Formulation Development and Characterization of Novel Antipsoriatic Gel for Topical Drug Delivery System.

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***Abstract*—Studies using FTIR spectroscopy verified that the medicine and excipients are compatible. Dimethyl sulfoxide, Carbopol 10NF, propylene glycol, glycerol, methyl paraben, propyl paraben, and water were used to make the gel. Out of all the formulations, the Optimized formulation (F3) is the most effective. The prepared gel demonstrated satisfactory physical characteristics, including assay (97%w/w) and pH (4.99). Additionally, 98.2% of the medication was released in 12 hours according to in vitro diffusion experiments. For one, two, and three months, the formulation was loaded for stability at accelerated conditions of 40°C/75%RH and 30°C/65%RH. The optimized formulation (F3) has demonstrated satisfactory in vitro performance and good stability.**

I. INTRODUCTION

A. Skin

Structure of skin

There are numerous histological layers that make up the multilayered human skin. The body's most accessible organ is the skin. Approximately one-third of the blood flowing through an adult's body is received by the skin, which has a surface area of roughly two square meters. The skin is a complicated organ that permits different chemicals to enter and move through it. A few systemically active medications are administered through the skin, where they are absorbed and subsequently delivered to target tissues via the systemic circulation. With a surface area of roughly 1.5–2 m2 in adults, it is the largest organ in the body and is home to glands, hair, and nails.

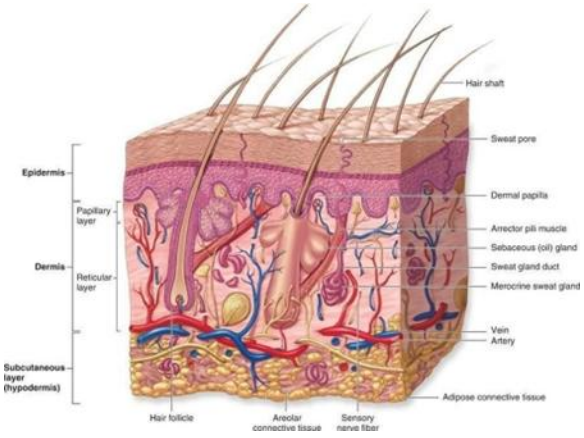

Figure 1: Structure of skin

B. Skin consists of two primary layers:
a) Epidermis
b) Dermis

a) Epidermis:
The skin's outermost layer, known as the epidermis, is a stratified squamous epithelium that is mainly made up of keratinocytes at various stages of development. Keratinocytes are the main cells that make up the epidermis and are responsible for producing the protein keratin. Because the epidermis lacks blood vessels, it is totally reliant on the dermis underneath it for waste removal and nutrient delivery via the basement membrane. The epidermis' primary job is to serve as a biological and physical barrier to the outside world, keeping allergens and irritants out. In addition, it keeps internal equilibrium and stops water loss. the majority of body parts have four layers, but those with the thickest skin have five.

1. The horny layer, or stratum corneum;
2. Stratum lucidum (found exclusively in thick skin, such as the fingers, palms, and soles of the feet);
3. Stratum granulosum (granular layer);

4. Stratum spinous (prickle cell layer); and
5. Stratum basales (germinative layer).

There are other cell structures in the epidermis. About 95% of epidermal cells are keratinocytes; the remaining cells are melanocytes, Merkel cells, and Langerhans cells.

b) Dermis:
The dermis is elastic and hard. Collagen and elastic fibers are intertwined in the matrix, which is composed of connective tissue.
When the skin is overstretched, these elastic fibers may rupture, leaving behind permanent striate, or stretch scars, which are frequently seen in pregnancy and obesity. Wrinkles develop because the skin's tensile strength, which is provided by collagen fibers binding with water, diminishes with age. The primary cells in the dermis are fibroblasts, macrophages, and mast cells. The areolar tissue and variable levels of adipose (fat) tissue lie under its deepest layers. The dermis contains the following structures:
1. Vessels of Blood
2. Vessels of lymph
3. Endings of Sensory Nerves
4. Sweat Glands
5. Hairs
6. The muscles of the rector pili and
7. Sebaceous glands.

1 Blood vessels: Sweat glands, sebaceous glands, and hair follicles are supplied to the dermis by the capillary branches of the arterioles, which form a thin network. The interstitial fluid from the blood vessels in the dermal papillae provides oxygen and nutrients to the epidermis, which lacks a blood supply.

2. Lymph vessels:
These make up the dermis's network.

3 Sensory nerve ends:
The dermis has a large number of sensory receptors, which are specialized nerve endings that are sensitive to pressure, temperature, touch, and pain. The various sensory receptors are triggered based on the input. Sensory nerves carry nerve impulses produced in the dermis to the spinal cord and then to the cerebrum's sensory region, where the sensations are perceived.

4 Sweat glands:
Sweat glands are found all over the skin, although they are most prevalent in the groin, axilla, palms of the hands, and soles of the feet. They are made up of cells called epithelial cells. The glands' bodies are wound into the subcutaneous tissues. A few ducts open onto the skin. surface at microscopic indentations, holes, and other openings into hair follicles. It is not until puberty that glands that expand into hair follicles become active. They exude a milky, odorless fluid in the axilla that, when broken down by surface microorganisms, produces an offensive smell. Sympathetic nerves trigger the production of sweat in reaction to fear and elevated body temperature. Sweat, which is secreted by glands that open on the skin's surface, is mostly used to regulate body temperature. The hypothalamus's temperature-regulating region controls how much perspiration is produced as it evaporates from the body's surfaces, drawing heat from the body's core. If water and salt intake are not suitably adjusted, excessive perspiration can cause dehydration and significant sodium chloride depletion. Water loss is still considerable after seven to ten days of exposure to high temperatures, but salt loss is much decreased.

5 Hairs:
These are created when epidermal cells, known as hair follicles, descend into the dermis or subcutaneous tissue. The bulb is a collection of cells located at the base of the follicle. The bulb's cells multiply to create hair, but as they are forced upward and away from their food source, they die and become keratinized. The shaft is the portion of the hair above the ski, and the rest is the root. The amount of melanin in the hair determines its color, which is genetically determined. Tiny air bubbles take the place of pigment in white hair.

6. The muscles of the rector pili:
The little bundles of smooth muscle fibers connected to the hair follicles are known as the arrector pili muscles. When these muscles contract, the hair stands straight up and the sin surrounding it rises. resulting in "goose meat." In reaction to fear and cold, sympathetic nerve fibers activate the muscles. Air is trapped by erect hairs, providing an insulating layer. When combined with shivering, or the

involuntary contraction of skeletal muscles, this is an effective warming technique.

7. Sebaceous glands:
The secretary epithelial cells that make up the sebaceous gland are generated from the same tissue as the hair follicles. They are found in everyone's skin and release sebum, an oily substance, into the hair follicles. sections of the body other than the soles of the feet and the palms of the hands. The skin of the scalp, face, axillae, and groin is where they are most prevalent. In areas where different types of superficial epithelium are transitioning, Sebum is secreted directly onto the surface by sebaceous glands that are separate from hair follicles in areas like the lips, eyelids, nipple, labia minora, and glans penis. Sebum offers hair a glossy look while making it more malleable and smoother. It functions as a bactericidal and fungicidal agent on the skin, reducing infection and providing some waterproofing. Additionally, it keeps skin from drying out and breaking, particularly when exposed to heat and sunlight. Babies and elderly individuals are more vulnerable to the effects of excessive moisture (maceration) since the activity of the glands increases throughout puberty and decreases at extremes of age.

II. SKIN PENETRATION MECHANISMS

A. Molecules can pass through the stratum corneum in a number of ways, including:
The intercellular pathway the transcellular pathway and Appendageal route (through either sweat gland or hair follicle) In typical situations the low surface that the appendages occupy contributes to the appendageal route's lack of significance. Differentiating between the transcellular and intercellular pathways is challenging. Fick's law of diffusion solutions was used to assess in vivo research on methyl nicotinate skin absorption. A diffusional route length of 350 nm was discovered to provide the best fit to the data. It was hypothesized that the intercellular pathway was significant because the skin's thickness is about 1/20 of this. The intercellular gaps contain a mixture of ceramides, free fatty acids and their esters, cholesterol, and its sulfate, according to advances in analytical techniques. Skin Absorption & Barrier

Drug absorption through skin mainly occurs via the intercellular route, not appendages (hair follicles, glands).

Skin acts as a strong barrier due to Tortuous pathway, Structured lipid bilayers (ceramides, fatty acids, cholesterol). Only a small percentage of drug reaches the target site when applied topically.
To improve delivery, systems like liposomes, noisome, transferosomes, ethosomes, nanoparticles, and hydrogels are used.

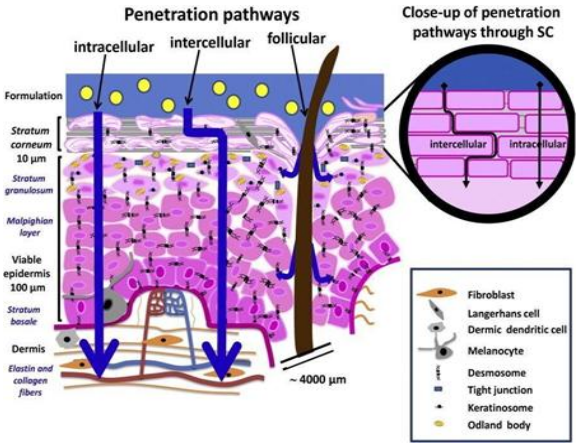

Figure 2: Skin Penetration Pathways

B. Topical Drug Delivery
Effective for low-dose drugs applied to small areas.

Stratum corneum:
40% lipids, 40% protein, 20% water
Favors lipophilic drugs
Hydrophilic drugs penetrate poorly

Ideal drug properties:
Molecular weight < 500 Da
Good lipophilicity

Benefits:
Better bioavailability
Reduced side effects
Improved patient compliance

Figure 3: Local and Systemic Actions.

Uses of Topical Preparations

- Surface effects:

cleansing, cosmetic, protective, antimicrobial

- Stratum corneum effects:

moisturizing, keratolytic

- Deeper layers:

anti-inflammatory, anesthetic, antihistamine

- Systemic effects:

e.g., nitroglycerin, clonidine

- Additional effects:

emollient, antiperspirant, depilatory

C. Advantages & Disadvantages

Advantages

- Avoids first-pass metabolism
- Non-invasive & painless
- Easy application
- Better bioavailability
- Reduced systemic toxicity

Disadvantages

- Skin irritation & allergies
- Poor permeability
- Limited to low-dose drugs
- Large molecules poorly absorbed

D. Gels

- Semisolid systems with liquid trapped in a 3D polymer network.
- Widely used due to:
  - Biocompatibility
  - Stability
  - Good drug delivery properties

1. Structure

- Polymer network forms a film on skin after application.

2. Types

- Inorganic gels: two-phase (e.g., bentonite)
- Organic gels: single-phase (e.g., carbomer)
- Hydrogels (water-based)
- Organo gels (oil-based)

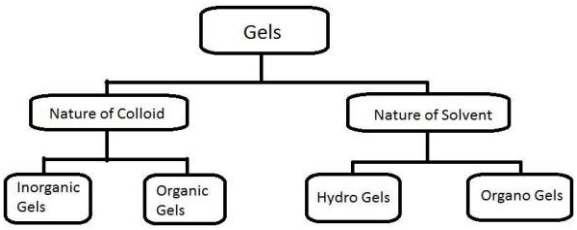

Figure 4: Classification of Gels

3. Properties of Gels

- Swelling: uptake of liquid
- Syneresis: liquid separation on standing
- Ageing: network becomes denser over time
- Structure: network gives rigidity
- Rheology: non-Newtonian (viscosity decreases with shear)

4. Psoriasis

- Chronic inflammatory skin disease affecting 2–3% of population
- May lead to psoriatic arthritis
- Triggered by:
  - Stress
  - Injury
  - Drugs
  - Infection

5. Symptoms

- Inflammation, scaling, itching
- Keratinocyte overgrowth
- Plaques, nail & joint involvement

6. Pathophysiology of Psoriasis

- Caused by immune system dysregulation
- Key cells involved:
  - Dendritic cells
  - T cells (Th1, Th17)
- Important cytokines:
  - IL-17, IL-23, TNF-α, IFN-γ

7. Process

- Dendritic cells activate → release cytokines
- T cells proliferate → inflammation increases
- Leads to:
  - Skin thickening
  - Increased blood vessels
  - Chronic inflammation

III. MATERIAL AND METHODS

1) APA07

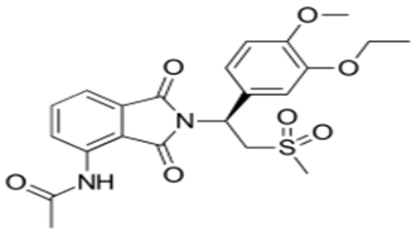

Figure 5: Structure of APA07

- Type: PDE4 inhibitor for psoriatic arthritis and psoriasis
- Classification: immunomodulator, antirheumatic, anti-psoriatic
- Characteristics: o Powder that is yellow-white

BCS Class IV (poor permeability and solubility)
Molecular Weight: 460.5 g/mol
Low solubility (225.4 mg/L)
Half-life: six to nine hours
Bioavailability: 73% • Pharmacokinetics: o Peak at about 2.5 hours, well absorbed CYP3A4 is the primary metabolizer.

Mechanism:
o Inhibits TNFα, IL2, IL17, and other inflammatory mediators by blocking PDE-4 → cAMP → •

Toxicity:
o Suicidal thoughts and depression o Reduction of weight Profile of Excipients

Excipients
1. Carbopol (Carbopol 10 NF)

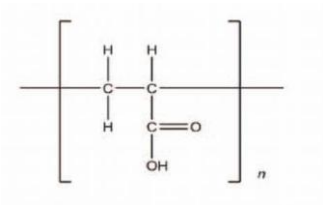

Figure 6: Structure of Carbopol

Molecular Formula: - C3H4O2
IUPAC name: - Prop-2-enoic acid
Solubility: - Insoluble in water and swells I water up to 1000 times their initials volume.
pH: - 4.0-6.0
Specific gravity: - 1.41

Sr. No.	Polymer	Viscosity (cps)
1	Carbopol Ultrez 10 NF	45000-65000
2	Carbopol 934 NF	30500-39400
3	Carbopol 934 P NF	39400-39400
4	Carbopol 71 G NF	4000-11000

Table 1: Viscosity range of different Carbopol polymers

- Acrylic acid polymer that is cross-linked
- Features: Gelling agent Controlled release of drugs o Stabilizer and thickener
- Applied to bio adhesive systems, gels, creams, and suspensions

2) DMSO, or dimethyl sulfoxide

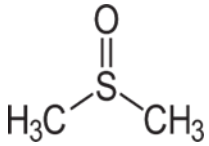

Figure 7: Structure of DMSO

Nonproprietary names: Dimethyl sulfoxide, Dimethylis sulphoxidum
Synonyms: Dimexide; dimetyl sulpoxide; DMSO; kemso; methylsulfoxide; Rimso-50; sulphinylbismethane.
Chemical name: Sulfinylbimethane
Empirical formula: C2H4O5
Molecular weight: 78.13
CAS Number: [67-68-5]
Function:

- Enhancer of penetration and solvent
- Miscible with organic solvents and water Extremely hygroscopic
- Used to enhance skin absorption of medications
- It could irritate your skin.

3) Glycerol

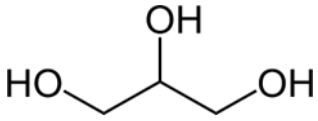

Figure 8: Structure of Glycerol

Synonyms: Glycerin, propanetriol, 1,2,3-Trihydroxypropane, 1,2,3-propanetriol
Formula: C3H8O3
Solubility: freely soluble in ethanol, completely soluble in water
Description: It is a colorless, odorless, viscousliquid that is sweet-tasting and non-toxic

Function:
- solvent, lubricant, and humectant
- A pleasant, thick, colorless liquid
- Applied to: o Skin care o Cosmetics, toothpaste, and syrups
- Enhances wetness and suppleness

4) Ethanol

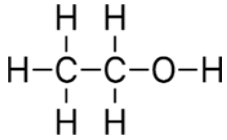

Figure 9: Structure of ethanol

Synonyms: Alcohol, Cologne Spirit, Denatured Alcohol, Fermentation Alcohol, Grain Alcohol, Ethyl Alcohol, Ethyl Hydrate, Ethyl Hydroxide, Fermentation Alcohol, Grain Alcohol, Methyl Carbinol, Molasses Alcohol, Spirits of Wine.

CAS Registry Number: 64-17-5
Structure Formula: C2H5OH
Molecular Weight: 46.0414
Boiling Point: - 270 5°C
Freezing Point: - 125.2°C
Functional Category: - Fungicide, anti-androgenic
Function:
- Co-solvent and solvent
- A flammable, volatile liquid
- Frequently utilized in drug formulations
- Needs to be stored carefully, away from heat sources and oxidizers.

5) Paraben Methyl

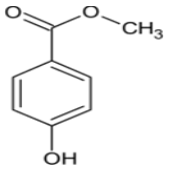

Figure 10: Structure of Methyl Paraben

Synonyms: Methyl paraben Methyl p-hydroxybenzoate
Description: Almost odourless, small colourless crystals or white crystalline powder
CAS Number: 99-76-3
Chemical Formula: CH3(C6H4(OH)COO)
Boiling Point: 270.5°C
Freezing Point: 125.2°C
Functional category: Fungicide, anti-androgenic
Function:
- Antimicrobial preservative
- Applied to medications and cosmetics
- Quickly eliminated, safe, and non-toxic

6) Paraben Propyl

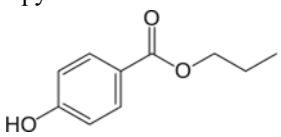

Figure 11: Structure of Propyl Paraben

Synonyms: Propyl paraben 4-Hydroxybenzoic acid propyl ester
Description: Colorless crystals or white powder or chunky white solid
Molecular formula: C10H12O3
Molecular weight: 180.203 g/mol
Physical Description: Colorless crystals or white powder or chunky white solid. Melting point 95-98°C. Odorless or faint aromatic odor. Low toxicity, tasteless (numbs the tongue)
pH: 6.5-7.0
CAS Number: 94-13-3
Boiling Point: 271 ° F at 1 mm Hg
Melting point: 203 to 208°F
Density: 1.287 g/cu cm at 20 °C

Function:
- Antimicrobial preservative
- Comparable to methyl paraben
- Widely used and low toxicity

IV. FORMULATION DEVELOPMENT

1. The goal of the formulation

APA07 is only available orally at this time, which results in:
- GI distress, nausea, and vomiting Side effects of first-pass metabolism
- The purpose of topical gel was to: o Provide localized action
- Steer clear of first-pass metabolism Enhance patient safety and adherence
- Approximately 80% of individuals have mild to moderate psoriasis.

2. Research on Reformulation

Performed to guarantee a stable, safe, and efficient formulation

Included: Highest solubility in DMSO, according to solubility studies

FTIR studies: Verified the compatibility of the medication and excipient

Linear range: 10–50 µg/ml;

calibration curve: -λmax: 263 nm the formula is y = 0.0849x + 0.0541 (r = 0.998).

3. Design of Formulation

chosen ideal composition:

- Carbopol 10 NF: 1.2% (gelling agent)
- 10% DMSO (solvent and penetration booster) 29.3% of the co-solvent is propylene glycol.
- Glycerine (humectant): 24.3% • 6% ethanol (preservative assistance and co-solvent)

4. Rationale

Gels offer:

- Quick medication release and onset Improved absorption
- Steer clear of first-pass metabolism
- Perfect for managing persistent psoriasis

5. Method of Preparation

- Combine propylene glycol, glycerine, and water.
- Stir in the carbopol for two hours.
- In DMSO, dissolve APA07 and add
- Add ethanol-dissolved parabens.
- Use NaOH to adjust the pH.

6. Assessment Criteria

Manufacturing Formula:

Formulation	F1	F2	F3	F4
Ingredient	gm/100g	gm/100g	gm/100g	gm/100g
API	2.0	2.0	4.0	4.0
DMSO	10.0	15.0	15.0	10.0
Carbopol 10NF	1.2	1.2	1.2	1.2
Propylene glycol	27.3	24.3	24.3	24.3
Glycerine	28.3	26.3	24.3	29.3
Ethanol	6.0	6.0	6.0	6.0
Methyl paraben	0.1	0.1	0.1	0.1
Propyl paraben	0.1	0.1	0.1	0.1
Purified water	25.0	25.0	25.0	25.0

Table 2: Formulae of different formulations (For 100 g)

- Physical characteristics:

consistency, color, & look Measurement pH of the gels were measured using digital pH meter

- HPLC assay: retention period approximately 3.9 minutes
- Viscosity: Viscosities of the prepared gels were measured using cone and plate viscometer with spindle no. 1 at 25°C±0.5°C. • The percentage of drugs 1g of prepared gel formulation containing drug equivalent to 100 mg was taken. 100 ml of phosphate buffer of pH 7.4 was added to it and the solution was mixed properly. The solution was filtered. The absorbance of the resulting solution was measured at 229 nm using a UV spectrophotometer after suitable dilutions. The drug content of the formulation was determined using the following equation:

% Drug content = (Actual concentration of drug in the formulation) / (Theoretical concentration of drug) × 100

- Test for skin inflammation

Skin irritation test was performed for the gel formulations on human volunteers to find out any irritation problems which could make it unsuitable for topical use. About 1 g of final formulation to be tested was applied to the sensitive part of the skin (like wrist portion of the hand).

- Spread ability test

1 g of the formulation was placed within a circle of 1cm diameter pre-marked on a ground glass slide. The gel formulation was sandwiched between this slide and the second slide having the same dimension. A weight of 500 g was allowed to rest on the upper glass slide for 5 min. The increase in the diameter due to gel spreading was noted. The spread

ability was then calculated from the following formula: Spread ability= M × L/T Where, M = mass in gram, L =distance traveled b

- Franz diffusion cell for in vitro diffusion • Stability studies: examined at various humidity and temperature levels

V. RESULT AND DISCUSSION

1. Calibration Curve

Concentration (µg/mL)	Absorbance
10	0.2216
20	0.3979
30	0.5593
40	0.736
50	0.9011
Intercept	0.0541
Slope	0.0849
Correlation coefficient (R^2)	0.9986

Table 3: Calibration curve for the estimation of APA07 (in pH 7.4 phosphate buffer)

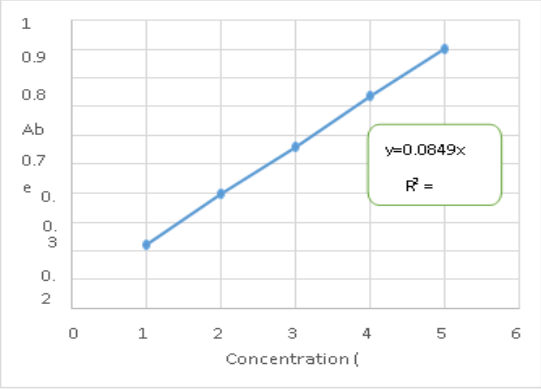

Figure 12: Calibration curve of APA07 2 IR Analysis

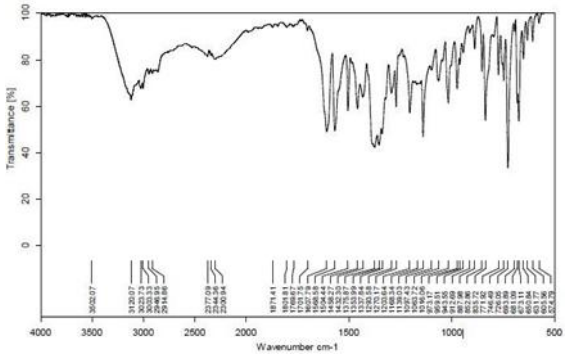

Figure13: FT-IR of Drug

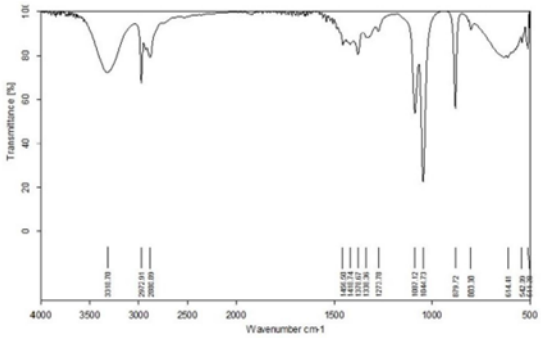

Figure 14: FTIR of APA07 and Ethanol

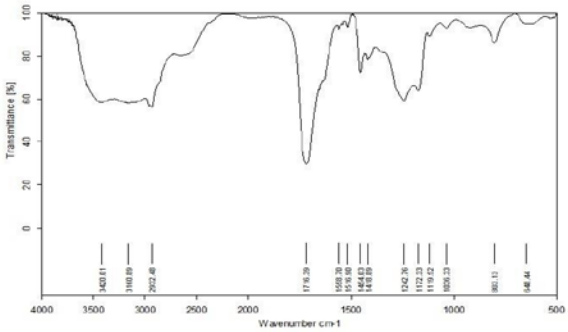

Figure 15: FT-IR of APA07 and Carbopol

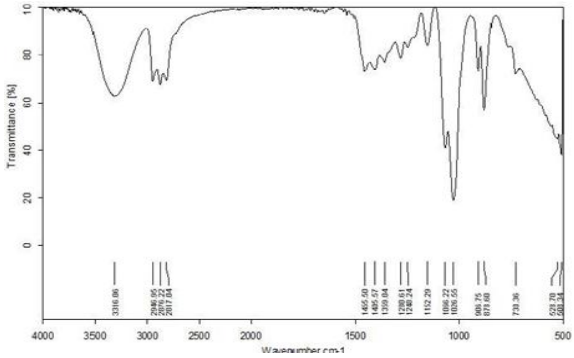

Figure 16: FT-IR of APA07 and Dimethyl Sulphoxide

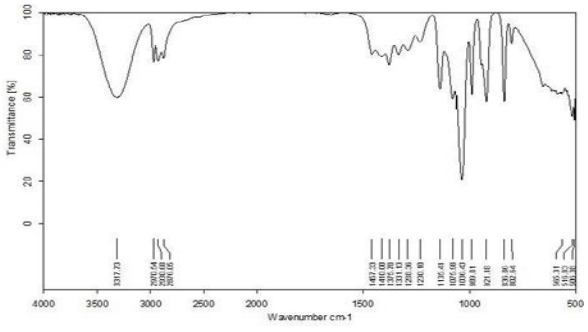

Figure 17: FT-IR of APA07 and Propylene Glycol

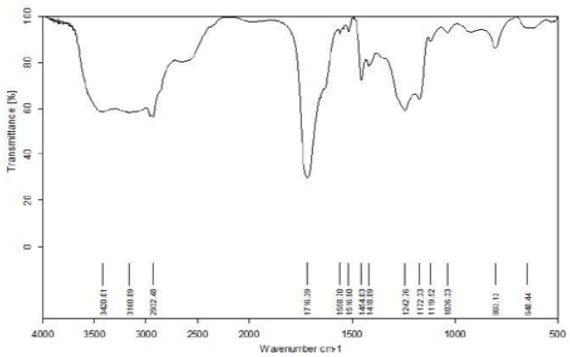

Figure 18: FT-IR of APA07 and Glycerol

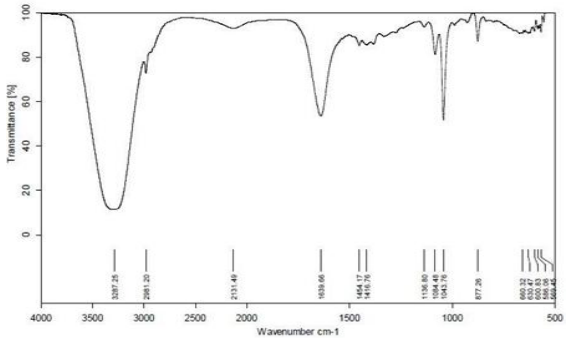

Figure 19: FT-IR of physical mixture

2. Evaluation of Formulated APA07 Topical Gels

Formulations→	F1	F2	F3	F4
Test parameters↓				
Description	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel
pH	4.84	4.92	4.99	4.88
Assay (% w/w)	96	96.40	97	96.60
Viscosity (cps)	3654	3701	4078	3800
Spread ability (gm.cm/sec)	6.578	6.530	6.529	6.552
Drug Content %	90	91	91.5	90.5

Table 4: Physical properties for APA07 topical gels (F1 – F4):

3. In vitro drug diffusion study for the formulations (F1 F4):

Time (Hrs)	Formulation codes and respective drug release profiles (%) of APA07 topical gel			
	F1	F2	F3	F4
0	0	0	0	0
2	14.7	18.7	19.1	15.2
4	19.8	21.0	24.0	23.5
6	75.2	59.2	69.9	60.4
8	81.5	85.2	96.4	85.2
12	89.5	91.2	98.2	94.2

Table 5: In vitro drug diffusion profiles of formulations (F1 – F4)

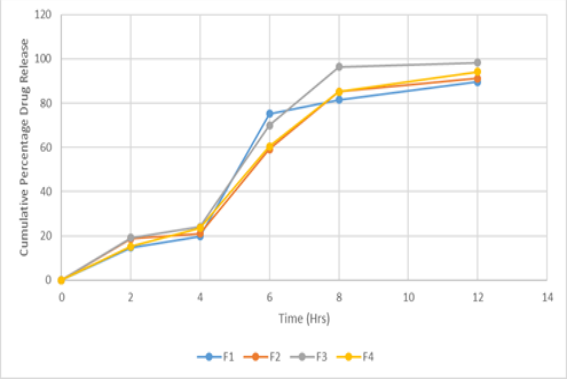

Figure 20: In-vitrodrug diffusion profiles for formulations (F1 – F4)

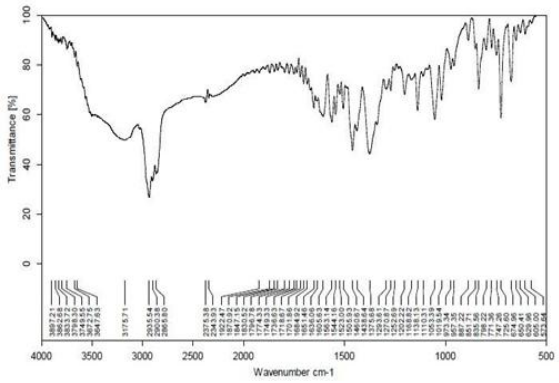

Figure 21: FT-IR of Optimized formulation (F3)

4. Stability studies for the formulation:

Condition→ Parameter↓	Initial/RT	1 Month	2 Month	3 Month
Description	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel
pH	4.84	4.97	4.86	4.98
Assay (% w/w)	97	96.80	96.40	96
Viscosity (cps)	4078	3891	3765	3689
Spread ability gm.cm/sec	6.529	6.50	6.525	6.523

Table 6: Physical parameters for Stability loaded formulations at condition (40°C/75%RH) (F3)

Condition→ Parameter↓	Initial/RT	1 Month	2 Month	3 Month
Description	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel	White to off white viscous gel
pH	4.84	4.92	4.95	4.98
Assay (% w/w)	97	96.70	96.50	96.20
Viscosity (cps)	4078	3910	3865	3690
Spread ability (gm.cm/sec)	6.529	6.501	6.4800	6.450

Table 7: Physical parameters for Stability loaded formulations at condition 30°C/65% (F3)

5. In Vitro Drug Diffusion study of Optimized formulation:

Condition→	40°C/75%RH	30°C/65%RH				
Time point↓	1 month	2 months	3 months	1 month	2 months	3 months
0	0	0	0	0	0	0
2	17.2	17.1	16.8	18.2	18.5	17.8
4	22.9	23.2	22.9	25.4	24.6	23.8
6	65.8	65.1	63.8	71.2	69.5	69.7
8	92.5	93.5	94.5	94.2	93.7	93.2
12	98.2	98.0	96.2	97.2	97.4	96.7

Table 8: In vitro-drug diffusion data for stability loaded formulations (F3)

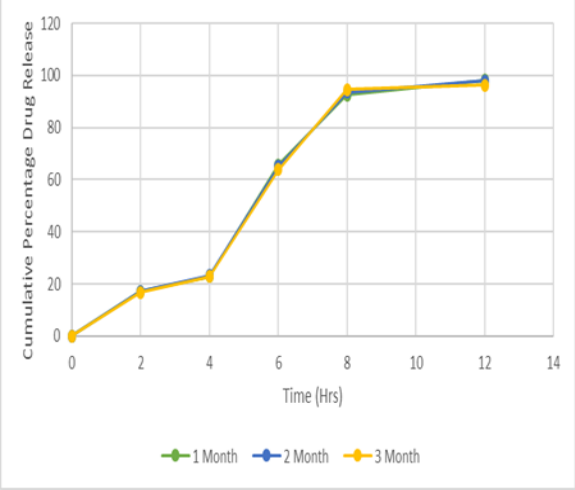

Figure 22: In vitro-drug diffusion profiles for stability loaded formulations (F3) at condition 40°C/75%RH

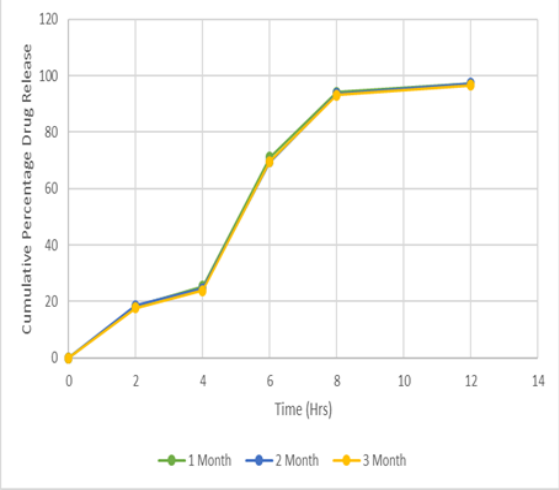

Figure 23: In vitro-drug diffusion profiles for stability loaded formulations (F3) at condition 30°C/65%RH

VI. PRE FORMULATION STUDIES

Fourier Transfer Infrared Spectrophotometry (FT-IR): Infrared spectra for pure drug, excipients, physical mixture and Optimized topical gel of APA07 were determined to find the compatibility of the drug in the mixture using FTIR-Spectrophotometer by disc method. The FTIR were performed and the spectra obtained are represented from Figure 13 to Figure 19, Figure 21. The FT-IR results showed that the prominent characteristic peaks of the drugs are maintained in the physical mixtures as well as in the final formulations which is an indication that there are no interactions affecting the activity of the drug. These excipients could be used for further study using these combinations.

VII. CONSTRUCTION OF CALIBRATION CURVE

1. Calibration curve for APA07 using pH 7.4 phosphate buffer: The calibration curve was constructed by preparing 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml and 50 µg/ml concentrations as the serial dilutions and then finding the corresponding absorbance values Spectro photometrically at 240nm. The data is represented in Table 03. The slope and intercept values were found to be 0.0849 and 0.0541 respectively and the correlation coefficient was 0.9986. The calibration curve is represented in Figure 12. From the slope and intercept values it is observed that the curve is having a positive slope and positive intercept. The coefficient of correlation value of 0.9986 is satisfactory. From the data it is evident that the concentration range from 10 µg/mL to 50 µg/mL is within the linearity range as per the Beer's Lamberts law.

2. Preparation of APA07 Topical Gel:
The APA07 Topical Gels were prepared as per the desired method. The formulae for the four formulations are tabulated in Table 2. And the manufacturing process are shown in Figure 11.

3.Evaluation studies of APA07 Topical Gel:

1) Description:
The formulated gels were physically examined for the color, appearance and consistency, the results were found satisfactory for all the four formulations (F1-F4).

2) pH measurement:
pH for all the formulation was tested using pH meter, among the four formulations F3 showed pH 4.99.

3) Assay (% w/w):
The assay for formulations was checked, among all the four formulations, the assay value for F3 formulation was 97 %w/w.

4) Viscosity (cps):
The viscosity for the formulations was measured using cone and plate viscometer, for F3 formulation the viscosity was 4078 cps, which showed the best consistency among all the four formulations.

5) Drug Content %:
The % drug content of APA07 was carried out. Overall, the four formulations (F1- F4), the F3 showed the highest percentage of drug content i.e., 91.5%.

6) Skin irritation study:
The skin irritation study was carried out. All the four batches gave 100% result. The gel was very comfortable for skin.

7) Spread ability:
Spread ability is an important factor to consider in the formulation of gel. The spread ability of prepared gel formulation was tested. Among all four formulations F3 batch showed spread ability of 6.529 gm.cm/sec.

8) In vitro-drug diffusion study:
The release of APA07 from the topical gels was carried out.

Overall, the four formulations (F1- F4), the F3 showed the highest percentage of drug release 98.2% for 12 hours

VIII. CONCLUSION

APA07 is a BCS class IV medication with low permeability and solubility that has anti-psoriatic properties. We can increase its permeability through the skin by utilizing co-solvents and permeation enhancers. All of the results indicate that it has good in vitro drug release and penetration, as determined by the Franz diffusion cell. Future research will continue to examine APA07's anti-psoriasis impact in animal models.

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