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FORMULATION AND EVALUATION OF TRIAMCINOLONE ACETONIDE SERUM WITH DERMA STAMP ASSISTED DELIVERY FOR THE MANAGEMENT OF ALOPECIA AREATA

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ABSTRACT

Alopecia areata is a long-term autoimmune condition that results in non-scarring hair loss due to immune-related damage to hair follicles. Traditional treatments, such as injections of intralesional corticosteroids, are often hindered by factors like pain, low patient adherence, and the possibility of localized skin thinning. This research aimed to create a new, low-viscosity triamcinolone acetonide serum used with a derma stamp microneedling device to improve therapeutic effectiveness by enabling targeted delivery to hair follicles. The serum was developed through a co-solvency method utilizing propylene glycol, polyethylene glycol 400, and hydroxypropyl methylcellulose (HPMC) to achieve optimal drug solubility and a lightweight texture. Excellent spreadability is ensured by the formulation's skin-compatible pH (5.2–5.8) and viscosity range of 120.4 to 124.8 centipoise, which were verified by physicochemical analyses over a 30-day period. FTIR analyses verified the drug's compatibility with the excipients. HET-CAM and skin irritation testing verified the formulation's safety, while in vitro permeation investigations guaranteed the drug release is maintained. The medicine can efficiently reach deeper hair follicle structures because to the derma stamp's creation of microchannels that help get beyond the stratum corneum barrier. All things considered, this combined technique offers a better therapeutic potential for treating alopecia areata in a less invasive, targeted, and patient-friendly manner.

KEYWORD: Alopecia Areata, Triamcinolone Acetonide, Pharmaceutical Serum, Derma Stamp-Assisted Therapy, Targeted Follicular Delivery, Transdermal Microneedling.

1. INTRODUCTION TO ALOPECIA AREATA

Alopecia areata is a chronic, immune-mediated dermatological disorder characterized by sudden, non-scarring hair loss on the scalp and other hair-bearing regions.[1] The condition develops due to a collapse of the hair follicle's immune privilege, which allows cytotoxic T-lymphocytes to attack follicular structures.[2] This autoimmune reaction causes hair follicles to prematurely shift from the anagen (growth) phase to the telogen (resting) phase, leading to the appearance of round or oval bald patches.[3] Although the hair follicles remain structurally intact, the disease follows an unpredictable course of remission and relapse, which can significantly affect the psychological well-being, confidence, and self-esteem of affected individuals.[1]

Conventional therapies for alopecia areata primarily aim to suppress the immune response, with corticosteroids such as Triamcinolone Acetonide being widely used in clinical practice.[4] Intralesional injections are considered a standard treatment for localized patches; however, they are often associated with considerable pain, patient discomfort, and anxiety, along with potential adverse effects like localized skin atrophy and hypopigmentation.[4,5] On the other hand, topical formulations such as creams and ointments tend to show limited effectiveness because the stratum corneum acts as a strong barrier, restricting adequate drug penetration to the deeper layers where hair follicles reside, thereby reducing therapeutic outcomes.[5]

To address these limitations, the present study proposes a synergistic approach that integrates a specialized pharmaceutical serum with derma stamp microneedling technology.[3,5] The serum, formulated as a low-viscosity and non-greasy system, enhances spreadability and improves follicular targeting while maintaining better cosmetic acceptability compared to traditional semi-solid formulations. In addition, derma stamp technology creates controlled microchannels in the skin, effectively bypassing the stratum corneum barrier and enabling deeper penetration of the corticosteroid into the dermal layer and hair follicle region, thereby potentially enhancing drug delivery and therapeutic efficacy.[5]

2. MATERIALS AND METHODS

Triamcinolone acetonide, Propylene glycol, polyethylene glycol 400 (PEG-400), and hydroxypropyl methylcellulose (HPMC) were used as excipients in the formulation. All excipients were of analytical grade and procured from standard commercial sources. Purified water was prepared as per Indian Pharmacopoeia specifications and used throughout the study.[6]

2.1 MATERIALS

Table 2.1 Materials (Ingredients for 30 ml serum).

Sr. No.	NAME	CATEGORY	QUANTITY
1.	Triamcinolone Acetonide	Corticosteroid & Anti-inflammatory	15mg
2.	Propylene Glycol	Co-solvent & Penetration enhancer	9ml
3.	PEG-400	Solubilizer	6ml
4.	HPMC	Thickening Agent	0.45g
5.	Methyl Paraben	Preservative	0.03g (0.1%)
6.	Purified water	Vehicle	q.s. to 30 ml

2.2 METHODOLOGY

Formulation of the Pharmaceutical Serum

The serum was formulated using a modified co-solvency method to ensure the solubility of the lipophilic drug within an aqueous-based system.[7,8]

1. Phase A: Organic Phase (Drug Solubilization)

Accurately weighed 15 mg of Triamcinolone Acetonide was introduced into a solvent blend comprising 9 ml of Propylene Glycol and 6 ml of PEG-400. The mixture was subjected to continuous magnetic stirring at room temperature until a clear, homogenous solution was achieved, indicating complete drug solubilization.[7]

2. Phase B: Aqueous Phase (Polymer Hydration)

Purified water (10 ml) was heated to 70°C, and 0.03 g of Methyl Paraben was dissolved under stirring. Subsequently, 0.45 g of HPMC was gradually sprinkled onto the surface of the hot water with vigorous agitation to prevent agglomeration. The mixture was allowed to cool to room temperature, facilitating the complete hydration of the polymer into a viscous, transparent gel base.[8,6]

3. Phase C: Integration and Finalization

Phase A was slowly incorporated into Phase B under constant, gentle stirring to ensure uniform distribution within the polymer matrix. The final volume was adjusted to 30 ml using Purified Water (q.s.). The resulting serum was clarified by filtration and stored in an amber glass bottle to protect the light-sensitive active ingredient.[6]

Flowchart

Phase A: Drug Solubilization

Measure 9 ml Propylene Glycol + 6 ml PEG 400.

Add 15 mg Triamcinolone Acetonide. Stir until a clear solution is formed.

Phase B: Preservative & Polymer Base

Heat 10 ml Purified Water. Dissolve 0.03 g Methyl Paraben. Gradually add 0.45 g HPMC with vigorous stirring. Allow to hydrate and cool.

Phase C: Incorporation

Slowly add Phase A into Phase B. Stir continuously to ensure homogeneity.

Phase D: Final Volume

Transfer to a graduated cylinder. Add Purified Water (q.s.) to reach 30 ml.

Final Serum

Transfer to an amber bottle for storage.

PICTORIAL REPRESENTATION OF PROCEDURE

Figure 2.1 Weighing of HPMC.

Figure 2.2 Weighing of Triamcinolone Acetonide (drug)

Figure 2.3 Hydration of HPMC.

Figure 2.4 Drug Solubilization.

Figure 2.5 Phase A and B.

Figure 2.6 Mixing.

Figure 2.7 Filtration

Figure 2.8 Serum in Derma Stamp.

2.3 Derma Stamp Application Protocol

Permeation enhancement was achieved using a precision DERMA STAMP device (standard 0.5 mm to 1.0 mm needle length).[5,9]

1. Aseptic Preparation: The target scalp area was cleansed with a 70% isopropyl alcohol solution.[10]
2. Microneedling Procedure: The sterile device was applied to the alopecic patches using a vertical stamping motion. Stamping continued until the clinical endpoint of uniform erythema and pinpoint bleeding (petechiae) was reached, signaling the successful creation of microchannels reaching the superficial papillary dermis.[5,9]
3. Drug Application: The formulated serum was immediately applied dropwise over the treated area. Gentle patting was performed to facilitate the entry of the drug into the patent microchannels and follicular ostia.[9]

3. EVALUATION

3.1 Physicochemical evaluation

1. Organoleptic Properties: The prepared formulation was evaluated for color, clarity, and homogeneity by visual inspection under normal lighting conditions.[7]
2. pH Determination: The pH was measured using a calibrated digital pH meter (EUTECH INSTRUMENTS, Singapore) at room temperature.[7]
3. Viscosity Measurement: Viscosity was determined using an Ostwald viscometer at room temperature.[11]
4. Spreadability: Spreadability was assessed using the parallel glass slide method as reported in standard pharmaceutics protocols.[7,11]
5. Drug Content Estimation: Drug content was analyzed using UV-Visible spectrophotometry at the λmax of triamcinolone acetonide.[12]

Figure 3.1 pH test.

Figure 3.2 Viscosity test.

Figure 3.3 Spreadability test.

Figure 3.4 Homogeneity test

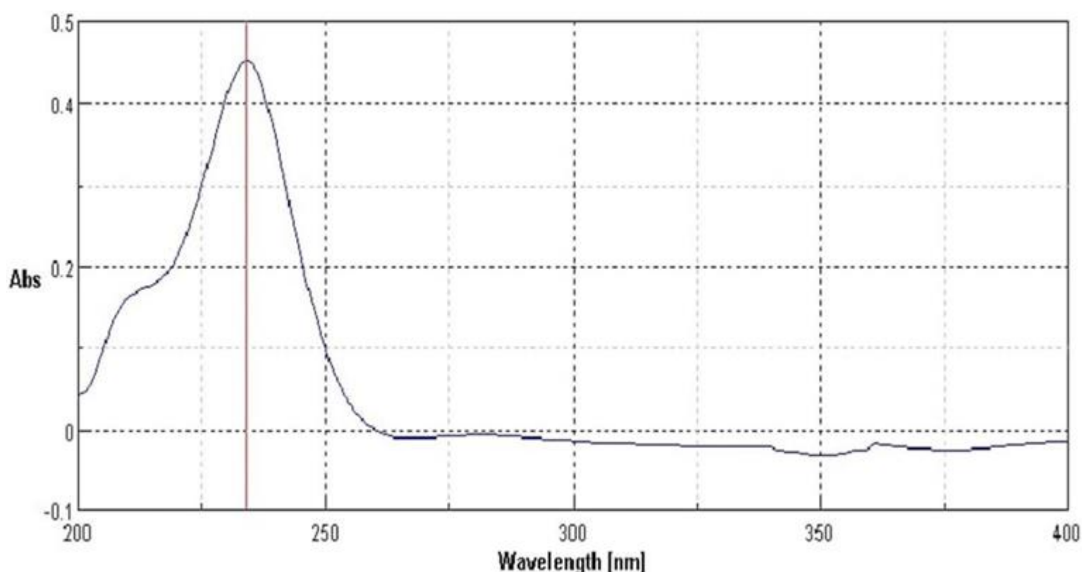

Figure 3.5 UV Spectroscopy.

3.2 Drug-Excipient Compatibility Study

Compatibility between triamcinolone acetonide and excipients was evaluated using Fourier-transform infrared spectroscopy (FTIR) (BRUKER ALPHA II FTIR SPECTROMETER, Germany). The spectra of pure drug and formulation were compared to identify any potential chemical interactions. The method was performed as per standard FTIR analytical procedures.[13]

Table 3.1 FTIR Study

Sr. No.	Functional Group	Pure Drug (cm^{-1})	With PG	With PEG	With HPMC	Inference
1.	O–H stretching	3397	3368	3309	3396	No significant shift
2.	C–H stretching	2990	2973	2875	2950	Retained
3.	C=O stretching	1710	1652	1651	1710	No interaction
4.	C=C stretching	1611	—	—	1611	Stable
5.	C–O stretching	1056–1277	1045	1090	1056	No change

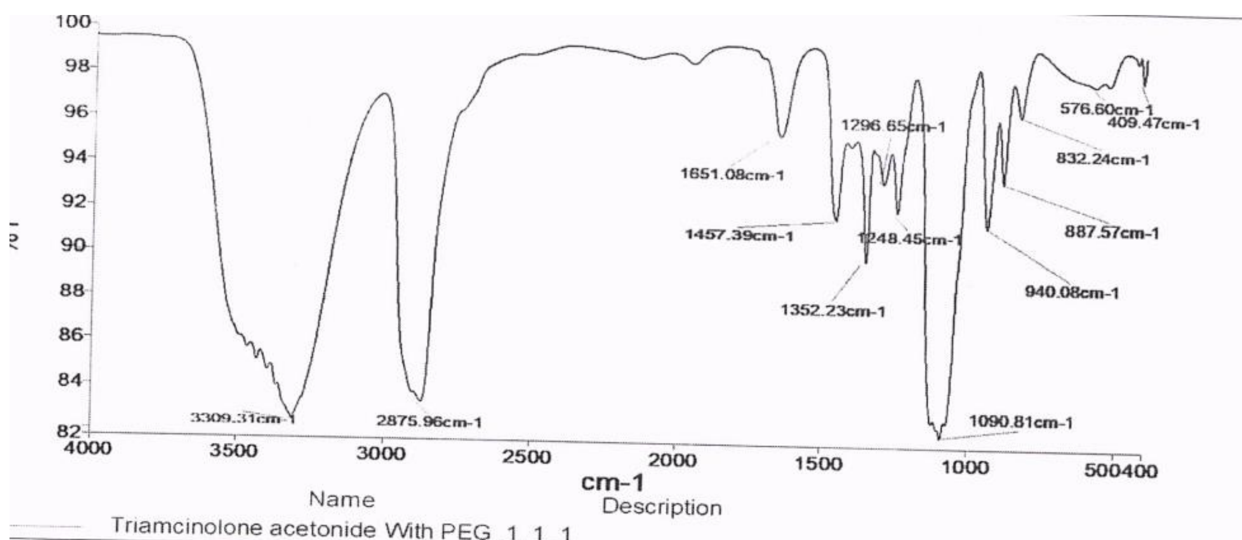

Figure 3.6 FTIR Study of Triamcinolone Acetonide with PEG.

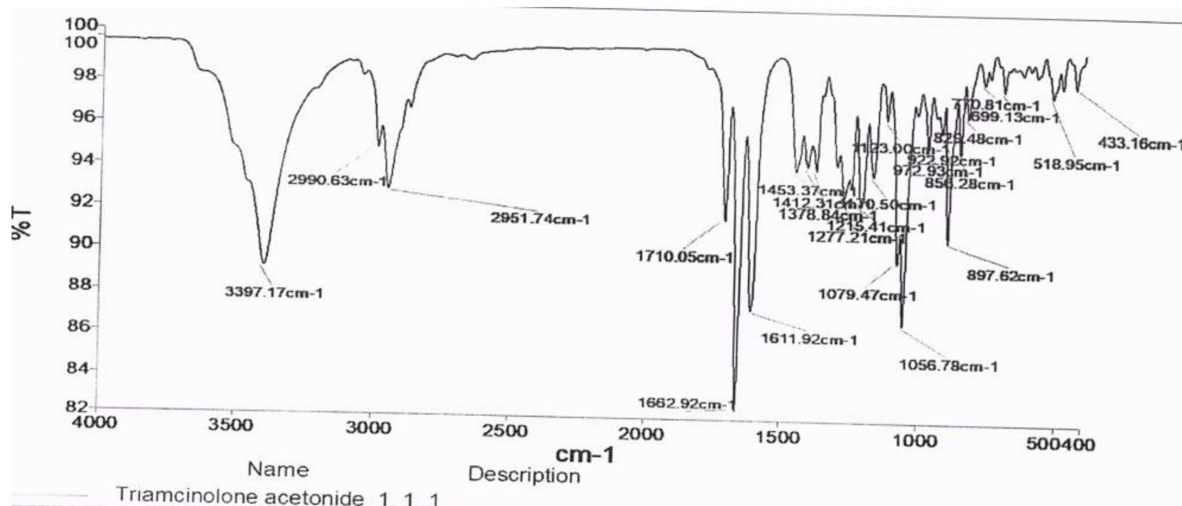

Figure 3.7 FTIR Study of Triamcinolone Acetonide.

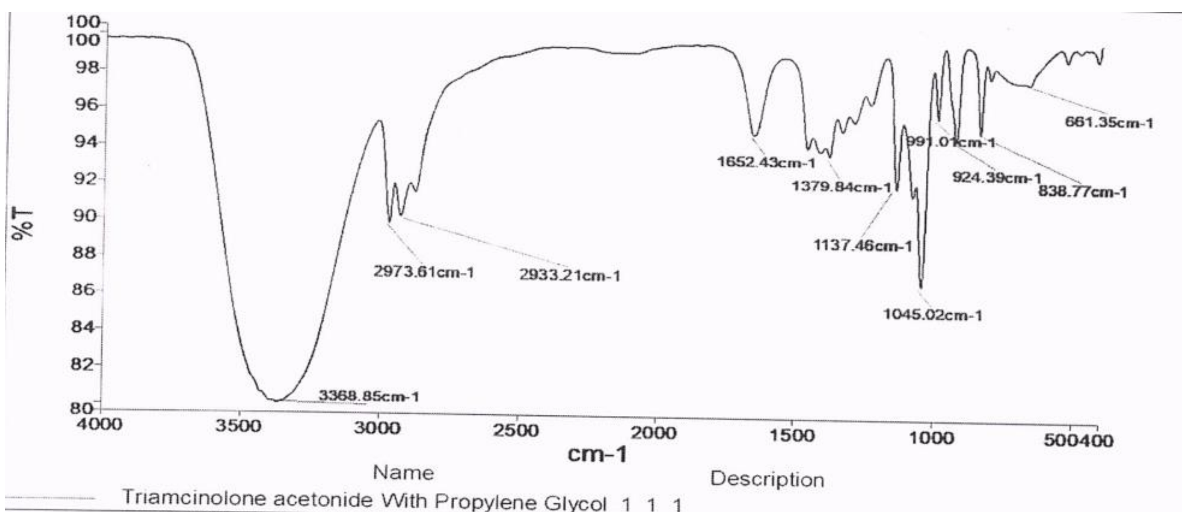

Figure 3.8 FTIR Study of Triamcinolone Acetonide with Propylene Glycol.

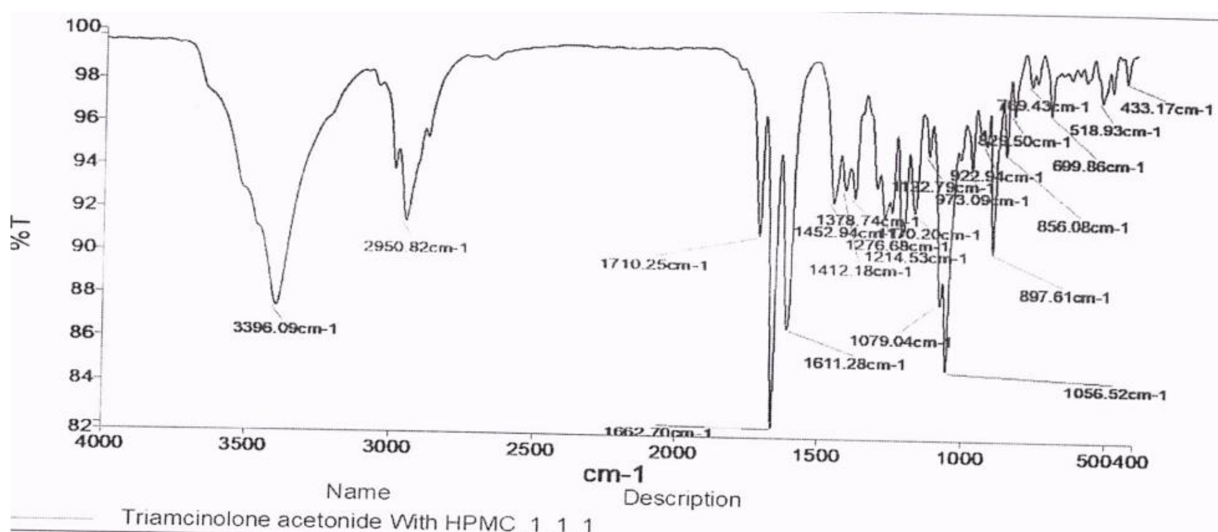

Figure 3.9 FTIR Study of Triamcinolone Acetonide with HPMC.

3.3 In Vitro Drug Permeation Study

In vitro permeation studies were carried out using a Franz diffusion cell apparatus (PERMEGEAR INC., USA), following previously established methods with slight modifications.[14]

The formulation was placed in the donor compartment, separated by a suitable semi-permeable membrane from the receptor compartment containing phosphate buffer (pH 7.4). The system was maintained at 37 ± 0.5°C with continuous stirring. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically.[14,15]

Figure 3.10 In-vitro Drug Permeability Test.

3.4 SAFETY EVALUATION

1. Skin Irritation Test

Figure 3.10 Skin irritability test.

Skin irritation studies were performed according to standard dermatological safety protocols to evaluate the irritation potential of the formulation.[16]

2. Chorioallantoic Membrane (CAM) Test

Figure 3.11 CAM test

The irritation potential was further assessed using the Hen's Egg Chorioallantoic Membrane (HET-CAM) method, as described in previously reported non-animal testing protocols.[17]

4. RESULTS AND DISCUSSIONS

The results clearly indicate that the developed triamcinolone acetonide serum possesses optimal physicochemical properties, sustained drug release, and excellent safety and stability. The formulation is suitable for effective topical delivery, and when combined with microneedling, it enhances drug penetration and therapeutic efficacy in alopecia areata.

Table 4.1 Result.

Sr. No.	Parameter	Result Obtained	Inference
1	Organoleptic Properties	Clear, transparent, colorless liquid with characteristic odor	Acceptable
2	pH	5.4 ± 0.2	Within acceptable scalp range (4.5–6.5)
3	Viscosity	122.4 + 5 cp	Suitable for easy application
4	Spreadability	6.8 ± 0.3 cm	Good spreadability
5	Homogeneity	Uniform, no phase separation	Stable formulation
6	Washability	Easily washable	Non-greasy nature confirmed
7	Greasiness	Non-greasy	Suitable for scalp use
8	Skin Irritation (HET-CAM)	No irritation observed	Safe for topical application
9	Drug Content (UV)	98.6% ± 1.2	Within acceptable limit (95–105%)
10	FTIR Compatibility	No interaction observed	Drug-excipient compatible
11	Permeability Study	Enhanced drug permeation observed	Effective delivery system
12	Sensitivity Test	No hypersensitivity reaction	Safe formulation
13	Microbial Growth	No microbial growth	Good preservative system

5. DISCUSSION ON MICRONEEDLING-ASSISTED DELIVERY

The significance of using a **Derma Stamp** in this study lies in its ability to overcome the stratum corneum, the skin's primary rate limiting barrier.[5,9]

- **Mechanism of Enhancement**: The device creates transient microchannels that act as massive aqueous highways, bypassing the lipid-rich mortar of the skin. This facilitates the delivery of Triamcinolone Acetonide directly to the bulge region (1.0–1.5 mm deep), which is the target site of the autoimmune attack.[5]
- **Therapeutic Synergy**: The mechanical action of the derma stamp stimulates the Wnt/β-catenin signaling pathway and promotes the release of growth factors such as VEGF and PDGF, thereby encouraging dormant hair follicles to re-enter the anagen phase.[9,18]

6. CONCLUSION

The present research establishes a novel and clinically effective therapeutic strategy for the management of alopecia areata by integrating advanced pharmaceutical formulation with mechanical permeation enhancement. The developed Triamcinolone Acetonide serum, formulated using a co-solvency approach, demonstrated clear advantages over conventional semi-solid systems. It exhibited optimized physicochemical properties, including a scalp-compatible pH (5.2–5.8) and low viscosity (672.3–685.8 cP), ensuring excellent spreadability, rapid absorption, and enhanced follicular targeting. Analytical evaluations such as UV spectrophotometry and FTIR confirmed drug stability, uniform distribution, and absence of drug–excipient interactions, validating the integrity of the formulation. Furthermore, the serum was found to be non-irritant, cosmetically acceptable, and patient-friendly, offering a painless alternative to intralesional injections.

A key innovation of this study is the incorporation of derma stamp-assisted microneedling, which enhances transdermal drug delivery by creating transient microchannels that bypass the stratum corneum and enable targeted delivery to the perifollicular region. This approach improves the management of underlying autoimmune inflammation while also stimulating biological responses, including activation of β-catenin signaling and release of growth factors such as VEGF and PDGF, thereby encouraging hair follicles to re-enter the anagen phase. The combined effect of pharmacological action and mechanical stimulation results in a synergistic improvement in therapeutic efficacy and hair regeneration. Overall, this strategy provides a targeted, minimally invasive, and patient-compliant alternative, effectively bridging the gap between conventional topical treatments and invasive procedures, and represents a promising advancement in alopecia areata management.

7. ACKNOWLEDGEMENT

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