IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 4, November 2026
Impact Factor: 8.2

Nanotechnology in Herbal Drug Delivery: Architecture, Biopharmaceutical Mechanisms, and Clinical Translation

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Abstract : ***Background:*** *Medicinal plants and isolated secondary metabolites—spanning polyphenols, flavonoids, alkaloids, terpenoids, and saponins—represent a foundational pillar of global pharmacotherapy, yet their clinical utility is severely constrained by poor aqueous solubility, limited epithelial permeability, gastric instability, rapid enzymatic degradation, hepatic first-pass clearance, and non-specific biodistribution.* ***Objective:*** *This review aims to critically evaluate the physicochemical bottlenecks of botanical bioactives, classify nanoscale herbal drug delivery architectures, elucidate trans-barrier transport mechanisms, and examine preclinical and clinical translation alongside toxicological and regulatory considerations.* ***Methods:*** *A comprehensive literature synthesis was conducted across peer-reviewed pharmaceutical and nanomedicine studies, patent databases, and clinical trial registries covering vesicular lipid carriers, solid and nanostructured lipid matrices, polymeric systems, dendrimers, mesoporous silica, and greensynthesized metallic nanoparticles.* ***Results:*** *Nanoencapsulation (1–1000 nm) alters dissolution kinetics in accordance with the Noyes–Whitney and Ostwald–Freundlich relationships, promotes mesenteric lymphatic uptake that enhances oral curcumin bioavailability up to 155-fold, enables tumor accumulation via the enhanced permeability and retention (EPR) effect and active receptor ligands, and facilitates blood–brain barrier transcytosis across oncology, metabolic, neurodegenerative, and antimicrobial models.* ***Conclusion:*** *Nanotechnology resolves core biopharmaceutical limitations of phytochemicals, though widespread clinical commercialization requires standardized raw-material quality control, scalable solvent-free Good Manufacturing Practice (GMP) production, and harmonized nanotoxicological frameworks.*

Keywords: Herbal drug delivery; Nanocarriers; Phytochemicals; Bioavailability; Liposomes; Solid lipid nanoparticles; Phytosomes; Green synthesis; Targeted therapy

I. INTRODUCTION

Botanical therapeutics have anchored human healthcare systems for millennia, serving as the empirical foundation for traditional medical frameworks such as Ayurveda, Siddha, Unani, and Traditional Chinese Medicine [1]. According to World Health Organization estimates, nearly 80% of populations across developing regions depend primarily on plant-derived preparations for frontline medical care, while more than half of modern prescription and over-the-counter pharmaceuticals originate directly or structurally from natural products [3]. Unlike single-target synthetic drugs, botanical extracts contain diverse suites of secondary metabolites that act synergistically across multiple signaling pathways, frequently yielding broad therapeutic windows and reduced off-target toxicity [1].

Nevertheless, translating promising preclinical phytochemistry into reproducible clinical outcomes remains a persistent challenge. Roughly 70% of pharmacologically active plant constituents exhibit pronounced hydrophobicity or

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unfavorable macromolecular dimensions that restrict gastrointestinal dissolution and transmembrane transport [2]. Compounds such as curcumin, quercetin, resveratrol, berberine, and silymarin display high potency in cell-culture models yet achieve negligible plasma concentrations following oral administration due to rapid glucuronidation, sulfation, P-glycoprotein efflux, and hydrolytic breakdown in the digestive tract [1, 11].

Nanotechnology offers a transformative solution to these biopharmaceutical bottlenecks. The objective of this review is to systematically analyze the physicochemical barriers limiting native phytochemicals, categorize modern herbal nanocarrier architectures and fabrication methodologies, elucidate trans-barrier delivery mechanisms, and synthesize clinical translation outcomes alongside nanotoxicological challenges. By engineering carrier matrices at the nanometer scale (1–1000 nm), pharmaceutical scientists can modulate apparent solubility, partition coefficients, and release kinetics without altering native covalent structures [12], shielding labile bioactives from degradation and concentrating payloads within diseased microenvironments [1, 13].

II. MATERIALS AND METHODS

This review synthesizes peer-reviewed scientific literature, registered clinical trials, and granted patents pertaining to nanoscale herbal drug delivery systems (NHDDS). Information was systematically compiled across four analytical dimensions: (i) biopharmaceutical classification and physicochemical dissolution modeling of major phytochemical classes; (ii) structural taxonomy and comparative evaluation of lipid-based, polymeric, vesicular, mesoporous, and green-synthesized inorganic nanocarriers; (iii) top-down, bottom-up, and biogenic fabrication protocols paired with physicochemical characterization criteria; and (iv) preclinical pharmacodynamic studies, ClinicalTrials.gov registries, and United States Patent and Trademark Office (USPTO) records spanning oncology, metabolic disorders, neurodegeneration, ocular therapy, and antimicrobial resistance.

2.1 Fabrication Methodologies and Green Biosynthesis

Selecting an appropriate manufacturing protocol is essential to preserve the stereochemistry and thermolability of botanical bioactives while achieving narrow polydispersity indices (PDI < 0.3) [2]:

- **High-Pressure Homogenization (HPH):** Widely employed for industrial-scale production of solid lipid nanoparticles (SLNs), nanostructured lipid carriers (NLCs), and nanoemulsions. In hot HPH, the phytochemical is dissolved in molten lipid above its melting point and forced through a narrow micron-scale gap at 100–2000 bar [2]. For heat-sensitive terpenoids and flavonoids, cold HPH solidifies the drug–lipid melt in liquid nitrogen, mills it into microparticles, and homogenizes the cold suspension to prevent thermal degradation [6].
- **Nanoprecipitation (Solvent Displacement):** A water-miscible organic solvent containing dissolved polymer and hydrophobic phytochemical is injected into an aqueous stabilizer phase under mild agitation, causing spontaneous polymer precipitation into uniform nanospheres or nanocapsules [2].
- **Emulsion–Solvent Evaporation and Diffusion:** Lipophilic polymers and plant actives dissolved in a volatile water-immiscible solvent are emulsified into an aqueous surfactant solution via highshear ultrasonication, followed by controlled solvent evaporation [37].
- **Thin-Film Hydration and Reverse-Phase Evaporation:** Phospholipids and lipophilic herbal compounds dissolved in organic solvents are dried under vacuum to form a thin lipid film, which hydrates upon agitation in aqueous buffer to generate multilamellar vesicles [38].
- **Ionic Gelation and Complex Coacervation:** Polyelectrolyte nanoparticles are formed under mild aqueous conditions without organic solvents by cross-linking cationic chitosan chains with polyanionic sodium tripolyphosphate (STPP) or sodium alginate [39].
- **Supercritical Fluid (SCF) Technology:** Utilizes supercritical carbon dioxide above its critical temperature (31.1 °C) and pressure (73.8 bar) as a tunable anti-solvent or spraying medium to precipitate solvent-free, micronized or nanosized herbal particles [2].
- **Green Synthesis of Metallic and Metalloid Nanocarriers:** Replaces toxic reducing agents (such as sodium borohydride or hydrazine) with aqueous extracts of medicinal plants rich in phenolic acids, flavonoids, terpenoids,

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and alkaloids [34]. When mixed with precursor metal salts (e.g., $AgNO^1$, $HAuCl_4$, Na_2SeO_3, or cerium nitrate), hydroxyl and carbonyl functional groups donate electrons to reduce metal ions ($M^{n+} \rightarrow M^0$), initiate nucleation, and adsorb onto nascent crystal facets as a biocompatible capping corona [35, 40].

2.2 Analytical Characterization Matrix

Standardized physicochemical evaluation of herbal nanoformulations relies on four complementary analytical techniques:

- **Hydrodynamic Size, Polydispersity, and Zeta Potential:** Dynamic Light Scattering (DLS) determines intensity-weighted hydrodynamic diameter and PDI, while electrophoretic light scattering measures Zeta potential. Surface potentials exceeding +30 mV or below −30 mV confer robust electrostatic stabilization against aggregation [7].
- **Morphological and Topological Imaging:** Transmission Electron Microscopy (TEM) resolves internal core–shell architecture and bilayer lamellarity, Scanning Electron Microscopy (SEM) maps surface texture, and Atomic Force Microscopy (AFM) provides three-dimensional height profiles under ambient conditions [8].
- **Solid-State Crystallinity and Interaction Profiling:** Differential Scanning Calorimetry (DSC), Powder X-Ray Diffraction (PXRD), and Fourier-Transform Infrared Spectroscopy (FTIR) verify amorphous drug dispersion within lipid or polymer matrices and confirm hydrogen bonding in phytosomal complexes [19].
- **Chromatographic Quantification:** Validated HPLC, HPTLC, and LC–MS/MS assays determine encapsulation efficiency (EE%) and drug loading (DL%), calculated as $EE\% = [(W_{total} - W_{free}) / W_{total}] \times 100$ [41].

3. RESULTS

- **Alkaloids (Camptothecin, Berberine, Vincristine, Vinblastine, Vinorelbine):** Nitrogencontaining heterocyclic bases exhibit pH-dependent ionization and lactone-ring instability; for instance, the active lactone ring of camptothecin rapidly hydrolyzes into an inactive, nephrotoxic carboxylate form at physiological pH 7.4 unless sequestered inside a hydrophobic core [15].
- **Terpenoids and Essential Oils (Paclitaxel, Docetaxel, Artemisinin, Thymol, Zedoary Oil):** Bulky diterpenoids like paclitaxel possess negligible water solubility (< 1 µg/mL), requiring toxic co-solvents (such as Cremophor EL) in conventional formulations, while volatile monoterpenes evaporate or oxidize rapidly upon exposure to air, light, and heat [16].
- **Glycosides, Saponins, and Tannins:** High molecular weights (> 500 Da) and excessive hydrogenbonding capacity prevent passive transcellular diffusion across lipophilic enterocyte membranes, resulting in poor oral bioavailability despite high water solubility [2].

Reducing solid phytochemical particle dimensions from the micrometer regime to the sub-100 nm domain alters dissolution mass-transfer kinetics according to the classical Noyes–Whitney relationship:

$$dC/dt = (D \times A / h) \times (C_s - C) \quad \textit{(Equation 1)}$$

where D denotes the diffusion coefficient, A represents total interfacial surface area, h is the stagnant hydrodynamic diffusion layer thickness, C_s is saturation solubility at the particle surface, and C is bulk luminal concentration. Comminuting hydrophobic phytoconstituents into nanoparticles increases A by orders of magnitude while decreasing h

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[1] **.1 Biopharmaceutical Bottlenecks and Nanoscale Dissolution Kinetics**

Designing an effective nanocarrier requires matching carrier physicochemical attributes to the specific structural liabilities of four major secondary metabolite families [14]:

- **Polyphenols and Flavonoids (Curcumin, Quercetin, Genistein, Kaempferol, Morin, Luteolin):** Characterized by planar aromatic rings and multiple hydroxyl groups, these compounds suffer from poor aqueous solubility, rapid keto–enol tautomerism or alkaline hydrolysis at intestinal pH, and extensive phase II metabolic conjugation in enterocytes and hepatocytes [1].

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ISSN: 2581-9429 Volume 6, Issue 4, November 2026 Impact Factor: 8.2

[4]. Furthermore, nanoscale particle curvature elevates surface free energy and saturation solubility (C_s) per the Ostwald–Freundlich equation:

$$ln(S / S_0) = (2 \times \gamma \times V_m) / (r \times R \times T) \quad (Equation\ 2)$$

where S is the solubility of a spherical nanoparticle of radius r, S_0 is equilibrium bulk crystal solubility, γ is solid–liquid interfacial tension, V_m is molar volume, R is the universal gas constant, and T is absolute temperature. Elevated C_s establishes a steep concentration gradient across the intestinal mucosa, driving passive absorption [14].

3.2 Structural Taxonomy of Herbal Nanocarriers

Modern pharmaceutical engineering employs diverse colloidal and solid-state architectures to accommodate phytochemicals with varying polarity, molecular weight, and thermal sensitivity [1,]. Vesicular lipid systems include (25–1000 nm phospholipid bilayers capable of PEGylation for stealth circulation [,]), (stoichiometric 1:1 or 2:1 hydrogen-bonded complexes of polyphenols with phosphatidylcholine that prevent payload leakage [,]), (non-ionic surfactant–cholesterol vesicles overcoming phospholipid oxidation [,]), and ultra-deformable containing edge activators or 20–45% v/v ethanol for deep transdermal permeation [,]. Matrix lipid carriers comprise first-generation (50– 1000 nm crystalline physiological lipids [,]) and second-generation (100–400 nm solid–liquid lipid blends creating imperfect crystal voids for higher drug loading [,]). Additional classes include biodegradable (PLGA, PLA, PCL, chitosan, alginate [–]), hyper-branched (PAMAM, PPI, 2–20 nm []), (> 800 m/g surface area []), (AuNPs, AgNPs, CeO NPs, SeNPs [,]), and theranostic (2–30 nm []).5**liposomes**1718**phytosomes/herbosomes**1920**niosomes**2122**transfersomes and ethosomes**2324**SLNs**2526**NLCs**127**polymeric nanoparticles, micelles, and hydrogels**2831**dendrimers**32**mesoporous silica nanoparticles (MSNs)**^{2}33**green-synthesized metallic nanoparticles**$_2$3435**quantum dots**36

Table 1: Comparative Taxonomy of Herbal Nanocarrier Classes

Nanocarrier Class	Structural Composition	Size Range	Primary Advantages	Key Limitations	Herbal Payloads
Liposomes	Phospholipid bilayer enclosing aqueous core	25 nm–1 µm	Amphiphilic dual loading; high biocompatibility	Phospholipid oxidation; payload leakage	Curcumin, Quercetin, Vincristine
Phytosomes	Stoichiometric Hbonded polyphenol–phospholipid complex	50–500 nm	Superior oral absorption; minimal drug leakage	Restricted to actives with H-bonding groups	Silybin, Luteolin, Curcumin
Niosomes	Non-ionic surfactant + cholesterol bilayer vesicle	50–800 nm	Chemically stable; cost-effective vs. liposomes	Potential vesicle aggregation or fusion	Lawsone, Quercetin, Curcumin
Transfersomes & Ethosomes	Phospholipids + edge activator or 20–45% ethanol	35–300 nm	Ultra-deformable; deep transdermal permeation	High ethanol can irritate sensitive skin	Apigenin, Paclitaxel, Triptolide
SLNs	Solid lipid core stabilized by surfactant shell	50–1000 nm	Protects labile actives; solvent-free scaling	Crystalline polymorphism causes expulsion	Camptothecin, Wogonin, Curcumin

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NLCs	Imperfect blend of solid and liquid lipids	100–400 nm	High payload capacity; negligible storage expulsion	Complex phase behavior during cooling	Thymol, Morin, Quercetin
Polymeric NPs	PLGA, PLA, PCL, or Chitosan matrix/capsule	10–1000 nm	Tunable release kinetics; facile ligand conjugation	Residual solvent concerns; slower clearance	Genistein, Naringenin, Berberine
Dendrimers	Hyper-branched radial polymer (PAMAM, PPI)	2–20 nm	Monodisperse; high density of surface groups	Cationic surface hemolytic toxicity	Berberine, Paclitaxel
Mesoporous Silica (MSNs)	Ordered porous silicon dioxide framework	50–300 nm	High surface area; rigid thermal/pH stability	Slow biodegradation of silica matrix	Curcumin, Camptothecin
Green Metallic NPs	Zero-valent Au/Ag or metal oxide + plant corona	1–100 nm	One-pot ecosynthesis; synergistic bioactivity	Potential heavy metal organ accumulation	Kaempferol, Silymarin, Neem

3.3 Trans-Barrier Transport and Targeted Delivery Mechanisms

Gastrointestinal Mucosal Permeation and Lymphatic Uptake: Mucus-penetrating PEGylated nanoparticles traverse the viscoelastic intestinal mucin meshwork, whereas mucoadhesive chitosan nanoparticles transiently open epithelial tight junctions (zonula occludens) via electrostatic interaction with sialic acid residues [42]. Lipid-based carriers stimulate endogenous bile salt and phospholipid secretion to form mixed micelles that are packaged by enterocytes into chylomicrons, entering the intestinal mesenteric lymphatic system rather than the portal vein. This bypasses hepatic cytochrome P450 first-pass metabolism and elevates oral curcumin bioavailability up to 155-fold [1].

Passive Accumulation (EPR Effect) and Active Receptor Targeting: Solid tumors exhibit wide inter-endothelial fenestrations (100–780 nm) and defective lymphatic drainage, enabling longcirculating nanocarriers (20–200 nm) to extravasate and accumulate passively via the Enhanced Permeability and Retention (EPR) effect [43, 44]. Active cellular internalization is achieved by conjugating surface ligands targeting overexpressed receptors [45]: **Folate Receptors (FR-α)** in ovarian, breast, and osteosarcoma cells using folic acid-conjugated PLGA-PEG nanoparticles and liposomes for genistein, quercetin, and morin [46, 47]; **Transferrin Receptors (TfR)** using transferrin-decorated MSNs that increase curcumin cytotoxicity threefold in MIA PaCa-2 pancreatic carcinoma cells [33]; **CD44 and Glycyrrhetinic Acid Receptors** via hyaluronic acid coatings for prostate/lung tumors [48] and glycyrrhetinic acid-modified liposomes for hepatic carcinoma [49]; and

Epidermal Growth Factor Receptor (EGFR) via cetuximab-conjugated porous silicon nanoparticles delivering camptothecin to breast cancer bone metastases [50].

Blood–Brain Barrier (BBB) Transcytosis and Nose-to-Brain Bypass: Over 98% of small-molecule therapeutics fail to traverse the tight endothelial junctions and P-glycoprotein efflux pumps of the BBB [51]. Coating PLGA or lipid nanoparticles with Polysorbate 80 (Tween 80) or glutathione promotes adsorption of endogenous apolipoproteins (ApoE and ApoB), triggering low-density lipoprotein receptor-mediated transcytosis across brain capillary endothelial cells for docetaxel and curcumin [52, 53]. Alternatively, intranasal administration of quercetin-loaded elastic liposomes bypasses the BBB directly via olfactory and trigeminal nerve pathways across the cribriform plate []. 54

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3.4 Preclinical Therapeutic Outcomes and Clinical/Patent Landscape

In oncology, nanocarriers co-delivering phytochemical chemosensitizers alongside conventional cytotoxics suppress ATP-binding cassette efflux transporters (P-gp/ABCB1, ABCC1, ABCG2) and downregulate PI3K/AKT/mTOR, NF-κB, and Nrf2 survival pathways [55, 56], while wogonin and curcumin nanoformulations induce ferroptosis in pancreatic cancer by inhibiting the Nrf2/GPX4 axis [57]. Table 2 summarizes representative preclinical oncology outcomes.

Table 2: Selected Preclinical Herbal Nanoformulations in Oncology

Phytochemical	Botanical Source	Nanocarrier System	Target Disease / Model	Pharmacological Outcome & Mechanism
Curcumin	*Curcuma longa*	Transferrin-PEG-MSNs; SPC/HSPC Liposomes	Pancreatic & Bladder Cancer	3× higher cytotoxicity in MIA PaCa-2; inhibits NF-κB, COX-2, MMP-9; sensitizes cells to gemcitabine [33].
Camptothecin	*Camptotheca acuminata*	Cetuximab-pSiNPs; Trilaurin SLNs	Metastatic Breast & Colon Cancer	Preserves active lactone ring from hydrolysis; inhibits topoisomerase I; reduces bone metastasis [50].
Silymarin / Silybin	*Silybum marianum*	PHBHV NPs; Selenized SeNPs; Phytosomes	Gastric, Colon & Prostate Cancer	Downregulates PI3K/AKT/mTOR; induces G1/G2 arrest via p21/p27; protects hepatocytes [35].
Naringenin	*Citrus* spp.	pH/Thermo-responsive SPNPs; Chitosan NPs	Breast & Lung Carcinoma	Triggers selective apoptosis above LCST and at acidic tumor pH; nontoxic to 3T3 fibroblasts [58].
Genistein	*Glycine max*	Folate-PLGA-PEG NPs; Lecithin Nanoemulsions	Ovarian & Prostate Cancer	Inhibits tyrosine kinase; induces G2/M mitotic arrest; enhances SKOV-3 receptor uptake [46].
Morin	*Maclura pomifera* / Guava	Folate-CeO_2-NH_2 nanohybrids; HSA NPs	Breast Carcinoma (MDA-MB-468)	Binds Bcl-2 (−7.1 kcal/mol); elevates intracellular ROS and cytochrome c release [59].
Kaempferol	*Ginkgo biloba* / Broccoli	PEO-PPO-PEO micelles; Green AgNPs	Ovarian & HepG2 Liver Cancer	Depletes GSH, elevates lipid peroxidation and LDH leakage; inhibits metastatic invasion [40].
Quercetin	*Allium cepa* / Green tea	Folate-Liposomes; Chitosan-TPGS SLNs	Osteosarcoma & NSCLC	Binds JH2 domain of JAK2 to block STAT3–PD-L1 immune evasion; suppresses EGFR [47].

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Berberine	*Berberis vulgaris*	Liquid Crystalline NPs; G4 PAMAM Dendrimers	NSCLC & Breast Cancer	Attenuates β-catenin and epithelial–mesenchymal transition; inhibits ABCG2 efflux [60].
Resveratrol	*Vitis vinifera*	Gold NP conjugates; Alginate-Chitosan Hydrogels	Breast & Colorectal Cancer	Impairs E2/ERα/neuroglobin survival pathway; provides pH-sensitive sustained release [61].
Vincristine & Vinblastine	*Catharanthus roseus*	HA-Thiolated Chitosan NPs; Graphene QDs	Prostate & Colorectal Cancer	Disrupts mitotic microtubule assembly; reduces peripheral neurotoxicity [48].
Paclitaxel & Docetaxel	*Taxus brevifolia*	Albumin NPs; LHRHPCL NPs; PEGylated Ethosomes	Ovarian, Breast & Melanoma	Stabilizes β-tubulin; eliminates Cremophor hypersensitivity; enables photothermal synergy [62].
Lawsone	*Lawsonia inermis*	Span-Cholesterol Nanoniosomes	Breast Carcinoma (MCF-7)	Achieves 70% encapsulation efficiency; sustained release enhances cytotoxicity vs. free drug [21].
Luteolin	*Reseda luteola* / Vegetables	Nanophytosomes (coloaded with Doxorubicin)	Triple-Negative Breast Cancer	Suppresses Nrf2-mediated chemoresistance; sensitizes MDAMB-231 cells to doxorubicin [56].

Beyond oncology, nanoencapsulation of curcumin, berberine, and *Annona reticulata* bioactives within SLNs and chitosan–alginate matrices improves insulin sensitivity, protects pancreatic β-cells from oxidative apoptosis, and suppresses pro-inflammatory cytokines (TNF-α, IL-1β, IL-6) in diabetic and arthritic models [63, 64], while topical transfersomal and ethosomal gels of triptolide, matrine, or thymol attenuate synovial and dermal inflammation [1]. In neurodegenerative and ocular disorders, curcumin-loaded chitosan–alginate–STPP nanoparticles and resveratrol-coated gold nanoparticles cross the BBB to scavenge reactive oxygen species, inhibit amyloid-β fibrillogenesis, and ameliorate memory deficits [65, 66], whereas mucoadhesive microemulsions and electrospun core–shell nanofiber mats overcome tear-film washout to accelerate corneal alkali-burn healing [67, 68]. Furthermore, biosynthesized silver, copper oxide, and zinc oxide nanoparticles capped with phytochemicals from *Azadirachta indica*, *Beta vulgaris*, and *Aloe vera* eradicate multidrug-resistant
Staphylococcus aureus, *Pseudomonas aeruginosa*, and *Escherichia coli* biofilms while electrospun chitosan–phytochemical scaffolds promote wound angiogenesis [69, 70].
Clinically, albumin-bound paclitaxel nanoparticles (nab-paclitaxel / Abraxane) pioneered commercial herbal nanomedicine by eliminating Cremophor EL toxicity and utilizing gp60-mediated endothelial transcytosis [71]. Active clinical trials and granted US patents further advance nanocurcumin, plantderived exosomes, and targeted taxane or alkaloid nanoconjugates (Table 3).

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Table 3: Clinical Trials and Patents in Herbal Nanomedicine

Formulation / Trial Title	Identifier / Patent	Stage / Year	Active Herbal & Carrier	Clinical Indication / Innovation
Plant Exosomes Delivering Curcumin	NCT01294072	Phase I Trial	Curcumin + plantderived exosomes	Targeted oral delivery to normal and malignant colon tissue [1].
Nanocurcumin in Prostate Radiotherapy	NCT02724618	Phase II Trial	Nanocurcumin + radiation therapy	Radiosensitization and mitigation of radiationinduced toxicity [1].
Nanosomal Docetaxel Lipid Suspension	NCT03671044	Phase III Trial	Docetaxel lipid nanosuspension	Efficacy and safety vs. Taxotere in triple-negative breast cancer [1].
NanoDoce Intravesical Instillation	NCT03636256	Phase I/II Trial	Submicron docetaxel particles	Localized bladder retention in urothelial carcinoma [1].
Carrier-Free Curcumin–Erlotinib NPs	US20210369861A1	US Patent (2021)	Curcumin + erlotinib + PEG	Self-assembled dual-agent therapy for EGFR-positive cancers [72].
Folate-Targeted Curcumin PCL-PEG NPs	US20130045162A1	US Patent (2012)	Curcumin + PCL-PEG-Folate	Active receptor-mediated targeting of solid tumors [73].
Berberine–Ursodeoxycholic Salt NPs	US10301303B2	US Patent (2019)	Berberine + ursodeoxycholic acid	Enhanced oral bioavailability and metabolic activity [74].
Albumin–Paclitaxel–Anti-VEGF Complex	US10376579B2	US Patent (2019)	Paclitaxel + albumin + bevacizumab	Immunonanoparticle complex combining antiangiogenic and taxane therapy [75].

IV. DISCUSSION

The comparative analysis of herbal nanocarrier systems demonstrates that selecting an optimal delivery platform depends on balancing payload polarity, chemical stability, and target tissue physiology. While stoichiometric phytosomes directly resolve the poor lipid miscibility of polar polyphenols through molecular complexation without carrier leakage [19, 20], NLCs overcome the crystalline expulsion limitations of first-generation SLNs by introducing liquid-lipid structural imperfections [1, 27]. Similarly, ligand-decorated polymeric and mesoporous nanocarriers transform passive EPR biodistribution into receptor-specific intracellular delivery, effectively reversing multidrug resistance by co-delivering efflux inhibitors alongside cytotoxic drugs [55, 56].

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Despite compelling preclinical efficacy and commercial milestones such as nab-paclitaxel [71], significant nanotoxicological, standardization, and regulatory hurdles impede broad clinical translation [9]:

- **Organ Bioaccumulation and Clearance Kinetics:** Particles with hydrodynamic diameters below 6–10 nm undergo rapid renal glomerular filtration, whereas carriers larger than 200 nm are opsonized by serum complement proteins and sequestered by hepatic Kupffer cells and splenic macrophages [76]. Non-biodegradable inorganic cores can persist in reticuloendothelial organs, provoking chronic oxidative stress, lipid peroxidation, and fibrotic granulomas [10].
- **Complement Activation and Immunogenicity:** Positively charged cationic liposomes and dendrimers interact electrostatically with anionic erythrocyte membranes, inducing hemolysis, platelet aggregation, or Complement Activation-Related Pseudoallergy (CARPA) [77]. Repeated administration of PEGylated carriers may also elicit anti-PEG IgM antibodies, accelerating blood clearance upon subsequent doses.
- **Phytochemical Variability and Quality Control:** Unlike single-molecule synthetic pharmaceuticals, whole herbal extracts exhibit seasonal, geographical, and extraction-dependent fluctuations in secondary metabolite ratios [2]. Coupling chemically complex extracts with multistep nanofabrication complicates Critical Quality Attribute (CQA) definition, encapsulation quantification, and batch-to-batch reproducibility.
- **Harmonization of Regulatory Frameworks:** Global regulatory agencies (US FDA, EMA, CDSCO) currently evaluate herbal nanomedicines on a case-by-case basis under hybrid botanical and nanotechnology guidance documents. Establishing standardized protocols for endotoxin testing, in vitro–in vivo correlation (IVIVC), and long-term nanotoxicity assessment remains imperative [9].

Emerging technological horizons are poised to address these limitations [6]. **Stimuli-responsive (smart) nanocarriers** utilize acid-labile hydrazone linkers (cleaving at tumor pH 5.5–6.5), glutathione-sensitive disulfide bridges in reducing tumor cytoplasm [78], and thermo-responsive copolymers [58] to minimize off-target toxicity. Concurrently, **artificial intelligence and in silico formulation design** employ machine learning, quantitative structure–property relationship (QSPR) models, and molecular dynamics simulations to predict drug–polymer miscibility and protein-corona formation prior to wet-lab synthesis [6], while **3D bio-nanoprinting** enables personalized polypills and transdermal microneedle arrays with spatially compartmentalized phytochemical release profiles [79].

V. CONCLUSION

The integration of nanotechnology into herbal drug delivery resolves the core biopharmaceutical limitations—poor aqueous solubility, chemical instability, rapid metabolic clearance, and non-specific biodistribution—that have historically restricted the clinical potential of plant-derived therapeutics. Across diverse carrier architectures ranging from phytosomes, liposomes, and nanostructured lipid carriers to biodegradable polymeric nanoparticles and green-synthesized metallic systems, nanoscale engineering consistently amplifies bioavailability, enhances intracellular uptake, and enables targeted intervention in oncology, metabolic disease, neurodegeneration, and antimicrobial therapy. Realizing the full clinical and commercial promise of herbal nanomedicines now depends on standardizing phytochemical raw materials, scaling solvent-free manufacturing under GMP guidelines, and establishing harmonized nanotoxicological frameworks.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this review article.

ACKNOWLEDGEMENT

The authors express their sincere gratitude to the Principal, faculty members, and library facilities of Shri Goraksha College of Pharmacy and Research Centre, Khamgaon, Maharashtra, India, for their constant guidance, encouragement, and academic support during the preparation of this manuscript.

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Volume 6, Issue 4, November 2026
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