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Ketoconazole Hair Spray: An Innovative Topical Approach for the Treatment of Tinea capitis

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Abstract
Trichophyton and Microsporum species are the main culprits behind tinea capitis, a frequent superficial fungal infection of the scalp and hair shafts. It mostly affects kids and teenagers, causing inflammation of the scalp, itching, and hair loss. Oral antifungal medications and topical creams or shampoos are examples of conventional treatments that frequently have drawbacks such limited drug penetration, systemic adverse effects, and decreased patient compliance.

The broad-spectrum imidazole antifungal medication ketoconazole has shown strong effectiveness against the dermatophytes that cause tinea capitis. However, the primary site of infection—the hair follicles—is not adequately reached by conventional topical medicines. The development of a ketoconazole antifungal hair spray offers a unique, practical, and patient-friendly method for localized scalp therapy in order to overcome these difficulties. Easy application, quick drying, consistent medication distribution, improved penetration, and decreased systemic exposure are just a few benefits of the spray formulation.

The formulation techniques, assessment criteria, benefits, and drawbacks of hair spray systems intended for antifungal treatment are the main topics of this study. It draws attention to the potential of ketoconazole hair spray as a novel and successful topical administration method for the treatment of tinea capitis. Future prospects include improving treatment efficacy and patient acceptance through the use of sophisticated delivery systems such liposomes, polymeric systems, and nanoemulsions.

Keywords: Ketoconazole, Hair Spray, Tinea Capitis, Antifungal Therapy, Topical Drug Delivery, Dermatophytes

Introduction

A infectious fungal condition that mostly affects the scalp and hair shafts is called tinea capitis, or scalp ringworm. Dermatophyte species primarily from the genera Trichophyton and Microsporum are responsible. Although adults can sometimes be affected, the illness is most common in youngsters, especially in tropical and subtropical areas where humidity and temperature encourage fungal growth [1].

Depending on the causative organism and host immunological response, the infection manifests as scalp scaling, hair loss, pruritus, erythema, and occasionally pustule formation. Direct contact with diseased people, contaminated items like hats and combs, or animals harboring dermatophytes can all result in transmission [2].

Clinically, there are two forms of tinea capitis: non-inflammatory (black dot, gray patch) and inflammatory (kerion, favus) [3]. It may result in permanent hair loss and scarring alopecia if treatment is not received. Therefore, timely diagnosis and efficient antifungal treatment are crucial for treatment [4].

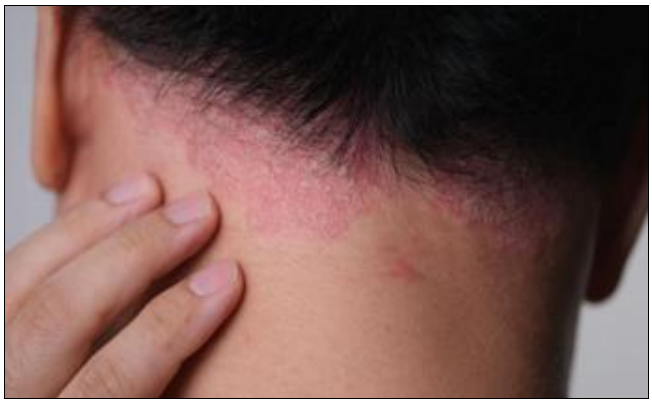


Fig 1: Tinea capitis

Even with the availability of systemic antifungal medications like azoles, terbinafine, and griseofulvin, treatment is still difficult because of long treatment durations, low patient compliance, and possible adverse effects [5]. The necessity for better topical delivery methods that boost drug penetration into hair follicles and scalp layers is further highlighted by the rise in treatment resistance and relapse occurrences [6]. In order to obtain localized and prolonged distribution of antifungal drugs like ketoconazole, itraconazole, and terbinafine, recent pharmaceutical research has concentrated on creating innovative formulations, such as gels, sprays, and systems based on nanoparticles [7]. These developments are intended to increase patient acceptance, decrease systemic exposure, and improve treatment efficacy [8].

Thus, the goal of this research is to offer new therapeutic approaches, with an emphasis on innovative topical antifungal formulations [9].

Ketoconazole hair spray for Tinea Capitis

Systemic antifungal medications such as terbinafine, itraconazole, or griseofulvin are the mainstay of conventional treatment for Tinea capitis [10]. Nevertheless, these oral drugs sometimes have drawbacks such lengthy treatment durations, hepatic side effects, and low patient compliance. Furthermore, topical formulations frequently exhibit limited efficiency due to insufficient medication penetration through the stratum corneum and hair shaft due to the deep-seated nature of the infection within hair follicles [11].

The broad-spectrum imidazole antifungal drug ketoconazole has demonstrated exceptional efficacy against Malassezia species and dermatophytes [12]. It has fungistatic and fungicidal actions by preventing the formation of ergosterol, a crucial component of the fungal cell membrane [13]. Although ketoconazole is commonly accessible in lotions, shampoos, and creams, these traditional topical preparations frequently have low follicular delivery and poor scalp retention, which decreases their therapeutic efficacy in treating tinea capitis [14].

Recent studies have concentrated on creating innovative topical medication delivery methods, such as hair sprays, gels, and carriers based on nanoparticles, to get around these problems [15]. Easy application, consistent drug distribution, quick drying, increased patient compliance, and greater local penetration into the scalp and hair follicles are some of the unique benefits that hair spray formulations provide [16]. Ketoconazole can be administered directly to the site of infection, increase retention duration, and reduce systemic exposure and adverse effects by being formulated as a hair spray [17].

Thus, a promising strategy for the successful treatment of Tinea capitis is the development and testing of a ketoconazole antifungal hair spray. The pharmacological profile of ketoconazole, the etiology and treatment of Tinea capitis, and the potential of spray-based topical delivery devices to improve treatment results and patient adherence are the main topics of this study [18].

Types of Hair Spray Formulations

1. Aerosol Hair Sprays

Pressurized devices called aerosol sprays use a propellant-driven mechanism to deliver the formulation. They aid in atomizing the liquid into tiny droplets and are made up of a container, valve, actuator, and propellant [19].

2. Non-Aerosol (Pump) Hair Sprays

These are mechanically operated systems where the liquid formulation is expelled using a pump mechanism instead of a propellant [20]. The formulation is typically water or alcohol-based.

3. Water-Based Hair Sprays

These formulations use water as the primary solvent and are generally mild, non-irritating, and suitable for therapeutic purposes.

4. Alcohol-Based Hair Sprays

Ethanol or isopropyl alcohol serves as the primary solvent, enhancing the solubility of lipophilic drugs and quick drying of the spray.

5. Polymer-Based (Film-Forming) Hair Sprays

These formulations contain polymers that form a thin film over the hair or scalp surface, enhancing drug retention and controlled release [21]. Commonly used polymers include polyvinylpyrrolidone (PVP), Eudragit, cellulose derivatives, and acrylic polymers.

6. Novel Hair Spray Systems

Recent advances have led to innovative spray systems for pharmaceutical applications:

- **Nanoemulsion-based sprays:** Enhance solubility and scalp penetration.
- **Liposomal sprays:** Provide sustained release and better follicular delivery [22].
- **Hydroalcoholic medicated sprays:** Combine fast drying with efficient drug delivery.
- **Herbal or bioactive sprays:** Incorporate plant extracts for combined antifungal and hair-conditioning effects [23, 24].

Advantages

1. Ease of Application
2. Enhanced Drug Penetration
3. Rapid Drying and Non-Greasy Nature
4. Uniform and Targeted Drug Delivery
5. Improved Patient Compliance
6. Reduced Systemic Side Effects
7. Controlled Drug Release and Retention
8. Hygienic and Contamination-Free Application [24]

Disadvantages
1. Scalp Irritation and Dryness
2. Limited Drug Penetration in Some Cases
3. Potential for Product Instability
4. Difficulty in Dose Measurement [25]

Drug Profile
Name of drug: Ketoconazole
Molecular Formula: $C_{26}H_{23}Cl_2N_4O_4$
IUPAC Name: (1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3dioxolan-4-yl]methoxy]phenyl]piperazine.
Molecular Weight: 531.43g/mol
Melting Point: 146 - 148 °C
Form: Powder
Colour: White
BCS Classification: BCS Class II (Low solubility, High permeability)
Solubility: Practically insoluble in water; soluble in methanol, ethanol, acetone; slightly soluble in chloroform [26].
Toxicity: Systemic use may cause hepatotoxicity, gastrointestinal disturbances, and endocrine effects (inhibition of steroid synthesis). Topical application shows minimal systemic toxicity [27].
Mechanism of Action: Ketoconazole inhibits fungal cytochrome P450 enzyme lanosterol 14-α-demethylase, leading to inhibition of ergosterol synthesis. This causes increased cell membrane permeability and ultimately fungal cell death [28].

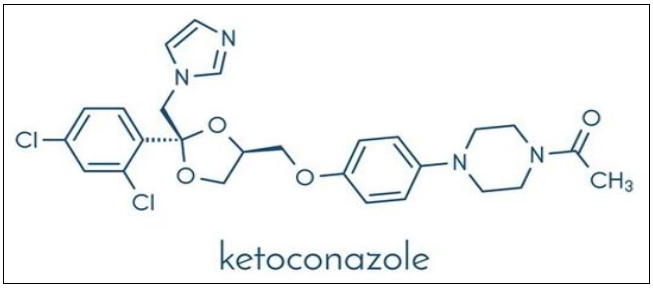


Fig 2: Ketoconazole

Preformulation
Organoleptic Test
The organoleptic properties of ketoconazole were evaluated to assess its physical characteristics.

Fig 3: Organoleptic test

Appearance: White to off-white powder
Odour: Odourless or faintly aromatic
Taste: Bitter
Tactile feel: Smooth and non-gritty
Texture: Fine crystalline

Interpretation
The organoleptic characteristics observed were consistent with the reported standard properties of ketoconazole, indicating the purity and suitability of the drug for formulation development [29].

Solubility Studies
Solubility studies were carried out in different solvents to understand the solubility behavior of ketoconazole [30].

Results
Soluble in methanol
Insoluble in paraffin oil

Interpretation
Ketoconazole showed good solubility in methanol and was insoluble in paraffin oil, confirming its poor aqueous and oily solubility [31]. This supports the need for suitable solvents and solubilising agents in the formulation of a topical hair spray [32].

pH Determination –
The pH of ketoconazole was determined to evaluate its ionic nature and compatibility with topical application [33].

Fig 4: pH determination

Results
pH value: 5.6

Nature: Slightly acidic compound
Interpretation: The pH range indicates that ketoconazole is weakly basic and falls within an acceptable range for topical scalp application, minimising the risk of irritation [34].

FT-IR Analysis
FT-IR spectroscopy was performed to confirm the identity of ketoconazole and to detect the presence of characteristic functional groups [35].

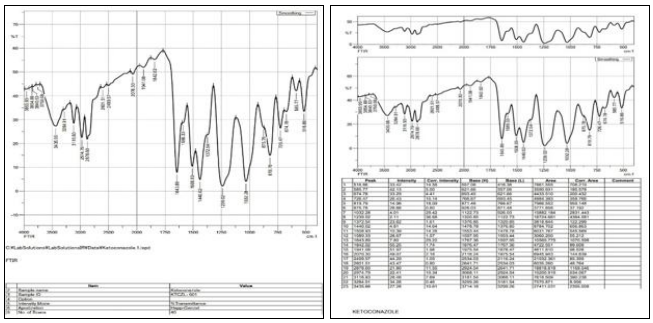


Fig 5: FT-IR analysis

Results

The FT-IR spectrum showed characteristic peaks corresponding to ketoconazole, indicating the presence of key functional groups [36].

Interpretation

The FT-IR analysis confirmed the identity and purity of ketoconazole, with no significant interference, making it suitable for further formulation studies [37].

UV Spectrophotometric Analysis of Ketoconazole

One popular analytical method for the quantitative determination of pharmaceutical compounds is UV-visible spectrophotometry [38]. This technique is predicated on the idea that many medications absorb UV light at particular wavelengths because their molecules include chromophoric groups [39]. Ketoconazole is an imidazole antifungal drug that may be quantitatively estimated using UV spectrophotometry due to its strong ultraviolet absorption [40].

A UV-visible spectrophotometer was used in this investigation to quantitatively analyze ketoconazole. In order to achieve a standard concentration, a precisely weighed quantity of ketoconazole was dissolved in an appropriate solvent to create a stock solution. A number of working standard solutions were made from this stock solution by diluting it appropriately to achieve concentrations between 5 and 25 µg/mL [41].

A quartz cuvette with a path length of 1 cm was used in a UV spectrophotometer to measure the absorbance of these solutions at the maximum wavelength (λmax) of ketoconazole. The blank solution was the dilution solvent. A calibration curve was created using the absorbance values obtained at various amounts [42].

It was discovered that the absorbance values for ketoconazole solutions increased proportionately with concentration, suggesting that the medication complies with Beer-Lambert's law within the chosen concentration range [43]. Beer-Lambert's law states that, when measured at a constant path length and wavelength, the absorbance of a solution is directly proportional to the concentration of the absorbing species [44].

Table 1: Absorbance data of Ketoconazole at Different Concentrations

Reading	Concentration (µg/mL)	Typical Absoprtion(λmax)
1	25 µg/mL	0.531
2	20 µg/mL	0.421
3	15 µg/mL	0.335
4	10 µg/mL	0.228
5	5 µg/mL	0.128

Plotting concentration (µg/mL) on the X-axis and absorbance on the Y-axis allowed for the creation of a calibration curve. Concentration and absorbance have a linear relationship, according to the calibration graph that was produced [45]. The calibration curve's linearity demonstrates the UV spectrophotometric method's dependability and appropriateness for the quantitative measurement of ketoconazole.

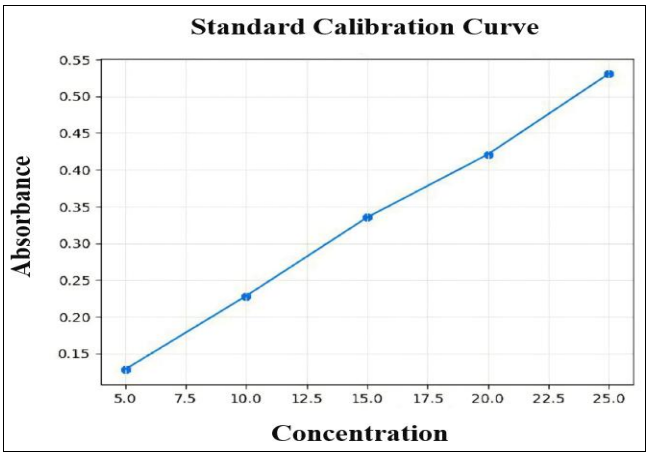


Fig 6: Calibration curve of Ketoconazole obtained by UV spectrophotometric method

For doses of 5, 10, 15, 20, and 25 µg/mL, the corresponding measured absorbance values were 0.128, 0.228, 0.335, 0.421, and 0.531. These findings support the linear behavior of ketoconazole in the chosen analytical range by showing a steady rise in absorbance with increasing concentration [46].

The calibration curve derived from the experimental data demonstrated good linearity, indicating that the established UV spectrophotometric approach for ketoconazole quantification is straightforward, precise, and dependable. As a result, ketoconazole in pharmaceutical formulations can be routinely analyzed using this approach [47].

Preparation of Ketoconazole Hair Spray

Materials

Formulation of the antifungal hair spray was prepared using all excipients. The formulation components, quantities and their roles are listed below.

Table 2: Ingredients of Formulation

S. No	Ingredient	Role	Quantity (per 100 mL)
1	Ketoconazole	API	2.0 g
2	Ethanol	Solvent	65 mL
3	Propylene glycol	Humectant	5.0 mL
4	Polysorbate 80	Emulsifier	0.5 mL
5	HPMC or HPC	Film former	1.0 g (dissolved)
6	Phenoxyethanol	Preservative	0.5 mL
7	Sodium hydroxide	pH adjuster	q.s.
7	Rosemary	Fragrance	0.1 mL

Method of Preparation

First, a clear solution was achieved by dissolving propylene glycol in an amount of purified water and stirring the mixture. After that, polysorbate 80 was added to the mixture while being constantly stirred to guarantee even mixing.

In a separate beaker, ethanol was utilized as the solvent phase. To create a uniform and transparent solution, the

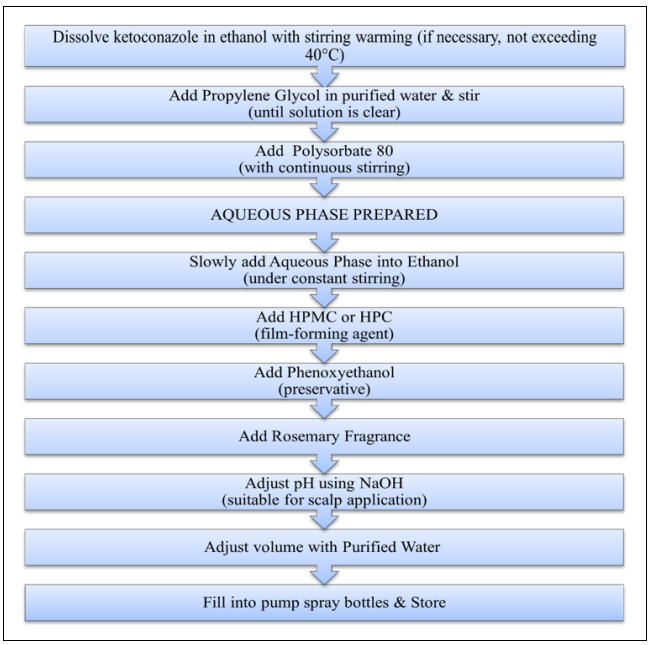
previously produced aqueous phase was gradually added to the ethanolic phase while being continuously stirred.

Fig 7: Preparation of formulation

HPMC was added as a film-forming ingredient and given enough time to disperse after thorough mixing. After adding phenoxyethanol as a preservative, rosemary was added as a scent.

A sodium hydroxide solution was used to alter the formulation's pH to a level appropriate for scalp application. Lastly, filtered water was used to regulate the volume. Pump spray bottles were filled with the finished clear solution and kept for further analysis.

Flow Chart



Evaluation Test

1. Organoleptic Test

Definition: This assessment evaluates the physical sensory characteristics of the formulation, including its color, clarity, and odor.

2. Homogeneity Test

Definition: This visual and physical inspection checks the formulation for uniform active ingredient distribution and the absence of phase separation or visible particles.

3. pH Test

Definition: This test measures the acidity or alkalinity of the hair spray formulation using a calibrated pH meter.

4. Viscosity Test

Definition: This test quantifies the internal friction and resistance to flow of the liquid formulation, usually measured in centipoise (cP).

5. Spray Pattern Test

Definition: This test evaluates the geometric distribution, shape, and uniformity of the mist generated by the spray nozzle.

6. Spreadability Test

Definition: This test measures the ability of the formulation to expand and glide smoothly across a surface under a specific amount of force.

7. Evaporation/Drying Time

Definition: This parameter measures the exact duration required for the applied spray formulation to dry completely on a surface.

8. Irritation Test

Definition: This safety evaluation monitors the skin for signs of adverse reactions like erythema (redness) or edema (swelling) after application.

9. Stability Test

Definition: This study monitors the physical and chemical properties of the formulation over time under varying temperature and humidity conditions.

Results & Discussions

1. **Organoleptic Test:** The formulation was clear, colorless, and had a pleasant odor, indicating good patient aceptability.

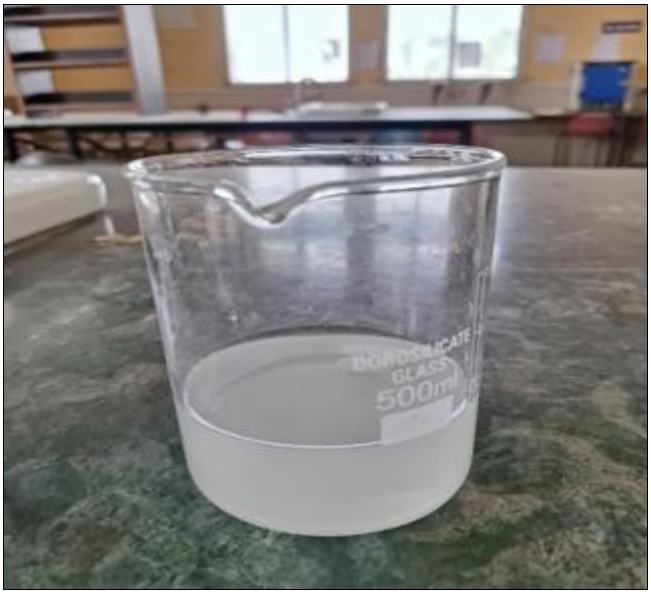


Fig 8: Organoleptic Test

2. **Homogeneity test:** The formulation was found to be homogeneous, clear, and free from any visible particles or phase separation, indicating uniform distribution of ingredients.

Fig 9: Homogeneity test

3. **pH test:** The pH of the ketoconazole hair spray formulation was found to be 6.25 which lies within the acceptable range for scalp application, indicating good compatibility and minimal irritation potential.

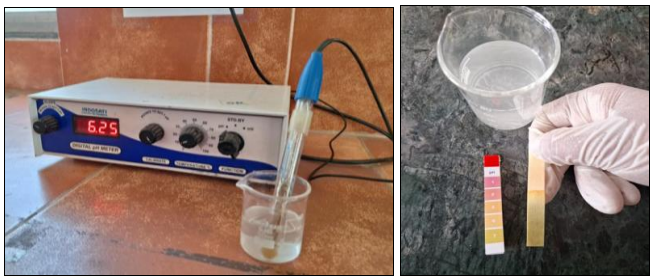


Fig 10: pH test

4. **Viscosity:** The viscosity of the formulation was 3.5 cP, indicating suitable flow properties for easy spraying.
5. **Spray Pattern Test:** The spray pattern was found to be uniform and circular, indicating good atomization and proper nozzle performance.

Fig 11: Spray Pattern Test

6. **Spreadability Test:** Indicating good spreading ability and ease of application on the scalp.

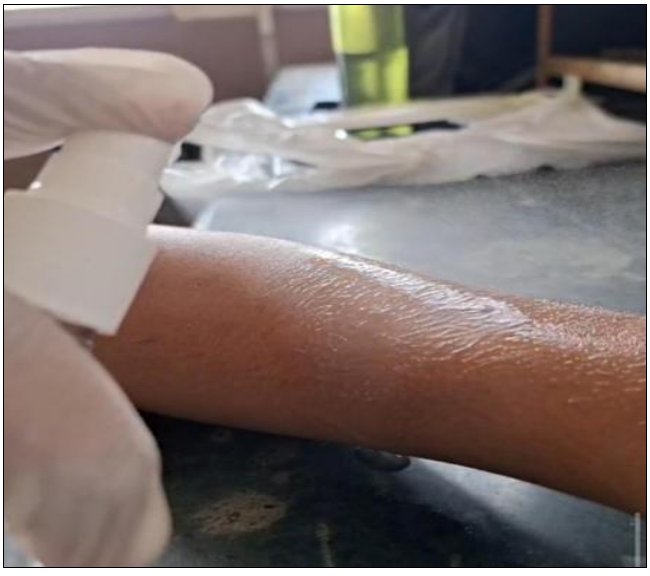


Fig 12: Spreadability Test

7. **Evaporation/ Drying Time:** The formulation dried within 60 seconds, ensuring convenience and user compliance.
8. **Irritation Test:** No signs of erythema, edema, or irritation were observed during the study period, indicating that the formulation is non-irritant and safe for topical application.
9. **Stability Test at Room Temperature:** Under both long-term and accelerated conditions, the ketoconazole hair spray formulation's stability studies showed no appreciable changes in physicochemical parameters such pH, viscosity, drug content, and spray characteristics. Over the course of the research, the formulation remained safe, stable, and effective.

Table Brief summary of evaluation parameter

S. No	Test	Observation
1	pH	6.25
2	Homogeneity test	Passed
3	Spread ability test	9-10cm
4	Viscosity test	Not viscous
5	Irritation test	No irritation
6	Stability test	3months
7	Spread ability	Easily spreadable

Outcomes

In terms of therapeutic efficacy, patient compliance, and formulation performance, the development and testing of ketoconazole antifungal hair spray for the treatment of Tinea capitis produces a number of positive results. The goal of creating this innovative topical delivery system is to get beyond the drawbacks of traditional topical and oral antifungal treatments.

1. Enhanced Therapeutic Efficacy
2. Improved Drug Retention and Controlled Release
3. Reduced Systemic Side Effects
4. Better Patient Compliance and Acceptability
5. Stable and Safe Formulation
6. Improved Localized Drug Delivery
7. Potential for Commercial and Clinical Application

Future Prospectives

A noteworthy development in topical medication delivery systems for the treatment of Tinea capitis is the creation of ketoconazole antifungal hair spray. Even while recent research shows promising outcomes in terms of efficacy, stability, and patient compliance, there is still a great deal of room for advancement, creativity, and clinical validation.

1. Development of Advanced Drug Delivery Systems
2. Combination Therapy Approaches
3. Exploration of Herbal and Bioactive Additives
4. Smart and Patient-Centric Formulations
5. Clinical Trials and Long-Term Safety Studies
6. Improved Packaging and Delivery Systems
7. Commercialization and Scalable Production

Conclusion

Tinea capitis is still a major dermatological concern, especially for children and people living in tropical areas. Poor patient compliance, systemic side effects, and insufficient medication penetration into the scalp and hair follicles are common problems with conventional antifungal therapy, including oral and topical preparations. The

creation of a ketoconazole antifungal hair spray is a novel and promising strategy for the successful treatment of fungal infections of the scalp in order to overcome these obstacles.

The broad-spectrum imidazole antifungal drug ketoconazole has strong activity against the dermatophytes that cause tinea capitis. It can be incorporated into a spray formulation to administer drugs in a targeted, homogenous, and localized manner with minimum systemic exposure and improved penetration. The spray form guarantees enhanced patient acceptability, rapid drying, and ease of application—features that greatly improve therapeutic adherence.

Drug stability, retention, and prolonged release can be further enhanced by formulation optimization with the right solvents, polymers, and excipients. Furthermore, innovations like combination sprays, polymeric systems, and nanoformulations have a lot of potential to improve the safety and effectiveness of ketoconazole-based treatments.

To sum up, ketoconazole hair spray is a practical, effective, and patient-friendly topical treatment option for tinea capitis. This innovative delivery system may become a useful therapeutic option in contemporary antifungal therapy with further study concentrating on formulation improvement, clinical validation, and large-scale development.

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