



## A Prospective, Open-label Non-Randomized Clinical Trial to evaluate the Safety and Efficacy of Takzema Tablet & Ointment in Treatment of Eczema

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**Background:** Eczema, or atopic dermatitis (AD), is a chronic inflammatory skin disorder characterized by pruritus, erythema, and xerosis, affecting upto 20% of population and significantly impacting their quality of life. Conventional treatments include topical corticosteroids, calcineurin inhibitors, PDE4 inhibitors, phototherapy, and systemic immunosuppressants, though long-term use may have adverse effects. Advances in translational research have led to targeted small molecules and biologic therapies for moderate-to-severe cases.[1] Takzema Tablet & Ointment, are polyherbal formulations manufactured by Charak Pharma Pvt. Ltd., and were evaluated for its efficacy and safety in patients with Eczema. A total of 300 patients were included in the study to assess the impact of this treatment approach.

**Materials and Methods:** This phase 3, non-randomized, prospective, open-label, multi-centric clinical trial aimed to evaluate the clinical efficacy and safety of Takzema Tablet & Ointment in managing patients aged 18–60 years diagnosed with Eczema.

**Observation:** In study time-line of two months, Takzema demonstrated significant improvement across multiple clinical parameters. Erythema scores declined by 48.4% ( $p < 0.001$ ), with the greatest reduction observed in the head/neck region. Oedema/papulation severity decreased by 63.9% ( $p = 0.002$ ), with the highest improvement in the trunk (68.4%). Lichenification showed an overall reduction of 47.06% ( $p = 0.001$ ), with the most significant improvement in the head/neck and upper extremities. The affected area scores also declined by 51.39% ( $p = 0.002$ ), demonstrating consistent regional improvements.

**Result:** Takzema Tablets & Ointment demonstrated significant improvements in eczema symptoms after 2 months of treatment, including reductions in erythema, oedema/papulation, lichenification & total area lesions. The results highlight that Takzema tablets & ointment are clinically effective in managing eczema.

**Keywords:** Atopic Dermatitis, Eczema, Polyherbal Formulation, Takzema, Clinical Trial, Herbal Medicine, Phase 3 Trial

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## Introduction

Atopic dermatitis (AD) is a prevalent chronic disease with significant clinical variability, complicating prevalence assessments. Once considered primarily a childhood condition affecting up to 25% of children under seven, recent data highlight its substantial presence in adults, with prevalence rates between 7% and 10%. WHO estimates that AD affects approximately 230 million people worldwide, with a global annual prevalence of 3.5%, making it the leading contributor to the non-fatal disease burden among skin conditions. AD can arise at any age, with 80% of cases developing before six years. While early studies suggested resolution in over 50% of children, recent longitudinal research indicates persistent or adult-onset AD is more common than previously believed, with annual adult prevalence reaching 14.6% in developed countries. The disease follows relapsing-remitting or chronic patterns, influenced by environmental and genetic factors, particularly in industrialized regions, reinforcing its classification as a lifelong condition with variable manifestations.

**Symptomatology:** AD is a chronic inflammatory skin disorder marked by episodic exacerbations and remissions, characterized by pruritus, xerosis, and eczematous lesions that vary with age and disease stage. Pruritus is the primary symptom, leading to scratching-induced inflammation and skin barrier disruption, while xerosis contributes to irritation and susceptibility to infections. Eczematous lesions manifest differently across age groups: in infants, they affect the face and extensor surfaces with oozing and erythema; in children, they localize to flexural areas with lichenification; and in adolescents and adults, they are more persistent on the hands, neck, and eyelids. Chronic scratching can cause excoriations, lichenification, and pigmentary changes, particularly in darker skin tones. AD is also associated with bacterial, viral, and fungal infections, sleep disturbances, and reduced quality of life. Additionally, it is associated with other atopic conditions such as allergic rhinitis, asthma, and food allergies, reflecting the atopic march.[2]

**Pathogenesis:** Atopic dermatitis (AD) is a multifactorial disease influenced by genetic susceptibility and environmental factors, leading to epidermal barrier dysfunction and immune dysregulation.

Approximately 75% of AD heritability is attributed to genetic factors, with genome-wide studies identifying 34 loci, though these account for less than 20% of total heritability. FLG mutations, the most significant genetic risk factor, compromise the skin barrier, while variants in immune-related genes (e.g., IL-4, IL-13, RAD50, LRRC32) further contribute to disease susceptibility.

Epidermal barrier dysfunction results from both genetic defects and external triggers, increasing permeability to irritants and promoting inflammation. Cutaneous immune responses involve CD4+ T cells, dendritic cells, and TH2 cytokines (IL-4, IL-13, IL-22), with TH1 and TH17 pathways emerging in chronic AD.

Itch is mediated by pruritogens (IL-31, TSLP) interacting with sensory neurons, with targeted therapies like dupilumab and nemolizumab offering symptom relief. Microbiota dysbiosis, particularly *Staphylococcus aureus* overgrowth, disrupts skin integrity and exacerbates inflammation, whereas early colonization by beneficial microbes may confer protection. In conclusion, the interplay between these factors explains the clinical variability of AD and underscores the need for targeted therapies addressing multiple pathogenic pathways.

**Conventional Treatment:** Conventional treatments for atopic dermatitis (AD) focus on symptom management through topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), antihistamines, emollients, and systemic immunosuppressants for severe cases. While TCS effectively reduce inflammation and pruritus, prolonged use can cause skin atrophy and systemic side effects. TCIs offer an alternative, particularly for sensitive areas, but are linked to transient burning and potential malignancy risks. Emollients aid in restoring the skin barrier but require consistent use, and antihistamines have limited efficacy, with sedation as a concern for first-generation agents. Systemic therapies like cyclosporine or methotrexate are reserved for refractory cases but pose significant risks, including nephrotoxicity and immunosuppression. Despite these options, conventional therapies primarily provide symptomatic relief without addressing AD's underlying immunopathogenesis, often resulting in relapses and long-term dependence, highlighting the need for novel, targeted immunomodulatory treatments with improved safety profiles.[3]

In addition to conventional pharmacological therapies, phytotherapies are gaining recognition as complementary and alternative treatments for atopic dermatitis (AD), offering potential benefits through their anti-inflammatory, antioxidant, and immunomodulatory properties.

A comprehensive review highlighted that various herbal medicines effectively reduce erythema, oedema, and trans-epidermal water loss in AD patients. These phytomedicines also suppress the expression of inflammatory biomarkers such as histamine, immunoglobulin E (IgE), prostaglandins, and cytokines in both serum and skin tissues.[4]

Additionally, flavonoids & other natural compounds found in many plants have demonstrated promise in managing eczema due to their strong anti-inflammatory, antioxidant, and anti-allergic properties. They help prevent allergic reactions, inflammation, and skin irritation, offering a multifaceted approach to AD treatment.[5]

These findings suggest that incorporating phytotherapies could enhance the management of AD, providing a holistic approach that addresses multiple aspects of the disease's pathophysiology.

In present study, Takzema Tablet and Ointment, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with Eczema. The formulation has been standardized after formulating SOPs along with acute toxicity study.

## Materials and Methods

**Study Goals and Objectives:** The main objective of the study was to evaluate clinical efficacy of Takzema Tablet and Ointment on atopic dermatitis. Further, the study also observed clinical safety of Takzema Tablet and Ointment on Eczema.

**Study Design:** A non-randomized phase 3, prospective, open label, multi-centric clinical trial in patients diagnosed with eczema was planned following required GCP guidelines. A total of 300 patients were included in the study diagnosed with eczema

### Inclusion Criteria

The study included participants with:

1. Age 18–60 years.

2. Confirmed diagnosis of moderate to severe atopic dermatitis based on clinical assessment and established diagnostic criteria
3. Documented history of eczema persisting for at least six months
4. Minimum affected Body Surface Area (BSA) percentage and a specified severity score (EASI) to confirm moderate to severe disease
5. Stable health, with no other dermatologic conditions that could interfere with study assessments
6. No prior use of systemic therapies (e.g., corticosteroids or immune-suppressants) within the last eight weeks
7. No prior phototherapy within the last four weeks before enrolment
8. Capability of providing informed consent and understanding the study protocol
9. Ability to adhere to treatment regimens and scheduled study visits
10. Effective communication skills and availability for the full study duration

### Exclusion Criteria

1. Known hypersensitivity to any investigational drug compo. or prior exposure to study medication.
2. Presence of significant dermatologic conditions (e.g., psoriasis, chronic urticaria) that could confound study outcomes.
3. History of immunodeficiency disorders.
4. Active or recurrent infections (including tuberculosis, hepatitis B or C, or HIV), or uncontrolled systemic diseases
5. Ongoing pregnancy or lactation.
6. Recent use of systemic therapies within specified timeframes (Corticosteroids, immune-suppressants, biologics within eight weeks prior to enrolment or Phototherapy within four weeks prior to enrolment)
7. A history of substance abuse, psychiatric disorders, or unstable medical conditions
8. Current participation in other clinical trials.
9. Unregulated comorbidities (e.g., hypertension, diabetes) or any condition potentially confounding the study outcomes
10. Any condition or comorbidity deemed by investigators to pose a risk to participant safety or data integrity.

### Methodology

A non-randomized, prospective open-label clinical trial was planned for 300 patients diagnosed with Eczema,

Conducted in accordance with Good Clinical Practice (GCP) guidelines. After carefully screening, selected eligible participants who agreed to participate in the clinical study were fully informed/explained about the study procedures and asked to sign a Patient Consent Form.

During the initial visit (baseline at Day 0), participants received a Patient Information Sheet in their preferred language. The attending physician completed a Case Record Form (CRF), which included the participant's detailed medical history, relevant personal information, and any existing comorbidities.

The safety and efficacy of the treatment were monitored at baseline, end of 1-month and end of study (2-month). All data were documented in the Case Record Form, and adverse events were closely observed, with severity and relationship to the study medication recorded by the investigator.

### Clinical assessments

Efficacy was assessed based on The Eczema Area and Severity Index (EASI) which integrates body surface (head and neck, upper extremities, trunk, and lower extremities) and the intensity (scored from 0 to 3, with 0 being absent; 1, mild; 2, moderate; and 3, severe) of lesional skin into one composite final EASI score which is the summation of the 4 regional scores, ranging from 0 to 72. Where a score of 0 indicates clear or no eczema, 0.1 to 1.0 indicates almost clear, 1.1 to 7 indicates mild disease, 7.1 to 21 indicates moderate disease, 21.1 to 50 indicates severe disease, and greater than 51 indicates very severe disease.[6] Necessary laboratory investigations (e.g. Red Blood Cell Count, Reticulocyte Count, ESR, Prothrombin Time, Liver Function Tests and Renal Function Tests), were conducted before initiating treatment and after treatment completion.

### Intervention

Takzema Tablet and Ointment, manufactured by Charak Pharma Pvt. Ltd., was evaluated for its efficacy and safety in patients with atopic dermatitis. Takzema Tablet contains *Neem, Haridra, Khadir, Manjistha & Triphala*. Takzema Ointment contains *Neem, Karanj, Haridra & Daruharidra*. The treatment regimen consisted of two tablets taken twice daily after meals with water and ointment applied locally over the affected area twice in a day,

Starting from first day of study & continued for period of 2 months. Patients were assessed at baseline and after 2 months of treatment.

## Observation

Table 1 shows demographic data of participants. Table 2, 3, 4 & 5 shows assessment of before & after treatment scores for Erythema, Oedema/Papulation, Lichenification and Area Scores for Takzema Tablet and Ointment. Table 6 show scores for 4 areas and the final EASI score. Table 7 shows laboratory investigations of participants before and after treatment.

**Table 1: Demographic data of Participants**

Demographic Factor		Data Summary
Age (years)		Mean: 35.2 (Range: 18–65)
Gender	Male	144 (48%)
	Female	156 (52%)
Disease Duration (years)		Mean: 7.4 (Range: 1–20)
Severity	Mild	60 (20%)
	Moderate	180 (60%)
	Severe	60 (20%)
Previous Treatment	Topical Steroids	192 (64%)
	Moisturizers Only	60 (20%)
	Immuno-suppressants	48 (16%)
Family History of Eczema	Yes	108 (36%)
	No	192 (64%)
Allergy History	Yes	240 (80%)
	No	60 (20%)
Smoking Status	Smoker	72 (24%)
	Non-Smoker	228 (76%)

**Table 2: Assessment of Takzema for Erythema**

Region	Erythema (0-3)				
	Day 0	1-Month	2-Month	p value	% Reduction
Head/neck	2.3 ± 0.5	1.8 ± 0.45	1.1 ± 0.4	<0.001	52.2
Trunk	2.7 ± 0.6	2.1 ± 0.5	1.4 ± 0.5	<0.001	48.1
Upper extremities	2.5 ± 0.5	2.0 ± 0.45	1.3 ± 0.4	<0.001	48.0
Lower extremities	2.8 ± 0.7	2.2 ± 0.55	1.5 ± 0.6	<0.001	46.4
Total	10.3 ± 1.16	8.1 ± 0.98	5.3 ± 0.96	<0.001	48.4

**Table 3: Assessment of Takzema for Oedema/Papulation Top of Form**

Region	Oedema/Papulation (0-3)				
	Day 0	1-Month	2-Month	p value	% Reduction
Head/neck	2.1 ± 0.7	2.0 ± 0.7	0.8 ± 0.5	0.002	61.9
Trunk	1.9 ± 0.8	1.8 ± 0.8	0.6 ± 0.4	0.001	68.4
Upper extremities	2.3 ± 0.6	2.2 ± 0.6	0.9 ± 0.5	0.003	60.9
Lower extremities	2.0 ± 0.7	1.9 ± 0.7	0.7 ± 0.4	0.004	65.0
Total	8.3 ± 2.8	7.9 ± 2.8	3.0 ± 1.8	0.002	63.9

**Table 4: Assessment of Takzema for Lichenification**

Region	Lichenification (0-3)				
	Day 0	1-Month	2-Month	p value	% Reduction
Head/neck	2.4 ± 0.6	2.1 ± 0.5	1.2 ± 0.5	0.001	50.0
Trunk	2.6 ± 0.5	2.3 ± 0.5	1.4 ± 0.6	0.002	46.15
Upper extremities	2.5 ± 0.7	2.2 ± 0.6	1.3 ± 0.4	0.001	48.0
Lower extremities	2.7 ± 0.6	2.4 ± 0.5	1.5 ± 0.5	0.001	44.44
Total	10.2 ± 1.21	9.0 ± 2.1	5.4 ± 2.0	0.001	47.06

**Table 5: Area scores for Assessment of Takzema**

Region	Area score (0-6)				
	Day 0	1-Month	2-Month	p value	% Reduction
Head/neck	3.4 ± 1.2	2.8 ± 1.1	1.5 ± 1.0	0.002	55.88
Trunk	4.2 ± 1.4	3.5 ± 1.3	2.0 ± 1.1	0.001	52.38
Upper extremities	3.8 ± 1.3	3.2 ± 1.2	1.9 ± 1.0	0.003	50.00
Lower extremities	4.5 ± 1.5	3.7 ± 1.4	2.3 ± 1.2	0.004	48.89
Total	15.9 ± 5.4	13.2 ± 5.0	7.7 ± 4.3	0.002	51.39

**Table 6: Final EASI Scores for Assessment of Takzema**

Region	Final EASI Score				
	Day 0	1-Month	2-Month	p value	% Reduction
Head/neck	2.95 ± 0.37	2.50 ± 0.33	1.45 ± 0.30	<0.002	50.85
Trunk	6.03 ± 0.63	5.40 ± 0.58	2.82 ± 0.46	<0.001	53.23
Upper extremities	5.00 ± 0.49	4.50 ± 0.45	2.28 ± 0.40	<0.003	54.40
Lower extremities	7.84 ± 0.73	7.10 ± 0.68	3.60 ± 0.53	<0.004	54.08
Total (Sum of the 4 region scores 0-72)	21.82 ± 1.14	19.50 ± 2.04	10.15 ± 1.69	<0.004	51.16

**Table 7: Clinical Parameters for Evaluating the safety of Takzema Tablet**

Parameter		Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	P-value
Red Blood Cell Count		4.7 ± 0.3 × 10 <sup>6</sup> /μL	4.8 ± 0.3 × 10 <sup>6</sup> /μL	0.162
ESR (mm/hr)		16 ± 4	13 ± 5	0.234
Prothrombin Time (sec)		12.1 ± 0.5	11.8 ± 0.4	0.198
Liver Function Tests	AST (U/L)	26 ± 6	25 ± 4	0.298
	ALT (U/L)	29 ± 6	28 ± 5	0.412
	Alkaline Phosphatase (U/L)	84 ± 14	82 ± 13	0.378
	Bilirubin (mg/dL)	0.9 ± 0.2	0.8 ± 0.2	0.290
Renal Function Tests	Creatinine (mg/dL)	1.0 ± 0.1	0.9 ± 0.1	0.229
	Blood Urea Nitrogen (BUN, mg/dL)	14 ± 3	13 ± 2	0.325
	eGFR (mL/min/1.73m <sup>2</sup> )	96 ± 11	98 ± 8	0.189

## Results

The demographic profile of the study participants (N=300) demonstrated a mean age of 35.2 years (range: 18–65). The gender distribution was balanced, with 144 males (48%) and 156 females (52%). The mean disease duration was 7.4 years, spanning from 1 to 20 years. Regarding disease severity, 60 participants (20%) had mild symptoms, 180 (60%) had moderate symptoms, and 60 (20%) had severe symptoms. A majority of participants (64%) had received topical steroid treatment, while 20% used only moisturizers, and 16% had been treated with immunosuppressants. Family history of eczema was reported by 108 participants (36%), and 240 participants (80%) had a history of allergies. Smoking status indicated that 72 participants (24%) were smokers, while 228 (76%) were non-smokers. This demographic distribution provides a comprehensive overview of the study population's characteristics.

The clinical trial assessing the efficacy of Takzema Tablet and Ointment demonstrated significant improvements across multiple clinical parameters in patients with eczema. Takzema demonstrated significant improvement in erythema scores across all body regions assessed in patients with eczema. The clinical assessment for erythema demonstrated a significant reduction across all body regions over the two-month trial period. Baseline erythema scores were highest in the lower extremities (2.8 ± 0.7) and lowest in the head/neck region (2.3 ± 0.5). Progressive improvement was observed, with mean erythema scores decreasing at one month and further at two months. The total erythema score declined from 10.3 ± 1.16 at baseline to 5.3 ± 0.96 at two months, reflecting an overall reduction of 48.4%. Region-wise percentage reductions ranged from 46.4% to 52.2%, with the greatest improvement noted in the head/neck region. Statistical analysis confirmed the efficacy of Takzema, with a highly significant p-value (<0.001) across all parameters, indicating its potential in reducing erythema in clinical settings. These findings suggest Takzema effectively reduces erythema severity in patients with eczema.

The assessment of oedema/papulation in patients treated with Takzema (tablet and ointment) demonstrated a significant reduction over the course of two months.

At baseline (Day 0), total oedema/papulation score across all body regions was  $8.3 \pm 2.8$ , which progressively decreased to  $7.9 \pm 2.8$  at 1 month and further reduced to  $3.0 \pm 1.8$  at 2 months ( $p = 0.002$ ), reflecting an overall 63.9% reduction. Region-wise analysis revealed highest reduction in trunk (68.4%), followed by lower extremities (65.0%), head/neck (61.9%), and upper extremities (60.9%). The statistical significance across all regions ( $p \leq 0.004$ ) indicates a consistent and clinically meaningful improvement in oedema and papulation severity, supporting efficacy of Takzema in alleviating these symptoms over the treatment duration.

Assessment of Takzema for lichenification demonstrated significant reduction across all body regions over two-month treatment period. At baseline (Day 0), total lichenification score was  $10.2 \pm 1.21$ , which decreased to  $9.0 \pm 2.1$  at one month & further reduced to  $5.4 \pm 2.0$  at two months ( $p = 0.001$ ), indicating statis. significant improvement. Region-wise analysis revealed highest initial severity in lower extremities ( $2.7 \pm 0.6$ ) & trunk ( $2.6 \pm 0.5$ ), both of which showed consistent reductions over time, culminating in 44.44% and 46.15% improvement, respectively. The head/neck ( $2.4 \pm 0.6$ ) & upper extremities ( $2.5 \pm 0.7$ ) also exhibited sign. reductions (50.0% & 48.0%, respectively). These findings suggest that Takzema effectively reduces lichenification across different body regions, with an overall 47.06% improvement, reinforcing its therapeutic potential in managing lichenification.

The assessment of Takzema's efficacy based on area scores across different body regions demonstrated a statistically significant reduction over two months. At baseline (Day 0), total area score was  $15.9 \pm 5.4$ , which progressively decreased to  $13.2 \pm 5.0$  at one month and further to  $7.7 \pm 4.3$  at two months ( $p = 0.002$ ), indicating an overall 51.39% reduction. Region-wise analysis showed greatest improvement in head/neck region (55.88% reduction,  $p = 0.002$ ), followed by trunk (52.38%,  $p = 0.001$ ), upper extremities (50.00%,  $p = 0.003$ ), and lower extremities (48.89%,  $p = 0.004$ ). These findings suggest that Takzema significantly reduces affected area over time, with a consistent and notable improvement across all body regions. The Final Eczema Area and Severity Index (EASI) scores for different body regions were assessed over a two-month period to evaluate efficacy of Takzema in patients with eczema.

At baseline (Day 0), the highest Final EASI score was observed in the lower extremities ( $7.84 \pm 0.73$ ), followed by the trunk ( $6.03 \pm 0.63$ ), upper extremities ( $5.00 \pm 0.49$ ), and head/neck ( $2.95 \pm 0.37$ ). A progressive reduction in EASI scores was noted at the one-month and two-month follow-ups across all regions. The most significant improvement at two months was observed in the upper extremities (54.40% reduction,  $p < 0.003$ ), followed closely by the lower extremities (54.08%,  $p < 0.004$ ), trunk (53.23%,  $p < 0.001$ ), and head/neck (50.85%,  $p < 0.002$ ). The total EASI score decreased from  $21.82 \pm 1.14$  at baseline to  $10.15 \pm 1.69$  at two months, representing an overall 51.16% reduction ( $p < 0.004$ ). These statistically significant reductions indicate that Takzema demonstrated substantial efficacy in reducing eczema severity across all body regions over the study period.

The safety of Takzema tablet & ointment was evaluated using various laboratory parameters before and after treatment. Results demonstrated no statistically significant changes in key clinical parameters following treatment. Red blood cell count, ESR, and prothrombin time remained stable with p-values of 0.162, 0.234, and 0.198, respectively. Liver function markers, including AST, ALT, alkaline phosphatase, and bilirubin, showed minimal variation with p-values ranging from 0.290 to 0.412. Renal function parameters, such as creatinine, BUN, and eGFR, also exhibited non-significant changes (p-values between 0.189 and 0.325). These results suggest that Takzema Tablet did not induce adverse effects on hematological, hepatic, or renal functions, supporting its favorable safety profile for clinical use.

## Discussion

Eczema, also known as atopic dermatitis, is a chronic inflammatory skin condition characterized by pruritus, erythema, and xerosis. It affects individuals of all ages and is commonly associated with other atopic conditions such as asthma and allergic rhinitis. Conventional treatment options for eczema aim to manage symptoms and reduce flare-ups. Topical corticosteroids are the mainstay treatment, effectively reducing inflammation and itching. However, prolonged use of corticosteroids is linked to potential side-effects such as skin thinning, striae, and adrenal suppression.[7]

Calcineurin inhibitors, are non-steroidal alternatives that modulate the immune response and are particularly useful for sensitive areas like the face and eyelids. Despite their efficacy, calcineurin inhibitors may cause transient burning sensations and increase the risk of local skin infections.[8] Additionally, systemic treatments such as oral corticosteroids, immunosuppressants and biologic therapies are reserved for severe, treatment-resistant cases. These systemic options pose risks including immune-suppression, increased infection susceptibility, and potential malignancy risks with long-term use. While conventional therapies provide significant symptom relief, concerns about adverse effects necessitate exploring safer, long-term treatment options, prompting ongoing research in alternative interventions for eczema management. In recent years, herbal treatments have emerged as promising alternatives for eczema management. Herbal remedies have demonstrated anti-inflammatory, antimicrobial, improving skin barrier function and soothing properties, potentially reducing eczema symptoms with minimal side effects.

A holistic alternative is offered by Takzema Tablet and Ointment, polyherbal Ayurvedic formulations specifically designed for the management of eczema. Unlike conventional therapies, Takzema Tablet and Ointment targets the underlying key pathological mechanisms by addressing oxidative stress, modulating immune response, and aiding in the reduction of inflammation. Takzema Tablet contains *Daruharidra* (*Berberis aristata*), *Manjishtha* (*Rubia cordifolia*), *Guduchi* (*Tinospora cordifolia*) & *Ashwagandha* (*Withania somnifera*). Whereas Takzema Ointment contains *Neem* (*Melia azadirachta*), *Haridra* (*Curcuma longa*), *Daruharidra* (*Berberis aristata*), *Kumari* (*Aloe barbadensis*) & Flax seed oil (Oil of *Linum usitatissimu*), each of which has been traditionally recognized for its dermatological benefits. These ingredients work synergistically to enhance immune regulation, aiding in anti-inflammatory, antioxidant, antimicrobial & immune-modulatory action to promote dermal repair and enhance overall skin health. In the topical formulation, emollients and occlusive agents provide hydration, reduce trans-epidermal water loss (TEWL), and create a protective barrier to prevent irritants from exacerbating symptoms. The combined pharmacological actions of these ingredients effectively target the inflammatory,

Microbial, and barrier dysfunction aspects of eczema pathogenesis, offering a more comprehensive and sustainable approach to eczema management. Atopic eczema patients exhibit high levels of *Staphylococcus aureus* (*S. aureus*) skin colonization. *S. aureus* can stimulate macrophages and the expression of proinflammatory cytokines. Berberine from *Berberis aristata* suppresses *S. aureus*-induced inflammation via inhibition of TNF- $\alpha$  release, ROS production, and expression of key genes involved in the inflammatory pathway.[9] Purpurin, is an alizarin-based anthraquinone with particularly high antioxidant activity is present as a glycoside in the roots of *Rubia cordifolia*. A study investigated the anti-inflammatory activity of purpurin in HaCaT (human keratinocyte) cell lines stimulated with a mixture of tumor necrosis factor- $\alpha$  (TNF- $\alpha$ )/Interferon- $\gamma$  (IFN- $\gamma$ ). Purpurin suppressed cytokines (IL-6, IL-8, and IL-1 $\beta$ ) and chemokine (TARC, MDC, and RANTES) dose-dependently. Purpurin also inhibited protein kinase B (AKT), mitogen-activated protein kinase (MAPKs), and nuclear factor kappa-light-chain-enhancer of activated B (NF- $\kappa$ B) activation in TNF- $\alpha$ /IFN- $\gamma$ -stimulated HaCaT cells.[10] A study aimed to explore the therapeutic effects of turmeric extract against atopic dermatitis in a BALB/c mouse disease model established using 1-chloro-2,4-dinitrobenzene. It effectively suppressed symptoms by reducing the skin severity score, TEWL, scratching, ear thickness, serum Ig levels, inflammatory cell infiltration, and degranulation of mast cells, as well as the enlargement of the spleen and lymph nodes.[11] Another study have shown *Curcuma longa* essential oil topically mitigating inflammatory markers, pruritic & CRP levels & Mast cells in acetone-induced atopic dermatitis in wistar albino rats.[12] *Aloe vera* gel is widely used in treatment of an array of disturbances, especially skin disorders. The wound-healing effects have been attributed to its moisturizing and anti-inflammatory effects as well as its beneficial effect on maturation of collagen. A study compared effects of topically applied extracts of *Aloe ferox* with that of *Aloe vera* on symptoms as well as IgE levels of a mouse model of atopic dermatitis. *Aloe* gels of inhibited cutaneous inflammatory response as well as serum IgE levels in rats. According to study *A. vera* gel, applied topically, may be a safe and useful alternative to antihistamines and topical corticosteroids, for treatment of patients suffering from recurring chronic atopic dermatitis.[13]

Takzema is comprehensive formulation designed to target pathophysiology of eczema. Key ingredient such as *Guduchi* (*Tinospora cordifolia*) contribute to immune modulation, enhancing body's ability to manage hypersensitivity reactions. Additionally, *Manjishtha* (*Rubia cordifolia*) possess antimicrobial and detoxifying properties, supporting reduction of microbial colonization and promoting skin healing. The ointment offers soothing effect, with emollient and hydrating agents that help restore skin barrier function, reducing dryness and irritation. *Haridra* (*Curcuma longa*) exhibits potent anti-inflammatory effects by inhibiting cyclooxygenase (COX) and lipoxygenase (LOX) pathways, reducing production of pro-inflammatory mediators. Together, these herbal constituents synergistically manage eczema symptoms by restoring TEWL, reducing inflammation, controlling itching, balancing immune system & promoting skin repair, making it an effective solution for managing eczema.

## Conclusion

The present study demonstrates that Takzema, a polyherbal formulation, is both effective and safe in managing the signs and symptoms of Eczema (Atopic Dermatitis) and its related complications. It significantly reduces pruritus, erythema & skin barrier dysfunction; further crucially targeting multiple immune & inflammatory pathways for effective management of eczema.

### Cost of Study

All medications required during the 2 months of trial were provided by the sponsor. Laboratory test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

### Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of Chaudhari Clinic & Vidnyanam Clinic HCPs who are not associated with the sponsors.

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