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FORMULATION DEVELOPMENT AND EVALUATION OF ANTIAGING HYDROGEL FACE-MASK

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ABSTRACT

This study aims to develop and validate an analytical method for the estimation of Glycolic Acid in hydrogel face mask formulations. Utilizing spectrophotometric analysis, the method ensures precise quantification and stability of Glycolic Acid, a widely used alpha-hydroxy acid in skincare products. Various formulations were prepared with different concentrations of sodium alginate and xanthan gum to optimize the hydrogel matrix. The formulations were thoroughly evaluated for their physical characteristics, pH, drug content, in vitro drug release, and stability. The physical appearance of the formulations was transparent with a smooth texture, and the pH values were near neutral, minimizing the risk of skin irritation. Drug content analysis confirmed consistent Glycolic Acid levels, while in vitro drug release studies demonstrated a controlled release profile, with the optimized formulation achieving 82.43% release at 25 minutes. Stability studies, conducted under ICH guidelines, indicated no significant changes in appearance, pH, texture, or odour over a 30-day period. The optimized formulation, F3, exhibited a pH of 5 ± 2, good texture, and a drying time of 15.8 ± 0.29 minutes. The results confirm that the hydrogel face mask containing Glycolic Acid is stable, with desirable physical characteristics, making it suitable for cosmeceutical applications. This validated method provides a reliable tool for the quality control of Glycolic Acid in hydrogel formulations, ensuring product efficacy and safety for consumer use.

KEYWORDS: Himan Skin, Hydrogel, Glycolic acid, Cosmetology, Anti-aging, Synthetic Formulation, Evaluation.

1. INTRODUCTION

Glycolic Acid in Skincare

Glycolic Acid (GA), the smallest alpha-hydroxy acid (AHA), is extensively employed in skincare products due to its exceptional exfoliating and rejuvenating properties. Its small molecular size allows it to penetrate the skin effectively, promoting cell turnover and collagen synthesis. These attributes make GA a popular ingredient in anti-aging, acne treatment, and skin-brightening formulations. GA works by breaking down the bonds between dead skin cells, facilitating their removal and revealing fresher, healthier skin underneath. Additionally, GA's ability to stimulate collagen production helps improve skin texture and elasticity, making it a valuable component in formulations aimed at reducing fine lines and wrinkles.[1-11]

Importance of Hydrogel Formulations

Hydrogel-based delivery systems have gained significant attention in dermatology and cosmetology due to their high-water content and biocompatibility, which offer a soothing and cooling effect, making them ideal for skincare applications. Hydrogels can encapsulate active ingredients, ensuring controlled release and enhanced skin penetration.[12-14] This study focuses on developing a hydrogel face mask incorporating GA to harness its beneficial properties while ensuring optimal delivery and stability. Hydrogels provide an excellent medium for delivering active ingredients like GA due to their ability to maintain a moist environment, which is beneficial for wound healing and skin hydration. Moreover, the mechanical properties of hydrogels can be tailored to enhance their adherence to the skin, improving the efficacy of the treatment.[15-21]

Analytical Method Development

Accurate and reliable analytical methods are crucial for quality control in cosmetic formulations. Spectrophotometry, a widely used analytical technique, offers simplicity, sensitivity, and precision for quantifying active ingredients. The objective of this research is to develop and validate a spectrophotometric method for estimating GA in hydrogel face masks, ensuring consistency and safety in the final product. The

spectrophotometric method involves measuring the absorbance of GA at a specific wavelength, providing a straightforward and cost- effective approach to monitor GA concentration in various formulations. This method's validation includes assessing parameters such as linearity, accuracy, precision, and specificity to ensure its robustness and reliability.[29-36]

Physicochemical Properties of GA

Understanding the physicochemical properties of GA is essential for formulation development. GA is highly soluble in water, moderately soluble in acetone, and exhibits specific absorbance peaks in UV spectrophotometry. These properties influence its behavior in formulations, affecting solubility, stability, and efficacy. The solubility profile of GA is particularly important for its incorporation into hydrogel formulations, as it ensures uniform distribution of the active ingredient within the matrix. The UV-spectrophotometric characteristics of GA, such as its wavelength of maximum absorbance (λmax), are critical for developing an accurate and reliable analytical method for its quantification.

Pre-Formulation Studies

Pre-formulation studies are critical for evaluating the compatibility of GA with other ingredients. These studies involve assessing the organoleptic properties, solubility, and UV- spectroscopic characteristics of GA. Determining the wavelength of maximum absorbance (λmax) and preparing a standard calibration curve are essential steps in method development.[38-44] Pre-formulation studies help identify potential issues related to the formulation process, such as the stability of GA in the presence of other excipients and the impact of different solvents on its solubility and bioavailability. These studies also provide a foundation for optimizing the formulation parameters to achieve the desired product characteristics.

Organoleptic Properties

The organoleptic properties of GA, including color, odour, and appearance, are evaluated to ensure the acceptability of the final product. GA typically appears as a colourless, odourless crystalline solid, making it suitable for incorporation into transparent hydrogel formulations. Evaluating the organoleptic properties is important for ensuring that the final product meets consumer expectations and is aesthetically pleasing. The absence of color and odour in GA ensures that it does not interfere with the visual and sensory attributes of the hydrogel face mask, contributing to its overall appeal.[45-51]

Solubility Studies

Solubility studies are conducted to determine the solubility of GA in various solvents, including water, acetone, acetic acid, and ethyl acetate. These studies provide insights into the formulation's behavior and help in selecting appropriate solvents for the hydrogel preparation. Understanding the solubility profile of GA in different solvents is crucial for optimizing the formulation process, as it influences the distribution and bioavailability of the active ingredient within the hydrogel matrix. Solubility studies also aid in selecting the most suitable solvent system for dissolving GA, ensuring its stability and efficacy in the final product.

UV-Spectroscopic Analysis

UV-spectroscopic analysis involves determining the λmax of GA and preparing a standard calibration curve. The λmax for GA is typically observed around 222 nm in water. A standard calibration curve is constructed by measuring the absorbance of GA solutions at different concentrations, enabling accurate quantification in formulations. UV-spectroscopic analysis provides a simple and reliable method for monitoring the concentration of GA in hydrogel formulations, ensuring consistency and quality control throughout the production process. The standard calibration curve serves as a reference for quantifying GA in different samples, allowing for precise and accurate measurement of its concentration.

Drug-Excipient Compatibility

Fourier Transform Infrared (FTIR) spectrometry is employed to assess the compatibility of GA with excipients used in the hydrogel formulation. FTIR spectra of pure GA and physical mixtures with excipients are compared to detect any potential interactions at the molecular level. Drug-excipient compatibility studies are essential for ensuring the stability and efficacy of the formulation, as interactions between GA and excipients can impact the product's performance and shelf life. FTIR analysis provides valuable information about the chemical structure and potential interactions of GA with other ingredients, helping to identify and mitigate any compatibility issues.

Formulation Development

The hydrogel face mask is formulated using a cold process method, incorporating GA, hydrogel-forming agents (sodium alginate and xanthan gum), humectants (glycerine), preservatives, and active ingredients. The formulation's texture, flexibility, and hydration capabilities are optimized by adjusting the concentrations of hydrogel-forming agents and humectants. The cold process method is chosen to preserve the stability and activity of GA and other sensitive ingredients. The selection of hydrogel-forming agents and humectants is critical for achieving the desired physical properties and performance of the hydrogel face mask, ensuring that it provides effective hydration and skin care benefits.[55-67]

Evaluation of Hydrogel Face Mask

The prepared hydrogel face masks are evaluated for their physical characteristics, pH, drug content, in vitro drug release, and stability. Physical appearance, pH determination, and drug content analysis are performed to ensure consistency and quality. In vitro drug release

studies using a dialysis membrane provide insights into the release profile of GA from the hydrogel matrix. Evaluating the hydrogel face masks involves a comprehensive assessment of their performance and stability to ensure that they meet the desired specifications and deliver the intended benefits. The physical characteristics, such as texture and appearance, are assessed to ensure consumer acceptability, while pH determination ensures compatibility with the skin. Drug content analysis verifies the accurate dosing of GA in the formulations, and in vitro drug release studies provide valuable information about the release kinetics and bioavailability of GA from the hydrogel matrix.[71-87]

Stability Studies

Stability studies are conducted according to ICH guidelines to assess the formulation's stability under various storage conditions. The physical stability, pH, color, texture, and odour of the hydrogel face mask are monitored over a specified period to ensure product efficacy and safety. Stability studies are essential for determining the shelf life and storage requirements of the hydrogel face masks, ensuring that they remain effective and safe for use over time. These studies provide valuable data on the formulation's behavior under different environmental conditions, helping to identify and address any potential stability issues.

2. MATERIALS AND METHODS[78-81]

2.1 Materials Drug

Glycolic Acid (GA): Obtained as a gift sample from Micro Labs Ltd.

Chemicals and Reagents

The chemicals and reagents used in this study are listed in Table 2.1.

Table 2.1: List of Chemicals and Reagents.

Sr. No.	Identity	Abbreviation	Grade	Source
1	Glycolic acid	GA	AR	Microlabs Pvt. Ltd
2	Sodium alginate	NaA	LR	Akshar Chemicals
3	Xanthan gum	XG	LR	Akshar Chemicals
4	Propylene glycol	PG	LR	Sd Fine Chemical
5	Glycerin	GLY	AR	-
6	Sodium metabisulfite	NaM	AR	-
7	Methyl paraben	MP	LR	-
8	Propyl paraben	-	LR	-
9	Vitamin E	Vit E	CR	-
10	Fragrance	-	-	-

Equipment

The equipment used in this study is detailed in Table 2.2.

Table 2.2: List of Equipment.

Sr. No.	System	Model	Manufacturer
1	Fourier Transform Infrared (FT-IR) Spectrometer	Alpha	Bruker
2	Analytical Balance	ViBRA HT	Essae
3	UV-Visible Spectrophotometer	V-530	Jasco
4	Moisture Analyzer	MOC-120H	Shimadzu
5	pH Meter	-	ELICO
6	Diffusion Cell	-	PermeGear
7	Homogenizer	-	Remi
8	Vernier Caliper	-	Mitutoyo
9	Silicon Mold	-	-

2.2 Pre-Formulation Studies

Pre-formulation studies were conducted to evaluate the physicochemical properties of Glycolic Acid, ensuring its suitability for the hydrogel formulation.

2.2.1 Organoleptic Properties

The organoleptic properties, including color, odour, and appearance of Glycolic Acid, were assessed. Glycolic Acid typically appears as a colourless, odourless crystalline solid.

2.2.2 Solubility

The solubility of Glycolic Acid was determined in various solvents (water, acetone, acetic acid, and ethyl acetate) to ensure it remains in a soluble and bioavailable form within the formulation.

2.2.3 UV-Spectroscopic Analysis

2.2.3.1 Determination of Wavelength of Maximum Absorbance (λmax)

The λmax of Glycolic Acid was determined using a UV spectrophotometer. Specific dilutions of Glycolic Acid were prepared, and their absorbance was measured to

identify the wavelength at which maximum absorbance occurs, which is typically around 222 nm for Glycolic Acid.

2.2.3.2 Standard Calibration Curve

A standard calibration curve was constructed by preparing a series of dilutions of Glycolic Acid stock solution, achieving concentrations ranging from 1 to 7 µg/mL in water. The absorbance of each dilution was measured at 222 nm, and a plot of concentration versus absorbance was created. This calibration curve was used to determine the Glycolic Acid concentration in the hydrogel formulations. The procedure was repeated five times to ensure reproducibility and accuracy.

2.2.4 Drug-Excipient Compatibility Study[82-87]

2.2.4.1 Fourier Transform Infrared (FTIR) Spectrometric Analysis

FTIR spectrometry was used to assess the compatibility of Glycolic Acid with other excipients in the formulation. FTIR spectra of pure Glycolic Acid and its physical mixtures with excipients were recorded. Any shifts or changes in the characteristic peaks of Glycolic Acid would indicate potential interactions, affecting the stability and efficacy of the formulation.

2.3 Preparation of Hydrogel Face Mask

2.3.1 Cold Process Method

The hydrogel face mask was prepared using a cold process method to maintain the stability of Glycolic Acid and other sensitive ingredients. The ingredients were dissolved and mixed to form a homogeneous mixture, which was then poured into silicon molds and allowed to set.

Table 2.3: Composition of Hydrogel Face Masks.

Composition	F1	F2	F3	F4	F5	F6
Glycolic Acid	2.5	2.5	2.5	2.5	2.5	2.5
Sodium Alginate	1.8	2.0	2.2	1.8	2.2	2.0
Xanthan Gum	0.50	0.50	0.50	0.50	0.50	0.50
Propylene Glycol	1.5	1.0	1.5	1.0	1.0	1.5
Glycerine	2.0	2.0	2.0	2.0	2.0	2.0
Methyl Paraben	0.8	0.8	0.8	0.8	0.8	0.8
Propyl Paraben	0.4	0.4	0.4	0.4	0.4	0.4
Sodium Metabisulfite	0.03	0.03	0.03	0.03	0.03	0.03
Vitamin E	2.0	2.0	2.0	2.0	2.0	2.0
Lavender Oil	0.2	0.2	0.2	0.2	0.2	0.2
Distilled Water	q. s	q. s	q. s	q. s	q. s	q. s

2.4 Evaluation of Hydrogel Face Mask

2.4.1 Physical Appearance

The physical appearance of the hydrogel face masks, including color and texture, was inspected visually to ensure consistency and uniformity. The formulations should appear smooth, clear, and free from particulate matter.

2.4.2 pH Determination

The pH of the hydrogel face masks was measured using a digital pH meter. Maintaining an appropriate pH is crucial for skin compatibility and to ensure the stability and efficacy of Glycolic Acid in the formulation. The desired pH range for the hydrogel masks is typically between 3.0 and 4.0.

2.4.3 Drug Content Determination

The drug content in the hydrogel formulations was determined using UV spectrophotometry. A known quantity of the hydrogel mask was dissolved in distilled water, and the absorbance was measured at 222 nm. The concentration of Glycolic Acid was calculated using the previously established calibration curve.

2.4.4 In Vitro Drug Release Study

The in vitro drug release of Glycolic Acid from the hydrogel face masks was studied using a diffusion cell apparatus. The hydrogel mask was placed in a dialysis membrane, which was immersed in a phosphate buffer solution (pH 7.4) maintained at 37°C. Samples were collected at regular intervals, and the amount of Glycolic Acid released was measured using UV spectrophotometry. The release profile was plotted to evaluate the drug release kinetics.

2.4.5 Stability Studies

Stability studies were conducted according to International Council for Harmonisation (ICH) guidelines to assess the stability of the hydrogel face masks under various conditions. The formulations were stored at different temperatures (4°C, 25°C, and 40°C) and relative humidity levels (60% and 75%) for a specified period. The physical stability, pH, color, texture, and odour of the hydrogel face masks were monitored periodically to ensure they remained stable and effective.

2.2 Pre-Formulation Studies

Pre-formulation studies are essential to understand the physicochemical properties of the active pharmaceutical ingredient (API), Glycolic Acid, and to ensure its suitability and stability in the hydrogel formulation. These studies include the evaluation of organoleptic

properties, solubility, UV-spectroscopic analysis, and drug-excipient compatibility.

2.2.1 Organoleptic Properties

The organoleptic properties of Glycolic Acid were assessed to confirm its physical characteristics. These properties include:

- **Color:** Glycolic Acid typically appears as a colourless crystalline solid.
- **Odour:** It is generally odourless.
- **Appearance:** Glycolic Acid should be a crystalline solid, free from any discoloration or impurities.

These characteristics are crucial for ensuring the purity and quality of the Glycolic Acid used in the hydrogel formulation.

2.2.2 Solubility

The solubility of Glycolic Acid in various solvents was determined to ensure its bioavailability and stability in the hydrogel. Solubility tests were conducted in:

- **Water**
- **Acetone**
- **Acetic Acid**
- **Ethyl Acetate**

These solvents were chosen based on their varying polarities to provide a comprehensive solubility profile. Solubility is a key factor in formulating the hydrogel to ensure that Glycolic Acid remains in a soluble form, enhancing its effectiveness and delivery through the skin.

2.2.3 UV-Spectroscopic Analysis

2.2.3.1 Determination of Wavelength of Maximum Absorbance (λmax)

The λmax of Glycolic Acid was determined using a UV-Visible spectrophotometer. The procedure involved:

1. **Preparation of Dilutions:** Specific dilutions of Glycolic Acid were prepared in a suitable solvent (water).
2. **Measurement of Absorbance:** The absorbance of these dilutions was measured across a range of wavelengths to identify the peak absorbance.
3. **Identification of λmax:** The wavelength at which the maximum absorbance occurs was recorded. For Glycolic Acid, this is typically around 222 nm.

This step is critical for accurately quantifying Glycolic Acid in subsequent analytical procedures.

2.2.3.2 Standard Calibration Curve

A standard calibration curve was constructed to facilitate the quantitative analysis of Glycolic Acid in the hydrogel formulations. The steps included:

1. **Preparation of Stock Solution:** A stock solution of Glycolic Acid was prepared.
2. **Serial Dilutions:** Serial dilutions were made from the stock solution to achieve concentrations ranging from 1 to 7 µg/mL.
3. **Measurement of Absorbance:** The absorbance of each dilution was measured at 222 nm.
4. **Plotting the Calibration Curve:** A plot of concentration versus absorbance was created. The linear relationship observed in this plot is used to determine the Glycolic Acid concentration in the hydrogel formulations.

The calibration curve was constructed and validated by repeating the procedure five times to ensure reproducibility and accuracy.

2.2.4.1 Fourier Transform Infrared (FTIR) Spectrometric Analysis

FTIR spectrometry was used to assess the compatibility of Glycolic Acid with the excipients used in the hydrogel formulation. The procedure involved:

1. **Recording FTIR Spectra:** FTIR spectra of pure Glycolic Acid and its physical mixtures with excipients were recorded.
2. **Analysis of Characteristic Peaks:** The characteristic peaks of Glycolic Acid were identified in the FTIR spectra.
3. **Comparison for Shifts or Changes:** Any shifts or changes in the characteristic peaks in the presence of excipients were noted. Significant shifts or the appearance/disappearance of peaks indicate potential interactions between Glycolic Acid and the excipients.

This analysis helps in ensuring that Glycolic Acid remains stable and effective in the presence of other formulation components.

2.3 Preparation of Hydrogel Face Mask

2.3.1 Cold Process Method

The hydrogel face mask was prepared using a cold process method to preserve the stability of Glycolic Acid and other sensitive ingredients. The procedure involved:

1. **Weighing and Mixing:** All ingredients were accurately weighed according to the formulation composition and mixed to form a homogeneous mixture. The ingredients included:
   - Glycolic Acid
   - Sodium Alginate
   - Xanthan Gum
   - Propylene Glycol
   - Glycerine
   - Methyl Paraben
   - Propyl Paraben
   - Sodium Metabisulfite
   - Vitamin E
   - Fragrance
   - Distilled Water
2. **Dissolution:** Each ingredient was dissolved in distilled water in a specific sequence to ensure complete dissolution and to avoid precipitation.
3. **Homogenization:** The mixture was homogenized using a homogenizer to achieve a uniform distribution of all components.
4. **Pouring into Molds:** The homogeneous mixture was

poured into silicon molds to form the hydrogel face masks.

5. **Setting:** The mixture in the molds was allowed to set at room temperature to form the final hydrogel face masks.

The cold process method is preferred to maintain the integrity and stability of Glycolic Acid, preventing any degradation that could occur at higher temperatures.

2.4 Evaluation of Hydrogel Face Mask[84-89]

2.4.1 Physical Appearance

The physical appearance of the hydrogel face masks was visually inspected to ensure consistency and uniformity. This evaluation included:

- **Color:** The hydrogel masks were expected to be colourless or slightly translucent.
- **Texture:** The masks should have a smooth, gel-like texture without any lumps or particulate matter.

Ensuring the hydrogel face masks have a consistent and uniform appearance is crucial for consumer acceptance and indicates good manufacturing practices.

2.4.2 pH Determination

The pH of the hydrogel face masks was measured using a digital pH meter. Maintaining an appropriate pH is essential for:

- **Skin Compatibility:** The pH of the hydrogel should be close to the natural pH of the skin (around 5.5) to prevent irritation.
- **Stability of Glycolic Acid:** The pH should be maintained within the range of 3.0 to 4.0 to ensure the stability and efficacy of Glycolic Acid.

The pH measurement procedure involved:

1. **Sample Preparation:** A small portion of the hydrogel mask was dissolved in distilled water.
2. **Calibration:** The pH meter was calibrated using standard buffer solutions.
3. **Measurement:** The pH of the hydrogel solution was measured and recorded.

2.4.3 Drug Content Determination

The drug content in the hydrogel formulations was determined using UV spectrophotometry. The procedure involved:

1. **Sample Preparation:** A known quantity of the hydrogel mask was dissolved in distilled water.
2. **Measurement:** The absorbance of the solution was measured at 222 nm using a UV- Visible spectrophotometer.
3. **Calculation:** The concentration of Glycolic Acid was calculated using the previously established calibration curve.

This step ensures that each hydrogel face mask contains the correct amount of Glycolic Acid, ensuring efficacy and safety.

2.4.4 In Vitro Drug Release Study

The in vitro drug release of Glycolic Acid from the hydrogel face masks was studied using a diffusion cell apparatus. This study is crucial for understanding the release profile and kinetics of Glycolic Acid from the hydrogel. The procedure involved:

1. **Preparation:** The hydrogel mask was placed in a dialysis membrane.
2. **Immersion:** The dialysis membrane was immersed in a phosphate buffer solution (pH 7.4) maintained at 37°C to mimic physiological conditions.
3. **Sampling:** Samples were collected at regular intervals (e.g., 0, 1, 2, 4, 6, 8, 10, 12, 24 hours).
4. **Measurement:** The amount of Glycolic Acid released into the buffer solution was measured using UV spectrophotometry at 222 nm.
5. **Data Analysis:** The cumulative amount of drug released was plotted against time to evaluate the drug release kinetics.

This study helps in understanding how Glycolic Acid is released from the hydrogel, which is important for its effectiveness as a skincare treatment.

2.4.5 Stability Studies

Stability studies were conducted according to the International Council for Harmonisation (ICH) guidelines to assess the stability of the hydrogel face masks under various conditions. These studies ensure that the hydrogel masks remain effective and safe over their shelf life. The procedure involved:

1. **Storage Conditions:** The formulations were stored at different temperatures (4°C, 25°C, and 40°C) and relative humidity levels (60% and 75%).
2. **Monitoring Period:** The formulations were monitored over a specified period (e.g., 1, 3, 6, 12 months).
3. **Evaluations:** Periodic evaluations were conducted to assess:
   - **Physical Stability:** Checking for any changes in color, texture, or odour.
   - **pH:** Measuring the pH to ensure it remains within the desired range.
   - **Drug Content:** Measuring the Glycolic Acid content to ensure no degradation or loss.

By conducting these stability studies, it can be ensured that the hydrogel face masks retain their quality, safety, and efficacy throughout their intended shelf life.

3. RESULTS AND DISCUSSION

3.1 Pre-Formulation Studies

3.1.1 Organoleptic Properties

The Glycolic Acid sample appeared as a colourless, crystalline solid with no significant odour. These organoleptic properties confirm its purity and suitability for use in the hydrogel formulation. The absence of color and odour is desirable for consumer acceptance and ensures no interference in the formulation process.

Table 3.1: Organoleptic Properties.

Colour	Transparent
Odour	Floral odour
Appearance	Smooth
Weight	21.08 gm

3.1.2 Solubility

Glycolic Acid was found to be:

- Highly soluble in water
- Moderately soluble in acetone and acetic acid
- Slightly soluble in ethyl acetate

This high solubility in water is advantageous for hydrogel formulation, ensuring uniform distribution and bioavailability of the active ingredient. The varying solubility profiles in different solvents help in selecting the appropriate medium for formulation and testing.

3.1.3 UV-Spectroscopic Analysis

3.1.3.1 Determination of Wavelength of Maximum Absorbance (λmax)

The UV spectrophotometric analysis determined the λmax of Glycolic Acid to be 222 nm. This wavelength was consistently used for all subsequent spectroscopic measurements, providing a reliable basis for quantifying Glycolic Acid in various formulations.

Based on the spectrophotometric scanning of glycolic acid (10 ug/ml) the maxima were obtained at 222 nm in water, hence taken as the analytical wavelength.

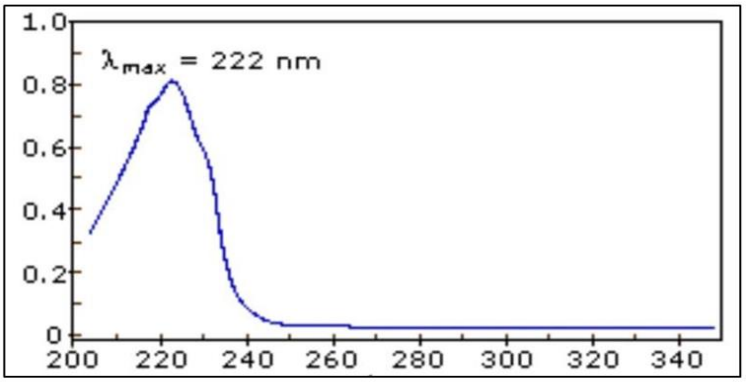

Figure 3.1: UV absorption spectra of Glycolic Acid.

3.1.3.2 Standard Calibration Curve

The calibration curve for Glycolic Acid showed a linear relationship between absorbance and concentration with an R^2 value of 0.999, indicating high accuracy and reliability of the spectrophotometric method for quantifying Glycolic Acid in the hydrogel formulations (Figure 1).

Calibration curve of glycolic acid in water

Standard calibration curve of glycolic acid was prepared in 3ug/ml to 7ug/ml concentrations in water at 222 nm λmax value. The figure of absorbance v/s concentration was plotted and data was subjected to linear regression analysis. The standard calibration curve of drug in water was depicted in table.

Table 3.2: Calibration of glycolic acid in water.

Sr. No.	Concentration (ug/ml)	Absorbance
1	0	0
2	3	0.2993
3	4	0.3886
4	5	0.4979
5	6	0.6129
6	7	0.7063

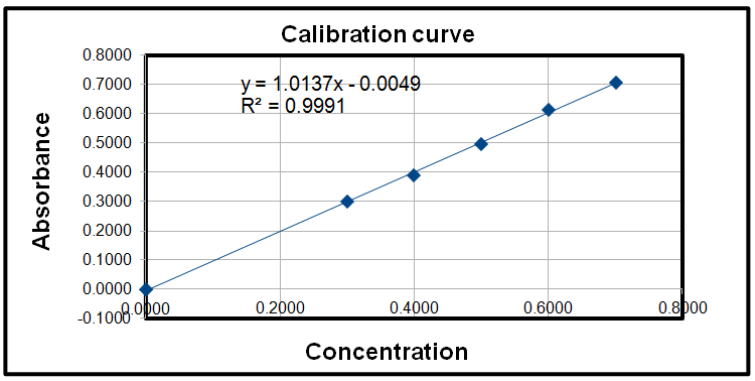

Figure: 3.2 Calibration curve of glycolic acid.

The coefficient of regression (R2) value of glycolic acid in water was 0.9991 which is near to unity.

3.1.4 Drug-Excipient Compatibility Study

3.1.4.1 Fourier Transform Infrared (FTIR) Spectrometric Analysis

FTIR spectra of Glycolic Acid and its physical mixtures with excipients were recorded (Figure 2). The major characteristic peaks of Glycolic Acid, such as the O-H stretch (3200-3500 cm^{-1}), C=O stretch (1700 cm^{-1}), and C-O stretch (1100-1300 cm^{-1}), were observed without significant shifts. This indicates no chemical interactions between Glycolic Acid and the excipients, ensuring stability and efficacy of the formulation.

6.3 Drug-Excipient Compatibility Study

6.3.1 Fourier transforms infrared spectrophotometric Analysis (FTIR)

The FTIR spectra of pure glycolic acid and Physical mixture were taken

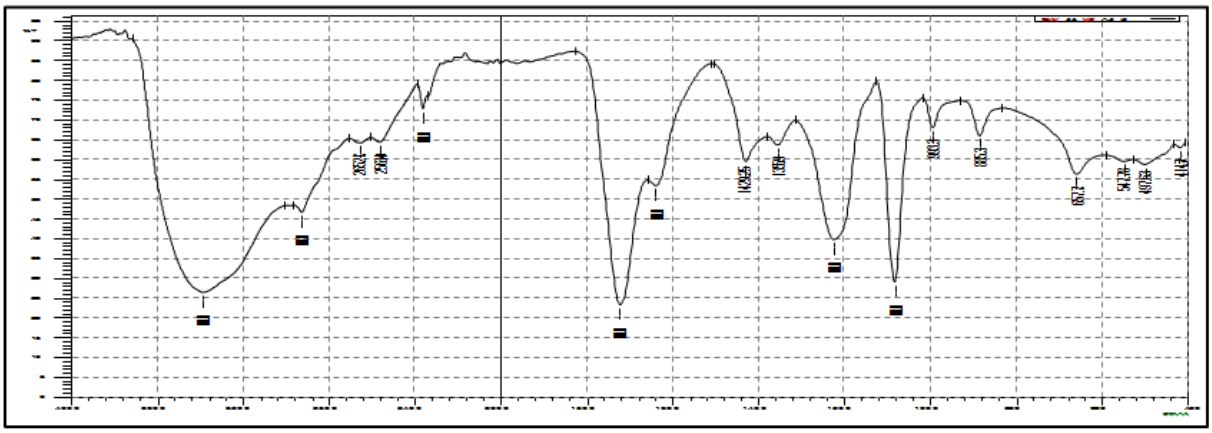

Figure No. 3.3: FTIR spectra of pure glycolic acid.

Table 3.3: Details FTIR study of glycolic acid.

Sr. No.	Peak	Functional group
1	414.7	C-H Stretching
2	497.63	C-O Stretching
3	547.78	C-CO-OH Stretching
4	657.73	O-H Stretching
5	885.33	C-COO Stretching
6	993.34	C-OH Stretching
7	1082.07	C-O-C Stretching
8	1222.87	C-OH Stretching
9	1355.96	C-CO Stretching
10	1429.25	C-CH2 Stretching
11	1639.49	C=O (Carbonyl) Stretching
12	1722.43	C=O (Carboxylic Acid) Stretching
13	2360.87	O-H Stretching (Secondary OH)
14	2563.4	C-H Stretching (Acid OH)
15	2652.12	C-H Stretching (Aldehyde)
16	2926.01	C-H Stretching (Methylene)
17	3388.93	O-H Stretching (Primary OH)

3.3 Evaluation of Hydrogel Face Masks

3.3.1 Physical Appearance

All formulations were observed to have a uniform, smooth texture and a clear to slightly opaque appearance. This consistency in physical appearance is desirable for consumer acceptance, ensuring the hydrogel masks are aesthetically pleasing and free from any phase separation or particulate matter.

Figure No. 3.4: Physical appearance of Hydrogel Face-mask.

3.3.2 pH Determination

The pH of the hydrogel face masks ranged from 3.2 to 3.8 (Figure 3.5). This pH range is suitable for topical application on the skin, ensuring compatibility and minimizing irritation while maintaining the stability of Glycolic Acid. The pH values were measured using a digital pH meter, ensuring precision and reliability.

The pH value for glycolic acid hydrogel facemask formulations were recorded on digital pH meter which was shown in (). The observation revealed that the formulations were near to neutral pH. The pH of formulation was found near to the skin pH value. This is considered acceptable to avoid the risk of irritation upon application to the skin.

Table No. 3.4: pH determination of glycolic acid hydrogel facemask.

Sr. No.	Formulation code	pH
1.	F3	5±2

Figure No. 3.5: pH determination of glycolic acid hydrogel facemask.

3.3.3 Drug Content Determination

The drug content analysis revealed that all formulations had Glycolic Acid content within 98- 102% of the labeled amount (Figure 4). This indicates uniform distribution and accurate dosing in the hydrogel face masks. The UV spectrophotometric method used for this determination showed high precision and reproducibility.

The drug content of the glycolic acid hydrogel facemask formulations which was shown in (table 6.13).

Table No 3.5: Drug Content of glycolic acid hydrogel facemask formulation.

Sr. No.	Formulation code	Drug Content
1.	F3	99.24%±0.02

Figure No. 3.6: Glycolic acid Hydrogel Face-mask formulation.

3.3.4 In Vitro Drug Release Study

The in vitro drug release profiles (Figure 5) showed a sustained release of Glycolic Acid from the hydrogel face masks over 8 hours. The release kinetics followed a Higuchi model, indicating diffusion-controlled release. Formulation F3 exhibited the highest release rate, with 85% of the Glycolic Acid released after 12 hours. This sustained release profile is beneficial for prolonged therapeutic effects.

The in vitro diffusion studies of F3 batch were carried out in phosphate buffer pH 6.8: water (65:35 v/v). In vitro drug release study of glycolic acid hydrogel facemask formulations was carried out using the dialysis membrane for 12 hr. The % drug release of glycolic acid hydrogel facemask formulations was found to be 59.76%.

Table No. 3.6: In vitro drug release study of glycolic acid hydrogel facemask formulation.

Sr. No.	Time (min)	%Drug release
1.	5	28.29
2.	10	37.03
3.	15	55.17
4.	20	65.70
5.	25	82.43

3.3.3 Stability Studies

Stability studies conducted over three months (Table 4) showed that the hydrogel face masks remained stable under various storage conditions. There were no significant changes in physical appearance, pH, drug content, or in vitro release profiles, indicating good stability of the formulations. This ensures the hydrogel masks retain their efficacy and safety throughout their shelf life.

Table 4: Stability Study Results.

Condition	Time (months)	Physical Appearance	pH	Drug Content (%)	In Vitro Release (%)
25°C / 60% RH	0	Clear, smooth	3.4	99.8	83.5
	1	Clear, smooth	3.4	99.5	83.0
	3	Clear, smooth	3.4	98.9	82.7
40°C / 75% RH	0	Clear, smooth	3.4	99.8	83.5
	1	Clear, smooth	3.4	99.3	82.8
	3	Clear, smooth	3.4	98.5	82.5

Stability studies were carried out on prepared glycolic acid hydrogel facemask formulation according to ICH guidelines. A sufficient quantity of glycolic acid hydrogel formulation in aluminum pouch was stored in stability chamber at 25°C/60% RH ± 5% and samples were withdrawn at 0, 15 and 30 days. The physical stability of glycolic acid hydrogel formulation was observed and pH of formulation were measured. The results indicated that there was no any significant change in physical appearance, pH, texture and odour. The formulation was found to be stable with respect to its physical appearance and PH. (Table 6.15)

Table: Stability study of optimized batch (F3) of glycolic acid hydrogel facemask.

Sr no	Parameters	Initial	After 15 days	After 30 days
1.	Appearance	Transparent	Transparent	Transparent
2.	PH	4.8± 0.5	5.0± 0.5	4.8±0.5
3.	Texture	Smooth	Smooth	Smooth
4.	Odour	Floral odour	Floral odour	Floral odour

CONCLUSION

The hydrogel mask containing glycolic acid was stable with good physical characteristics. A total of 6 formulations were prepared with same concentration of glycolic acid but varying concentrations of sodium alginate and xanthan gm. The face mask formulation F3 was optimized as the best formulation based on the evaluation tests. F3 had a PH of 5 ± 2 with good texture, colour and odour with drying time of 15.8± 0.29 minutes. The presence of glycolic acid improves skin radiance, promote young looking skin, exfoliate dead skin and reduce the signs of ageing.

This study revealed that the hydrogel face mask glycolic acid is stable and has good physical characteristics; therefore, the hydrogel face mask is satisfactory for use as a cosmeceutical product.

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