

## Formulation and Optimization of Polyherbal Gel Containing Aloe vera and Azadirachta indica for the Management of Psoriasis Using 3<sup>2</sup> Factorial Design

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**Abstract-** Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by epidermal hyperproliferation, erythema and scaling. Although several topical and systemic therapies are available, prolonged treatment may be associated with tolerability, adherence and safety challenges. Plant-derived bioactive compounds have therefore attracted interest as potential components of topical pharmaceutical formulations.

The present study was undertaken to develop and evaluate a polyherbal topical gel containing extracts of *Aloe barbadensis* and *Azadirachta indica* using a systematic factorial formulation approach.

Authenticated *Aloe barbadensis* and *Azadirachta indica* materials were extracted by Soxhlet extraction. The combined herbal extract was incorporated into a Carbopol 940-based gel containing propylene glycol and other pharmaceutical excipients. A 3<sup>2</sup> full-factorial design was employed to investigate the influence of Carbopol 940 and propylene glycol concentrations on

formulation performance. Nine formulations (AN1–AN9) were prepared and evaluated for appearance, pH, extrudability, spreadability, viscosity, grittiness, extract/drug content and in-vitro diffusion. Drug-release/diffusion behaviour was investigated using a Franz diffusion cell. Stability observations were recorded under different temperature conditions.

All nine formulations exhibited measurable and generally acceptable physicochemical characteristics. The pH values ranged from  $4.15 \pm 0.20$  to  $5.62 \pm 0.04$ . Viscosity varied from  $1211 \pm 60.3$  to  $1516 \pm 31.5$  cP, while spreadability ranged from  $34.66 \pm 8.7$  to  $54.43 \pm 5.6$  mm. AN9 exhibited the highest reported drug/extract content ( $97.43 \pm 23.5\%$ ) and diffusion value ( $96.16 \pm 16.6\%$ ). At 600 min, cumulative release values ranged from 80.34% to 88.92% across the formulations. Stability observations demonstrated maintenance of the evaluated physical characteristics over the reported three-month observation period for the tested formulation.

The findings demonstrate the feasibility of incorporating *A. barbadensis* and *A. indica* extracts into a Carbopol 940-based topical gel using factorial formulation development. The optimized/candidate formulation exhibited favourable physicochemical characteristics and sustained in-vitro diffusion behaviour. However, the findings represent pharmaceutical formulation and in-vitro performance evidence and should not be interpreted as clinical proof of anti-psoriatic efficacy. Further pharmacological, dermatological safety, in-vivo and clinical investigations are required.

**Keywords:** Psoriasis; *Aloe barbadensis*; *Azadirachta indica*; polyherbal gel; Carbopol 940; factorial design; topical drug delivery; Franz diffusion cell; herbal formulation; stability.

## I. INTRODUCTION

Psoriasis is a chronic immune-mediated inflammatory skin disorder involving complex interactions between genetic susceptibility, environmental triggers, innate and adaptive immune responses, inflammatory mediators and epidermal cells. Contemporary understanding of psoriasis has particularly emphasized the importance of the IL-23/Th17/IL-17 inflammatory axis,

which has also contributed to the development of targeted biological therapies. [1]

Topical therapy remains an important component of psoriasis management, particularly when disease involvement is limited. However, treatment selection depends on disease severity, anatomical site, patient characteristics and treatment tolerability. Consequently, formulation approaches capable of providing localized delivery with acceptable physicochemical and sensory characteristics remain relevant to pharmaceutical research.

The use of medicinal plants in dermatological preparations has a long history. *Aloe barbadensis* (Aloe vera) contains multiple biologically active constituents and has been investigated for several dermatological applications. A systematic review of clinical trials specifically evaluating Aloe vera in psoriasis identified clinical studies investigating its effectiveness and safety, although the available evidence was limited and heterogeneous. [2] A randomized comparative clinical study has also investigated topical Aloe vera in mild-to-moderate plaque psoriasis, demonstrating

the scientific interest surrounding topical Aloe preparations. [3]

*Azadirachta indica* (Neem) is another traditionally used medicinal plant with extensive pharmacological literature. Reviews describe antimicrobial, anti-inflammatory, antioxidant and immunomodulatory activities associated with diverse neem constituents. [4,5] Experimental investigations have additionally reported anti-inflammatory activity associated with neem extracts and their constituents. [6]

The combination of multiple plant extracts within a single pharmaceutical dosage form may provide a rational strategy for incorporating different phytochemical profiles into a topical delivery system. Nevertheless, formulation quality, reproducibility, physicochemical characteristics and drug/extract release behaviour must be systematically established before therapeutic claims can be made. The present study therefore focused on the development of a polyherbal gel containing *A. barbadensis* and *A. indica*. A 3<sup>2</sup> full-factorial design was employed to systematically vary Carbopol 940 and propylene glycol concentrations, followed

by evaluation of the resulting formulations for physicochemical characteristics and in-vitro diffusion performance.

The experimental work reported in the present manuscript is based on the M.Pharm dissertation data and focuses specifically on formulation development and pharmaceutical evaluation.

## II. MATERIALS AND METHODS

**Plant materials and authentication:** *Aloe barbadensis* and *Azadirachta indica* were used as the herbal components of the formulation. According to the supporting dissertation, the plant materials were authenticated by the Botany Department, University of Rajasthan, Jaipur. The authentication numbers reported were RUBL22026 for *Aloe barbadensis* and RUBL22027 for *Azadirachta indica*.

The plant materials were processed before extraction. Aloe leaves were washed, the external rind was removed and the inner material was collected and dried. Neem leaves were washed, shade dried and powdered.

### Extraction procedure

Soxhlet extraction was employed for preparation of the herbal extracts. The

dissertation describes Soxhlet extraction as a continuous hot extraction technique in which solvent repeatedly passes through the plant material, facilitating extraction of phytoconstituents. The reported extraction procedure involved loading powdered plant material into a thimble, using ethanol as extraction solvent, heating the extraction assembly and continuing extraction until completion. The extracted material was subsequently concentrated to obtain the herbal extract.

The combined extract used in the gel was reported as:

**Aloe vera extract + Neem extract = 4.6 g + 4.4 g = 9.0 g.**

#### **Formulation of polyherbal gel**

Carbopol 940 was selected as the primary gelling polymer. Propylene glycol was incorporated as a formulation component/penetration-enhancing excipient, while ethanol, methyl paraben, propyl paraben, EDTA, triethanolamine and purified water were used as additional

formulation components. For preparation, the required quantity of herbal extract was dispersed/dissolved in one portion of the formulation vehicle with ethanol and propylene glycol. Carbopol 940 was dispersed in another portion, followed by incorporation of preservatives and EDTA. The two phases were combined and triethanolamine was added gradually to obtain the gel consistency. The final batch size was 25 g.

#### **2.4 Experimental design**

A 3<sup>2</sup> full-factorial design was employed to investigate the effect of two formulation variables:

- **X1: Carbopol 940 concentration:** 1, 2.5 and 4 g
- **X2: Propylene glycol concentration:** 1, 2.5 and 4 g

The principal response variables identified in the dissertation were viscosity and drug release/diffusion. Nine experimental batches (AN1–AN9) were therefore prepared

**Table 1. Composition of experimental formulations**

| <b>Formulation</b> | <b>Carbopol 940 (g)</b> | <b>Extract (g)</b> | <b>Propylene glycol (g)</b> | <b>Ethanol (g)</b> | <b>Preservative (g)</b> | <b>EDT A (g)</b> | <b>Triethanolamine (mL)</b> |
|--------------------|-------------------------|--------------------|-----------------------------|--------------------|-------------------------|------------------|-----------------------------|
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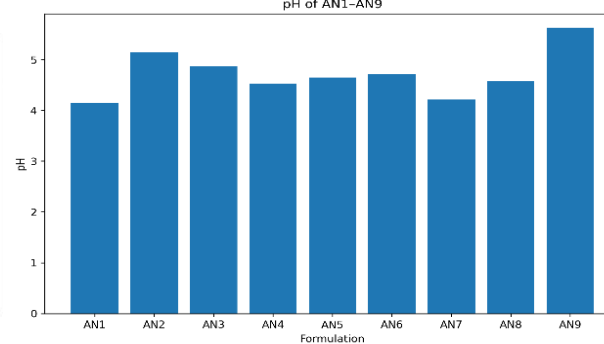
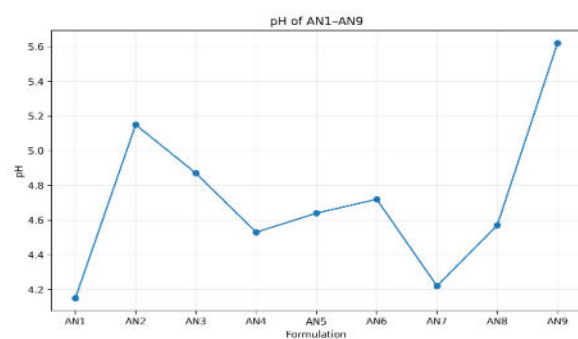
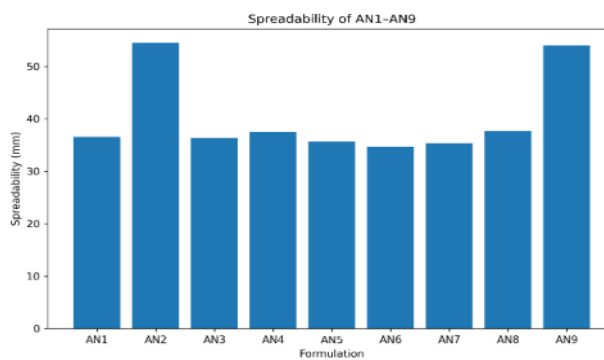
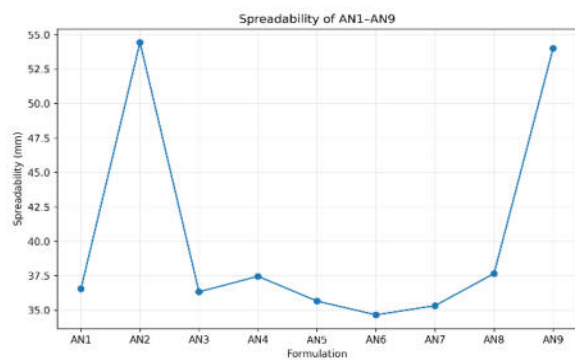
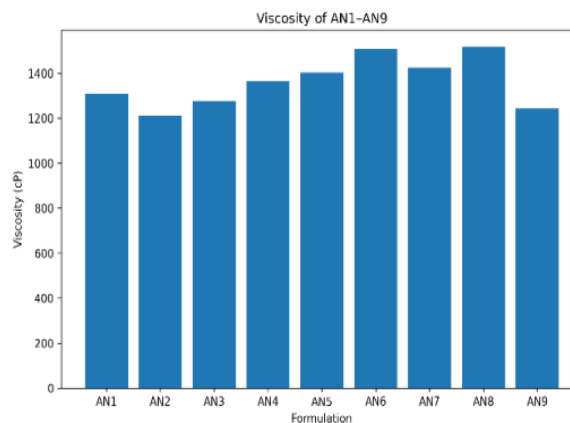
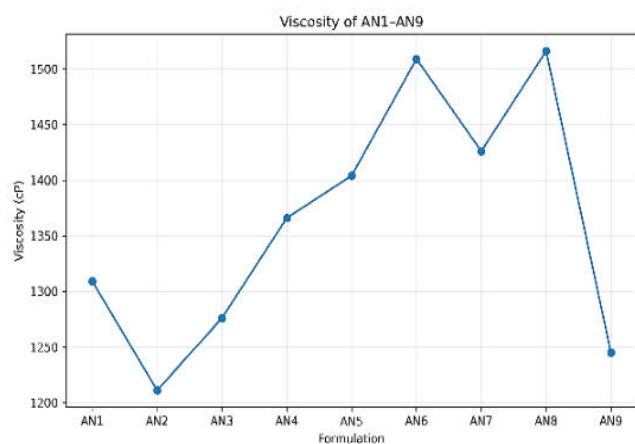
|     |     |   |     |   |      |      |     |
|-----|-----|---|-----|---|------|------|-----|
| AN1 | 1.0 | 9 | 1.0 | 3 | 0.22 | 0.05 | 1.5 |
| AN2 | 2.5 | 9 | 1.0 | 3 | 0.22 | 0.05 | 1.5 |
| AN3 | 4.0 | 9 | 1.0 | 3 | 0.22 | 0.05 | 1.5 |
| AN4 | 1.0 | 9 | 2.5 | 3 | 0.22 | 0.05 | 1.5 |
| AN5 | 2.5 | 9 | 2.5 | 3 | 0.22 | 0.05 | 1.5 |
| AN6 | 4.0 | 9 | 2.5 | 3 | 0.22 | 0.05 | 1.5 |
| AN7 | 1.0 | 9 | 4.0 | 3 | 0.22 | 0.05 | 1.5 |
| AN8 | 2.5 | 9 | 4.0 | 3 | 0.22 | 0.05 | 1.5 |
| AN9 | 4.0 | 9 | 4.0 | 3 | 0.22 | 0.05 | 1.5 |

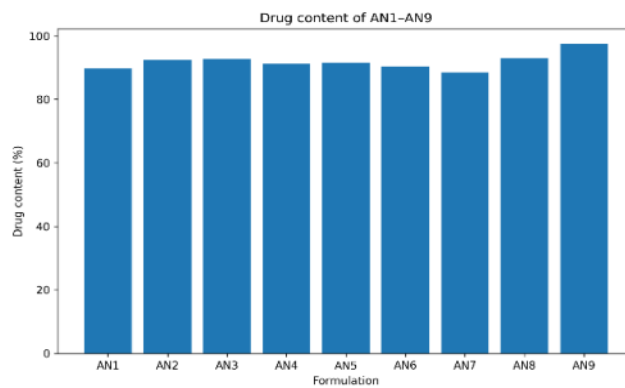
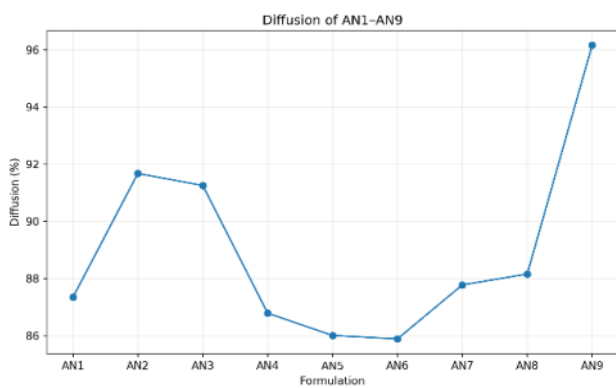
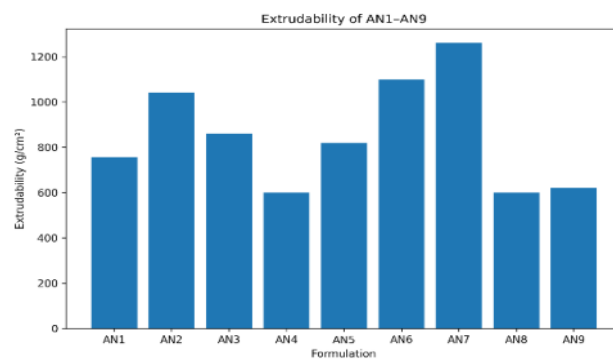
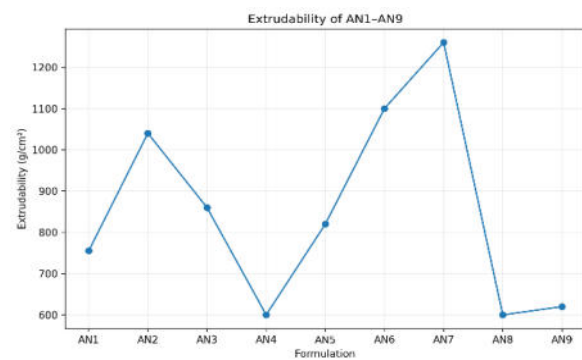
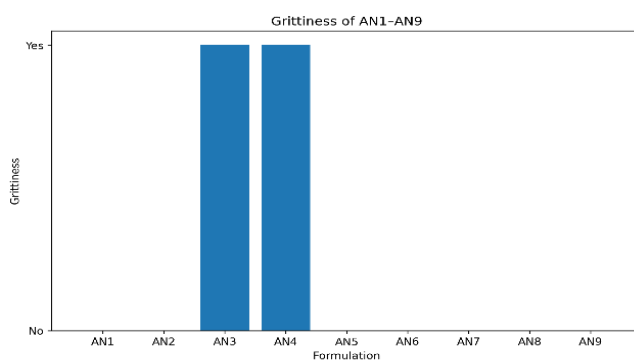
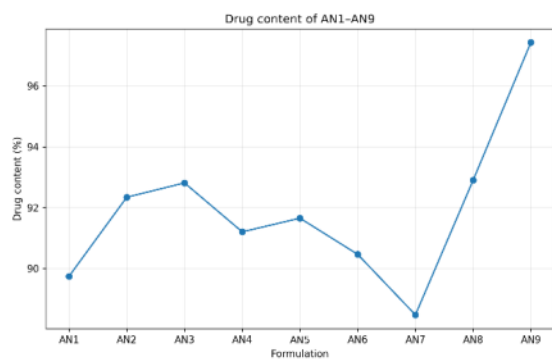
**Evaluation of formulations:** The prepared formulations were evaluated using the following parameters: (1) pH: measured using a digital pH meter to assess suitability for topical application; (2) viscosity: determined using a Brookfield viscometer to evaluate the consistency and flow characteristics of the gel; (3) spreadability: assessed to determine the ease of spreading the gel over the skin, with results expressed in millimetres; (4) extrudability: evaluated to determine the ease of removing the gel from its container; (5) drug/extract content: determined and expressed as percentage content to assess the amount of active constituent present in the formulations; (6) in-vitro diffusion: studied using a Franz

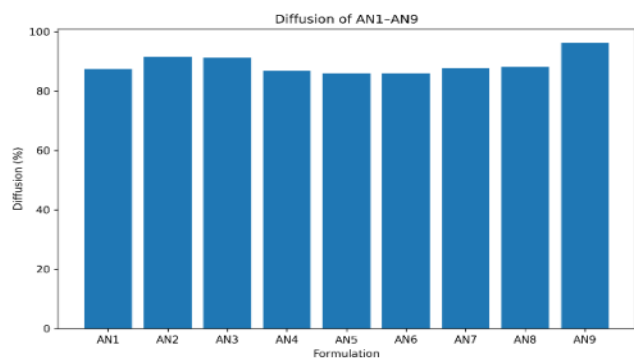
diffusion cell, in which the gel was placed in the donor compartment and separated from the receptor compartment by a membrane, with samples withdrawn at predetermined intervals and analysed for cumulative drug/extract release over 600 minutes; (7) stability assessment: the selected formulation was evaluated for appearance, pH, spreadability, drug content and viscosity under storage conditions of  $5 \pm 2^\circ\text{C}$ ,  $25 \pm 2^\circ\text{C}$  and  $40 \pm 2^\circ\text{C}$  for a period of three months. Overall, nine formulations were successfully prepared and showed measurable differences in their physicochemical characteristics, drug/extract content and in-vitro diffusion behaviour.

**Table 2. Physicochemical characteristics of the formulations**

| <b>Formulation</b> | <b>pH</b>   | <b>Extrudability (g/cm<sup>2</sup>)</b> | <b>Spreadability (mm)</b> | <b>Viscosity (cP)</b> | <b>Grittiness</b> | <b>Drug content (%)</b> | <b>Diffusion (%)</b> |
|--------------------|-------------|-----------------------------------------|---------------------------|-----------------------|-------------------|-------------------------|----------------------|
| AN1                | 4.15 ± 0.20 | 755 ± 10.1                              | 36.56 ± 2.5               | 1309 ± 2.5            | No                | 89.74 ± 9.6             | 87.34 ± 2.5          |
| AN2                | 5.15 ± 0.60 | 1040 ± 15.2                             | 54.43 ± 5.6               | 1211 ± 60.3           | No                | 92.34 ± 10.5            | 91.67 ± 5.6          |
| AN3                | 4.87 ± 0.02 | 860 ± 14.6                              | 36.33 ± 8.4               | 1276 ± 40.5           | Yes               | 92.81 ± 11.25           | 91.25 ± 8.9          |
| AN4                | 4.53 ± 0.05 | 600 ± 19.5                              | 37.46 ± 6.9               | 1366 ± 39.5           | Yes               | 91.20 ± 20.5            | 86.78 ± 10.5         |
| AN5                | 4.64 ± 0.08 | 820 ± 10.2                              | 35.66 ± 4.9               | 1404 ± 38.6           | No                | 91.65 ± 21.6            | 86.00 ± 15.6         |
| AN6                | 4.72 ± 0.06 | 1100 ± 26.6                             | 34.66 ± 8.7               | 1509 ± 36.6           | No                | 90.46 ± 12.6            | 85.88 ± 9.15         |
| AN7                | 4.22 ± 0.09 | 1260 ± 50.1                             | 35.33 ± 10.6              | 1426 ± 28.5           | No                | 88.47 ± 14.5            | 87.77 ± 11.25        |
| AN8                | 4.57 ± 0.10 | 600 ± 20.5                              | 37.66 ± 6.6               | 1516 ± 31.5           | No                | 92.90 ± 20.5            | 88.15 ± 15.6         |
| AN9                | 5.62 ± 0.04 | 620 ± 36.1                              | 54.00 ± 4.8               | 1245 ± 21.9           | No                | 97.43 ± 23.5            | 96.16 ± 16.6         |







The pH values of the formulations ranged from 4.15 to 5.62. AN9 showed a pH of  $5.62 \pm 0.04$ , which was close to the value generally targeted for topical formulations. The viscosity values showed formulation-dependent variation, with AN8 exhibiting the highest reported viscosity and AN2 the lowest. AN9 showed the highest reported drug/extract content and diffusion value

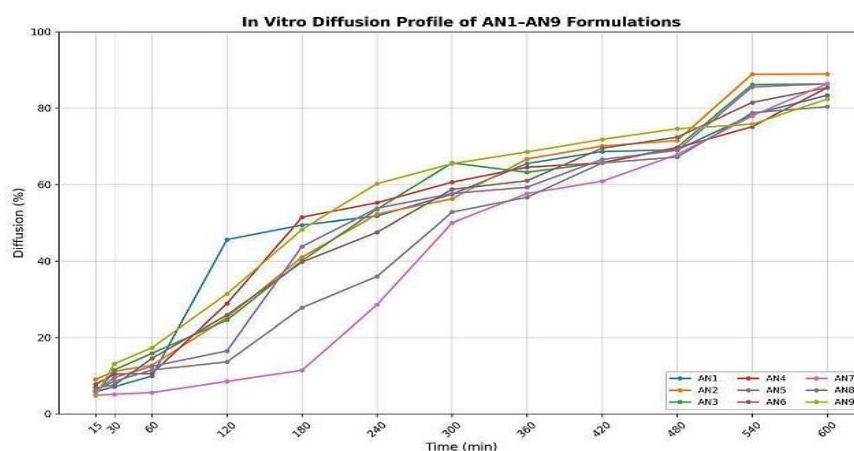
among the nine batches. Its spreadability was also among the highest observed values, while its viscosity was lower than several formulations containing intermediate or high polymer concentrations.

**In-vitro diffusion:** The cumulative release/diffusion profiles demonstrated progressive release from all formulations over the 600-min study period.

**Table 3. Cumulative percentage release/diffusion**

| Time (min) | AN1   | AN2   | AN3   | AN4   | AN5   | AN6   | AN7   | AN8   | AN9   |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 15         | 5.82  | 9.05  | 4.98  | 7.74  | 5.77  | 6.86  | 4.85  | 6.23  | 4.80  |
| 30         | 7.11  | 11.16 | 11.54 | 10.43 | 9.55  | 7.56  | 5.14  | 8.54  | 13.15 |
| 60         | 9.92  | 12.74 | 15.87 | 10.57 | 12.47 | 14.54 | 5.58  | 11.51 | 17.34 |
| 120        | 45.65 | 25.22 | 24.54 | 28.86 | 16.51 | 25.87 | 8.51  | 13.63 | 31.41 |
| 180        | 49.46 | 41.03 | 40.11 | 51.45 | 43.84 | 39.76 | 11.43 | 27.78 | 48.28 |
| 240        | 51.75 | 52.26 | 53.55 | 55.23 | 53.78 | 47.56 | 28.56 | 35.98 | 60.22 |
| 300        | 57.47 | 56.26 | 65.66 | 60.62 | 57.64 | 58.73 | 50.00 | 52.77 | 65.48 |

|     |       |       |       |       |       |       |       |       |       |
|-----|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 360 | 65.52 | 66.72 | 63.22 | 64.56 | 59.31 | 61.00 | 57.64 | 56.68 | 68.57 |
| 420 | 68.66 | 70.10 | 65.77 | 65.66 | 66.58 | 69.54 | 60.87 | 65.66 | 71.84 |
| 480 | 69.11 | 71.56 | 69.77 | 69.64 | 68.98 | 72.42 | 67.87 | 67.22 | 74.68 |
| 540 | 78.32 | 88.86 | 86.12 | 75.20 | 85.53 | 81.45 | 77.98 | 78.77 | 75.83 |
| 600 | 83.34 | 88.92 | 86.34 | 85.34 | 86.34 | 85.34 | 86.34 | 80.34 | 82.34 |



### III. RESULTS AND DISCUSSION

At 600 min, AN2 showed the highest cumulative release value (88.92%), followed by AN3 (86.34%), while AN9 showed 82.34%. These findings indicate that the influence of formulation composition on release was not linear and supports the use of systematic formulation optimization rather than relying on a single formulation variable.

**Stability:** The stability data available in the dissertation showed that the tested formulation retained a light-green

appearance under  $5 \pm 2^\circ\text{C}$ ,  $25 \pm 2^\circ\text{C}$  and  $40 \pm 2^\circ\text{C}$  during the reported three-month observation period. pH, spreadability, drug content and viscosity showed only limited variation within the reported observations.

### 4. Discussion

The present study demonstrates a formulation-development approach for a polyherbal topical gel containing *Aloe barbadensis* and *Azadirachta indica*. The selection of these botanicals is pharmacologically plausible because both plants have been investigated for biological

activities relevant to dermatological applications. Aloe vera has been specifically investigated in psoriasis, while neem has been extensively studied for anti-inflammatory, antimicrobial and other dermatological activities. [2–6]

The principal pharmaceutical challenge in topical herbal formulation is to convert botanically derived materials with complex chemical compositions into a reproducible dosage form possessing appropriate application characteristics and predictable release behaviour. In the present investigation, Carbopol 940 was used to provide gel structure, while propylene glycol was incorporated as an important formulation variable.

The  $3^2$  factorial design enabled simultaneous investigation of three levels of Carbopol 940 and three levels of propylene glycol. This generated nine formulations and permitted direct comparison of formulation-dependent changes in viscosity and release behaviour. The dissertation data demonstrate clear differences between formulations. For example, viscosity ranged from approximately 1211 to 1516 cP, demonstrating that changes in polymer and propylene glycol concentrations influenced the rheological characteristics of the system.

AN9, containing the highest investigated concentrations of both Carbopol 940 and propylene glycol, showed the highest reported drug/extract content and diffusion value among the formulations. Its pH was  $5.62 \pm 0.04$  and spreadability was  $54.00 \pm 4.8$  mm. These characteristics support its consideration as a candidate formulation for further optimization. However, AN9 did not exhibit the highest cumulative release at 600 min; AN2 showed the highest value at that time point.

This apparent difference is scientifically important. A formulation cannot appropriately be considered optimized solely because it has the highest value for one response. In a factorial design, optimization should ideally be based on a predefined desirability function incorporating all critical responses, supported by analysis of variance and model diagnostics. The current dissertation provides the formulation matrix and response observations but does not provide sufficient statistical modelling information to substantiate a statistically validated design-space optimization. Therefore, the present manuscript describes AN9 as a candidate optimized formulation based on the observed response profile,

rather than claiming statistically proven global optimality.

The progressive release observed during the Franz diffusion study indicates that the formulation was capable of releasing measurable quantities of extract-derived constituents over the experimental period. At 600 min, the cumulative release ranged from 80.34% to 88.92% across the nine batches.

The release behaviour is likely to reflect the combined effects of polymer concentration, formulation viscosity, solvent system and the physicochemical characteristics of the multiple phytoconstituents present in the herbal extracts. Because the formulation contains a complex mixture rather than a single chemically defined drug, the term "drug release" should preferably be interpreted as extract/marker release unless a validated quantitative marker assay is available.

The physicochemical findings further indicate that the prepared gels were generally suitable for topical pharmaceutical evaluation. pH values were within a range compatible with topical application, while spreadability and extrudability measurements provided information regarding ease of application and removal from the container. The absence of grittiness

in most formulations further supports acceptable physical characteristics.

The stability observations are also encouraging at the preliminary formulation-development level. The reported formulation maintained a light-green appearance across the investigated temperatures, while pH, spreadability, drug/extract content and viscosity remained relatively consistent during the three-month observation period.

Nevertheless, the present work has important limitations. First, the study evaluates formulation characteristics and in-vitro diffusion rather than clinical anti-psoriatic efficacy. Second, no validated phytochemical marker assay is reported for quantitative standardization of the two extracts. Third, the available factorial data are not accompanied by complete ANOVA, regression coefficients, model adequacy statistics or desirability-function analysis. Finally, the stability dataset should be interpreted as preliminary unless conducted under a fully documented stability protocol with appropriate environmental controls and validated analytical methods.

These limitations do not diminish the formulation-development value of the work; rather, they define the appropriate scientific scope of the manuscript and identify the

experiments required for a stronger translational publication.

### Conclusion

A polyherbal topical gel containing *Aloe barbadensis* and *Azadirachta indica* was successfully developed using a Carbopol 940-based formulation platform. A  $3^2$  factorial design generated nine formulations with systematically varied concentrations of Carbopol 940 and propylene glycol. The formulations demonstrated measurable differences in pH, viscosity, spreadability, extrudability, extract/drug content and in-vitro diffusion.

Among the evaluated batches, AN9 demonstrated the highest reported drug/extract content and diffusion value, together with favourable pH and spreadability characteristics. The formulation also demonstrated sustained release of extract-derived constituents over the 600-min diffusion experiment. Preliminary stability observations indicated retention of key physical characteristics over three months under the investigated temperature conditions.

Overall, the study establishes the feasibility of developing a pharmaceutically acceptable polyherbal gel containing *A. barbadensis* and *A. indica*. However, the current

evidence supports formulation feasibility and in-vitro performance, rather than definitive clinical efficacy against psoriasis. Future studies should include standardized phytochemical marker quantification, complete factorial-design statistical modelling, skin permeation/deposition studies, dermatological safety assessment, validated anti-inflammatory/anti-psoriatic biological assays and appropriate in-vivo/clinical evaluation.

### Strengths and Limitations

#### Strengths

1. Use of authenticated medicinal plant materials.
2. Combination of two botanicals with complementary pharmacological literature.
3. Application of a systematic  $3^2$  factorial formulation design.
4. Preparation and evaluation of nine experimental batches.
5. Evaluation of multiple pharmaceutical quality attributes.
6. Use of Franz diffusion methodology.
7. Preliminary three-month stability assessment.

#### Limitations

1. No clinical efficacy assessment was performed.
2. No psoriasis-specific in-vivo pharmacological model was reported.
3. Quantitative marker standardization of the herbal extracts was not established.
4. Complete factorial ANOVA and model-validation statistics were not reported.
5. The release assay for the complex herbal extract requires clearer analytical validation.
6. The available stability data should be considered preliminary.
7. Skin irritation/dermatological safety data were not sufficiently reported to establish clinical safety.

#### IV. FUTURE PERSPECTIVES

The next stage of development should focus on standardization and mechanistic validation. Quantification of suitable phytochemical markers from both extracts would improve batch-to-batch reproducibility. The factorial formulation should then be statistically modelled using ANOVA, response-surface analysis and a predefined desirability function.

The optimized formulation should subsequently undergo membrane and preferably ex-vivo skin permeation/deposition studies to determine whether the formulation retains active constituents within relevant skin layers. Anti-inflammatory and psoriasis-relevant biological assays could provide mechanistic evidence, while appropriately designed in-vivo and clinical studies would be necessary to establish therapeutic efficacy.

Such a staged development pathway would convert the present formulation study from an initial pharmaceutical-development investigation into a more complete translational research program.

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