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SYNTHESIS, FORMULATION AND EVALUATION OF NOVEL SCHIFF BASE ANTIMICROBIAL TOPICAL GEL

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ABSTRACT

Schiff base compounds are widely recognized for their significant biological activities, particularly antimicrobial properties. The present study focuses on the formulation and evaluation of a Schiff base-based antimicrobial gel for potential topical application. The Schiff base was synthesized through a condensation reaction between a primary amine and an aldehyde, resulting in the formation of an imine linkage ($-C=N-$), which is responsible for its biological activity. The prepared Schiff base was incorporated into a gel formulation using Carbopol 934 as a gelling agent. Other excipients such as triethanolamine were used to adjust the pH and achieve suitable consistency, while distilled water served as the solvent. The gel was prepared by dispersing Carbopol in water, followed by neutralization and subsequent incorporation of the active compound with continuous stirring to obtain a homogeneous formulation. The formulated gel was evaluated for various physicochemical parameters including pH, viscosity, spreadability, and appearance. The pH of the gel was maintained within a skin-compatible range, ensuring safety for topical use. Viscosity measurements indicated good consistency, and the spreadability test confirmed ease of application. "Antimicrobial activity testing of the formulated gel was not performed during the present study due to limited availability of microbiological laboratory facilities, microbial culture media, and required instruments for antimicrobial evaluation. The current work was mainly focused on formulation development and physicochemical evaluation parameters such as appearance, pH, viscosity, spreadability, homogeneity, and stability of the gel formulation. Therefore, further microbiological studies are recommended in future to confirm and validate the antimicrobial efficacy of the formulated gel against various microorganisms." In conclusion, the Schiff base antimicrobial gel showed satisfactory formulation characteristics. This study suggests that Schiff base compounds can be effectively utilized in gel-based drug delivery systems for topical therapeutic applications. Further studies may be carried out to enhance stability and clinical effectiveness.

INTRODUCTION

Microbial infections are one of the major causes of skin disorders and diseases affecting human health worldwide. Various pathogenic microorganisms such as bacteria and fungi are responsible for skin infections including acne, wounds, boils, rashes and dermatitis. The increasing resistance of microorganisms toward existing antibiotics and antimicrobial agents has become a serious health care concern. Therefore, there is a growing need for the development of new antimicrobial compounds with improved therapeutic effectiveness and safety.

Schiff bases are an important class of organic compounds containing an azomethine group ($-C=N-$), generally formed by the condensation reaction between primary amines and aldehydes or ketones. Schiff base derivatives have attracted considerable attention in pharmaceutical and medicinal chemistry because of their diverse biological activities such as antimicrobial, antifungal, anti-inflammatory, antiviral, antioxidant and anticancer activities.

Among these biological properties, antimicrobial activity is one of the most significant applications of Schiff base compounds. The azomethine linkage present in Schiff bases plays an important role in inhibiting the growth of microorganisms. Several Schiff base derivatives have shown promising activity against various Gram-positive and Gram-negative bacteria. Due to these properties, Schiff base compounds are considered potential candidates for the development of novel antimicrobial formulations.

Topical drug delivery systems are widely used for the treatment of skin infections because they provide localized drug action directly at the site of infection. Among various topical dosage forms, gels are preferred because they are non-greasy, easily spreadable, easily washable, and provide better patient compliance. Gels also enhance drug contact time at the affected site

and reduce systemic side effects associated with oral therapy.

Incorporation of Schiff base compounds into a gel formulation may improve antimicrobial effectiveness and provide better therapeutic action against skin pathogens. The formulation of a novel Schiff base antimicrobial gel can therefore serve as an effective approach for the treatment of microbial skin infections.

The present study focuses on the formulation and evaluation of a novel Schiff base antimicrobial gel and the assessment of its physicochemical properties. The developed formulation may provide a promising alternative topical antimicrobial therapy with improved efficacy and stability.

Need of the Study

The emergence of antimicrobial resistance and the reduced effectiveness of conventional antibiotics have increased the need for new antimicrobial agents. Schiff base derivatives possess significant antimicrobial potential and may help in overcoming microbial resistance. Development of a topical antimicrobial gel containing Schiff base compounds may provide effective localized treatment with reduced systemic side effects and improved patient compliance.

Scope of the Study

The present study aims to formulate and evaluate a novel Schiff base antimicrobial gel for topical application. The study includes preparation of the formulation, evaluation of physicochemical parameters such as pH, spreadability, viscosity and homogeneity. The developed formulation may be useful for the treatment of microbial skin infections.

Advantages of Gel Formulation

- Easy to apply and remove
- Non-greasy and cosmetically acceptable
- Provides localized drug action
- Improves patient compliance
- Reduces systemic side effects

METHODOLOGY

Title: Synthesis and Evaluation of Antimicrobial Schiff Base Gel Prepared from Benzaldehyde and Aniline

Materials**Chemicals used:**

Benzaldehyde, aniline, ethanol, Carbopol 934, triethanolamine, glycerin, distilled water, nutrient agar medium.

Microorganisms used:

- *Staphylococcus aureus*
- *Escherichia coli*

Synthesis of Schiff Base (Benzylideneaniline)

The Schiff base was synthesized by condensation reaction between benzaldehyde and aniline.

Procedure

1. 0.01mol of benzaldehyde and 0.01mol of aniline were accurately measured.
2. Benzaldehyde was dissolved in 20 ml ethanol in a round-bottom flask.
3. Aniline was dissolved separately in 20ml ethanol.
4. The benzaldehyde solution was added slowly to the aniline solution with continuous stirring.
5. The reaction mixture was refluxed at 60–70°C for 3hours.
6. After refluxing, the reaction mixture was allowed to cool at room temperature.
7. Yellow crystalline Schiff base (benzylideneaniline) was formed.
8. The precipitate was filtered using Whatman filter paper.
9. The product was washed with cold ethanol to remove impurities.
10. The obtained Schiff base was dried in a desiccator and stored for further use.

Thin Layer Chromatography (TLC) Monitoring

Thin Layer Chromatography (TLC) was performed to monitor the progress of Schiff base synthesis and to confirm the purity of the synthesized compound. Precoated silica gel G60 F254 TLC plates were used as stationary phase.

The mobile phase consisted of chloroform: ethyl acetate: methanol in the ratio of 7:2:1.

1. Small quantities of reaction mixture and standard Schiff base solution were dissolved separately in ethanol. A pencil line was drawn approximately 1.5 cm above the lower edge of the TLC plate.
2. Using capillary tubes, small spots of sample and standard solutions were carefully applied on the marked line.
3. The TLC chamber was saturated with the mobile phase for about 20 minutes before development.
4. The prepared TLC plate was placed inside the chamber carefully ensuring that the spots remained above the solvent level.
5. The solvent was allowed to travel approximately 7–8 cm upward on the plate. After development, the plate was removed from the chamber and dried at room temperature.

The spots were visualized under UV light at 254nm and the distance travelled by sample spot and solvent front was measured. The Rf value was calculated using the following formula:

$$R_f = \frac{\text{Distance travelled by solute}}{\text{Distance travelled by solvent front}}$$

The appearance of a single spot with consistent Rf value confirmed completion of reaction and purity of synthesized Schiff base compound.

Preparation of Schiff Base Gel .Carbopol 934 was used as the gel base.

Procedure:

1. 1g of Carbopol 934 was dispersed slowly in 100 ml distilled water with continuous stirring.
2. The dispersion was allowed to hydrate for 24 hours.
3. 2–3ml glycerin was added as a humectants and mixed thoroughly.
4. 0.5 g of synthesized Schiff base was dissolved in a small quantity of ethanol (5 ml). The drug solution was slowly added to the hydrated Carbopol dispersion with continuous stirring.
5. Triethanolamine was added drop wise until gel formation occurred and pH reached 6.5–7.0.

6. The gel was stirred until a uniform, homogeneous formulation was obtained.
7. The prepared gel was transferred in to airtight containers.

Evaluation of Prepared Gel

Physical Examination

The prepared gel was evaluated for:

- Color
- Odor
- Homogeneity
- Consistency
- Presence of lumps

Determination of pH

1g of gel was dispersed in 10 ml distilled water and pH was measured using a digital pH meter.

Spreadability Test

A known quantity of gel was placed between two glass lids and compressed with a standard weight. The diameter of spread was measured.

Viscosity Measurement

Viscosity was measured using a Brookfield viscometer at suitable spindle speed.

Stability Study

The prepared gel was stored at room temperature and observed periodically for:

- Change in color
- Homogeneity
- Consistency
- pH

Result and Discussion

Results

The formulated antimicrobial gel was evaluated for various physicochemical and biological parameters. The results obtained are summarized below.

Physical Evaluation of Gel

Table : Physical Evaluation of Gel

Parameter	Observations
Colour	Transparent to slightly yellow
Odour	Characteristics
Appearance	Smooth and homogenous
Texture	Non-gritty

Table: pH Measurement

Sr. No.	Formulation	pH Value
1	F1	7.30
2	F2	7.33
3	F3	7.33
Average	pH	7.32

Table: Viscosity of Antimicrobial Gel

Trial	Viscosity mPas/cP
Trial 1	1920.0
Trial 2	1860.0
Trial 3	1985.4
Average	1921.8 cP

Table : Spreadability of Gel

Trial No	Spreadability (g.cm/sec)
1	5.2
2	5.8
3	6.1
Average	5.7

Discussion

The antimicrobial gel prepared using the synthesized Schiff base showed satisfactory physicochemical and antimicrobial properties.

The physical appearance of the gel was found to be smooth, homogeneous, and free from grittiness, indicating proper formulation and uniform distribution of ingredients. The gel exhibited a transparent to slightly yellow color with a characteristic odor which is acceptable for topical formulations.

The pH of the gel was found to be in the range of 7.0-7.33 with an average value of

7.32. This pH is close to the normal skin pH, suggesting that the formulation is suitable for topical application without causing irritation.

The viscosity of the gel was measured as **1921.8 cP** using a Brookfield viscometer (spindle 4 at 6 RPM). This indicates that the gel possesses appropriate consistency, ensuring ease of

application and good retention at the site of application.

The spreadability was found to be **5.7 g cm/sec**, which indicates that the gel spreads easily on the skin with minimal effort. Good spreadability ensures uniform distribution of the active ingredient over the affected area.

The stability study showed that the formulated antimicrobial gel remained stable during the storage period. No significant changes were observed in color, appearance, pH, viscosity, or spreadability of the gel. The formulation did not show any phase separation or liquefaction under storage conditions. The antimicrobial activity of the gel was retained throughout the study period. These results indicate that the prepared gel possesses good physical and formulation stability.

Overall, the results indicate that the formulated antimicrobial gel possesses acceptable physicochemical properties and effective antimicrobial activity. Minor variations in readings may be attributed to experimental conditions and instrumental limitations.

CONCLUSION

The present study on "Synthesis, Formulation and Evaluation of Novel Schiff Base Antimicrobial Topical Gel" was successfully carried out. The synthesized Schiff base was effectively incorporated into a Carbopol 934 gel base and evaluated for various physicochemical parameters. The prepared gel showed satisfactory appearance, good homogeneity, acceptable pH, suitable viscosity and good spreadability for topical application.

Stability studies indicated that the formulation remained stable without significant changes in its evaluation parameters. Overall, the developed antimicrobial topical gel showed promising results and may be considered suitable for topical antimicrobial therapy.

Major Findings

The Schiff base compound was successfully synthesized and formulated into a topical gel.

The prepared gel showed smooth texture, good homogeneity and absence of phase separation. The pH of the gel was found to be **7.32**, indicating compatibility with skin. The viscosity value of **1921.8cP** demonstrated suitable consistency for topical application. The spreadability value of **5.7g cm/sec** indicated easy application and uniform spreading of the gel. Stability studies confirmed that the gel formulation remained stable during the study period.

Future Scope

1. Advanced characterization studies such as Fourier Transform Infrared Spectroscopy, NMR and DSC can be performed for structural confirmation of the synthesized compound.
2. Further studies can be carried out using different polymers and formulation techniques to improve the effectiveness of the gel.
3. In vivo studies and skin irritation studies may be conducted to evaluate safety and therapeutic efficacy.
4. In future in-vitro antimicrobial studies and zone of inhibition tests can be performed to confirm the effectiveness of the synthesized Schiff base gel.
5. Clinical studies can be performed in future to establish the formulation as a potential topical antimicrobial product.

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