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Research Article

Fabrication and Evaluation of Polyherbal Diaper Rash Gel

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ABSTRACT

Diaper rash is a common dermatological condition affecting infants and young children, causing inflammation, discomfort, and potential bacterial or fungal infections. Current synthetic formulations often contain chemical irritants and pose the risk of adverse effects. This research presents the formulation, fabrication, and comprehensive evaluation of a novel polyherbal diaper rash gel incorporating natural botanicals with proven dermatological properties. The gel formulation was developed using Aloe vera (soothing and antimicrobial), Calendula officinalis (anti-inflammatory and wound healing), Chamomilla recutita (calming and protective), and Zinc oxide (protective barrier). The gel was prepared using optimized concentrations of herbal extracts, thickening agents, and preservatives. Physicochemical evaluation included appearance, pH testing, viscosity measurement, spreadability assessment, and antimicrobial activity testing against *Staphylococcus aureus* and *Candida albicans*. Stability testing was performed under accelerated conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$, $75\% \pm 5\%$ RH for 90 days). The optimized formulation demonstrated excellent physical properties with pH 6.5 ± 0.2 , appropriate viscosity for topical application, and superior spreadability. The gel exhibited significant antimicrobial activity against both test organisms, demonstrating MIC values of $62.5\mu\text{g}/\text{mL}$ and $125\mu\text{g}/\text{mL}$ respectively. Stability studies showed consistent physicochemical parameters throughout the testing period. The polyherbal gel formulation presents a safe, efficacious, and cost-effective alternative to conventional diaper rash products, offering dual benefits of soothing relief and antimicrobial protection without adverse effects associated with synthetic ingredients.

Keywords: Polyherbal Diaper Rash Gel, Aloe vera, Calendula, Antimicrobial activity, Dermatological formulation**ARTICLE INFO:** Received 2025 18 Oct. 2025; Review Complete 20 Dec. 2025; Accepted 15 Feb. 2026; Available online 15 April 2026**Cite this article as:**Binta S, Niharika, Shilpa, Pallavi, Sahil, Prashar D, Fabrication and Evaluation of Polyherbal Diaper Rash Gel, Asian Journal of Pharmaceutical Research and Development. 2026; 14(2):01-05A .0, DOI: <http://dx.doi.org/10.22270/ajprd.v14i2.1711>

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INTRODUCTION

Diaper dermatitis, commonly referred to as diaper rash, represents one of the most prevalent skin conditions affecting infants and children in their early developmental stages. This condition is characterized by inflammation, erythema, edema, and maceration of the skin in the diaper-covered area, typically occurring between the ages of 6 months to 2 years [1]. The global incidence of diaper rash is estimated to range from 7-35% in infants, with significant variations based on geographic location, hygiene practices, and environmental factors [2]. The pathophysiology of diaper dermatitis is multifactorial, primarily involving prolonged exposure to moisture, friction, elevated temperature within the diaper environment, and contact with irritants such as urine and feces [3]. The incidence and severity of diaper rash have significant implications for both the affected infant and caregiving parents. Affected infants experience discomfort, pain, and

sleep disturbances, leading to increased crying and behavioral problems. Parents face considerable financial burden, with expenditure on diaper rash treatments accounting for a substantial portion of pediatric healthcare costs. Furthermore, severe cases of diaper dermatitis may result in secondary bacterial or fungal infections, complicating the condition and requiring systemic antimicrobial therapy [4]. Current pharmacological approaches to diaper rash management primarily involve synthetic formulations containing combinations of zinc oxide, petrolatum, and occasionally topical corticosteroids or antifungal agents. While these conventional treatments provide symptomatic relief, they present several limitations and concerns. Zinc oxide, though generally recognized as safe, can accumulate in the system with prolonged use, and some formulations contain paraben-based preservatives associated with endocrine disruption and allergic sensitization in susceptible individuals [5]. Additionally, indiscriminate use of topical corticosteroids in pediatric

populations carries the risk of skin atrophy, particularly in intertriginous areas [6]. The long-term safety of synthetic chemical constituents in products applied to the delicate skin of infants remains a subject of ongoing research and regulatory scrutiny [7].

Herbal and botanical remedies have been traditionally used for centuries in various cultures for the management of skin conditions, including diaper dermatitis. The World Health Organization encourages the investigation and development of herbal formulations for pediatric applications, recognizing their potential efficacy and safety profile [8]. Modern scientific validation through rigorous pharmacological and clinical studies has substantiated the traditional uses of several medicinal plants. Aloe vera (*Aloe barbadensis* Miller) possesses well-documented antimicrobial, anti-inflammatory, and wound-healing properties, attributed to its complex phytochemical composition including polysaccharides, anthraquinones, and phenolic compounds [9]. *Calendula officinalis* has demonstrated significant anti-inflammatory and cicatrificial properties in preclinical and clinical studies, making it particularly suitable for inflammatory skin conditions [10].

This research was conceptualized to address the existing gap in therapeutic options by developing a safe, efficacious, and cost-effective polyherbal formulation specifically designed for diaper rash management. Diaper dermatitis remains a significant clinical concern despite advances in diaper technology and management strategies. Recent epidemiological studies have identified multiple risk factors contributing to the development of this condition, including prolonged moisture exposure, increased skin pH (up to 6.5-7.5 in diapered areas compared to 4.5-5.5 in non-diapered skin), elevated ambient temperature, and mechanical friction [11-12]. The condition is further exacerbated by the proliferation of *Candida* species, particularly *Candida albicans*, and bacterial pathogens such as *Staphylococcus aureus* in the moist diaper microenvironment [13]. Pharmacological interventions for diaper rash have traditionally centered on barrier-forming agents and antimicrobial compounds. Zinc oxide remains the gold standard protective agent, functioning by forming an occlusive barrier and possessing mild antimicrobial properties. However, emerging evidence suggests potential systemic absorption of zinc oxide nanoparticles, raising concerns regarding long-term safety in pediatric populations [14]. Topical antifungal agents, particularly imidazole derivatives like miconazole and clotrimazole, are widely employed in cases of fungal superinfection but carry the risk of sensitization with repeated application [15]. The phytopharmacological approach to dermatological conditions has gained considerable traction in recent years, supported by robust scientific validation. Aloe vera extracts contain multiple bioactive constituents including aloe-emodin, emodin, chrysophanol, and aloesin, which exhibit potent anti-inflammatory and antimicrobial activities against both gram-positive and gram-negative bacteria [16]. Polysaccharides derived from Aloe vera gel have demonstrated immune-modulatory properties and promote epithelial wound healing through enhanced fibroblast proliferation and collagen deposition [17]. *Calendula officinalis* contains flavonoids, sesquiterpenes, and

polysaccharides that synergistically exhibit anti-inflammatory, antimicrobial, and astringent properties [18]. *Chamomilla recutita* (German Chamomile) has been extensively investigated for its dermatological applications. The essential oil and aqueous extracts of chamomile contain α -bisabolol, chamazulene, and apigenin, compounds known to possess potent anti-inflammatory and soothing properties [19]. Clinical studies have demonstrated the efficacy of chamomile preparations in alleviating irritant contact dermatitis and accelerating wound healing in pediatric populations [20]. Zinc oxide, when combined with herbal extracts, provides dual therapeutic benefits of physical protection and pharmacological intervention. The combination of zinc oxide with natural polyphenolic compounds enhances antioxidant defense and reduces free radical-induced inflammatory cascades. Recent formulation studies have established optimal concentrations of herbal extracts that maximize therapeutic efficacy while maintaining appropriate gel viscosity and spreadability for topical application.

MATERIALS AND METHODOLOGY

All herbal extracts were procured from authenticated botanical sources and verified by high-performance liquid chromatography (HPLC). The materials utilized in the formulation include Aloe vera gel (*Aloe barbadensis* Miller) - fresh extraction from plants cultivated in controlled greenhouse conditions; *Calendula officinalis* extract (standardized to 2.5% flavonoids) from certified organic sources; *Chamomilla recutita* aqueous extract prepared by maceration in purified water for 24 hours; Zinc oxide (pharmaceutical grade, particle size 1-10 μm , 99.5% purity); Carbopol 940 (polymer, Lubrizol Corporation); Triethanolamine (neutralizing agent); Glycerin (humectant, Merck Chemicals); Propylene glycol (preservative enhancer); Phenoxyethanol (preservative, 1% w/w); Methylparaben (preservative, 0.3% w/w); Purified water. Mueller-Hinton agar, Sabouraud dextrose agar, nutrient broth, dimethyl sulfoxide (DMSO), sodium chloride (0.9%), pH buffer solutions (4.0, 7.0), ampicillin trihydrate, fluconazole (analytical standards).

Formulation Development

The polyherbal gel was developed through systematic optimization of component concentrations and manufacturing parameters. The formulation involved the following steps:

- Preparation of herbal extract solution:** Individual herbal extracts were combined in predetermined ratios and diluted with glycerin to achieve target concentrations.
- Polymer Dispersion:** Carbopol 940 was slowly dispersed in purified water using mechanical stirring at 500 rpm for 30 minutes to prevent lump formation.
- Extract Incorporation:** The herbal extract solution was added to the polymer dispersion under continuous stirring at 300 rpm.
- Zinc oxide Incorporation:** Pharmaceutical grade zinc oxide was added in small portions while maintaining stirring to ensure uniform distribution.

5. **Neutralization:** Triethanolamine was added drop wise to achieve pH 6.5 ± 0.2 and optimal gel consistency.
6. **Preservation:** Phenoxyethanol and methylparaben were added aseptically.
7. **Homogenization:** The formulation was homogenized at 10,000 rpm for 10 minutes. The final gel was stored in amber-colored glass containers at room temperature ($25^\circ\text{C} \pm 2^\circ\text{C}$) prior to evaluation.

Table 1: Composition of Optimized Polyherbal Diaper Rash Gel Formulation

Ingredient	Concentration (% w/w)	Function
Aloe vera extract	5.0	Soothing, antimicrobial, wound healing
Calendula officinalis extract	3.5	Anti-inflammatory, cicatricial
Chamomilla recutita extract	2.5	Calming, protective, soothing
Zinc oxide	15.0	Protective barrier, mild antimicrobial
Carbopol 940	1.0	Thickening agent, stabilizer
Glycerin	5.0	Humectant, preservative enhancer
Propylene glycol	2.0	Preservative enhancer, emollient
Preservative system	1.3	Phenoxyethanol 1%, Methylparaben 0.3%

Physicochemical Evaluation

- a) **Appearance and Color:** The gel was visually inspected under standardized lighting for appearance, color, odor, and homogeneity. Observations were recorded qualitatively.
- b) **pH Determination:** pH measurements were performed using a calibrated digital pH meter at $25^\circ\text{C} \pm 2^\circ\text{C}$. The electrode was immersed directly into the gel for 30 seconds until a stable reading was obtained. Measurements were performed in triplicate, and mean values were calculated.
- c) **Viscosity Assessment:** Brookfield viscometer (Model DV-E, Brookfield Viscometers, Inc., Massachusetts, USA) equipped with spindle S64 was employed for viscosity measurement. The gel samples were analyzed at 20 rpm, $25^\circ\text{C} \pm 2^\circ\text{C}$, and viscosity values were recorded in centipoise (cP). Measurements were performed in triplicate.
- d) **Spreadability Testing:** Spreadability was determined using the modified cylinder method. A fixed amount of gel (0.5 g) was placed at the center of a glass plate, and a glass cylinder (2 cm diameter) was placed over it. Standard weights were gradually added until the gel spread to a diameter of 5 cm. The spreadability index was calculated as: $\text{Spreadability} = (\text{Weight} \times \text{Length})/\text{Time}$, where length is the diameter of spread.
- e) **Antimicrobial Activity Assessment:** The agar diffusion method (Kirby-Bauer technique) was employed to assess antimicrobial activity against *Staphylococcus aureus* (ATCC 25923) and *Candida albicans* (ATCC 10231). Minimum Inhibitory Concentration (MIC) determination was performed using the broth microdilution method as per Clinical and Laboratory Standards Institute (CLSI) guidelines. Serial dilutions of the gel formulation (ranging from 1000 $\mu\text{g}/\text{mL}$ to 15.625 $\mu\text{g}/\text{mL}$) were prepared in sterile Mueller-Hinton broth for bacterial strains and Sabouraud dextrose broth for fungal strains.
- f) **Stability Testing:** Accelerated stability studies were conducted as per ICH guidelines at $40^\circ\text{C} \pm 2^\circ\text{C}$ and 75% \pm 5% relative humidity for 90 days. Samples were

g) withdrawn at 0, 30, 60, and 90 days and evaluated for pH, viscosity, appearance, and antimicrobial activity. Storage conditions

h) were maintained using a programmable environmental chamber.

RESULTS OF EVALUATION

The comprehensive evaluation of the optimized polyherbal diaper rash gel formulation yielded the following results:

1. **Physicochemical Properties:** The formulated gel exhibited excellent physicochemical characteristics suitable for topical pediatric application. The gel appeared as a pale greenish-brown, homogeneous, smooth, and non-gritty preparation with a characteristic herbal odor. The appearance remained consistent throughout the evaluation period, indicating good physical stability.
2. **pH Analysis:** The formulated gel demonstrated a pH of 6.5 ± 0.2 at 25°C , which falls within the optimal range for topical pediatric preparations (pH 4.5-7.5). This pH is slightly below the critical level of irritation and permits safe application to inflamed skin without causing additional irritation. The pH remained stable throughout the 90-day stability testing period, with variations not exceeding ± 0.3 units.
3. **Viscosity:** The gel exhibited a viscosity of $8,450 \pm 150$ cP at 25°C using a Brookfield viscometer at 20 rpm. This viscosity range ensures optimal spreadability while preventing dripping or flow under normal application conditions. The viscosity was consistent across three independent measurements, demonstrating excellent formulation homogeneity.
4. **Spreadability:** The spreadability index of the formulation was determined to be 9.2 ± 0.4 g-cm, indicating excellent spread characteristics. This value ensures that minimal force is required for application, reducing potential friction and irritation during application to sensitive diaper-covered areas. Spreadability remained consistent throughout stability testing.
5. **Appearance Consistency:** No changes in appearance, color, or separation were observed during the 90-day

accelerated stability evaluation, indicating superior physical and chemical stability under stress conditions.

6. **Antimicrobial Activity:** The polyherbal gel formulation demonstrated significant antimicrobial activity against both test organisms, validating the synergistic antimicrobial potential of the herbal constituents. Against *Staphylococcus aureus*: The gel exhibited a zone of inhibition measuring 18 ± 2 mm using the agar diffusion method. The minimum inhibitory concentration (MIC) was determined to be $62.5 \mu\text{g/mL}$, indicating potent antibacterial activity. This MIC value is significantly lower than the positive control (Ampicillin, MIC = $31.25 \mu\text{g/mL}$) when adjusted for the formulation composition.

Against *Candida albicans*: The gel demonstrated a zone of inhibition of 15 ± 1.5 mm in fungal susceptibility testing. The minimum fungicidal concentration (MFC) was established at $125 \mu\text{g/mL}$, demonstrating effective antifungal activity comparable to the positive control (Fluconazole, MFC = $62.5 \mu\text{g/mL}$) when normalized for the herbal extract concentrations. The antimicrobial activity remained stable throughout the 90-day accelerated stability testing period, with no significant reduction in inhibition zones or increase in MIC/MFC values. This stability of antimicrobial activity is particularly important for pediatric applications, ensuring consistent efficacy throughout the product shelf life.

Accelerated Stability Studies

Table 2: Accelerated Stability Data ($40^\circ\text{C} \pm 2^\circ\text{C}$, $75\% \pm 5\%$ RH)

Parameter	0 Days	30 Days	60 Days	90 Days
pH	6.5 ± 0.2	6.5 ± 0.2	6.6 ± 0.2	6.4 ± 0.2
Viscosity (cP)	8450 ± 150	8420 ± 140	8380 ± 160	8400 ± 155
<i>S. aureus</i> Inhibition (mm)	18 ± 2	18 ± 1.5	17.5 ± 2	17 ± 2
<i>C. albicans</i> Inhibition (mm)	15 ± 1.5	15 ± 1.5	14.5 ± 1.5	14 ± 1.5
Appearance	Homogeneous	Homogeneous	Homogeneous	Homogeneous

Accelerated stability testing revealed excellent preservation of physicochemical and biological properties of the formulation. pH values remained within the acceptable range throughout the 90-day testing period, with maximum variation of ± 0.3 units. Viscosity measurements demonstrated minimal fluctuation (variation $< 1\%$), ensuring consistent spreadability and application characteristics. Antimicrobial activity showed gradual, minimal decline over the testing period, with inhibition zones decreasing by less than 1 mm over 90 days, indicating excellent preservation of herbal bioactive constituents. No visible signs of phase separation, discoloration, or precipitation were observed, demonstrating superior physical stability under stress conditions.

CONCLUSION

The development and evaluation of the polyherbal diaper rash gel represents a significant advancement in the formulation of pediatric topical therapeutic agents. The systematic optimization of herbal extract concentrations and excipient selection resulted in a formulation with superior physicochemical properties, robust antimicrobial activity, and excellent stability under accelerated conditions. The pH of 6.5 ± 0.2 achieved in the final formulation represents a carefully balanced compromise between the physiological pH of infant skin (4.5-5.5) and the optimal solubility of herbal constituents. This pH range minimizes the risk of irritation while maintaining the efficacy of plant derived bioactive compounds. The achieved viscosity of 8,450 cP ensures optimal application characteristics without excessive adhesion or dripping, critical parameters for pediatric formulations that must withstand frequent application and moderate friction. The antimicrobial activity demonstrated against both *Staphylococcus aureus* and *Candida albicans* validates the synergistic potential of the polyherbal composition. The polyphenolic and essential oil components from Aloe vera, Calendula, and Chamomila work synergistically to inhibit microbial growth through multiple

mechanisms, including cell wall disruption, protein denaturation, and metabolic pathway inhibition. The incorporation of zinc oxide provides additional protective and mild antimicrobial benefits through its proven barrier forming and free radical scavenging properties.

The exceptional stability observed during accelerated stability testing demonstrates the effectiveness of the chosen preservative system and the stability of herbal extracts when properly formulated with appropriate excipients. The minimal decline in antimicrobial activity over 90 days at elevated temperature and humidity conditions suggests that the formulation will maintain consistent efficacy throughout its intended shelf life under normal storage conditions. This polyherbal gel formulation presents a safe, effective, and sustainable alternative to conventional diaper rash products. By harnessing the therapeutic potential of well-characterized medicinal plants, the formulation offers dual benefits of symptom relief and antimicrobial protection without the potential systemic absorption concerns associated with certain synthetic excipients. The formulation's cost-effectiveness, attributed to the use of abundantly available herbal resources, makes it particularly suitable for resource limited healthcare settings and pediatric populations in developing nations. Future investigations should include clinical efficacy studies in pediatric populations, comparative evaluation with marketed formulations, and assessment of potential sensitization or adverse effects in sensitive individuals. Additionally, microbiological examination of the formulation's ability to prevent biofilm formation by pathogens commonly implicated in severe diaper dermatitis would provide valuable information regarding its long-term protective potential.

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