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Novel Drug Delivery Systems for Vulvovaginal Candidiasis: A Systematic Review

Deepak Prashar*, Gaurav Sharma, Kajal Sharma, Anshika Chandel

Department of Pharmacy, LR Institute of Pharmacy, Jabli-Kyar, Solan (HP)-India
Email: prashardeepak99@yahoo.in

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Abstract: Vulvovaginal candidiasis (VVC) is a prevalent fungal infection affecting approximately 75% of women at least once during their lifetime. Conventional antifungal therapies are hampered by poor drug bioavailability, rapid vaginal clearance, and emerging resistance. Novel drug delivery systems (NDDS) offer promising alternatives by enhancing drug retention, permeation, and therapeutic efficacy.

Objective: This systematic review critically evaluates current NDDS including liposomes, niosomes, solid lipid nanoparticles (SLN), nano emulsions, polymeric nanoparticles, in situ gels, microemulsions, vaginal films, cyclodextrin complexes, and dendrimers developed for the treatment of VVC.

Methods: A comprehensive literature search was conducted across PubMed, Scopus, Web of Science, and Google Scholar (2010–2024) using MeSH terms including 'vulvovaginal candidiasis', 'novel drug delivery', 'vaginal nanoparticles', and 'antifungal formulation'. Patent databases including USPTO, EPO, and WIPO were also searched.

Results: A total of 27 primary research articles and 10 relevant patents were reviewed. Nanoparticle-based formulations demonstrated superior antifungal activity with significant improvements in MIC values (2–8-fold reduction), prolonged drug release (24–72 h), and enhanced vaginal retention compared to conventional formulations. *In situ* gelling systems and mucoadhesive platforms showed the greatest promise for patient compliance and sustained therapeutic effect.

Conclusion: NDDS represent a significant advancement in the management of VVC, offering improved drug bioavailability, reduced dosing frequency, and potential to overcome antifungal resistance. Further clinical translation and regulatory studies are required.

Keywords: Vulvovaginal candidiasis, Novel drug delivery systems, Nanoparticles, Antifungal, Intravaginal delivery, Liposomes, In situ gel, Candida albicans

1. Introduction

Vulvovaginal candidiasis (VVC) is one of the most common genital infections in women of reproductive age, with Candida albicans accounting for approximately 85–90% of all cases [1]. Studies indicate that 70–75% of women experience at least one episode of VVC during their lifetime, while 5–8% suffer from recurrent

vulvovaginal candidiasis (RVVC), defined as four or more symptomatic episodes per year [2,3]. The global prevalence has increased substantially over recent decades, driven by antibiotic overuse, immunosuppression, hormonal contraceptive use, diabetes mellitus, and HIV infection [4]. The vaginal microenvironment presents unique challenges for drug delivery, including a low pH (3.8–4.5), variable fluid volumes, enzymatic activity, and rapid mucociliary clearance that significantly limit the duration of action of conventional formulations [5]. Standard treatments such as topical azoles (clotrimazole, miconazole) and oral fluconazole, while effective for uncomplicated VVC, face limitations including poor mucoadhesion, short contact time, low drug solubility, and increasing resistance among non-albicans Candida species [6,7].

Novel drug delivery systems (NDDS) have emerged as promising strategies to overcome these limitations. By incorporating antifungal drugs into nanocarriers and specialized delivery platforms, NDDS can enhance drug solubility, prolong vaginal retention, improve epithelial permeation, and achieve targeted fungicidal activity. This systematic review provides a comprehensive evaluation of current NDDS developed for VVC management, with emphasis on formulation strategies, biopharmaceutical performance, preclinical and clinical evidence, and emerging patent landscape.

2. Epidemiology and Pathophysiology of VVC

2.1 Epidemiology

VVC affects women globally, with prevalence ranging from 29% to 49% in outpatient gynaecological settings [1,3]. Candida albicans remains the dominant pathogen; however, non-albicans species such as *C. glabrata*, *C. tropicalis*, *C. parapsilosis*, and *C. krusei* are increasingly implicated, particularly in RVVC and azole-resistant cases [4]. Risk factors include diabetes mellitus (OR: 3.1), immunosuppression, pregnancy, antibiotic therapy (OR: 2.7), and hormonal contraceptive use [2,5].

2.2 Pathophysiology

Candida colonizes the vaginal epithelium under favourable conditions, transitioning from commensal yeast to pathogenic hyphae through phenotypic switching mediated by transcription factors including EFG1, CPH1, and WOR1 [7]. Biofilm formation on vaginal epithelium is a key virulence factor, conferring resistance to conventional antifungals by reducing drug penetration and creating a hypoxic, nutrient-depleted environment [8]. Virulence factors include aspartyl proteinases (SAPs), phospholipases, hyphal adhesins, and immune evasion mechanisms [9].

2.3 Limitations of Conventional Therapy

Conventional antifungal agents face multiple pharmacokinetic barriers at the vaginal site: (i) Rapid mucociliary clearance reducing contact time; (ii) Poor aqueous solubility of azoles limiting bioavailability; (iii) Inadequate penetration into biofilms; and (iv) Increasing resistance (fluconazole MIC90 rising 4–8-fold for *C. glabrata*) [4,6,10]. These shortcomings underscore the urgent need for NDDS capable of overcoming these barriers.

3. Methodology

3.1 Literature Search Strategy

A systematic literature search was performed in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Databases searched included PubMed/ MEDLINE, Scopus, Web of Science, Embase, and Google Scholar. The search period encompassed January 2010 to March 2024. Patent databases including the United States Patent and Trademark Office (USPTO), European Patent Office (EPO), and World Intellectual Property Organization (WIPO) were searched for relevant formulation patents.

3.2 Inclusion and Exclusion Criteria

Studies were included if they: (i) Investigated NDDS for antifungal drug delivery specifically targeting VVC; (ii) Reported *in vitro, ex vivo,* or *in vivo* characterization data; (iii) Were published in peer-reviewed journals; and (iv) were in English. Studies were excluded if they: (i) Focused exclusively on systemic antifungal delivery; (ii) Lacked experimental data; or (iii) Were review articles, editorials, or conference abstracts without supporting data.

3.3 Data Extraction

Data extracted included formulation type, drug(s) incorporated, particle size,

encapsulation efficiency, drug release profiles, *in vitro* antifungal activity (MIC values), mucoadhesion studies, *in vivo* performance, and patent details. Quality assessment of included studies was performed using the adapted Newcastle-Ottawa Scale for *in vitro*/*in vivo* pharmacological studies.

4. Novel Drug Delivery Systems for VVC

4.1 Liposomes

Liposomes are spherical vesicles comprising phospholipid bilayers capable of encapsulating both hydrophilic and lipophilic antifungal agents. Their structural similarity to biological membranes facilitates fusion with vaginal epithelial cells, enhancing intracellular drug delivery [1]. Liposomal Amphotericin B formulations have demonstrated a 3.2-fold improvement in antifungal activity and significantly reduced cytotoxicity compared to the free drug [2]. Modifications including polyethylene glycol (PEG) coating and cationic lipids have been explored to enhance mucoadhesion and retention [5]. Key advantages include biocompatibility, biodegradability, and versatility in drug loading; limitations include physical instability and short shelf life.

4.2 Niosomes

Niosomes are non-ionic surfactant-based vesicles that offer advantages over liposomes in terms of stability and cost-effectiveness. Clotrimazole and miconazole-loaded niosomes prepared using Span 60 and Tween 80 have demonstrated enhanced antifungal activity with 90% drug release over 24 hours in simulated vaginal fluid [3,6]. Noisomely gels incorporating carbopol demonstrated sustained drug release kinetics following zero-order or Higuchi models, with significantly improved vaginal retention compared to plain drug gels [7]. The non-ionic surfactants provide protection against enzymatic degradation in vaginal fluids.

4.3 Solid Lipid Nanoparticles (SLN)

SLN represent lipid-based colloidal nanoparticles (50–1000 nm) composed of solid lipids such as Comprisal, Precirol, or stearic acid stabilized by surfactants. Fluconazole-loaded SLN demonstrated 2.5-fold higher vaginal epithelial permeation compared to drug solution, attributed to the lipid core facilitating membrane fusion [8]. Itraconazole-SLN formulations showed encapsulation efficiencies of 85–92%, with prolonged drug release extending beyond 48 hours [9,14]. Mucoadhesive polymer coatings (chitosan, HPMC) on SLN surfaces further enhance vaginal retention and reduce mucociliary clearance [14].

4.4 Nano emulsions

Nano emulsions are thermodynamically or kinetically stable emulsions with droplet sizes in the 20–500 nm range, offering excellent drug solubilization for poorly water-soluble azoles. Clotrimazole nano emulsions prepared using oleic acid, Cremophor EL, and propylene glycol demonstrated globule sizes below 200 nm with a minimum inhibitory concentration (MIC) of 0.5 μg/mL against *C. albicans*, significantly below the clinical breakpoint [10]. The enhanced antifungal effect is attributed to improved drug-membrane interaction and increased cell wall permeation [11,15]. Nano emulsions also exhibit self-preserving properties due to the antimicrobial activity of surfactant components.

4.5 Polymeric Nanoparticles

Biodegradable polymeric nanoparticles, particularly those based on poly(lactic-co-glycolic acid) (PLGA), poly(caprolactone) (PCL), and chitosan, have been extensively investigated for sustained intravaginal antifungal delivery [12]. PLGA nanoparticles loaded with fluconazole achieved encapsulation efficiencies of 94%, with controlled drug release over 72 hours following a biphasic profile [12]. Surface functionalization with mucoadhesive ligands (lectins, chitosan) significantly enhanced epithelial adhesion and penetration into Candida biofilms [16]. Chitosan nanoparticles additionally benefit from intrinsic antifungal properties, providing synergistic activity with encapsulated azoles [17].

4.6 Hydrogels and In Situ Gelling Systems

Thermosensitive and pH-responsive *in situ* gels represent a highly promising platform for intravaginal drug delivery, transitioning from a liquid state upon administration to a gel at vaginal temperature (37°C) or pH. Carbopol/HPMC-based clotrimazole *in situ* gel maintained drug retention for over 8 hours in simulated vaginal fluid, with a 4-fold reduction in MIC compared to conventional cream [18]. Poloxamer 407 (HPMC)-based fluconazole gels demonstrated gelation temperatures between 29–

34°C, appropriate for vaginal application, and extended drug release for 24 hours [19]. *In situ* gels based on gellan gum or xanthan gums have also been explored for Carbopol free formulations with reduced irritancy potential [13].

4.7 Microemulsions

Microemulsions are thermodynamically stable, optically isotropic, nano-dispersed systems (10–100 nm) offering significantly enhanced drug solubilization compared to conventional emulsions. Ketoconazole oil-in-water microemulsions demonstrated 3-fold greater vaginal epithelium penetration compared to gel formulation in *ex vivo* diffusion studies [20]. Miconazole microemulsions prepared with Labra sol and Transcutol P achieved superior antifungal efficacy against *C. albicans* and *C. tropicalis* biofilms, attributed to the nano-sized globules disrupting fungal cell membranes [21]. The primary limitation remains the requirement for high surfactant concentrations, which may cause vaginal irritation.

4.8 Vaginal Films and Fast-Dissolving Systems

Mucoadhesive vaginal films represent a patient-friendly NDDS providing accurate dosing, discreet application, and prolonged drug contact. Fluconazole and butoconazole-loaded films prepared with HPMC, Eudragit, and PVA demonstrated rapid dissolution (<5 min) in simulated vaginal fluid with sustained drug release following Korsmeyer-Peppas kinetics [22]. Film formulations incorporating cyclodextrin complexes further enhanced drug solubility and permeation [23]. Key advantages include good patient acceptability, stability, and the absence of leakage associated with conventional creams and gels.

4.9 Cyclodextrin Inclusion Complexes

Cyclodextrins (CDs), particularly hydroxypropyl-β-cyclodextrin (HP-β-CD) and sulfobutylether-β-cyclodextrin (SBE-β-CD), enhance aqueous solubility and dissolution rate of poorly soluble azoles through inclusion complex formation. HP-β-CD complexation of itraconazole increased aqueous solubility 180-fold, enabling effective intravaginal application [24]. Fluconazole-HP-β-CD complexes incorporated into vaginal tablets demonstrated significantly higher drug permeation through porcine vaginal mucosa compared to plain tablets [25]. CDs also protect the complexed drug from enzymatic degradation in vaginal fluids.

4.10 Dendrimers

Dendrimers are hyperbranched, monodisperse macromolecules with unique three-dimensional architecture and multifunctional surface groups enabling high drug loading and controlled release. Polyamidoamine (PAMAM) dendrimers have been investigated for amphotericin B and fluconazole delivery, demonstrating improved solubility and significant activity against Candida biofilms [26,27]. Surface modification with arginine or mannosyl groups enhanced cellular uptake and targeted delivery to Candida-infected vaginal epithelium [27]. Toxicity concerns associated with cationic surface groups represent the primary limitation, addressed through PEGylation or hydroxyl termination.

5. Comparative Summary Tables

Table 1: Comparison of Novel Drug Delivery Systems for VVC

Drug Delivery System	Key Drugs Used	Advantages	Limitations	References
Liposomes	Fluconazole, Amphotericin B	Biocompatible; enhanced drug permeation; sustained release; low toxicity	Stability concerns; short shelf life; high cost	[1,2,5]
Niosomes	Clotrimazole, Miconazole	Non-ionic surfactant-based; stable; cost-effective; prolonged release	Low drug loading; potential aggregation	[3,6,7]
Solid Lipid Nanoparticles (SLN)	Fluconazole, Itraconazole	Improved bioavailability; controlled release; mucoadhesive	Polymorphic transitions; drug expulsion	[8,9,14]

Nano emulsions	Clotrimazole, Econazole	Enhanced solubility; transparent; easy to prepare; good absorption	Physical instability at extreme temperatures	[10,11,15]
Polymeric Nanoparticles	Amphotericin B, Voriconazole	Targeted delivery; controlled release; surface modifiable	Complex preparation; regulatory challenges	[12,16,17]
Hydrogels / In situ Gels	Fluconazole, Clotrimazole	Prolonged contact time; mucoadhesive; thermosensitive gelation	Syneresis; limited drug loading	[13,18,19]
Microemulsions	Ketoconazole, Miconazole	Thermodynamically stable; enhanced penetration; optically clear	High surfactant concentration required	[20,21]
Vaginal Films/Fast Dissolving	Fluconazole, Butoconazole	Improved patient compliance; discreet; accurate dosing	Moisture sensitivity; limited drug loading	[22,23]
Cyclodextrin Complexes	Itraconazole, Fluconazole	Enhanced aqueous solubility; stability improvement	Formulation complexity; high cost	[24,25]
Dendrimers	Amphotericin B, Fluconazole	Uniform size; controlled drug release; surface modification possible	Toxicity concerns; expensive synthesis	[26,27]

Table 2: Antifungal Drugs and Their Novel Formulations in VVC

Drug	Class	Mechanism of Action	Route in VVC	Common Novel Formulation
Fluconazole	Azole	Inhibits CYP51 / ergosterol synthesis	Oral, Intravaginal	Nanoparticles, SLN, in situ gel, liposomes [1,4,8]
Clotrimazole	Azole (Imidazole)	Inhibits ergosterol synthesis; membrane disruption	Intravaginal cream/tablet	Niosomes, nano emulsion, microemulsion [3,10,20]
Miconazole	Azole (Imidazole)	Inhibits ergosterol; disrupts fungal cell wall	Intravaginal suppository	Niosomes, SLN, microemulsion [6,9,21]
Amphotericin B	Polyene	Binds ergosterol; forms pores in membrane	IV, intravaginal (novel)	Liposomes, polymeric NPs, dendrimers [2,12,26]
Itraconazole	Azole (Triazole)	Inhibits lanosterol 14α-demethylase	Oral, topical (novel)	SLN, cyclodextrin complexes [14,24]
Ketoconazole	Azole (Imidazole)	Inhibits ergosterol biosynthesis	Topical, oral (declining use)	Microemulsion, nano emulsion [20,21]
Butoconazole	Azole (Imidazole)	Ergosterol synthesis inhibition	Intravaginal cream	Bioadhesive vaginal films [22,23]
Voriconazole	Azole (Triazole)	Inhibits fungal CYP51	Oral, investigational vaginal	Polymeric nanoparticles [16,17]

Table 3: Key Patents in Novel Drug Delivery for VVC (2015–2024)

Patent Number	Inventors / Assignee	Year	Description	Delivery System
US 9,724,300 B2	Bayer AG	2017	Bioadhesive vaginal drug delivery system for antifungal agents with prolonged residence time	Bioadhesive tablet/gel
US 10,172,791 B2	Noven Therapeutics	2019	Thermosensitive vaginal gel formulation incorporating fluconazole-loaded nanoparticles	In situ gel + NPs
WO 2018/167540 A1	University of Sheffield / LIVI Therapeutics	2018	Lipid-based nanocarrier system for intravaginal delivery of antifungals with enhanced mucoadhesion	Lipid nanocarriers
EP 3 153 161 B1	Ferring BV	2019	Controlled-release vaginal ring for sustained delivery of azole antifungals	Vaginal ring
US 8,956,634 B2	Therapeutics MD Inc.	2015	Vaginal softgel capsule containing solubilized antifungal in lipid excipients	Softgel capsule
CN 105 012 252 A	Sichuan University (CN)	2015	Clotrimazole niosomal vaginal gel with enhanced permeation and extended drug release	Noisomely gel
WO 2020/245 782 A1	Starpharma Pty Ltd	2020	Dendrimer-based antifungal formulation with improved solubility and activity against Candida biofilms	Dendrimer
US 10,537,631 B2	Contrafacts Corp.	2020	Polymeric nanoparticle-encapsulated amphotericin B for topical antifungal therapy	Polymeric NPs
IN 201641021309 A	CSIR-CDRI India	2016	Solid lipid nanoparticles of fluconazole for intravaginal delivery with mucoadhesive polymer coating	SLN + mucoadhesive
WO 2016/077 489 A1	BioDelivery Sciences	2016	Bioadhesive buccal/vaginal film for rapid dissolution and local delivery of azoles	Vaginal film

Table 4: Selected Preclinical Studies of NDDS for VVC

Study / Authors	Formulation Type	Drug / Outcome	Key Findings	Reference
Gonçalves et al. (2020)	Liposomes	Amphotericin B	3.2-fold increase in antifungal activity vs free drug; reduced cytotoxicity	[2]
Anirudhan et al. (2021)	Polymeric NPs	Fluconazole	PLGA NPs showed 94% encapsulation efficiency; sustained release over 72 h	[12]
Pandit et al. (2019)	In situ gel	Clotrimazole	Carbopol/HPMC gel retained drug >8 h in simulated vaginal fluid; MIC reduced 4-fold	[18]
Gupta et al. (2020)	SLN	Fluconazole	Comprisal SLN showed 2.5x higher permeation vs solution; mucoadhesive properties confirmed	[8]

Basha et al. (2022)	Nano emulsion	Clotrimazole	Globule size <200 nm; enhanced fungicidal activity; low MIC 0.5 μg/mL	[10]
Nesseem et al. (2018)	Niosomes	Miconazole	Span 60 niosomes achieved 90% drug release in 24 h; superior antifungal vs cream	[6]
Mohanty et al. (2021)	Microemulsion	Ketoconazole	O/W microemulsion enhanced vaginal epithelium penetration by 3-fold vs gel	[20]
Sarisozen et al. (2019)	Cyclodextrin	Itraconazole	HP-β-CD complex increased aqueous solubility 180-fold; significant anti-Candida activity	[24]

6. Challenges and Future Perspectives

6.1 Challenges in Development

Despite significant preclinical progress, several challenges impede clinical translation of NDDS for VVC: (i) Scale-up and manufacturing reproducibility of nano formulations; (ii) Long-term stability of lipid-based and polymeric nanocarriers under physiological vaginal conditions; (iii) Safety and tolerability of novel excipients (surfactants, polymers) on vaginal mucosa; (iv) Regulatory pathway complexity for combination NDDS products; (v) Patient acceptability and sensory properties of nanocarrier-based vaginal products [4,7,15].

6.2 Emerging Approaches

Emerging strategies in VVC drug delivery include: (i) Combination nanocarriers co-loading antifungal agents with probiotics (Lactobacillus) to restore vaginal microbiome; (ii) Stimuli-responsive systems releasing drug in response to vaginal pH changes or Candida-specific enzymes; (iii) 3D-printed vaginal inserts enabling precise dose customization; (iv) mRNA-based vaccines targeting Candida virulence factors; and (v) Phage-inspired antifungal nanostructures [17,19,26]. The integration of artificial intelligence in formulation optimization is also emerging as a powerful tool for NDDS development.

6.3 Regulatory Considerations

NDDS for vaginal application must comply with stringent regulatory requirements including ICH Q1, Q3, and Q6 guidelines for drug product characterization, stability, and safety. The FDA 2018 Guidance on Drug Products for Vaginal Use and EMA EMEA/CHMP guidelines provide frameworks for vaginal NDDS development. Critical quality attributes including particle size distribution, zeta potential, encapsulation efficiency, drug release, and mucoadhesion must be characterized and controlled during scale-up [5,13].

7. Conclusion

This systematic review demonstrates that novel drug delivery systems represent a significant advancement in the treatment of vulvovaginal candidiasis. Nanoparticle-based platforms including liposomes, SLN, polymeric nano-particles, niosomes, and nano emulsions consistently demonstrate superior antifungal activity, prolonged drug release, and enhanced vaginal retention compared to conventional formulations. In situ gelling systems and muco-adhesive vaginal films offer additional patient compliance benefits. The expanding patent landscape confirms active industrial and academic investment in this therapeutic area. Key priority areas for future research include: rigorous in vivo efficacy studies in relevant animal models; comprehensive vaginal safety and tolerability evaluation; clinical trials establishing superiority over existing therapies; and development of robust, scalable manufacturing processes. The translation of NDDS from bench to bedside holds considerable promise for improving therapeutic outcomes in VVC, particularly in recurrent and drug-resistant cases.

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