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NOVEL APPROACHES FOR TOPICAL AND TRANSDERMAL DELIVERY OF ANTIFUNGAL DRUGS: CURRENT STATUS AND FUTURE PERSPECTIVES

Sakshi Laad and Pooja Tiwari *

IPS Academy College of Pharmacy, Knowledge Village, Rajendra Nagar, A.B. Road, Indore - 452012, Madhya Pradesh, India.

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Correspondence to Author:
Ms. Pooja Tiwari

Assistant Professor
IPS Academy College of Pharmacy, Knowledge Village, Rajendra Nagar, A.B. Road, Indore - 452012, Madhya Pradesh, India.

E-mail: poojatiwari@ipsacademy.org

ABSTRACT: Fungal infections constitute a significant global health challenge, necessitating prolonged therapeutic interventions and confronting limitations such as inadequate dermal penetration, emerging drug resistance, and systemic toxicity. Conventional topical formulations of antifungal agents often demonstrate suboptimal clinical efficacy owing to poor permeation across the stratum corneum and instability of active pharmaceutical ingredients. Recent advancements in pharmaceutical nanotechnology have catalysed the emergence of innovative drug delivery platforms designed to enhance cutaneous and transdermal antifungal drug administration. A broad spectrum of carrier-based systems including liposomes, noisome, ethosomes, solid lipid nanoparticles, nanostructured lipid carriers, and polymeric nanoparticles have exhibited superior drug solubilization, controlled release kinetics, targeted site-specific delivery, and improved patient adherence. These nanocarrier-mediated formulations not only facilitate deeper skin penetration and enhanced drug retention but also mitigate systemic exposure and associated toxicities. Furthermore, next-generation strategies such as microneedle-assisted delivery, nano emulsions, and transdermal patches have surfaced as potent and patient-friendly alternatives to conventional topical therapies. The incorporation of natural bioactive compounds and biodegradable polymers further augments the therapeutic efficacy and biocompatibility of these systems. This review provides a comprehensive overview of contemporary formulation strategies, mechanistic insights, and evaluation parameters of novel topical and transdermal antifungal delivery systems. Future perspectives underscore the imperative for translational research, robust clinical validation, and regulatory standardization to advance the development of safe, effective, and sustainable antifungal therapies.

INTRODUCTION:

Fungal: Fungal infections pose a significant global health burden, encompassing superficial skin and mucosal infections as well as invasive systemic mycoses affecting vital organs such as the lungs, liver, and heart. These infections are primarily caused by opportunistic fungal pathogens that exploit compromised host immune defences.

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Immunosuppressed populations, including individuals with HIV/AIDS, diabetes, or malignancies, are particularly vulnerable to airborne fungal infections, which can rapidly progress to severe or life-threatening conditions.

Despite the availability of various antifungal agents including azoles, polyenes, echinocandins, and allylamines therapeutic outcomes remain suboptimal due to poor aqueous solubility, limited tissue penetration, emerging drug resistance, and systemic toxicity associated with conventional formulations [1]. Recent advances in nanotechnology have facilitated the development of innovative antifungal delivery platforms that address these

limitations. Nanocarrier systems, including liposomes, solid lipid nanoparticles, polymeric nanoparticles, and nanostructured lipid carriers, provide controlled and targeted delivery of antifungal agents. These systems enhance drug concentration at infection sites through improved adherence to fungal cell walls and facilitated permeation across biological membranes. The nanoscale dimensions, large surface area, and tunable surface charge of these carriers enable enhanced interaction with fungal pathogens, resulting in superior therapeutic efficacy and reduced systemic exposure. Additionally, the incorporation of biocompatible and biodegradable polymers improves formulation stability, sustains drug release, and augments bioavailability. Evidence from recent studies demonstrates that topical nanocarrier-based antifungal formulations exhibit enhanced therapeutic performance relative to conventional creams or gels, with minimal cytotoxicity. Overall, nanoparticle-mediated antifungal delivery represents a promising strategy to overcome the limitations of traditional therapies, emphasizing the need for continued research on carrier–pathogen interactions, formulation optimization, and clinical validation to fully realize its translational potential [2].

History of Fungal: Fungi have long been recognized as a rich source of bioactive compounds, with traditional cultures exploiting them for medicinal and psychoactive purposes long before modern science. Systematic isolation of fungal metabolites began in the late 19th century, yet the modern era of fungal drug discovery is epitomized by Alexander Fleming's accidental discovery of penicillin in the 1940s [3]. This breakthrough established fungi as a prolific reservoir of therapeutic molecules, leading to subsequent discoveries such as cephalosporin C from *Acremonium chrysogenum* and fusidic acid from *Acremonium fusidioides*, both providing effective antibacterial activity with minimal eukaryotic toxicity. Fungi have also contributed directly to antifungal therapy; griseofulvin, isolated from *Penicillium griseofulvum*, treats dermatophyte infections, while echinocandins (caspofungin, micafungin, anidulafungin) target 1,3-β-D-glucan synthase in invasive mycoses [4]. Recently, enfumafungin derivatives, including ibrexafungerp, have expanded treatment options.

The ongoing emergence of multidrug-resistant fungi highlights the imperative for novel antifungal agents with diverse mechanisms.

Classification: This classification delineates antifungals according to their mechanistic modalities, encompassing membrane perturbation, cell wall biosynthesis inhibition, nucleic acid synthesis interference, and mitotic disruption, while emphasizing both traditional and emerging therapeutic categories [5].

- Azoles
- Polyenes
- Echinocandins
- Allylamines
- Morpholines

Fungal Skin Infections: Fungal skin infections are among the most common dermatologic conditions worldwide, affecting individuals across all age groups. Caused by dermatophytes, yeasts, and non-dermatophyte molds, these infections range from superficial, self-limiting conditions to invasive, potentially life-threatening diseases in immunocompromised hosts. Factors such as poor hygiene, environmental exposure, immunosuppression, and metabolic disorders increase susceptibility [6]. Despite the availability of topical and systemic antifungal therapies, treatment challenges persist due to drug resistance, recurrence, and limited skin penetration. Early recognition, accurate diagnosis, and appropriate therapy are essential to reduce morbidity and prevent complications associated with fungal skin infections [7].

Types:

Systemic Fungal Infections:

- Histoplasmosis
- Blastomycosis
- Crytptococcosis
- Systemic candidiasis
- Aspergilosis

- Coccidiodomycosis

Cutaneous Fungal Infections:

- Tinea corporis
- Tinea cruris
- Tinea pedis
- Tinea capitis
- Tinea unguium

Subcutaneous Fungal Infections:

- Chromomycosis
- Sporotrichosis

Superficial Fungal Infections:

- Pitryiasis versicolor
- Tinea nigra [8]

WHO Report: The World Health Organization (WHO) has highlighted the escalating threat of invasive fungal infections (IFIs), particularly among immunocompromised populations such as individuals undergoing cancer chemotherapy, living with HIV, or who have received organ transplants. These infections are increasingly resistant to treatment, with mortality rates reaching as high as 88% for certain pathogens. The WHO's Fungal Priority Pathogens List (FPPL) categorizes these pathogens into critical, high, and medium priority based on their public health impact and emerging antifungal resistance risks. The FPPL aims to guide research and development efforts to address the significant gaps in diagnostics and treatment options for IFIs, especially in low- and middle-income countries where access to healthcare resources is limited.

The global burden of fungal diseases remains considerable, with an estimated 6.5 million individuals annually developing life-threatening mycoses, resulting in approximately 3.8 million fatalities, of which 2.5 million are directly attributable to these infections (The Lancet). Principal contributors include invasive aspergillosis (2.1 million cases), chronic pulmonary aspergillosis (1.8 million cases), invasive candidiasis (1.5 million cases), pneumocystis pneumonia (≈500,000 cases), and cryptococcal meningitis (≈194,000 cases). Collectively, fungal infections account for higher annual mortality than tuberculosis, malaria, hepatitis, and pneumonia combined (GAFFI). These data underscore a critically elevated case-fatality rate of approximately 58%, highlighting the pressing need for enhanced diagnostic capabilities, novel antifungal therapeutics, and comprehensive public health strategies to mitigate this escalating global threat [9].

Antifungal Drugs [10-12]:

1. 1955 – Amphotericin B (AMB)

- The first major antifungal drug introduced.
- A polyene antifungal used to treat systemic fungal infections.
- Known for its broad-spectrum activity but also nephrotoxicity.

2. 1968 – Flucytosine (5-FC)

- A pyrimidine analog used primarily in combination therapies.
- Effective against Candida and Cryptococcus species.

3. 1990 – Fluconazole (FLC)

- A triazole antifungal with excellent oral bioavailability.
- Commonly used for candidiasis and cryptococcal meningitis.

4. 1992 – Itraconazole (ITC)

- Broader spectrum triazole compared to fluconazole.
- Used for aspergillosis, histoplasmosis, and other fungal infections.

5. 2001 – Caspofungin (CSF):

- First echinocandin antifungal introduced.
- Inhibits fungal cell wall synthesis (β-1,3-D-glucan synthase inhibitor).

6. 2002 – Voriconazole (VOR):

- Second-generation triazole antifungal.
- First-line treatment for invasive aspergillosis.

7. 2005 – Micafungin (MCF)

- Another echinocandin with improved safety profile.
- Effective for Candida infections and prophylaxis in hematopoietic stem cell transplant patients.

8. 2006 – Anidulafungin (ANF)

- Echinocandin with minimal hepatic metabolism.
- Used in invasive candidiasis.

9. 2006 – Posaconazole (POS)

- Broad-spectrum triazole with activity against resistant molds and yeasts.
- Used for prophylaxis and treatment of invasive fungal infections.

10. 10. 2013 – MGCD290

- A histone deacetylase (HDAC) inhibitor explored for antifungal synergy.
- Still in investigational stages, enhances azole efficacy.

11. 2015 – Isavuconazole (ISV)

- A newer triazole with broad-spectrum activity and better tolerability.
- Approved for invasive aspergillosis and mucormycosis.

12. 12. 2018 – CAMB and SUBA-ITC

- CAMB (CAmB): A lipid-based formulation of Amphotericin B to reduce toxicity.
- SUBA-ITC: Super bioavailable itraconazole formulation with improved absorption.

13. 2019–2020 – Next-Generation Antifungals

- VT-1161, CD101, SCY-078, APX001, F901318:
- These represent novel classes or improved agents targeting resistant fungal pathogens. Still under clinical or late preclinical development.
- Aim to overcome resistance, improve pharmacokinetics, and reduce toxicity.

Nanocarriers for Antifungal Therapy: Fungal skin infections are a widespread health concern worldwide. They are commonly treated using topical or systemic antifungal therapies, with topical treatment preferred due to targeted action and fewer side effects [13]. Conventional topical formulations often face challenges such as low drug retention and poor bioavailability. Recent advances in nanotechnology have led to the development of novel topical carriers, including liposomes, niosomes, solid-lipid nanoparticles, microemulsions, nanogels, and micelles, which enhance drug delivery. Studies show that antifungal drugs loaded into these nanocarriers provide improved therapeutic outcomes, better skin penetration, and reduced toxicity. This review highlights these innovative strategies [14].

TABLE 1: CLASSIFICATION INVOLVES SYSTEMATICALLY GROUPING DRUGS, EXAMPLES AND USES IN FUNGAL THERAPY

S. no.	Nanocarriers	Examples of nano carriers	Uses in fungal therapy
1.	Lipid-Based, Nanocarriers	Liposomes, Solid Lipid Nanoparticles (SLNs), Nanostructured Lipid Carriers (NLCs)	Enhance skin penetration and target delivery to infection sites, Reduce systemic toxicity of antifungal drugs, Improve solubility of poorly water-soluble antifungal agents
2.	Polymeric Nanocarriers	Polymeric Nanoparticles (e.g., PLGA, chitosan), Dendrimers	Provide controlled and prolonged drug release, Improve stability of antifungal drugs, Can be functionalized for targeted delivery, Enhance drug bioavailability at infection sites
3.	Inorganic Nanocarriers	Metallic Nanoparticles (e.g., silver, gold, zinc oxide), Mesoporous Silica Nanoparticles	High surface area allows high drug loading, Improve penetration through fungal biofilms, Provide stability and protection of drugs from degradation

4.	Vesicular Nanocarriers	Niosomes, Transfersomes, Ethosomes	Enhance localized delivery and reduce systemic side effects, Increase therapeutic efficacy of antifungal drugs
5.	Hybrid/Novel, Nanocarriers	Nanogels, Micelles	Reduce dosing frequency and improve patient compliance, Improve solubility and bioavailability of poorly soluble antifungals [3, 4]

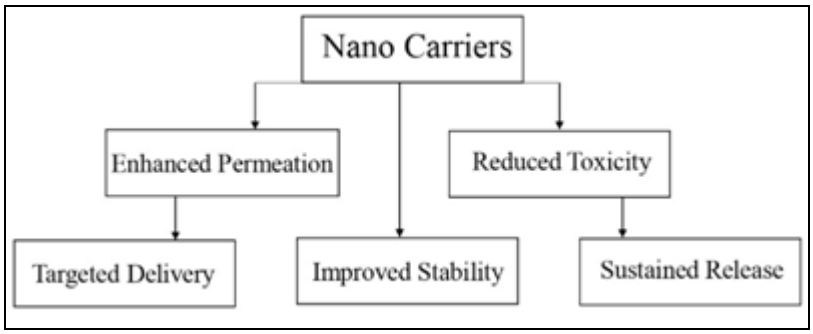

FIG. 1: POSITIVE ASPECTS OF NANOCARRIERS THERAPY

Transdermal Systems: Transdermal drug delivery systems (TDDS) are a growing area in pharmaceutical research, offering advantages over oral and injectable routes by avoiding first-pass metabolism and improving patient compliance. Research focuses on enhancing drug delivery through methods like drug/vehicle interactions, vesicles, stratum corneum modification, energy-driven techniques, and stratum corneum bypassing. Microneedle technology, in particular, allows delivery of both small and large molecules and intradermal therapy [17]. TDDS have shown potential in treating fungal skin infections by improving drug penetration, targeting the site of infection, and maintaining sustained antifungal activity, making them effective for fungal disease management.

Functional Advantages:

- Avoids first-pass metabolism - Drugs bypass the liver, improving bioavailability.
- Improves patient compliance – Easy and painless to use compared to injections.
- Controlled and sustained release – Provides steady drug levels over time.
- Targeted delivery – Directly delivers drugs to skin or systemic circulation.
- Reduces side effects– Minimizes gastrointestinal and systemic adverse effects.
- Versatile drug types – Suitable for small and large molecules with technologies like microneedles.
- Non-invasive therapy – Eliminates the need for needles and reduces infection risk [18].

Topical Formulations: Topical formulations, like creams and ointments, are designed to deliver active ingredients to the skin for cosmetic, protective, or therapeutic purposes. However, these formulations often show very low effectiveness, with only 1–2% of the applied dose actually reaching the target. This low performance is mainly due to the skin's natural barrier and limitations in how the active ingredients move through it. By understanding how drugs diffuse according to Fick's laws, researchers can design better topical products. Modern methods in research focus not just on the active ingredient but also on the behavior of the formulation itself. Advanced analytical techniques now allow scientists to track how and where actives reach the skin in real time. A strong knowledge of the physical chemistry of both the skin and the formulation is key to developing more effective topical products [19].

Future Perspectives in Antifungal Therapy:

Antifungal Vaccines: Recent advances in antifungal vaccine research have demonstrated notable progress, particularly in addressing both prevalent and life-threatening mycoses. Contemporary investigations have focused on optimizing immunogenicity, enhancing protective efficacy, and mitigating safety concerns, thereby paving the way for novel prophylactic and therapeutic strategies against pathogenic fungi. Emerging vaccine candidates, including recombinant protein formulations, live-attenuated

strains, and mRNA-based platforms, exhibit potential in eliciting robust humoral and cellular immune responses. Collectively, these developments underscore a paradigm shift in antifungal prophylaxis, heralding a new era of targeted immunotherapeutic interventions for vulnerable populations [20, 21].

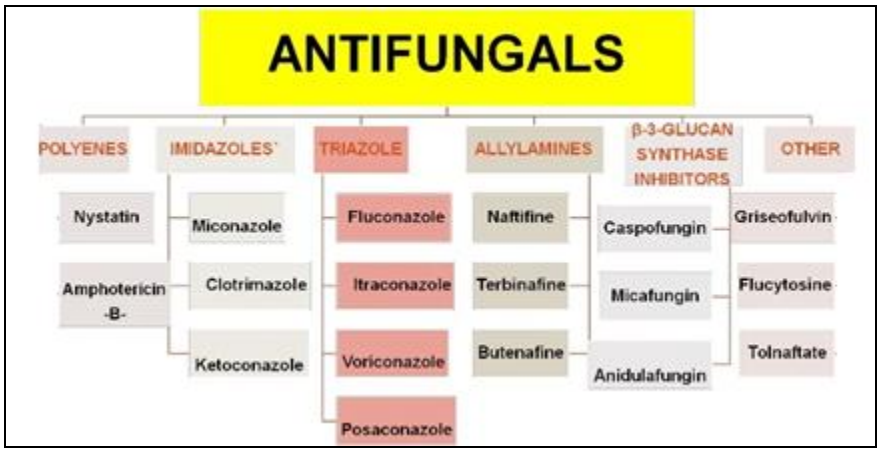

FIG. 2: LATEST ANTIFUNGAL VACCINES

Platform for Fungal Vaccine Development: Despite the wide spectrum of platforms explored for antifungal vaccine development, most candidates remain confined to preclinical evaluation. Only a limited number have advanced into clinical trials, and to date, no fungal vaccine has received regulatory approval. The subsequent section of this review will provide a comprehensive examination of the contemporary landscape of fungal vaccine development platforms.

TABLE 2: WHO FUNGAL PATHOGEN PRIORITY LIST [22]

Critical group	High group	Medium Group
Cryptococcus neoformans	*Candida glabrata*	*Scedosporium spp.*
Candida auris	*Histoplasma spp.*	*Lomentos poraprolificans*
Aspergillus fumigatus	*Eumycetoma causative agents*	*Coccidioides spp.*
Candida albicans	*Mucorales*	*Candida krusei*
	Fusarium spp.	*Cryptococcus gattii*
	Candida tropicalis	*Talaromyces marneffei*
	Candida parapsilosis	*Pneumocystis jirovecii*
		Paracoccidioides spp.

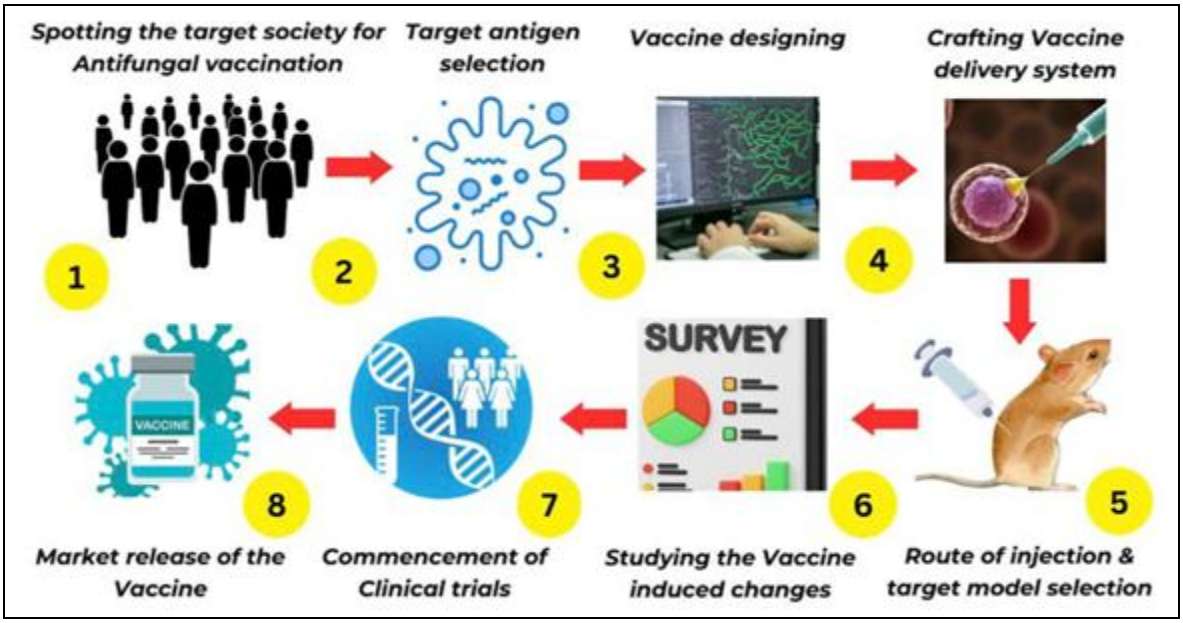

FIG. 3: ANTIFUNGAL VACCINE DEVELOPMENT MILESTONES

Recombinant (Subunit) Vaccine: Recombinant fungal vaccines, comprising purified antigenic elements such as proteins or polysaccharides, provide a safer alternative to live attenuated vaccines, particularly for immunocompromised populations [23]. These subunit vaccines typically require co-administration with potent adjuvants to generate robust immune responses. Notably, the recombinant vaccine NDV-3, targeting the *Candida albicans* adhesin/invasin protein, demonstrated a favorable safety profile and elicited specific immunity in women with recurrent vulvovaginal candidiasis in a phase 2, placebo-controlled, double-blind clinical trial. In preclinical evaluations, PEV7, a fusion of truncated *C. albicans* Sap2 protein with influenza virosomes, induced strong systemic and mucosal antibody responses, providing durable protection against vaginal candidiasis in rodent models. Subunit vaccines thus offer targeted immunity with enhanced safety, albeit with dependence on adjuvants for optimal efficacy [24].

Conjugate Vaccine: Conjugate fungal vaccines, consisting of polysaccharide antigens covalently linked to carrier proteins, enhance immunogenicity and induce durable, T cell-dependent antibody responses against fungal pathogens. By overcoming the inherently weak immunogenicity of polysaccharides alone, this strategy provides a promising platform for prophylaxis against invasive fungal infections. Preclinical studies demonstrate that conjugating Cryptococcus neoformans glucuronoxylomannan (GXM) to tetanus toxoid or galactoxylomannan (GalXM) to carrier proteins elicits potent antibody-mediated protection in murine models. Similarly, the Lam-CRM vaccine, comprising laminarin from *Laminaria digitata* conjugated to diphtheria toxoid CRM197, confers protection against systemic and mucosal *Candida albicans* infections and lethal *Aspergillus fumigatus* challenge. Anti-β-glucan antibodies generated inhibit fungal growth *in-vitro*. Despite these advances, production complexity and potential carrier-induced epitope suppression remain challenges for optimization [25].

DNA Vaccines: DNA vaccines, composed of plasmids encoding specific fungal antigens and, in some cases, co-stimulatory molecules or cytokines, provide a promising platform to induce robust immune responses via direct antigen presentation by host antigen-presenting cells. Preclinical studies have shown their efficacy in murine and rat models; for instance, a DNA vaccine encoding the P10 peptide conferred durable protection against *Paracoccidioides brasiliensis,* promoting memory CD4+ and regulatory T cell responses, while a p55-TAG DNA vaccine reduced pathogen load and lung inflammation in immunosuppressed rats. These vaccines enable targeted antigen expression and cellular immunity, offering improved safety over live attenuated vaccines, though challenges in delivery, limited clinical data, and potential genomic integration require further optimization [26, 27].

Nanotechnology in Fungal Vaccine Development: Nanoparticles have emerged as versatile platforms in vaccine development, serving as antigen carriers that enhance stability, improve immunogenicity, and function as immunostimulatory adjuvants. Various nanostructures including polymeric nanoparticles, nanostructured lipid carriers, phospholipid-based vesicles, dendrimers, nano emulsions, and metallic or magnetic nanoparticles are being investigated to optimize fungal vaccine efficacy. Liposomal nanoparticles incorporating fatty acyl derivatives of muramyl dipeptide (MDP) have demonstrated potent Th1-skewed immune responses and cellular proliferation, critical for antifungal defence [28].

Preclinical studies with liposomal and PLGA nanoparticle platforms delivering DNAhsp65 vaccines have shown protective immunity and reduced pulmonary fungal burden in murine Para coccidioidomycosis models. Intranasal delivery of liposomal formulations offers a non-invasive, patient-friendly route, enhancing clinical applicability. While nanoparticle-based vaccines provide targeted delivery, antigen stabilization, and superior immunogenicity, their advancement is constrained by biocompatibility considerations, regulatory complexities, and cost-effectiveness issues, necessitating further optimization to realize their translational potential in systemic fungal infections [29].

Natural and Herbal Formulations: Fungi responsible for human infections are broadly classified into three groups: filamentous fungi

forming thread-like structures, unicellular yeasts, and dimorphic fungi exhibiting both morphologies. Fungal infections are often chronic, requiring prolonged therapeutic interventions, and pose significant risks to immunocompromised individuals. Conventional antifungal therapy encompasses five primary classes azoles, allylamines, echinocandins, griseofulvin, and flucytosine yet treatment limitations, including resistance, toxicity, and incomplete efficacy, underscore the pressing need for novel antifungal agents. Historically, medicinal plants have served as a rich source of therapeutic compounds, with traditional knowledge guiding the use of plant extracts against fungal ailments. Phytochemical investigations have revealed bioactive secondary metabolites such as alkaloids, flavonoids, terpenoids, and phenolics that exhibit potent antifungal activity, often surpassing synthetic agents in selectivity and safety profiles.

Scientific validation of these plant-derived compounds has facilitated their incorporation into modern pharmacology as alternative or adjunctive antifungal therapies. Screening and evaluation of plant extracts remain a vital strategy for discovering new antimicrobial agents, leveraging centuries of ethnobotanical knowledge. This section provides a detailed overview of plants with demonstrated antifungal properties, highlighting their chemical constituents, mechanisms of action, and potential applications in the management of human fungal infections **Table 3.**

TABLE 3: LIST OF DIFFERENT PLANT HAVING ANTIFUNGAL EFFICIENCY

Plant name (Spices)	Family	Parts Used	Test spices	Reference
Asphodelus luteus	Liliaceae	Whole plant	*Trichophyton violaceum*	Ali-Shtayeh and Abu Ghdeib (1999)
Ocimum gratissimum	Labiatae	Leaves (hexane extract)	*Trichophyton mentagrophytes, Trichophyton rubrum, Microsporum canis, Microsporum gypseum*	Silva *et al.* (2005)
Mammea longifolia	Clusiaceae	Root	*Fusarium oxysporum*	Deng and Nicholson (2005)
Combretum woodii	Combretaceae	Leaves	*Candida albicans, Cryptococcus*	Masoko *et al.* (2007)
Camptotheca acuminata	Nyssaceae	Leaves	*Alternaria alternate, Epicoccum nigrum, Pestalotiaguepinii*	Li *et al*. (2005)
Bougainvillea glabra	Nyctaginaceae	Stem, leaves, flowers, fruits	*Coccidioides immitis*	Alanís-Garza *et al.* (2007) [30]

CONCLUSION: Fungal infections represent a major global health challenge, affecting both superficial and systemic sites and posing significant risks, particularly to immunocompromised populations. Conventional antifungal therapies are limited by poor solubility, inadequate tissue penetration, drug resistance, and systemic toxicity, resulting in suboptimal clinical outcomes. Recent advancements in nanotechnology and carrier-based drug delivery systems including liposomes, solid lipid nanoparticles, polymeric nanoparticles, and nanostructured lipid carriers have demonstrated enhanced skin permeation, targeted delivery, controlled release, and reduced systemic exposure. Next-generation strategies such as microneedle-assisted delivery, nano emulsions, and transdermal patches further improve patient adherence and therapeutic efficacy. Global epidemiological data, as highlighted by the WHO and Lancet reports, reveal a high incidence of life-threatening fungal infections, with significant mortality rates and a case-fatality ratio of approximately 58%. These findings underscore the urgent need for continued translational research, robust clinical validation, and regulatory standardization to develop safe, effective, and sustainable antifungal therapies.

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