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FORMULATION DEVELOPMENT AND EVALUATION OF CLOTRIMAZOLE LOADED TOPICAL PAINT USING NITROCELLULOSE POLYMER FOR EFFECTIVE ANTIFUNGAL THERAPY

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ABSTRACT

The present study was aimed at formulation development and evaluation of topical paint containing Clotrimazole for effective antifungal therapy. Fungal infections affecting skin and mucosal tissues require prolonged local treatment, and topical drug delivery systems offer advantages including localized action, reduced systemic side effects, and improved patient compliance. Clotrimazole, a broad-spectrum antifungal drug, was selected as the active pharmaceutical ingredient and Nitrocellulose polymer was selected as film-forming polymer for preparation of topical paint formulation. Preformulation studies including organoleptic properties, solubility analysis, melting point determination and drug-polymer compatibility study using Fourier Transform Infrared Spectroscopy (FTIR) were performed. Compatibility study confirmed absence of chemical interaction between drug and polymer. Eight formulations (F1–F8) were prepared by solvent evaporation method using varying polymer concentration and plasticizer concentration. Prepared formulations were evaluated for drying time, viscosity, non-volatile content, film integrity, drug content uniformity and antifungal activity using zone of inhibition method. Results indicated that optimized formulation showed satisfactory film formation, acceptable viscosity, good drug content and effective antifungal activity against fungal strain. The study concluded that Clotrimazole topical paint formulation can serve as a promising topical antifungal delivery system with improved therapeutic efficacy and patient convenience.

KEYWORDS: Clotrimazole, Topical Paint, Nitrocellulose, Antifungal Therapy, FTIR Compatibility Study, Film Forming Polymer.

INTRODUCTION

Topical drug delivery systems have gained considerable importance in pharmaceutical formulation development because they allow localized delivery of therapeutic agents directly to the site of infection while minimizing systemic side effects. Among topical dosage forms, topical paint preparations represent an effective dosage form where medicated liquid formulation is applied on skin or mucosal surface and forms a thin protective film after solvent evaporation.

Fungal infections remain one of the most common dermatological disorders affecting millions of individuals worldwide. Superficial fungal infections caused by Candida species, dermatophytes and related organisms require prolonged antifungal treatment for complete eradication. Conventional creams and ointments sometimes exhibit poor retention at site of application and may require repeated administration.

Clotrimazole is an imidazole derivative widely used as broad-spectrum antifungal drug effective against Candida albicans, Aspergillus species and dermatophytes. It inhibits fungal growth by interfering with ergosterol biosynthesis, an essential component of fungal cell membrane. Due to its broad antifungal spectrum and safety profile, Clotrimazole is considered suitable candidate for topical delivery systems.

Nitrocellulose polymer possesses excellent film-forming ability and therefore has been extensively used in pharmaceutical topical preparations. It rapidly forms thin adhesive film upon solvent evaporation, making it suitable for topical paint formulation. Addition of suitable plasticizer improves flexibility and mechanical strength of formed film.

The present research work focused on formulation development of Clotrimazole loaded topical paint using Nitrocellulose polymer and systematic evaluation of physicochemical characteristics and antifungal activity of prepared formulations.

MATERIALS AND METHODS

Materials

The following materials were used during formulation development:

- Clotrimazole (Active Pharmaceutical Ingredient)
- Nitrocellulose (Film Forming Polymer)
- Ethanol (Solvent)
- Dibutyl Phthalate (Plasticizer)
- Propylene Glycol
- Distilled Water
- Analytical Grade Chemicals

All chemicals and reagents used during study were of pharmaceutical or analytical grade.

METHODOLOGY

The research work was divided into following stages:

- Preformulation studies of drug
- Drug polymer compatibility study by FTIR
- Formulation development of topical paint
- Optimization of polymer concentration
- Evaluation of prepared formulations
- Antifungal activity study
- Statistical comparison and optimization

PREFORMULATION STUDIES

Preformulation studies were performed to determine physicochemical properties of drug and compatibility with selected excipients.

Organoleptic Evaluation

Drug sample was examined for color, odor and physical appearance.

Parameter	Observation
Color	White
Odor	Odorless
Appearance	Crystalline Powder

Solubility Study

Solubility of Clotrimazole was studied in different solvents.

Solvent	Solubility
Water	Slightly Soluble
Ethanol	Soluble
Methanol	Freely Soluble
Chloroform	Soluble

Melting Point Determination

Melting point was determined by capillary method.
Observed melting point = 146°C – 148°C

Drug Polymer Compatibility Study by FTIR

Drug polymer compatibility study was performed using FTIR spectroscopy in order to determine possible interaction between Clotrimazole and Nitrocellulose polymer.

Pure drug, polymer and physical mixture were analyzed in spectral range of 4000–500 cm^{-1} using potassium bromide pellet method.

Characteristic peaks of pure drug and polymer were compared with physical mixture.

The study showed retention of all characteristic peaks without significant shifting, confirming absence of chemical interaction and indicating compatibility between drug and polymer.

FORMULATION DEVELOPMENT

Eight formulations (F1–F6) of Clotrimazole topical paint were prepared by varying concentration of Nitrocellulose polymer and plasticizer. Solvent evaporation technique was employed for preparation of formulations.

Table 1: Composition of Formulations.

Ingredients	F1	F2	F3	F4	F5	F6
Clotrimazole (mg)	100	100	100	100	100	100
Nitrocellulose (%)	2.5	5	7.5	10	12.5	15
Dibutyl Phthalate (ml)	0.2	0.3	0.4	0.5	0.6	0.7
Ethanol (ml)	q.s	q.s	q.s	q.s	q.s	q.s

Preparation involved dissolving Nitrocellulose polymer in ethanol followed by addition of Clotrimazole with continuous stirring. Plasticizer was incorporated gradually and final volume adjusted with solvent. Prepared formulations were stored in airtight containers.

EVALUATION OF FORMULATIONS

Prepared formulations were evaluated for physicochemical characteristics.

Drying Time

Drying time determines film formation efficiency after topical application.

Table 2: Drying Time Evaluation.

Formulation	Drying Time (sec)
F1	42
F2	39
F3	36
F4	34
F5	32
F6	30

Decrease in drying time was observed with increase in polymer concentration.

Viscosity Determination

Viscosity was determined using Brookfield viscometer.

Table 3: Viscosity Study.

Formulation	Viscosity (cps)
F1	118
F2	124
F3	132
F4	145
F5	156
F6	167

Increase in polymer concentration resulted in gradual increase in viscosity.

Non-Volatile Content

Non-volatile content determines film residue after evaporation.

Table 4: Non-Volatile Content.

Formulation	Percentage (%)
F1	21.5
F2	24.2
F3	27.4
F4	31.6
F5	34.8
F6	37.2

Increase in polymer concentration increased non-volatile content.

Drug Content Uniformity

Drug content ensures uniform drug distribution.

Table 5: Drug Content Study.

Formulation	Drug Content (%)
F1	91.4
F2	92.6
F3	93.7
F4	95.2
F5	96.1
F6	97.4

All formulations showed acceptable drug content uniformity.

Film Integrity Test

Film integrity was observed after drying.

Table 6: Film Integrity.

Formulation	Observation
F1	Good
F2	Good
F3	Good
F4	Very Good
F5	Very Good
F6	Excellent

ANTIMICROBIAL ACTIVITY

Antifungal activity was evaluated using agar diffusion method against fungal strain.

Table 7: Zone of Inhibition.

Formulation	Zone of Inhibition (mm)
F1	16
F2	17
F3	18
F4	19
F5	21
F6	22

Optimized formulations demonstrated better antifungal activity due to uniform drug release.

RESULTS AND DISCUSSION

Preformulation studies confirmed suitability of drug for topical paint formulation. FTIR compatibility study demonstrated absence of chemical interaction between Clotrimazole and Nitrocellulose polymer.

All formulations showed satisfactory physicochemical characteristics. Increase in polymer concentration improved viscosity, non-volatile content and film integrity. Drug content remained within acceptable range for all formulations.

Antifungal activity evaluation showed gradual increase in zone of inhibition from F1 to F6. Formulation F6 exhibited maximum antifungal activity indicating improved formulation performance.

Nitrocellulose polymer effectively formed uniform film over applied surface and facilitated sustained local antifungal action.

CONCLUSION

The present study successfully developed Clotrimazole loaded topical paint formulation using Nitrocellulose polymer.

Preformulation studies confirmed compatibility between drug and polymer. Eight formulations were prepared and systematically evaluated for physicochemical and biological characteristics.

Among prepared formulations, higher polymer concentration formulations demonstrated better film formation, good drug content uniformity and superior antifungal activity.

The developed topical paint formulation can be considered promising drug delivery system for effective management of fungal infections with improved patient compliance.

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