Research Article

# Cosmeceutical for Cracked Heels: Development of Antifungal Film forming Gel using Traditional Pigment (Alta)

**Ashlesha Lambat, Avinash Kudhekar*, Vinita Kale, Rashmi Trivedi, Milind Umekar**
Smt. Kishoritai Bhoyar College of Pharmacy, Kamptee, Nagpur, Maharashtra, India- 441002.
***Corresponding author's E-mail:** avinashkudhekar1@gmail.com

**Received:** 06-03-2024; **Revised:** 23-04-2024; **Accepted:** 30-04-2024; **Published on:** 15-05-2024.

**ABSTRACT**

Cracked heels, resulting from thick, dry skin, pose risks of painful fissures and infections, especially in extreme weather conditions. Addressing the challenge of maintaining skin moisture balance, traditional treatments often fall short due to poor adhesion and compliance issues. In response, a cosmeceutical Alta gel formulation, incorporating turmeric extract and clotrimazole, was developed to enhance healing and aesthetics. Employing Response Surface Analysis, a Plackett Burmen statistical screening design assessed and optimized the formulation, with concentrations of key ingredients analyzed as independent variables and spreadability, viscosity, and color concentration as dependent variables. Results indicated color concentration significantly impacted viscosity, with the optimized formulation demonstrating favorable drying time, spreadability, and antimicrobial activity. This modified Alta pigment gel formulation, with film-forming properties and clotrimazole, exhibits promising characteristics for potential cosmetic applications, offering substantial antibacterial activity, improved cosmetic appeal, and non-staining properties.

**Keywords:** Topical Film-forming gel, Antimicrobial, Cracked heel, Regulations.

## INTRODUCTION

The thick, dry skin on the bottom of the heels can crack, split, and produce fissures, resulting in cracked heels. If the cracks aren't fixed, the heel fissures deepen and can become infected. Because the pores in the outermost layers close during an intense winter, cracks on the heels form. Low humidity in the air makes this issue worse.[1] Due to the migration of water from the deepest skin layers and subsequent evaporation from the outer skin surface in a low-humidity environment, cracks on heels also appear during the hottest summer months. In both situations, it's important to encourage wound healing and protect the integrity of the skin by maintaining a balance in the water content of the skin's layers.

Infection in cracked heels is untreated it can result in painful uncomfortable side effects like oedema, redness, and even cellulitis.[2]

Effective antimicrobials for treating these infections include the antifungal clotrimazole and the antibacterial turmeric extract. Clotrimazole combats fungal growth, while turmeric extract addresses bacterial infections. Together, they can offer a formulation for treating infections in cracked heels, lowering inflammation, and minimizing other problems, providing relief and encouraging the restoration of healthy skin.

The majority of medicines in the market are creams that are intended to treat infections brought on by cracked heels. These creams often contain a synthetic or natural antimicrobial agent along with some moisturizing and emollient properties.

Although there are several formulations for cracked heels on the market, so as to treat disorders of the body tissues, the medication needs to be remained at the treatment site for an adequate length of time. Traditional cracked heel creams have drawbacks such poor skin adhesion, low permeability, and decreased patient compliance.

In addition to their medicinal advantages, topical therapies must be visually pleasing. Cosmetic product Pure Alta has a stunning appearance and is captivating.[3] Natural colors or dyes are made mostly from primary materials such fruits, flowers, leaves, roots, and tree barks. Numerous activities, including painting, decorative arts, and garment adornment, as well as religious or cultural ceremonies, use these chemical compounds.[4] Alta is a liquid colour pigment that women use to paint their feet in the vast majority of India. Both an orange-coloured and a deep red-coloured version of the pure Alta formulation are available. Alta is mostly calming and safe for the skin. The liquid nature of the current Alta formulations has the two problems of occasionally making application messy and staining the user's clothing.

There is a need for cosmeceutical preparations that address drawbacks seen in liquid and cream formulations. These problems include colour staining and application to the skin in case of liquid Alta and in cracked heel creams the poor skin adhesion, low permeability, and reduced patient compliance. Innovative cosmeceuticals that enable effective and stain-free application, improved skin adherence, and increased cosmetic compliance will greatly improve the use and effectiveness of skincare and cosmetic products. Cosmeceuticals are cosmetic-pharmaceutical hybrids intended to enhance health and beauty through ingredients that influence the skin's biological texture and function.[5]

Accordingly, in this work a cosmeceutical film forming modified, Alta gel, formulation containing turmeric extract and clotrimazole for cracked heel is developed. This cosmeceutical formulation will help in healing of cracks and to provide aesthetic look to the heel because of its dye colour similar to traditional Alta.

In order to create a cosmeceutical film-forming gel for cracked heels, active moisturizing chemicals must be combined with substances that form films, such as polymers. These gels are made to stick to the skin, forming a barrier that keeps moisture in and speeds up the healing of cracked heels skin. Emollients, humectants, gelling agents, and additions like antifungal, herbal extracts and colouring dye to improve skin repair and cosmetic look are frequently important ingredients. The resulting cosmeceutical gel will be simple to use, dries quickly, and effectively addresses the pain and aesthetic issues connected to cracked heels.

## MATERIALS AND METHODS

### Materials

All the materials were obtained from the college laboratory. Turmeric powder was purchased from the market.

### Methods

#### *Preparation of Traditional Pigment (Alta)*

The powders of turmeric, alum, and borax were mixed together in a mortar and pestle to produce a homogeneous powder mixture. After that, citric acid was dissolved in the required volume of water to create a citric acid solution. The powder mixture was then added to the above solution and well-stirred until a slurry formed (Table 1). The reaction is allowed to take place for 2 days and then pigment solution is separated and dried completely into pigment powder.

**Table 1:** Preparation of Alta Pigment and Antibacterial film forming gel.

| Preparation of Alta Pigment | | |
|---|---|---|
| **Sr. No** | **Ingredients** | **Uses** |
| 1. | Turmeric | Antiseptic |
| 2. | Alum powder | Astringent |
| 3. | Borax powder | Antifungal /alkalizer |
| 4. | Citric acid | Stabilizer |
| 5. | Water | vehicle |
| **Formulation Ingredients of Antibacterial Film forming Gel** | | |
| **Sr. No** | **Ingredients** | **Uses** |
| 1. | Ethylcellulose | Film-forming polymer |
| 2. | Hydroxy propyl cellulose | Film-forming polymer |
| 3. | Propylene glycol | Plasticizer |
| 4. | Pigment (Alta) | Coloring agent |
| 5. | Ethanol | Vehicle, permeation enhancer |
| 6. | Clotrimazole | Antimicrobial agent |

#### *Preparation of Modified Traditional Pigment Film Forming Gel*

Ethyl cellulose and Hydroxy Propyl Cellulose were dissolved in 96% ethanol, which was then agitated at 50 rpm using a magnetic stirrer to make a transparent polymeric solution. Propylene glycol was added to the clear polymeric solution as a plasticizer (Table 1). The remaining amount of ethanol and the precisely weighed amount of pigment slurry were added to the resulting clear solution, and the mixture was continuously agitated at 50 rpm until it was a uniform red colour film forming gel.

### Elements of Quality by Design for Formulation Design

#### *Definition of QTPP and CQAs:*

The initial phase of product development, rooted in the Quality by Design principle, begins with defining the Quality Target Product Profile (QTPP). This comprehensive profile encompasses various parameters such as product formulation, dosage, route of administration, appearance, skin integrity, stickiness, drying time, spreadability, viscosity, cosmetic appeal, color concentration, and antimicrobial activity, among others. Through careful consideration of the QTPP, the foundation for product development is established. Subsequently, the focus shifts to identifying Critical Quality Attributes (CQAs) derived from the QTPP specifications. This step is crucial in determining the key characteristics that define the quality of the final product, guiding the subsequent stages of development.[6]

#### *Identification of critical material attributes and critical process parameters*

Critical material attributes (CMAs), which were linked to formulation preparation's composition, were the important factors that can affect CQA variability. The next set of factors influencing the variability of Critical Quality Attributes (CQAs) are termed Critical Process Parameters (CPPs). These parameters are directly associated with the manufacturing process of formulations. Identifying and controlling CPPs are essential steps in ensuring consistent product quality and meeting the defined QTPP specifications.

#### *Risk Assessment*

The ICH Q9 guidance states that "identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards" constitute risk assessment.[7] Due to the potential for identifying potential hazards in the formulation and process that could affect the quality of the finished product, this component was crucial throughout the development stage. Using the Ishikawa diagram, the risk assessment was conducted. The qualitative risk assessment was carried out using the FMEA method, which could pinpoint the CQAs most likely to result in product failure, i.e., not satisfying the QTPP (Table 2).

***Design of experiment***

MINITAB 17 statistical software (trial version) was utilized in this study to optimize the formulation of topical film-forming gel process parameters. The Central Composite Design (CCD) approach was used to conduct this research after employing the Plackett Burman Design (PBD) method.[8] The aim of use of these tools was to identify the significant variables that will affect the intended responses and then study how those variables will affect those responses to determine the best values for producing the most acceptable result. The effects of three independent variables—pigment concentration, plasticizer concentration, and hydroxy propyl cellulose concentration—were screened, and experimental trials were run in all 12 potential combinations. For independent variables, low levels (-1), medium levels (0), and high levels (+1) were chosen (Table 3). The dependent variables chosen were absorbance, spreadability, and viscosity. (Table 3) provides the various levels for the independent variables for the 12 runs of Plackett-Burman designs.

**Table 2:** Summary of FMEA Analysis

| Unit Operation | Failure Mode | Impact of change | S | Potential root or cause of failure | O | Detection or control method | D | RPN |
|---|---|---|---|---|---|---|---|---|
| **Mixing** | Mixing duration | Poor mixing | 6 | Machinery error | 1 | Lack of homogeneity | 2 | 12 |
| | Mixing speed | Lumps formation | 7 | Operation error | 2 | Change in viscosity | 2 | 28 |
| **Drying** | Duration of drying | Microbial contamination | 8 | Lack of process monitoring | 2 | Visual inspection | 1 | 16 |
| | Excessive temperature | Degradation | 7 | Malfunction of equipment | 3 | Lumps formation | 1 | 21 |
| **Order of addition** | Out of specification | Poor mixing | 5 | Lack of process monitoring | 2 | Uneven blend | 2 | 20 |
| **Viscosity** | Out of specification | Rheological behaviour | 5 | Machine error lack of knowledge | 2 | Variation in viscosity | 3 | 30 |
| **Spread ability** | Retention | Adhesion | 6 | Concentration of plasticizer | 3 | Application | 1 | 18 |
| **Raw materials** | Sources | Physical properties | 6 | Different vendor | 2 | Variation in sample | 1 | 12 |
| | Particle size | Uniformity | 5 | Supplier error | 2 | Visual | 2 | 20 |
| | Concentration | Lack of homogeneity | 4 | Weighing | 3 | Inspection | 1 | 12 |

**Statistical Methods**

Normal plots were employed to assess the significance of effects in the 12-run Plackett-Burman studies. If the responses align with the expected values from a normal distribution on the plots, the effect is deemed insignificant; conversely, if responses deviate from the expected values, the effect is considered significant. To validate the findings from the normal plots, t-tests and Pareto charts were generated using MINITAB 17 statistical software (trial version), employing a significance threshold of $p < 0.05$. Pareto charts aid in visualizing the relative magnitudes of each effect.

**EVALUATION OF FILM-FORMING GEL**[9,10]

**Appearance**

The appearance of the formulation was measured and graded by its roughness and color, by a visual inspection.

**Viscosity**

Viscosity measurements were conducted utilizing a Brookfield (DV-E) viscometer equipped with a spindle attachment. Gels were placed in jars, and the spindle was gradually lowered vertically, ensuring it did not touch the bottom of the jars. At 20 rpm, spindle number 63 was turned inside the gel. The relevant dial reading was recorded for each speed.

**Spreadability**

It refers to the ability of the gel to evenly spread and cover a given surface. Spreadability in the context of a film-forming gel refers to how easily and uniformly the gel can be applied across the skin as uneven spreading can lead to inadequate coverage. To determine spreadability, 0.5 g of the gel was precisely weighed onto a smooth, flat glass plate, and its initial diameter was recorded. Another glass plate with identical dimensions was then placed atop the first plate, covering the gel. A standard weight was positioned on the upper plate over the gel area for 60 seconds. Subsequently, the weight and upper plate were gradually lifted, and the final diameter of the gel was measured. Spreadability was computed using the following formula:

Spreadability = (Final Diameter - Initial Diameter) / Time in seconds

The result is often expressed in units like g.cm/s

**Outward Stickiness**

By applying light pressure to a dry film, cotton wool was used to assess the outer surface's stickiness. The assessment of stickiness involved categorizing it as high, medium, or low based on the quantity of cotton fibers adhering to the film. High stickiness indicated a dense accumulation of fibers, medium stickiness indicated a thin layer of fibers, and low stickiness indicated rare or no adherence of fibers.[11]

**Drying Time**

The formulation was applied to a volunteer's inner forearms in order to measure the drying time. A glass slide was lightly placed on the film after two minutes. The film was supposed to dry if there were no signs of liquid left behind on the glass slide following removal. The experiment was repeated as many times as necessary to ensure that the film was fully dry if there were any signs of liquid left on the glass slide.[11]

**Integrity of Film and Cosmetic Attractiveness**

For the purpose of measuring the drying time, the formulation was applied to a volunteer's forearm as instructed. The test participant then wore the dry film all night. After 24 hours, the test area was visually inspected to check for flaking or cracking and for film completion.[11,12]

Visual inspection of the dry films allowed for the evaluation of the films' aesthetic appeal. Colored films with low skin fixation had a high appeal, while those with medium skin fixation were viewed as less attractive since they showed some skin wrinkling, and those with strong skin fixation only had a low attractiveness.

**Concentration of pigment**

The $\lambda_{max}$ was determined on a UV spectrophotometer by using specific dilution. The calibration curve was prepared for the Colour in the solvent.

**Antimicrobial test**

The film forming gel was diluted for this Test for Screening. For this, 0.8 ml of ethanol was added to 0.2 g of gel, which was weighed. In order to evaluate the zone of inhibition, the antibacterial activity of gel was observed against *E. coli* using the well plate method. In an appropriate culture medium, microorganisms were raised. The diluted formulation was poured into the wells, and the plates were incubated at 37 °C for 48 hours. A distinct zone of inhibition that surrounds the wells indicates the activity of the film-forming gel and was noted.

**Table 3:** Factors and factor levels for PBD and 12 runs by Plackett-Burman design.

| **Factors (Independent variables)** | **Levels** | | |
|---|---|---|---|
| | **Low (-1)** | **Medium (0)** | **High (+1)** |
| (X1) Conc. of pigment | 3 | 4 | 5 |
| (X2) Conc. of plasticizer | 2 | 2.5 | 3 |
| (X3) Conc. of Hydroxy propyl cellulose | 2 | 2.5 | 3 |

**12 runs of Plackett-Burman design.**

| **Batches** | **Independent variables in coded forms** | | | **Independent variables in actual forms (All batches contain 2.5g ethyl cellulose and 30 ml of ethanol)** | | |
|---|---|---|---|---|---|---|
| | **X1** | **X2** | **X3** | **Concentration of color** | **Concentration of plasticizer** | **Concentration of Hydroxy propyl cellulose** |
| **F1** | +1 | +1 | +1 | 5 | 3 | 3 |
| **F2** | -1 | -1 | -1 | 3 | 2 | 2 |
| **F3** | +1 | -1 | +1 | 5 | 2 | 3 |
| **F4** | +1 | -1 | -1 | 5 | 2 | 2 |
| **F5** | +1 | -1 | +1 | 5 | 2 | 3 |
| **F6** | +1 | +1 | -1 | 5 | 3 | 2 |
| **F7** | -1 | -1 | -1 | 3 | 2 | 2 |
| **F8** | -1 | -1 | +1 | 3 | 2 | 3 |
| **F9** | -1 | +1 | +1 | 3 | 3 | 3 |
| **F10** | -1 | +1 | -1 | 3 | 3 | 2 |
| **F11** | +1 | +1 | -1 | 5 | 3 | 2 |
| **F12** | -1 | +1 | +1 | 3 | 3 | 3 |

## RESULTS AND DISCUSSION

### Elements of Quality by Design for Formulation preparation

***Definition of QTPP and CQAs:***

In the development of QbD-based formulations, the categorization of the QTPP is the first and most crucial step. The QTPP consists of quality standards that, ideally, lead to the end product's efficacy and safety. (Table 4) includes information about the Topical film forming gel's QTPP. Because their impact must be investigated and tracked, CQAs are the significant product quality attributes that were chosen from the QTPP and have an impact on the finished dosage form.

**Table 4:** QTPP of Topical film forming gel

| Target product profile | Target |
|---|---|
| Dosage form | Film forming solution |
| Route of administration | topical |
| Appearance | Red-coloured smooth textures solution |
| Integrity on skin | Compact film, no cracks |
| Outward stickiness | Low |
| Drying time | < 5 min |
| Spreadability | 2.5 % |
| Viscosity | 1362-1146 cp |
| Cosmetic attractiveness | High |
| Concentration of pigment | 1.4µg/ml to 3.8 µg/ml |
| Antimicrobial activity | 19 to 22 mm |

***Identification of CMA and CPP:***

The selection of critical material attributes (CMAs) and critical process parameters (CPPs) was carried out after finding the QTTP and defining the CQAs, as enlisted below-

**Critical material attributes.**

Hydroxy propyl cellulose

Ethyl cellulose

Propylene glycol

**Critical process parameters.**

Mixing duration

Mixing Speed

Temperature

### Statistical Methods

***Screening of Variables by Plackett– Burman Design***

In this work, a three-level Plackett-Burman factorial design with 12 runs was used to objectively identify the critical factors that significantly impact the effectiveness of Topical film-forming gel. The 12-run Plackett-Burman experimental design is shown in (Table 5) for the purpose of screening important process variables impacting gel that forms films. The probability value was used to determine the significance of each independent variable, therefore a p-value of less than 0.05 denotes the relevance of each factor. Pareto charts of the standardized effects for responses are shown in Fig 2(a)(b)(c).

After analysing the result, the Pareto chart for absorbance and spreadability revealed that the concentrations of color (A), propylene glycol (B), and HPC (C) are insignificant variables that do not affect the formulation's absorbance and spreadability. However, the Pareto chart for viscosity revealed that the color (A) concentration is a significant variable that affects the formulation's viscosity Fig 2 (d). Even though a variable like HPC concentration (C) did not result in a significant difference, it was nevertheless regarded as relevant because to its larger impact. As a result, this variable will move on to the CCD method's next round of optimization.

**Table 5:** Results of Plackett-Burman experimental design

| Batch no. | Conc. of color (X1) | Conc. of Propylene glycol (X2) | Conc. of Hydroxypropyl cellulose (X3) | Absorbance | Spreadability | Viscosity |
|---|---|---|---|---|---|---|
| **F1** | 5 | 3 | 3 | 0.73170 | 2.90 | 1470 |
| **F2** | 3 | 2 | 2 | 1.03370 | 1.32 | 1068 |
| **F3** | 5 | 2 | 3 | 1.03478 | 2.50 | 1490 |
| **F4** | 5 | 2 | 2 | 0.73150 | 1.52 | 1074 |
| **F5** | 5 | 2 | 3 | 0.75970 | 2.20 | 1495 |
| **F6** | 5 | 3 | 2 | 0.51170 | 3.30 | 1350 |
| **F7** | 3 | 2 | 2 | 0.67012 | 1.20 | 1062 |
| **F8** | 3 | 2 | 3 | 0.27862 | 3.10 | 1146 |
| **F9** | 3 | 3 | 3 | 0.75699 | 1.40 | 1074 |
| **F10** | 3 | 3 | 2 | 0.28700 | 1.90 | 1056 |
| **F11** | 5 | 3 | 2 | 0.36000 | 0.40 | 1320 |
| **F12** | 3 | 3 | 3 | 0.23600 | 1.90 | 1056 |

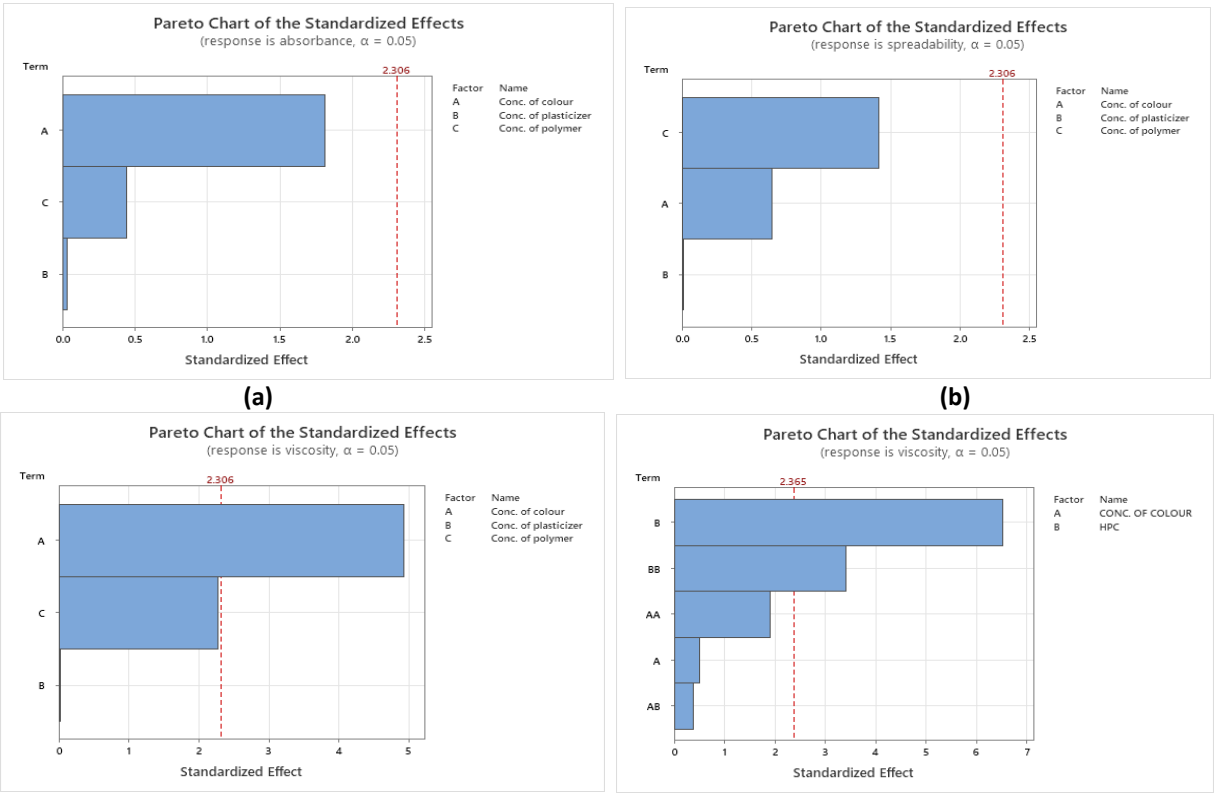


**Figure 2:** Pareto chart of the standardized effects of independent variables on a) Absorbance **b)** Spreadability **c)** Viscosity. **d)** Pareto chart of the standardized effects for viscosity.

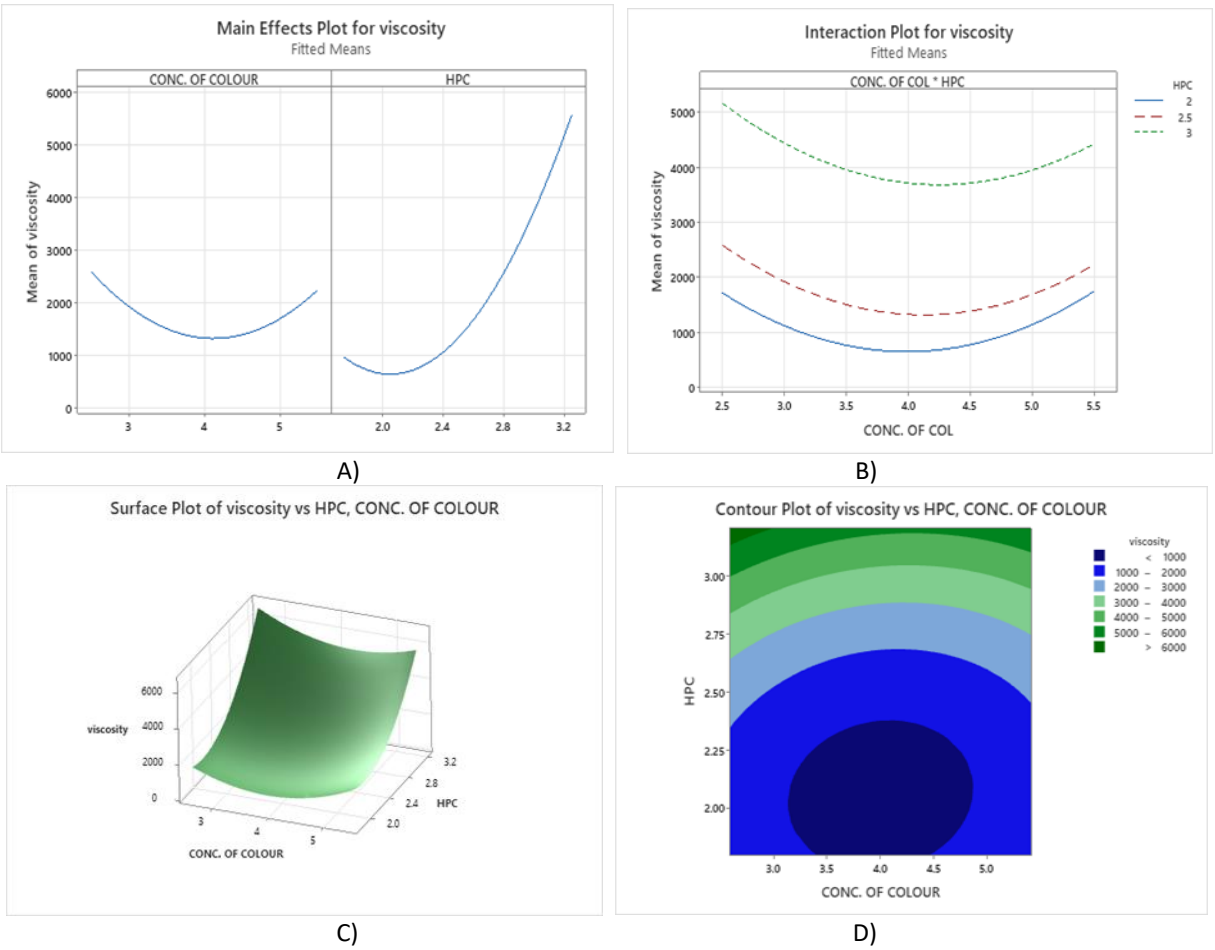


**Figure 3:** (A) Main Effect and (B) interaction effect plots for viscosity of the film forming gel. (C) 3D surface response (D) 2D contour plots for the viscosity of the film forming gel.

### Central Composite Design

CCD was used to examine the interactions between the important variables and to establish the best values for each. This strategy includes the concentration of pigment and the concentration of HPC, the two sorts of factors that had the most impact. CCD sought to examine the impact of test-taker responses. Figure 2(d) demonstrates that the viscosity of the film-forming gel is more affected by the concentration of HPC than by the concentration of pigment. After being statistically formulated in terms of CCD, this study obtained 13 formulations that will allow for the observation of viscosity presented in (Table 6).

**Table 6:** CCD formulation with observations

| Batch no. | Conc. of color (X1) | Conc. of Hydroxypropyl cellulose (X3) | Viscosity |
|---|---|---|---|
| 1. | 4 | 2.5 | 1320 |
| 2. | 4 | 2.5 | 1332 |
| 3. | 4 | 2.5 | 1320 |
| 4. | 3 | 3 | 5220 |
| 5. | 2.5 | 2.5 | 1422 |
| 6. | 3 | 2 | 1914 |
| 7. | 5 | 3 | 3552 |
| 8. | 4 | 2.5 | 1338 |
| 9. | 4 | 3.2 | 5016 |
| 10. | 5.4 | 2.5 | 2754 |
| 11. | 4 | 2.5 | 1320 |
| 12. | 4 | 1.7 | 666 |
| 13. | 5 | 2 | 756 |

### Response optimization of the viscosity of Film Forming Gel.

Fig 3 A) and B) were used to show the relevance of the major influence of the independent components and their interaction on the outcome, which can respond differently by the factors' varying levels, prior to getting the optimal response surface. There is no main effect if the outcome exhibits a parallel response to the x-axis, and its significance only becomes apparent if the response exhibits a slope behaviour. The interaction plot, on the other hand, illustrates how one independent component can have an impact on another and how this is represented in the outcome response. There is no relationship and therefore no interaction between the factors if the impact of the factors on the response are indicated by parallel lines or duplicate behaviour. Response surface maps (RSM) were built to clarify the link between the most critical variables. Fig 3 (C)(D) shows the viscosity of the film-forming gel as a function of (C) surface response and (D) 2D contour plots.

### Overlay plot

Fig (4) depicts the overlay response of the film-forming gel's viscosity parameter. The outcome of this overlay indicated that the value of the scatter in the white-shaded overlay may be used to make an acceptable output.

The F1, F2, F3, and F8 were found to satisfy in all respects after optimization of 13 batches, including appearance, viscosity, spreadability, cosmetic attractiveness, drying time, integrity on skin, outward stickiness, concentration of color, and antimicrobial activity. The final optimized formula for making topical film-forming gel is shown in (Table 7).

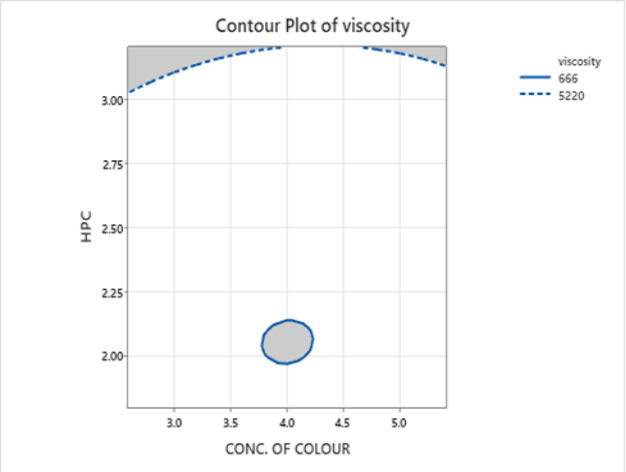


**Figure 4:** Overlay response of Viscosity parameter of film forming gel

**Table 7:** Optimized batch formula.

| Ingredients | Quantity |
|---|---|
| Ethyl cellulose | 2.5 gm |
| Hydroxy propyl cellulose | 2.5 gm |
| Propylene glycol | 2.5 ml |
| Colour | 4 gm |
| Clotrimazole | 1%w/w |
| Ethanol | 30 ml |

## EVALUATION OF THE FORMULATION

### Appearance

The prepared pigmented film forming gel showed a dark, rich red colour with a smooth and shiny feel. The colour intensity was uniform with no noticeable variations or streaks. Further the consistency of prepared product was slightly thick, yet it maintained a fluidity that allows it to be easily spread or applied as needed.[13] These quality would make it appropriate for the intended cosmeceutical product.

### Viscosity

The viscosity of pigmented film forming Gel is expressed in centipoise (cp), and it lies between 1156 and 1360 cp. This indicates that Gel has a medium-thick viscosity, like thick syrup or paint.[14]

EC has a weak affinity for water, making it predominantly hydrophobic that do not readily form gel however, it was used for its film-forming properties by mixing in an organic solvent.

HPMC is hydrophilic, meaning it has a strong affinity for water. This property allows HPMC to readily form gels in water.

The complimentary qualities of EC and HPMC make them excellent for film formatting gel preparation. While HPMC has good film-forming qualities in aqueous solutions, EC is noted for its improved film-forming performance in organic solvents. They work better together when combined in a hydroalcoholic solution, improving the ability to create films.

With the aid of this dual solvent system, both polymers are effectively dissolved and dispersed, creating a more uniform film forming gel. Also, required film thickness, mechanical strength etc could be achieved.[15]

**Spreadability**

It was found that the spreadability of the film-forming gel was between 1.4% and 2.5%. This indicates that the gel spreads readily and consistently when applied to a surface, effectively covering the region.[16] This property ensures equal distribution, greater absorption, and a more comfortable user experience, which makes it especially effective in desired cosmeceutical application.

**Drying time**

The formulation was found to dry in less than 5 minutes. For a number of reasons, the amount of time a film-forming gel, comprised of ethyl cellulose (EC) and hydroxypropyl methylcellulose (HPMC), takes to dry is important. A complete drying process guarantees strong surface adherence and prevents the film from peeling off too readily. Proper drying can aid in achieving the ideal texture, look, and transparency of the film.

**Outward stickiness**

The stickiness of the outer surface was found to be low as there was occasional or no adherence of fibres on the dried film.

The degree to which a topical gel sticks to the skin after application is referred to as its "outer stickiness." If a gel is highly sticky, the user may find it uncomfortable and become dissatisfied with the product. For user acceptability and treatment adherence, it's important to ensure the proper amount of external stickiness.[10]

**Integrity of Film and Cosmetic attractiveness**

After 24 hours, there were no signs of cracks or flaking, indicating that the formulation was in perfect integrity with the skin. In film-forming topical gel formulations, the quality of "integrity on the skin" is crucial for both medicinal and cosmetic purposes. It testifies the gel's capacity to leave a smooth, continuous coating on the skin after use. The resulting film must offer a thorough, long-lasting coverage. Lack of integrity in the gel film may result in uneven application, patchiness or a temporary effect.

The cosmetic attractiveness of the film forming gel (Alta) found to be opaque. Due to their near invisibility, transparent films with a low skin fixation shows a high level of attraction. Films that are opaque and had a medium skin fixation are interpreted less attractive because the skin appears more prominent and wrinkled. Films that are whitish or that heavily wrinkle the skin because of strong skin attachment shows a poor sense of attractiveness.[17]

**Antimicrobial test**

Antimicrobial activity was observed against S. aureus, and the zone of inhibition was found to be 22.88 ± 0.19 mm.

## CONCLUSION

As an outcome, the modified Alta pigment gel formulation with film-forming properties that contains clotrimazole showed the desired properties. It can be a potential product in the cosmetic business due to its substantial antibacterial activity, improved cosmetic appeal, and non-staining properties.

**Source of Support:** The author(s) received no financial support for the research, authorship, and/or publication of this article

**Conflict of Interest:** The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## REFERENCES

1. Patil VV, Thorat YS, Kote NS, Hosmani AH. Formulation and Evaluation of Crack Cream from Plant Extracts. Int J Curr Pharm Res. 2020;130–2. Doi: http://dx.doi.org/10.22159/ijcpr.2020v12i3
2. Longhurst B, Steele C. Dry Heel Fissures: Treatment and Prevention. Dermatol Nurs. 2016 Sep 1;Longhurst B, Steele C. Dry heel fissures: treatment and prevention. Dermatological Nursing 2016;15(3):46-49.
3. Patkar KB, Bole PV. Herbal cosmetics in ancient India with a treatise on planta cosmetica. Bharatiya Vidya Bhavan; 1997. ISBN: 817276085X
4. Lavanya A, Sowmya SV, Rao RS, Augustine D, Haragannavar VC. Natural stain (Kumkum) formulated by the extract of Curcuma aromatica and slaked lime in histostaining of oral tissues: An observational study. J Oral Maxillofac Pathol JOMFP. 2021;25(1):88–96. doi: 10.4103/jomfp.JOMFP_90_20 PMID: 34349417
5. Saha R. COSMECEUTICALS AND HERBAL DRUGS: PRACTICAL USES. INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH. IJPSR. 2011; 3. DOI: http://dx.doi.org/10.13040/IJPSR.0975-8232.3(1).59-65
6. Nayak AK, Ahmed SA, Beg S, Tabish M, Hasnain MS. Chapter 18 - Application of Quality by Design for the Development of Biopharmaceuticals. In: Beg S, Hasnain MS, editors. Pharmaceutical Quality by Design [Internet]. Academic Press; 2019:399–411. DOI: 10.1016/B978-0-12-815799-2.00019-8 ISBN: 978-0-12-815799-2
7. Abraham J. International Conference on Harmonisation of Technical Requirements for Registration Of Pharmaceuticals For Human Use. In: Tietje C, Brouder A, editors. Handbook of Transnational Economic Governance Regimes [Internet]. Brill

| Nijhoff; 2010 [cited 2024 Mar 8]. p. 1041–53. DOI: https://doi.org/10.1163/ej.9789004163300.i-1081.897

8. Plackett RL, Burman JP. The Design of Optimum Multifactorial Experiments. Biometrika. 1946;33(4):305–325. DOI: https://doi.org/10.2307/2332195
9. Mukkirwar SP, Mukkirwar SS, Chatur VM. DEVELOPMENT AND EVALUATION OF HERBAL FOOT CRACK GEL. World J Pharm Res.; 2022;11(2):1558-1565. DOI: 10.20959/wjpr20222-22902
10. Baby A, Shivakumar HN, Alayadan P. Formulation and Evaluation of Film Forming Solution of Diphenhydramine Hydrochloride for Transdermal Delivery. Indian J Pharm Educ Res. 2022 Jan 12;56(1):43–9. DOI: 10.5530/ijper.56.1.6
11. Lunter DJ, Daniels R. New film forming emulsions containing Eudragit® NE and/or RS 30D for sustained dermal delivery of nonivamide. Eur J Pharm Biopharm. 2012 Oct 1;82(2):291–8. DOI: 10.1016/j.ejpb.2012.06.010
12. Ranade S, Bajaj A, Londhe V, Kao D, Babul N. Fabrication of Polymeric Film Forming Topical Gels. Int. J. Pharm. Sci. Rev. Res., 2014;26(2):52:306-313.
13. Bajaj H, Kumar T, Singh V. Film forming gels: a review. Res J Pharm Biol Chem Sci. 2016;7(4):2085–91.
14. Binder L, Mazál J, Petz R, Klang V, Valenta C. The role of viscosity on skin penetration from cellulose ether-based hydrogels. Skin Res Technol. 2019;25(5):725–34. DOI: 10.1111/srt.12709
15. Kriplani P, Guarve K, Singh Baghel U. Formulation optimization and characterization of transdermal film of curcumin by response surface methodology. Chin Herb Med. 2021 Apr 1;13(2):274–85. DOI: 10.1016/j.chmed.2020.12.001
16. Garg A, Aggarwal D, Garg S, Singla AK, Spreading of semisolid formulations: An update [Internet]. Pharmaceutical Technology North America. 2002;9:1-84. Accessed on: https://elibrary.ru/item.asp?id=6294411
17. Saudagar RB, Samuel S. Formulation Development and Evaluation of Topical Film-Forming Lotion Containing Butenafine Hydrochloride. Asian J Pharm Technol. 2016;6(4):238-44. DOI: http://dx.doi.org/10.5958/2231-5713.2016.00035.0