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A DOUBLE-BLIND, RANDOMIZED, PARALLEL GROUPS, PLACEBO-CONTROLLED, COMPARATIVE STUDY FOR ASSESSING THE EFFICACY AND TOLERABILITY OF ANDROPAN^{TM} IN INDIVIDUALS WITH UPPER RESPIRATORY INFECTION WITH OR WITHOUT STANDARD OF CARE.

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ABSTRACT

Background: Upper respiratory tract infections (URTIs) impose a significant clinical burden despite being generally self-limiting. AndroPan^{TM}, a standardized extract of Andrographis paniculata, is traditionally recognized for its immunomodulatory properties. This comprehensive Phase II randomized, double-blind, placebo-controlled study evaluates the efficacy, safety, and tolerability of AndroPan^{TM} in URTI management. **Methods**: The study used a double-blind, randomized, placebo-controlled, parallel-group design to assess the effectiveness of an investigational product (IP) in treating a condition. 38 subjects were randomly assigned in a 1:1 ratio, with the goal of obtaining complete data from at least 30. The screening period involved various procedures, including obtaining written informed consent, recording demographic information, and conducting clinical examinations. The study continued with follow-up visits, IP compliance checks, and global assessment scales. The study concluded if no adverse events were reported or if all reported adverse events were resolved. **Results**: LCQ scores significantly improved in the AndroPan^{TM} group by 99.7% compared to 20.8% in placebo ($p<0.05$). Complete symptom resolution was achieved by 15.8% of the AndroPan^{TM} group. No adverse events were reported. Global Assessment Scores confirmed high tolerability. **Conclusion**: AndroPan^{TM} demonstrates significant efficacy in symptomatic relief of URTI, with excellent safety and tolerability. These findings encourage further larger-scale studies.

KEYWORDS: Upper Respiratory Tract Infection, Randomized Controlled Trial, Immunomodulatory, *Andrographis paniculata*.

1.) INTRODUCTION[1,6]

Upper respiratory tract infections (URTIs) are among the most common acute illnesses worldwide, affecting individuals across all age groups and imposing a significant public health burden. [1] These infections encompass a range of clinical conditions, including the common cold, pharyngitis, sinusitis, laryngitis, and otitis media, typically caused by viral pathogens. [2] Rhinoviruses, coronaviruses, adenoviruses, respiratory syncytial virus, and influenza viruses are the predominant viral agents implicated in URTIs.[3]

Despite being self-limiting in most cases, URTIs are a major contributor to outpatient visits, school and work absenteeism, and inappropriate antibiotic prescriptions, which contribute to antimicrobial resistance. [4] The transmission of URTIs commonly occurs through respiratory droplets, direct contact, or contaminated surfaces, making them highly contagious in community settings.[5]

Effective management primarily involves symptomatic treatment, with emphasis on patient education, supportive care, and judicious use of antibiotics. [6] The ongoing challenge of antimicrobial resistance highlights the need for evidence-based guidelines and rational prescribing practices. [7] Understanding the epidemiology, etiology, and management strategies of URTIs is essential for clinicians to optimize patient care and reduce public health risks.[8]

2.) MATERIALS AND METHODS

Study Design: This Phase II, double-blind, randomized, placebo-controlled trial was conducted at Parul Sevashram Hospital, Gujarat, India. The trial followed the Declaration of Helsinki and Good Clinical Practice guidelines. Ethics Committee approval was obtained, and written informed consent was secured from all participants.

Phase of development: II
Test product: AndroPan™ Capsule, 150 mg (twice daily)

Name of Sponsor: K Patel Phytoextractions Pvt Ltd., Mumbai
507, Eureka Tower, Mind Space, Off Link Road, Malad West, Mumbai-400064, Maharashtra, India

Investigator(s) and Study center(s): The study was conducted at a single center in India. Subjects were enrolled and randomized at the below listed study center.

Principal Investigator: Dr. Mehul Marwadi
Study Centre: Parul Sevashram Hospital, Near Parul University Campus, Waghodia Road, P.O. Limda, Ta. Waghodia – 391760, Dist. Vadodara, Gujarat, India.

Ethics Committee: This study protocol was approved by The Parul University Institutional Ethics Committee on Human Research (PU-IECHR) on 11 Aug 2023.

Informed Consent: Participants were made fully aware of the Study Objectives, their rights and Procedure of the study, with the help of the patient information sheet, which was available in English, Hindi and Gujarati. Participants who gave written informed consent were included in study.

Participants: A total of 38 subjects were randomly assigned in a 1:1 ratio to receive Test Product or Placebo and among them 1 participant withdrew their consent before completing study.

Key Inclusion Criteria

- Male or Female aged between 18 to 50 years (inclusive), as of the screening date.
- Individuals with symptoms of acute upper respiratory tract infection as assessed by the investigator at the time of screening.
- Symptoms of upper respiratory tract infection were present for at least 24 hours but not more than 72 hours prior to the screening visit.
- Those who had a score of ≥ 5 for at least 2 symptoms out of runny nose, plugged nose, sneezing, sore throat, scratchy throat, or head congestion on the WURSS-21.
- Participants who did not require hospitalization.
- Participants with a negative COVID-19 RT-PCR report.
- SPO2 level was ≥ 90%.
- Those who demonstrated an understanding of the study details and had a willingness to participate as evidenced by voluntary written informed consent.
- Based upon the investigator's judgment, if any patient was on standard treatment for a condition like diabetes, cardiovascular or pain etc., which did not seem to affect the current study outcomes, then the patient could be included in the study.

Key Exclusion criteria

- Participants did not have a COVID RT-PCR test report.
- Participants had a history of COVID +ve, since more than 14 days from the date of screening.
- High grade fever was defined as body temperature ≥ 40°C.
- They had a history of allergy (allergic rhinitis) along with symptoms such as sneezing, runny nose, and red, watery, and itchy eyes.
- Chest X-rays showed signs of pneumonia.
- Participants had a history of Chronic obstructive pulmonary disease, pulmonary fibrosis, or Asthma.
- Participants had rhinitis medicamentosa or chronic cough of viral or allergic origin (other than bacterial and fungal). They also had anatomical nasal obstruction/deformity or nasal reconstructive surgery, etc.
- Participants had a history of heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies.
- Participants had a history of an immune-compromised state, with or without organ transplant.
- Participants had known or suspected hypersensitivity or intolerance to herbal products.
- Alanine transaminase (ALT) or aspartate transaminase (AST) was ≥2.5 times the upper limit of normal.
- Participants were diagnosed with Sickle cell disease, Thalassemia, Type I/uncontrolled Type II diabetes mellitus, or cystic fibrosis.
- They had diagnosed cases of hypertension.
- Those who had been vaccinated for influenza, swine flu, or COVID, 3 months prior to the screening visit.
- Those who had taken or should be taking or were taking antibiotics, antivirals, steroids, nasal decongestants, antihistamines, or other medications that were expected to alleviate cold symptoms within one week of the start of the study.
- Those who had severe mental illnesses, such as dementia, Parkinson's disease, Alzheimer's Disease, depression, or anxiety disorders, or those who were currently taking psycho-neurological drugs, such as antidepressants.
- Those who had participated in other clinical trials within 30 days, prior to the screening visit or

planned to participate in other clinical trials during the trial period.

- Participants had substance abuse as per last two-year history, which included the use of but was not limited to drugs such as cocaine, amphetamine, marijuana, etc.
- Individuals had a history of smoking or were currently smoking or using any form of smokeless tobacco.
- Females who were pregnant/planning to be pregnant/lactating or taking any oral contraceptives.
- Any condition that could, in the opinion of the investigator, have precluded the participant's ability to successfully and safely complete the study or that may have confounded study outcomes.
- Based on the investigator's judgment, the patients who required treatment which may have affected the outcome of the current study, such as Anti-viral, Anti-microbial, Anti- inflammatory, Anti-allergic treatments.

Intervention: Participants in The AndroPan^{TM} group received 150 mg capsules twice daily for 7 days and The Placebo group received visually identical capsules.

METHODOLOGY

This study was designed as a double-blind, randomized, placebo-controlled, parallel-group clinical trial. A total of 38 subjects were enrolled and randomized in a 1:1 ratio, with the objective of obtaining complete data from at least 30 participants. Both the subjects and investigators remained blinded to the treatment assignments throughout the study to maintain the integrity of the results.

The screening period (Visit 1: Day -3 to Day 1) involved several procedures to assess subject eligibility. Written informed consent was obtained from all participants before enrollment. Demographic data, anthropometric measurements, and vital signs were recorded. A detailed medical history and information on concomitant medications were collected, and a thorough clinical examination was conducted. Female subjects underwent a urine pregnancy test. Additionally, clinical laboratory investigations and subject assessment questionnaires were completed during this phase.

On Day 1 (Visit 2), eligible subjects underwent randomization and baseline assessments. Vital signs were measured, concomitant medications recorded, and clinical examinations performed. Assessment questionnaires were completed, and inclusion and exclusion criteria were reviewed for final eligibility confirmation. The investigational product (IP) or placebo was dispensed and administered according to the randomization plan. Study diaries were provided to subjects for compliance tracking, and monitoring for adverse events (AE) and serious adverse events (SAE) commenced.

The administration of the investigational product continued daily from Day 1 to Day 8. Compliance with the dosing regimen was verified through telephonic communication. AE and SAE monitoring was conducted continuously during this period.

The first follow-up visit (Visit 3: Day 5 ± 1) included vital sign measurements, recording of concomitant medications, clinical examinations, and completion of assessment questionnaires. Investigational product compliance was assessed, study diaries were reconciled, and AE/SAE monitoring continued.

At the end-of-study visit (Visit 4: Day 8 ± 1), a comprehensive assessment was performed. This included a final compliance check, safety evaluations, clinical laboratory tests, vital sign measurements, and clinical examinations. Concomitant medication records and assessment questionnaires were updated, and a global assessment scale was used to evaluate treatment response. Investigational product reconciliation and diary review were conducted, and AE/SAE monitoring continued until study completion.

The study was considered complete if no adverse events were reported at the final visit or if all reported adverse events had been resolved. The overall study procedure consisted of four key visits: Visit 1 (Screening, Day -3 to Day 1), Visit 2 (Randomization/Baseline, Day 1), Visit 3 (First Follow-up, Day 5 ± 1), and Visit 4 (End of Study Visit, Day 8 ± 1).

Duration of study

The anticipated treatment duration was around 7 days, commencing from Day 1.

- **Visit 1 Screening:** Day -3 to 1
- **Visit 2 Enrolment / Randomization visit:** Day 1
- **Visit 3 Follow Up 1:** Day 5 + 1
- **Visit 4 End of Study:** Day 8 + 1

The total duration of the study was approximately 11 days from the screening visit (Day -3) until the Visit 4 – End of Study Visit (Day 8 + 1)

Primary objective

- The efficacy and tolerability of AndroPan^{TM} were compared with placebo in individuals with upper respiratory tract infection.

Secondary objective

1. The safety of AndroPan^{TM} was compared with placebo in individuals with upper respiratory tract infection.

Clinical Variables

2. To assess the severity of cough, the Leicester cough questionnaire in both populations from baseline.
3. Days taken to attain complete resolution of Common Cold Symptoms
4. Percentage of Patients with Unresolved Common

Cold Symptoms
5. Percentage of Patients with Minimal Difference of <10.5 on WURSS21
6. % Improvement in WURSS21 from baseline.

Tolerability Variables

i. Tolerability Assessment Using Global Assessment Scale at End of Study.

Safety Variables

ii. Urine pregnancy tests were carried out at Visit 1: Screening (Day (-3) to 1) visit only.
iii. Number and type of Adverse Events (AEs) and serious adverse events (SAEs)
iv. Vital signs (Blood Pressure, Pulse rate, and Body temperature) were monitored at all visits.

Statistical Analysis

Data were analyzed using SPSS v27. Continuous variables were presented as mean ± SD. Paired t-tests compared baseline and Day 7 values within groups, and independent t-tests compared between groups. A p-value <0.05 was considered statistically significant.

Statistical method

Statistical analysis was conducted using SPSS software version 27 or higher, if applicable. All statistical tests were carried out at the 95% significance level, unless otherwise specified. The continuous data were summarized by treatment groups using descriptive statistics (number of subjects (n), mean, standard deviation (SD), median, minimum and maximum). Categorical data were summarized by treatment groups using frequency count (n) and percentages (%).
Demographic and baseline characteristics were presented using descriptive statistics. Clinical endpoints, such as improvement in the Leicester Cough Questionnaire, was assessed using descriptive statistics. The p-value was calculated using an independent mean t-test at a 95% confidence interval. Categorical clinical endpoints were measured using frequency and percentages. Tolerability variables was also being assessed using frequency and percentages.

Baseline Characteristics

Subjects were meticulously screened initially to ascertain their suitability and eligibility for participation in the study. Out of an initial cohort of 41 subjects who underwent screening, a detailed evaluation process led to the exclusion of 4 subjects due to various reasons such as not meeting the specific inclusion criteria or presenting with conditions that posed potential risks.

After these exclusions, a total of 37 subjects remained eligible and were randomized into treatment groups as part of the study protocol. However, during the course of the study, based on medical evaluations and considerations, 01 more subjects were discontinued as per physician decisions, bringing the total number of completed study subjects to 36.

Table 1 Subject Disposition.

Treatment Sequence				
Category	Statistics	Andropan^{TM} (N = 19)	Placebo (N = 18)	Overall (N = 41)
Subject Screened	n	-	-	41
Subjects Rescreened	n	-	-	00
Subject Screen failure	n	-	-	02
Subject discontinued before Randomization	n	-	-	01
Lost To Follow-Up	n	-	-	01
Physician Decision	n	-	-	00
Withdrawal Of Consent	n	-	-	00
Subjects Randomized	n	19	18	37
Subjects Dosed	n (%)	19 (51.4%)	18 (48.6%)	37 (100%)
Subjects completed	n (%)	19 (52.8%)	17 (47.2%)	36 (100%)
Subjects Discontinued	n (%)	-	01 (100.0%)	01 (100%)
Reason for Discontinuation				
Consent Withdrawal	n (%)	-	01 (100.0%)	01 (100%)
N: The number of subjects in the safety population for each sequence; n: The number of subjects in the specific category; %: calculated using the number of subjects in the safety population for each sequence, or the safety population for the overall, as denominator (n/N*100).				
Test Product (A): AndroPan^{TM} Capsule 150 mg (twice daily) of K Patel Phytoextractions Pvt Ltd				
Reference Product (B): Placebo Capsule of K Patel Phytoextractions Pvt Ltd.				

3.) RESULTS

I) Clinical Variables

i.) To assess the severity of cough, the Leicester cough questionnaire in both populations from baseline: The Leicester Cough Questionnaire (LCQ) is a validated, self-administered tool designed to assess health-related quality of life in patients with chronic cough. It contains 19 items grouped into three domains: Physical (8 items) Psychological (7 items) Social (4 items). Each item is scored on a 7-point Likert scale, with higher scores indicating better health status (less cough impact). The total score ranges from 3 to 21, and

domain scores are also summed separately. [9] At baseline, the Andropan™ group (N=19) exhibited a mean LCQ score of 72.4 (±36.0), while the Placebo group (N=17) had a higher mean score of 96 (±27.0). By day 5, the mean LCQ scores for Andropan™ and Placebo were 101.2 (±30.4) and 99.8 (±24.1), respectively. At the end of treatment (EOT), the mean LCQ scores further increased to 115.6 (±22.7) for Andropan™ and 109 (±22.8) for Placebo. Notably, the percent improvement in LCQ from baseline was statistically significant ($p<0.05$) for Andropan™, showing a mean improvement of 99.7 (±105.3) compared to Placebo's mean improvement of 20.8 (±37.7). These results, calculated using an independent t-test, suggest a substantial and statistically significant improvement in cough-related symptoms with Andropan™, supporting its efficacy in comparison to the Placebo.

Table 2: Improvement Leichester Cough Questionnaire from Baseline within Each Group: Andropan™ and Placebo Group.

Parameter & Visit	**Statistics**	**Andropan™ (N=19)**	**Placebo (N=17)**	**P-value**
LCQ at Baseline	N	19	17	-
	Mean (±SD)	72.4 (±36.0)	96 (±27.0)	
	Median	72	101	
	Min, Max	25, 125	39, 124	
CQ at Day 5	N	19	17	-
	Mean (±SD)	101.2 (±30.4)	99.8 (±24.1)	
	Median	117	120	
	Min, Max	42, 128	56, 128	
Parameter & Visit	Statistics	Andropan™ (N=19)	Placebo (N=17)	P-value
LCQ at Baseline	N	19	17	-
	Mean (±SD)	72.4 (±36.0)	96 (±27.0)	
	Median	72	101	
	Min, Max	25, 125	39, 124	
Q at Day 5	N	19	17	-
	Mean (±SD)	101.2 (±30.4)	99.8 (±24.1)	
	Median	117	120	
	Min, Max	42, 128	56, 128	
Improvement in LCQ from baseline to Day 5	N	19	17	0.003 ($p<0.05$) Significant
	Mean (±SD)	71.1 (95.2)	10.2 (38.9)	
	Median	35.1	3.3	
	Min, Max	-39, 318	-33, 148	
LCQ at EOT	N	19	17	-
	Mean (±SD)	115.6 (±22.7)	109 (±22.8)	
	Median	126	120	
	Min, Max	65, 133	61, 130	
% Improvement in LCQ from baseline to EOT	N	19	17	0.019 ($p<0.05$) Significant
	Mean (±SD)	99.7 (±105.3)	20.8 (±37.7)	
	Median	63.9	12.1	
	Min, Max	1, 364	-19, 143	

Abbreviations: LCQ: Leichester Cough Questionnaire; N = Number of patients in specified treatment group; SD: Standard Deviation. Note: P-value has been calculated using independent t-test. A small p-value ($p<0.05$) indicates stronger evidence against the null hypothesis. A larger p-value suggests weaker evidence.*

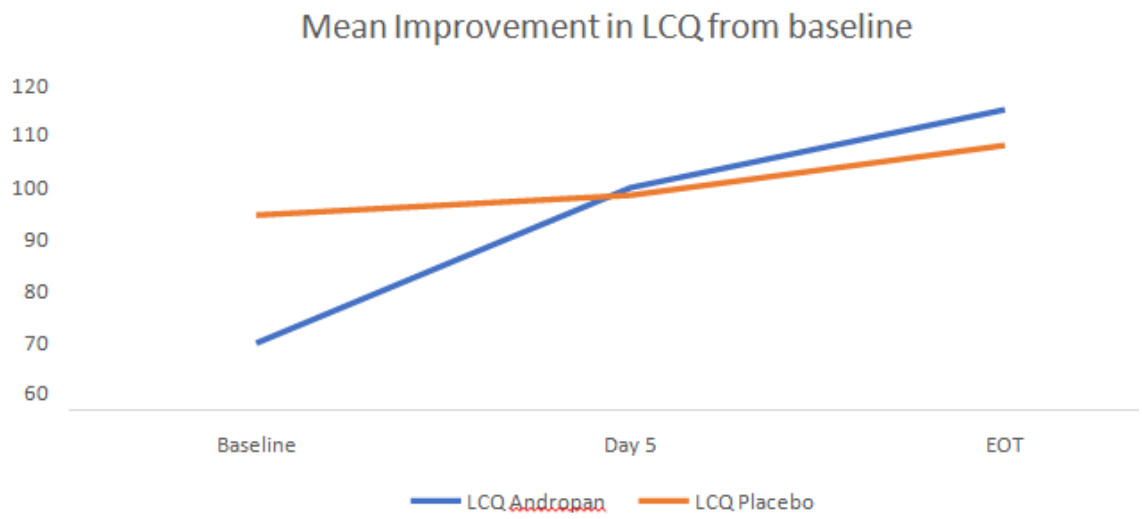

Figure: 1 % Improvement in LCQ Score from Baseline to Day 5 & End of Treatment (EOT).

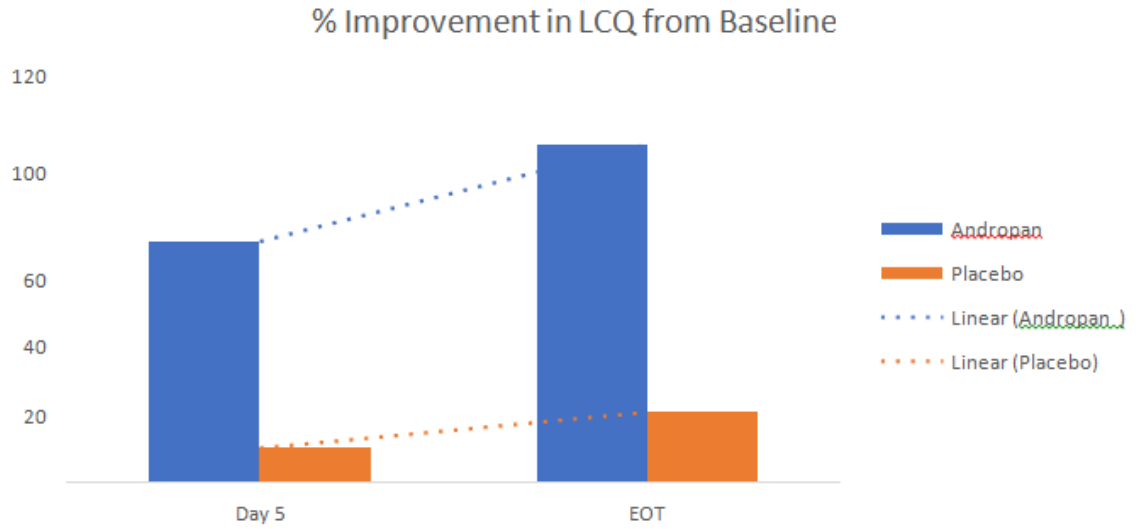

Figure 2: Mean Improvement in LCQ Score from Baseline to Day 5 & End of Treatment (EOT).

ii.) Days taken to attain complete resolution of Common Cold Symptoms: The **Wisconsin Upper Respiratory Symptom Survey (WURSS)** is a validated, patient-reported outcome measure specifically designed to assess the severity and impact of common cold symptoms. [10] The analysis of following parameter using the Wisconsin Upper Respiratory Symptom Survey (WURSS) showed distinct observations between the Andropan™ and Placebo groups. In the Andropan™ group (N=19), three participants experienced a notable reduction in common cold symptoms, with an average of 7 days required for complete resolution according to the WURSS. However, in the Placebo group (N=17), none of the participants reported complete resolution during the study period. This discrepancy suggests a potential efficacy of Andropan™ in improving the resolution of common cold symptoms compared to the placebo. The average of 7 days in the Andropan™ group indicates a relatively prompt recovery, while the absence of resolution in the Placebo group emphasizes the potential impact of Andropan™ on symptom relief. The details have been mentioned in the table below.

Table 3: Days to Complete Resolution of Common Cold Symptoms from Baseline within Each Group: Andropan™ and Placebo Group.

Parameter & Visit	Statistics	Andropan™ (N=19)	Placebo (N=17)
Days to complete resolution of common cold symptoms (WURSS)	n	3	0
	Days	7	-
"N" represents the total population, while "n" signifies the number of observations within a subset population.			

iii.) Percentage of Patients with Unresolved Common Cold Symptoms: The analysis of Percentage of patients with unresolved common cold symptoms showed noteworthy differences between the Andropan™ and Placebo groups. In the Andropan™ group (N=19), 16 out of 19 participants, representing 84.2%, reported unresolved common cold symptoms at the specified visit. On the other hand, in the Placebo group (N=17), all 17 participants, accounting for 100.0%, experienced persistent common cold symptoms. These findings suggest a higher proportion of participants in the Placebo group continued to have unresolved symptoms compared to the Andropan™ group. The observed 84.2% of unresolved symptoms in the Andropan™ group underscores that a significant portion of participants still faced symptoms, indicating a potential need for further investigation into the overall effectiveness of Andropan™ in managing common cold symptoms. In contrast, the 100.0% rate in the Placebo group highlights the absence of symptom resolution, emphasizing the potential impact of Andropan™ in reducing the symptoms. The observations have been listed below in the table.

Table 4: Percentage of Patients with Unresolved Common Cold Symptoms from Baseline within Each Group: Andropan™ and Placebo Group.

Parameter & Visit	Statistics	Andropan™ (N=19)	Placebo (N=17)
% of patients with unresolved common cold symptoms	n	16	17
	Percentages (%)	84.2%	100.0%
"N" represents the total population, while "n" signifies the number of observations within a subset population.			

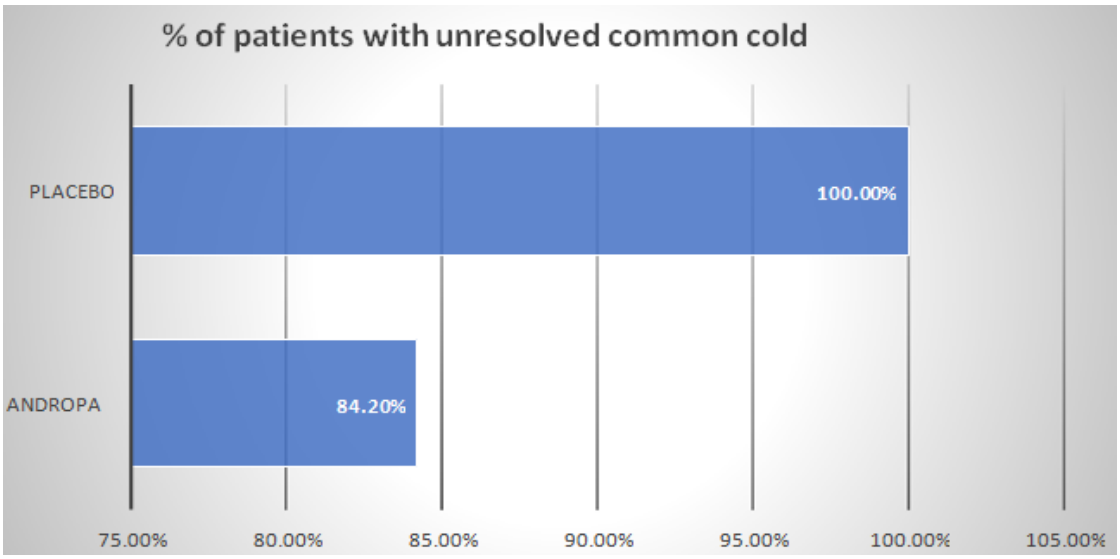

Figure 3: Patients with Unresolved Common Cold Symptoms.

iv.) Percentage of Patients with Minimal Difference of <10.5 on WURSS21: In the Andropan™ group (N=19), 18 out of 19 participants, constituting 94.7%, achieved this minimal difference. In comparison, the Placebo group (N=17) had 13 out of 17 participants, accounting for 76.5%, attaining the specified minimal difference. These findings suggest a notably higher proportion of participants in the Andropan™ group experiencing a clinically meaningful improvement, as denoted by a minimal difference of <10.5, compared to the Placebo group. This disparity underscores the potential efficacy of Andropan™ in symptom alleviation, emphasizing its ability to bring about a substantial improvement in common cold-related symptoms relative to the placebo. The observations have been listed below in the table.

Table 5: Percentage of Patients with Minimal Difference of <10.5 on WURSS21 from Baseline within Each Group: Andropan™ and Placebo Group.

Parameter & Visit	**Statistics**	**Andropan™ (N=19)**	**Placebo (N=17)**
% of patients with minimal difference of <10.5 on WURSS21	n	18	13
	Percentages (%)	94.7%	76.5%
"N" represents the total population, while "n" signifies the number of observations within a subset population.			

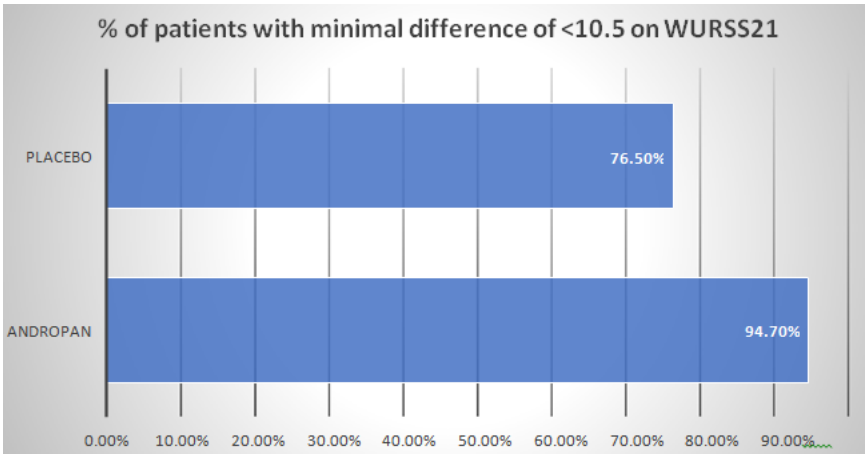

Figure 4: Percentage of Patients with Minimal Difference of <10.5 on WURSS21 from Baseline within Each Group.

v.) **% Improvement in WURSS21 from baseline:** The analysis of percentage improvement in WURSS21 from baseline showed notable trends among different treatment groups on Day 5 (D5) and at the End of Treatment (EOT). In the Andropan^{TM} - Day 5 group, a diverse distribution is observed, with participants showing improvement across various percentage ranges. Particularly, at Day 5, a substantial number of participants (5) exhibit a 0-40% improvement, while there is an increase in the 81-100% improvement range at 4 participants. Moving to Andropan^{TM} (EOT), a significant shift occurs, with a higher count (10 participants) now achieving an 81-100% improvement, indicating a potential positive response to the treatment over the course of the study. Conversely, the Placebo (Day 5) group is characterized by a larger proportion of participants (8) in the 0-40% improvement range, suggesting a limited impact of the placebo at this early stage. This pattern persists in the Placebo (EOT), where a substantial number showed higher improvement from Day 5 observations in the study

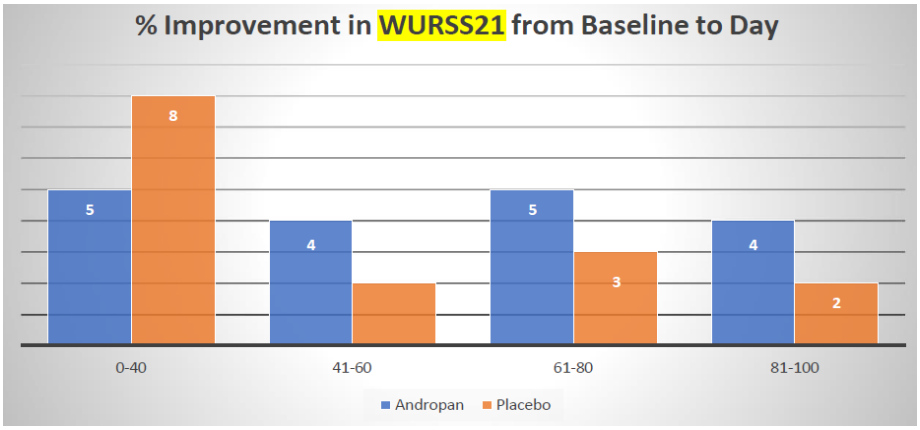

Figure 5 - % Improvement in WURSS21 from Baseline to Day 5 (Frequency Distribution).

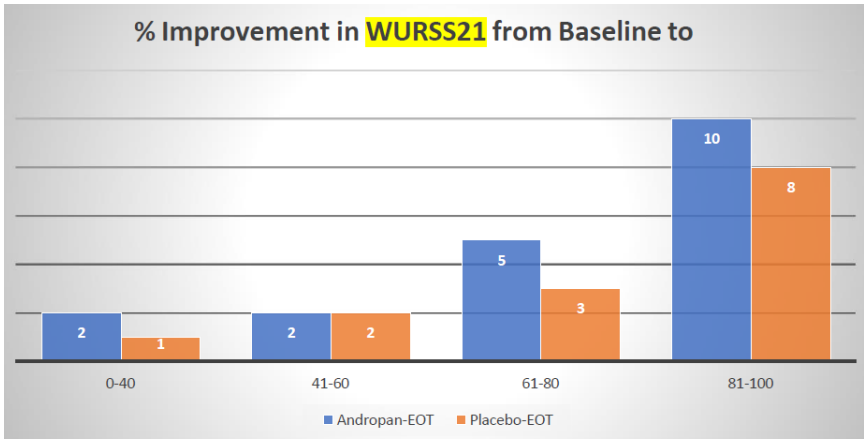

Figure 6 - % Improvement in WURSS21 from Baseline to End of Treatment (Frequency Distribution).

II.) Tolerability Variables

i.) Tolerability Assessment Using Global Assessment Scale at End of Study: The Global Assessment Scale (GAS), is a clinician-rated tool designed to measure the overall severity of psychiatric disturbance in patients. The scale provides a single score reflecting the clinician's judgment of the patient's psychological, social, and occupational functioning at the time of assessment. [11] The Tolerability Profile, as assessed by the Global Assessment Scale (GAS), provides insights into the distribution of tolerability scores for both Andropan™ and Placebo groups. In the Andropan™ group, one participant received a GAS score in the range of 61-70, while one participant each scored in the ranges of 71-80 and 81-90. The majority of participants, however, demonstrated high tolerability, with 16 receiving a GAS score in the range of 91-100. In the Placebo group, no participant fell within the 61-70 range, and one participant each received scores in the 71-80 and 81-90 ranges. The majority of participants, similar to Andropan™, demonstrated high tolerability, with 15 receiving a GAS score in the range of 91-100. The observations have been listed below in the table.

Table 6: Tolerability Assessment Using Global Assessment Scale at End of Study within Each Group: Andropan™ and Placebo Group.

Tolerability Profile Using GAS		
GAS Range	**Andropan™**	**Placebo**
61-70	1(5.27%)	0
71-80	1(5.27%)	1 (6.25%)
81-90	1(5.27%)	0
91-100	16 (84.2%)	15 (93.75)

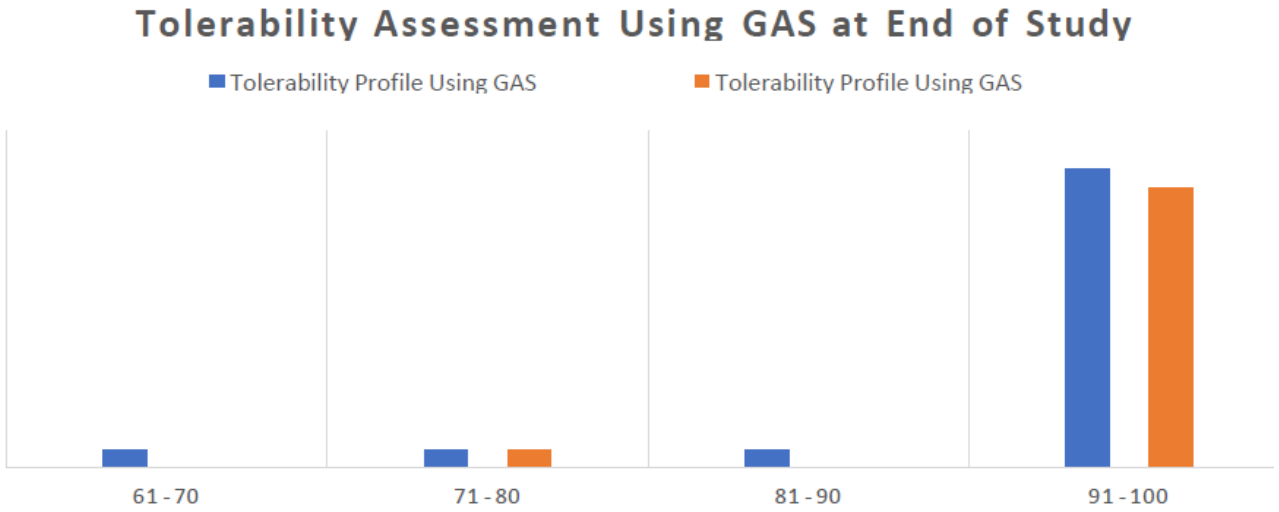

Figure 7: Tolerability Assessment Using Global Assessment Scale at End of Study within Each Group (Frequency Distribution).

III.) Safety Variables: No adverse events were reported in either group.

All treatments were well tolerated, with no adverse events, supporting the overall long-term safety of the test product.

4.) DISCUSSION

Upper respiratory tract infections (URTIs) remain among the most common acute illnesses, often leading to significant morbidity and healthcare utilization worldwide. [1, 8] Despite their typically self-limiting course, URTIs account for a high proportion of inappropriate antibiotic prescriptions, contributing to the global challenge of antimicrobial resistance.[4]

AndroPan™, a capsule formulation of standardized extract of *Andrographis paniculata* having 40% total Andrographolides content as per USP. AndroPan™ is a dietary supplement derived from *Andrographis paniculata*, a traditionally used herb, considered safe for human use. It has been listed in Ayurvedic Pharmacopoeia of India and FSSAI Schedule 4. [12-14] *Andrographis paniculata* has been traditionally used for respiratory infections, with clinical studies suggesting its immunomodulatory and anti-inflammatory properties may alleviate URTI symptoms. [12]

Andrographolides improved the tolerogenic properties of immature dendritic cells in experimental autoimmune encephalomyelitis (EAE) by inhibiting NF-kappa B activation, and reduced IFN-γ and IL-2 production in murine T cells stimulated with concanavalin A (Con A) in vitro. [15]

This study aims to prove the clinical benefits of Andrographis extract in treating upper respiratory tract

infections. A placebo is proposed as a control treatment arm to ensure external validity. The study population includes individuals with upper respiratory tract infections. Andrographis is expected to produce beneficial immunomodulatory effects at 150 mg twice daily, with 7 days of treatment required for noticeable effects. AndroPan^{TM}, a plant-derived nutritional supplement, is preferred for oral administration due to its plant-derived nature. The study's objective is to ensure subject safety and ensure the effectiveness of Andrographis in treating upper respiratory tract infections. [12,16]

The study was a double-blind, randomized, placebo-controlled, parallel-group trial conducted with 38 subjects, aiming to obtain at least 30 complete data sets. Both the subjects and the investigators, including the clinical team, were blinded to the randomized treatment allocation. The study involved a meticulous screening process for participants and screened total 41 participants, resulting in the exclusion of 4 subjects due to non-compliance with inclusion criteria or potential risks. After these exclusions, 37 subjects were eligible and randomized into treatment groups. However, based on medical evaluations, one more subject was discontinued, bringing the total number of completed subjects to 36. The study protocol aimed to determine the suitability and eligibility of participants.

The study involves a series of screenings, including demographics, anthropometrics, vital signs, medication history, clinical examinations, urine pregnancy tests, clinical laboratory investigations, and a clinical examination. Subjects are assessed based on inclusion and exclusion criteria. The study period includes randomization, baseline assessment, IP administration, monitoring and capturing of adverse events (AE/SAE), first follow-up assessment, IP compliance check, and end of study.

The study analyzed the severity of cough and common cold symptoms in patients with Andropan^{TM} and Placebo. The Andropan^{TM} group showed a significant improvement in cough-related symptoms, with a mean LCQ score of 99.7 compared to Placebo's 20.8. The Wisconsin Upper Respiratory Symptom Survey (WURSS) showed distinct observations between the two groups, with Andropan^{TM} showing an average of 7 days for complete resolution of common cold symptoms. The percentage of patients with unresolved symptoms showed notable differences between the two groups. In the Andropan^{TM} group, 84.2% of participants reported unresolved symptoms, while in the Placebo group, 100.0% experienced persistent symptoms. The Andropan^{TM} group had 94.7% of participants experiencing a clinically meaningful improvement, indicating its potential efficacy in symptom alleviation.

The percentage improvement in WURSS21 showed notable trends among different treatment groups on Day 5 and at the End of Treatment (EOT). In the Andropan^{TM} group, a diverse distribution of participants showed improvement across various percentage ranges, with a significant shift in the 81-100% improvement range at Day 5. The Tolerability Profile, assessed by the Global Assessment Scale (GAS), showed that the majority of participants demonstrated high tolerability, with 16 receiving a GAS score in the range of 91-100.

Overall, AndroPan^{TM} demonstrated statistically significant improvement in cough symptoms, a trend towards faster symptom resolution, and excellent tolerability compared to placebo. These results support the potential role of AndroPan^{TM} in managing acute upper respiratory tract infections and justify further investigation in larger, controlled trials.

5.) CONCLUSION

This study provides preliminary evidence supporting the symptomatic benefits of AndroPan^{TM} in patients with acute upper respiratory tract infections. The findings highlight a consistent trend of improved cough severity, reduced symptom burden, and favorable tolerability when compared to placebo. While the short treatment duration and modest sample size suggest the need for larger trials, the absence of adverse events strengthens the case for AndroPan^{TM} as a potentially safe adjunct in URTI management. These encouraging results warrant further research to explore its clinical application in broader patient populations and to establish its role within integrated care strategies for respiratory tract infections.

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