co-surfactant or co-solvent and the drug. Optional additives include antioxidants, precipitation inhibitors, viscosity modifiers, polymers and solid carriers for S-SMEDDS. The selection of each component should be justified by drug solubility, miscibility, emulsification efficiency, safety and regulatory acceptability.[4,8]

Table 2. Components commonly considered during SMEDDS development

Component	Examples	Main purpose	Selection consideration
Oil phase	Capryol 90, Labrafac PG, Maisine CC, oleic acid, medium-chain triglycerides, long-chain triglycerides	Solubilizes lipophilic drug and supports droplet formation	High drug solubility, digestibility, safety and compatibility
Surfactant	Tween 80, Cremophor RH 40, Cremophor EL, Labrasol, Solutol HS 15	Reduces interfacial tension and supports spontaneous emulsification	Non-ionic surfactants are often preferred due to acceptable safety and stability
Co-surfactant/co-solvent	Transcutol HP, PEG 400, propylene glycol, ethanol, glycerol	Improves interfacial flexibility and drug loading	Should not cause drug precipitation after dilution
Precipitation inhibitor	HPMC, PVP, Soluplus, hydroxypropyl cellulose	Maintains supersaturation and delays crystallization	Useful in supersaturable SMEDDS
Solid carrier	Neusilin US2, Aerosil 200, Syloid XDP, microcrystalline cellulose, magnesium aluminometasilicate	Converts liquid SMEDDS into powder, granule, pellet or tablet	High adsorption capacity, flowability and rapid redispersion

DRUG SELECTION CRITERIA

A drug is generally considered suitable for SMEDDS screening when it has poor aqueous solubility, moderate to high lipophilicity, low to moderate dose, acceptable solubility in lipidic excipients, adequate chemical stability and a need for improved or more reproducible oral exposure. A drug with a very high dose or very poor solubility in all lipid phases may be unsuitable because the formulation volume becomes impractical.[1,4]

Table 3. Drug-related criteria for selecting SMEDDS candidates

Parameter	Preferred character	Reason
Aqueous solubility	Poor solubility	SMEDDS can increase apparent solubility and dissolution
BCS class	Primarily class II; selected class IV drugs	Solubility-limited absorption is a major target
Dose	Low to moderate dose	Improves feasibility of lipid fill volume or solid carrier load
Lipophilicity	Moderate to high log P	Supports partitioning into oil/surfactant mixture
Chemical stability	Stable in selected lipidic excipients	Prevents degradation during storage
Precipitation tendency	Low or controllable after dilution	Maintains drug in solubilized or supersaturated state
Therapeutic need	Need for higher, faster or less variable exposure	Justifies lipid-based formulation development

FORMULATION DEVELOPMENT STRATEGY

A systematic development plan begins with drug solubility screening in oils, surfactants and co-surfactants. The excipients showing high drug solubility and good mutual miscibility are selected for constructing a pseudo-ternary phase diagram. The microemulsion region is then identified visually and by dilution testing. Candidate formulations are optimized by varying oil-to-surfactant and surfactant-to-co-surfactant ratios.[8],[9]

The optimized formulation should show rapid self-emulsification, small and uniform droplet size, acceptable zeta potential, no phase separation, resistance to drug precipitation, good dissolution performance and adequate stability. Quality-by-design principles can be applied by identifying critical material attributes and critical process parameters, followed by design of experiments for optimization.[5],[9]

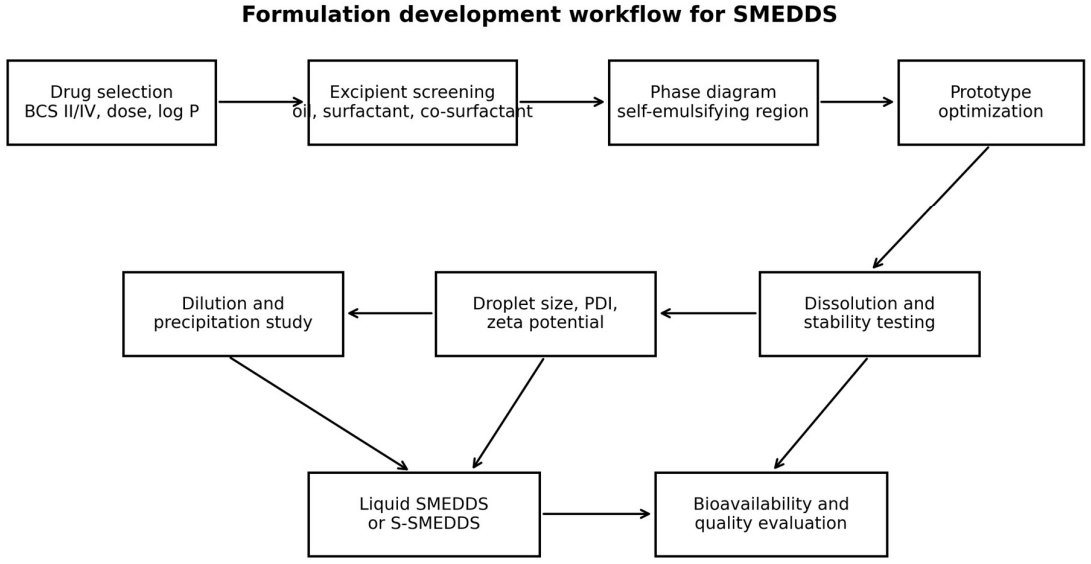

Figure Flow diagram showing the formulation development and evaluation strategy for SMEDDS.

CHARACTERIZATION AND EVALUATION

Evaluation of SMEDDS should not be limited to visual appearance. The formulation must be assessed before and after dilution because the final dispersion in gastrointestinal fluid determines biopharmaceutical performance. A stable preconcentrate may fail after dilution if the drug precipitates or if the droplet size increases significantly.[7],[9]

Table 4. Characterization parameters of SMEDDS

Evaluation parameter	Purpose
Drug solubility in excipients	Selection of oil, surfactant and co-surfactant
Pseudo-ternary phase diagram	Identification of microemulsion/self-emulsifying region
Self-emulsification time	Assessment of rapid dispersion ability
Droplet size and PDI	Confirmation of fine and uniform dispersion
Zeta potential	Prediction of physical stability and droplet interaction
Percent transmittance	Estimation of clarity and microemulsion formation
Cloud point	Evaluation of stability at physiological temperature
Dilution robustness	Assessment of stability under gastrointestinal dilution
Drug precipitation study	Determination of drug retention in solubilized state
In vitro dissolution	Comparison with pure drug and conventional dosage form
Thermodynamic stability	Centrifugation, heating-cooling and freeze-thaw stress
FTIR, DSC and XRD	Compatibility and physical-state assessment
SEM/TEM	Morphology or droplet visualization when required
In vivo pharmacokinetic study	Confirmation of bioavailability improvement

RECENT ADVANCES IN SMEDDS

Liquid SMEDDS can provide excellent drug solubilization but may be limited by leakage from capsules, incompatibility with shell materials, precipitation during storage and lower convenience during manufacturing. Solid SMEDDS was developed to overcome these limitations by converting the liquid preconcentrate into powders, granules, pellets, tablets or capsules using adsorption, spray drying, melt granulation or hot-melt extrusion.[6,7]

Supersaturable SMEDDS uses lower surfactant levels with precipitation inhibitors to generate and maintain a supersaturated drug concentration after dilution. The approach follows the spring-and-parachute concept, where the formulation first produces a high apparent concentration and then polymers delay crystallization. This is useful when high surfactant load creates tolerability or stability concerns.[10]

Computational approaches, design of experiments and machine-learning-guided excipient screening are emerging tools that may reduce trial-and-error development. These methods do not replace experimental testing but can support faster identification of promising excipient combinations and formulation ranges.[5]

NEWLY APPROVED DRUGS FROM 2023 TO 2026 AS POTENTIAL SMEDDS SCREENING CANDIDATES

The official FDA novel drug approval lists report 55 novel drugs in 2023, 50 in 2024, 46 in 2025 and 22 listed approvals for 2026, with the 2026 list current as of 18 June 2026 [12-15]. The examples in Table 5 are included only as potential SMEDDS screening candidates; individual drug solubility, dose, log P, permeability, stability and regulatory formulation status must be verified before selecting a molecule for formulation development.

Table 5. Selected FDA-approved drugs from 2023-2026 relevant for future SMEDDS screening (FDA sources: [12-15])

Year and source	Drug / active ingredient	Approved use on approval date	SMEDDS screening rationale
2023 [12]	Pirtobrutinib	Relapsed or refractory mantle cell lymphoma	Oral targeted oncology drug; solubility and dose loading can be screened.
2023 [12]	Elacestrant	ER-positive, HER2-negative, ESR1-mutated breast cancer	Oral endocrine oncology drug; suitable for lipid-solubility assessment.
2023 [12]	Omaveloxolone	Friedreich's ataxia	Rare-disease small molecule; candidate for solubility/bioavailability review.
2023 [12]	Fezolinetant	Moderate-to-severe vasomotor symptoms due to menopause	Oral non-hormonal therapy; potential for exposure consistency studies.
2023 [12]	Ritlecitinib	Severe alopecia areata	Oral kinase inhibitor; suitable for BCS-oriented screening.
2023 [12]	Quizartinib	Acute myeloid leukemia regimen	Oncology molecule where lipid-based solubilization may be explored.
2023 [12]	Zuranolone	Postpartum depression	CNS drug; rapid and consistent absorption is formulation-relevant.
2023 [12]	Fruquintinib	Refractory metastatic colorectal cancer	Oral targeted drug; useful in oncology-SMEDDS discussion.
2023 [12]	Repotrectinib	ROS1-positive non-small cell lung cancer	Oral targeted therapy; candidate for solubility and precipitation testing.
2023 [12]	Capivasertib	Selected breast cancer criteria	Oral kinase inhibitor; useful for lipid formulation screening.
2024 [13]	Resmetirom	Noncirrhotic NASH with moderate to advanced liver scarring	Metabolic drug; possible need for reproducible oral exposure.
2024 [13]	Aprocitentan	Hypertension	Oral antihypertensive; candidate depends on solubility and dose.
2024 [13]	Danicopan	Extravascular hemolysis with paroxysmal nocturnal hemoglobinuria	Oral complement inhibitor; lipid solubility screening may be relevant.
2024 [13]	Tovorafenib	Relapsed or refractory pediatric low-grade glioma	Oncology molecule; pediatric acceptability may favor solid systems.
2024 [13]	Deuruxolitinib	Severe alopecia areata	Oral JAK inhibitor; SMEDDS screening may target exposure variability.
2024 [13]	Vorasidenib	Grade 2 astrocytoma or oligodendroglioma	CNS-oncology molecule; solubility and absorption can be assessed.
2024 [13]	Lazertinib	Non-small cell lung cancer	Oral targeted oncology drug; lipid formulation study may be considered.
2024 [13]	Inavolisib	Locally advanced or metastatic breast cancer	Oral PI3K inhibitor; relevant to oncology lipid-formulation screening.
2024 [13]	Ensartinib	Non-small cell lung cancer	Oral ALK inhibitor; candidate after physicochemical confirmation.
2025 [14]	Suzetrigine	Moderate to severe acute pain	Oral non-opioid analgesic; rapid and reproducible absorption is relevant.
2025 [14]	Mirdametinib	Neurofibromatosis type 1 with symptomatic plexiform neurofibromas	Oral kinase inhibitor; potential candidate for lipid-based screening.
2025 [14]	Vimseltinib	Symptomatic tenosynovial giant cell tumor	Oral targeted therapy; solubility-limited exposure may be evaluated.
2025 [14]	Atrasentan	Reduction of proteinuria in IgA nephropathy	Oral receptor antagonist; candidate depends on dose and solubility.
2025 [14]	Avutometinib and defactinib	KRAS-mutated recurrent low-grade serous ovarian cancer	Combination therapy; co-loaded lipid systems may be studied.
2025 [14]	Taletrectinib	ROS1-positive non-small cell lung cancer	Oral oncology drug; candidate for SMEDDS feasibility studies.

2025 [14]	Sunvozertinib	NSCLC with EGFR exon 20 insertion mutations	Oral targeted anticancer molecule; lipid screening is relevant.
2025 [14]	Remibrutinib	Chronic spontaneous urticaria	Oral BTK inhibitor; potential candidate after solubility confirmation.
2025 [14]	Elinzanetant	Moderate-to-severe vasomotor symptoms due to menopause	Oral non-hormonal drug; suitable for bioavailability discussion.
2025 [14]	Ziftomenib	Relapsed or refractory AML with susceptible NPM1 mutation	Oral oncology drug; advanced formulation screening may be useful.
2026 [15]	Tebipenem pivoxil	Complicated urinary tract infections including pyelonephritis	Oral antibiotic; absorption enhancement and variability can be reviewed.
2026 [15]	Ensitrelvir	Post-exposure prophylaxis of COVID-19	Oral antiviral; lipid-based solubilization screening may be considered.
2026 [15]	Baxdrostat	Hypertension in combination with other antihypertensive drugs	Oral cardiovascular drug; candidate depends on solubility and dose.
2026 [15]	Sonrotoclax	Relapsed or refractory mantle cell lymphoma	Oncology drug; suitable for screening of lipidic solubilization.
2026 [15]	Vepdegestrant	ER-positive, HER2-negative, ESR1-mutated breast cancer	Oral endocrine degrader; formulation feasibility may be explored.
2026 [15]	Doravirine and islatravir	Replacement regimen for HIV-1 infection	Combination antiviral therapy; co-formulation issues may be considered.
2026 [15]	Orforglipron	Weight reduction in obesity or overweight with comorbidity	Oral metabolic therapy; advanced formulation interest is high.
2026 [15]	Relacorilant	Platinum-resistant ovarian, fallopian tube or primary peritoneal cancer	Oral oncology drug; candidate for lipid formulation screening.
2026 [15]	Icotrokinra	Moderate-to-severe plaque psoriasis	Oral immunology drug; relevant after physicochemical confirmation.
2026 [15]	Linerixibat	Cholestatic pruritus associated with primary biliary cholangitis	Oral hepatobiliary drug; candidate depends on dose and solubility.
2026 [15]	Milsaperidone	Schizophrenia and manic or mixed episodes of bipolar I disorder	CNS drug; reproducible oral exposure may be formulation relevant.

Note: The table gives formulation-screening examples only. Experimental solubility, log P, pKa, dose, permeability, stability and label route must be verified before selecting any drug for SMEDDS development.

DISCUSSION

The review indicates that SMEDDS is not a single formulation but a platform that can be adapted based on drug properties and clinical need. The most important decision is the balance between solubilization capacity and dilution stability. A formulation that dissolves a high amount of drug before administration may still fail if the drug precipitates after dilution in gastrointestinal fluid. Therefore, drug precipitation, digestion behavior and dissolution testing should be considered together rather than separately.[7],[9]

Solid SMEDDS is likely to remain a major direction because it combines the solubilization advantage of lipid systems with the manufacturing convenience of solid dosage forms. Adsorption onto porous carriers is simple and scalable, while spray drying, melt granulation and hot-melt extrusion can improve content uniformity and industrial control. However, the carrier should not trap the lipid phase so strongly that redispersion and drug release are reduced.[6],[7]

The selected 2023-2026 drugs demonstrate that modern pharmaceutical pipelines contain many orally relevant small molecules, especially in oncology and chronic diseases. Such molecules may benefit from SMEDDS if their absorption is limited by solubility or dissolution. However, formulation scientists must avoid unsupported claims. A drug should be called a SMEDDS candidate only after confirming route, dose, physicochemical data and stability.[12–15]

CHALLENGES AND LIMITATIONS

REGULATORY AND QUALITY CONSIDERATIONS

SMEDDS development should include a complete control strategy for excipient grade, drug loading, self-emulsification behavior, droplet size after dilution, dissolution, precipitation resistance, microbial quality where applicable and stability. When non-compendial excipients or high surfactant levels are used, safety justification and toxicological acceptability become important. For solid SMEDDS, powder flow, content uniformity, adsorption capacity and redispersion performance must be added to routine quality tests.[5],[7]

For review articles intended for RJPT, references should be cited in Arabic numerals in superscript and listed in the order of appearance. Tables and figures should be placed within the text, numbered consecutively, and should not duplicate the same information unnecessarily.[16]

FUTURE PERSPECTIVE

Future SMEDDS research is expected to focus on solid systems, supersaturable systems, patient-friendly dosage forms, pediatric-compatible approaches, computational excipient screening and QbD-based optimization. Newly approved oral small molecules should be screened using a decision tree that includes solubility

in excipients, dose feasibility, precipitation tendency, permeability, food effect and stability. Combining SMEDDS with polymers, porous carriers or controlled-release matrices may further expand the technology to drugs requiring sustained or targeted release.[5,6]

CONCLUSION

SMEDDS is a promising lipid-based drug delivery platform for improving the solubility, dissolution and oral bioavailability of poorly water-soluble drugs. Successful development requires rational drug selection, excipient screening, pseudo-ternary phase diagram construction, characterization after dilution, precipitation assessment and stability evaluation. Recent advances such as solid SMEDDS and supersaturable SMEDDS have improved the practicality and scalability of this technology. The 2023-2026 approved drug landscape provides several modern molecules for future SMEDDS screening, particularly in oncology, infection, CNS, metabolic and inflammatory disorders. However, each candidate requires experimental confirmation before any formulation claim is made.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest. This statement may be modified according to actual author disclosure before submission.

ETHICAL APPROVAL

Not applicable, as this is a review article and does not involve experiments on human participants or animals.

PLAGIARISM AND AI-USE NOTE

The manuscript has been drafted in original wording for academic review use. Authors should verify similarity and AI-detection requirements using the journal-accepted tools before submission, because automated reports depend on the final submitted version and the selected checking software.

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