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Formulation and Physicochemical Evaluation of A Hyaluronic Acid – Based Gel for Wound Healing in Diabetic Patients

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Abstract:

Wound healing in diabetic patients is often delayed due to impaired angiogenesis, infection susceptibility, and poor epithelial regeneration. Hyaluronic acid (HA), with its increasingly being explored as a key agent in topical formulation to accelerate with wound closure. Diabetes mellitus is a chronic metabolic disorder that impairs the body's ability to heal wound, often resulting in chronic, non – healing ulcers. Delayed wound healing in diabetic patients is caused by multiple factors including poor blood circulation, oxidative stress, increased inflammation, and compromised immune response. Effective wound management in such cases requires formulations that can provide hydration, promote cell migration, and possess anti – inflammatory and antimicrobial properties.

Keywords: Hyaluronic acid, diabetic wound healing, topical gel, Aloe Vera, Carbopol, glycerin, skin compatibility, PH balance.

Introduction:

Chronic wound are a major complication in patients with diabetes mellitus, often leading to severe infections,amputation, and increased healthcare costs. Impaired healing in diabetic wound is attributed to reduce collagen deposition, poor vascularization, neuropathy, and increased oxidative stress. Recent advanced in pharmacology highlight the use of biopolymers such as hyaluronic acid (HA) , which play a crucial role inn cell proliferation , migration , and hydration of the extracellular matrix. Aloe Vera, known for its anti – inflammatory and antibacterial properties, complements HA's regenerative effects. Carbopol, a synthetic polymer, is widely used as a gel base due to its consistency and stability. This study on formulation a HA – based topical gel with supportive agents like Aloe Vera,glycerin, NaOH (as a PH adjuster), and Carbopol. The aim is to create a PH – balanced, skin – friendly, and easily spreadable gel suitable for accelerating wound healing in diabetic patients. Globally, the burden of diabetic wound is rising in parallel with the increasing prevalence of diabetes mellitus. This has led to an urgent need for effective, affordable, an patient – friendly topical formulations that can support and accelerate the wound healing process. Wound healing is a complex physiological process involving hemostasis , inflammation , proliferation , and tissue remodeling. In diabetic patients , this process is significantly impaired due to various systemic and local factors such as neuropathy, vascular insufficiency , hyperglycemia - induced oxidative stress, and impaired immune responses. These complications lead to chronic , non – healing wound which are highly susceptible to infection and often result in serious outcomes , including limb amputation and prolonged hospitalizations. Hyaluronic acid (HA) is a naturally occurring glycosaminoglycan found in the extracellular matrix of connective tissue. It plays a critical role in tissue hydration , cellular migration , and wound repair. HA promote angiogenesis, enhance fibroblast proliferation , and acts as a scaffold for tissue regeneration. Its ability to retain water and provide a moist environment makes it deal for topical wound care applications.

Objective:

The present study aims to formulate and evaluate a topical gel containing hyaluronic acid, aloe vera,carbopol, and NaOH for effective wound in diabetic conditions. And improve wound healing, protect against bacteria that can impede healing, and such as recovery from an infection or minor injury. The goal was to develop a stable,biocompatible, and effective wound healing formulation specifically tailored for diabetic wound care.

Materials:

- **Hyaluronic acid (HA):**Used as the primary active pharmaceutical ingredient (API) due to its wound healing, moisturizing , and tissue-regenerative properties.
- **Aloe Vera Gel:** A natural extract know for its anti – inflammatory , antimicrobial , and skin-repair properties. It enhance soothing and healing at the wound site.

- **Glycerin:** Functions as humectant and skin-conditioning agent. It maintains hydration in the gel formulation and prevents drying of the wound site.
- **Carbopol 940:** A synthetic high molecular weight polymer used as the gelling agent. It provides the viscosity and consistency to the formulation.
- **(NaOH) Sodium Hydroxide:** Used to neutralize Carbopol and PH of the gel to a physiological acceptable range (around 6.5).
- **Distilled Water:** Used as the solvent and vehicle in the formulation. It ensure the uniform dispersion of all ingredients.

S.N	INGREDIENT	CATEGORY	QUANTITY
1	Hyaluronic Acid	API	1g
2	Aloe Vera Gel	Base/carrier	10g
3	Carbopol 940	Gelling Agent	1g
4	Glycerin	Humectant	4g
5	NaOH	PH Adjuster	02ml
6	Tea Tree Oil	Preservatives	0.6g
7	Distilled Water	Diluent	Q.S.

Methodology:

1. **Prepare the Aqueous Phase:**

Dissolve Carbopol 940 in distilled water (stir gently to avoid lumps) and allow it to hydrate for about 2–3 hours. Optionally, heat the water to 40–50°C to speed up the process.


Fig: 1.1

2. **Prepare the Hyaluronic Acid Solution:**

In a separate container, dissolve hyaluronic acid in a portion of distilled water (10–20 g of water). Stir continuously for several hours until completely dissolved and hydrated.


Fig:1.2

3. Add Humectants:

Slowly add glycerin and polyethylene glycol (PEG) into the Carbopol solution with continuous stirring to ensure proper mixing.

Fig;1.3

4. Add Active Ingredients:

Once the Carbopol has fully dispersed, slowly incorporate the hyaluronic acid solution into the main mixture. Add any optional ingredients like vitamin C or aloe vera extract at this point, along with the antimicrobial agent (e.g., silver nanoparticles).

Fig:1.4

5. PH Adjustment:

Add NaOH Solution drop wise to adjust the pH of the formulation to around 5.5–7, ensuring the hydrogel is skin-friendly.

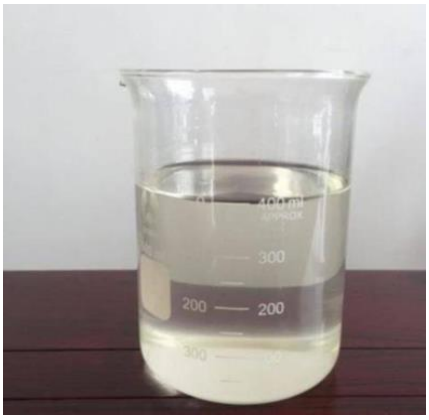

Fig: 1.5

6. Final Mixing:

Continue to mix the formulation until it forms a smooth, homogeneous hydrogel. If needed, adjust the consistency with additional water or Carbopol.

Fig: 1.6

Evaluation of Hydrogel:

1. **Odour**
Pleasant odour.

2. **Texture**
Smooth texture.

3. **Appearance**
Homogeneity.

4. **PH**
PH is 6.52

Fig:1.7

5. Spreadability
Easily applicable on skin.

6. Irritancy test
Mark an area (1 sq. cm) on the left hand dorsal surface. The lotion was applied to the specified area and time was noted. Irritancy, erythema, edema, was checked if any for regular intervals up to 24hrs and reported.
The hydrogel is non irritant

Result And Discussions:

The formulated Hyaluronic acid gel appeared smooth, translucent, and free from any particulate matter , with no signs of phases separation over a 7-days observation period , indicating acceptable physical stability. The PH of the gel was recoded between 6.6 and 6.9, aligning well with the physiological skin PH range (5.5-7.0), thus making the formulation safe non-irritating for topical use. Spread ability was found to be 6.4 g.cm/sec, reflecting a desirable consistency uniformly across the wound surface. Skin irritation testing , conducted o a shaved portion of rabbit skin , showed no sings of erythema or edema even after 24 hours , confirming the gels non=-irritant and biocompatible nature. The gel also passed the odour test, emitting mild, herbal fragrance due to aloe vera and tea tree oil, which enhance user acceptability. Antimicrobial testing performed using the agar well diffusion method revealed distinct zones of inhibition against staphylococcus aureus (15mm) and Escherichia coli (13mm). These result indicate the antimicrobial potential of the formulation, likely due to the presence of tea tree oil and aloe Vera gel , both known for their natural antimicrobial properties. No significant changes were observed in the gels physical properties during a 30- day room temperature stability study, further supporting the formulations robustness. Overall the result suggest that the formulated gel possesses suitable physical characteristics, safety, stability, and antimicrobial activity, making it a promising candidate for topical wound management in diabetic patients. The combination of Hyaluronic acid for hydration and tissue repair along with natural antimicrobial agents, offers a synergistic effect that enhance wound healing without relying on synthetic antiseptics.

Conclusion:

The formulated Hyaluronic Acid (HA) gel , enriched with aloe vera , glycerin, Carbopol , and Tea tree oil , demonstrated promising characteristics for the treatment of diabetic wound. The gel a physically stable , exhibited appropriate PH and spreadability , and was non-irritant to the skin. Its antimicrobial activity against both staphylococcus aureus and Escherichia coil suggest that it can effectively reduce the risk of infection at the wound site. Hyaluronic acid played a central role in promoting tissue regeneration and maintaining a moist wound environment , essential for effective healing. The incorporation of natural agents such as aloe vera and tea tree oil contributed additional anti-inflammatory benefits, creating a synergistic effect without the use synthetic preservatives or antiseptics. Overall , this study support the potential of the formulated gel as a safe, effective , and biocompatible alternative for diabetic wound management. Further clinical studies are recommended to evaluate its long-term efficacy and safety in human subjects.