International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

A Clinical Validation of Safety and Effectiveness of Pain Relief & Joint Mobility Tablet

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ABSTRACT

Introduction: Millions of people worldwide are dealing with joint discomfort and issues with mobility, which are mostly caused by diseases like rheumatoid arthritis and osteoarthritis. These illnesses not only hurt physically but also seriously limit mobility, which diminishes activity levels and impairs quality of life.

Materials and Methods: An open-label, single-arm, safety study was conducted on 32 individuals. One tablet of Pain Relief and Joint Mobility twice daily after a meal for 30 days was given. The research objectives were to evaluate changes in compliance, clinical, vital parameter assessment, and tolerability of the investigational product from baseline to the end of the study. Changes in complete blood count (CBC), liver function test (LFT), and renal function test (RFT) parameters on screening and day 30.

Results: The analysis of the vital sign parameters revealed a statistically significant decrease in diastolic blood pressure and body temperature from the screening to day 30 time points. Hematological and biochemical investigations demonstrated no clinically significant changes from baseline to endpoint, indicating the safety of the intervention. After a 30-day treatment regimen, significant reductions were observed across all Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) subscales: a 32.42%, 34.12%, and 34.76% decrease in pain, stiffness, and physical function scores respectively, indicating substantial alleviation of pain, improvement in stiffness, and enhanced physical function.

Conclusion: The study indicates that the Pain Relief and Joint Mobility Tablet is found to be safe and effective in managing joint pain and mobility issues, proving beneficial for patients ranging from those newly diagnosed to those with chronic conditions.

Keywords: Pain Relief and Joint Mobility, Safety, Efficacy, WOMAC Score, clinical validation.

INTRODUCTION

The population is aging worldwide as a result of decreased fertility, lower mortality, better healthcare facilities, and longer life spans. Approximately 104 million Indians are 60 years of age or older, making up 8.6% of the country's overall population. Musculoskeletal problems, which include conditions affecting the joints (osteoarthritis), bones (osteoporosis), muscles, the spine, and various other body parts, are more

common as people age [1]. The innovative formulation of Pain Relief & Joint Mobility tablets is designed to achieve the simultaneous objectives of relieving pain while optimizing joint function. The goal of this study is to mitigate the pain resulting from joint ailments like arthritis and enhance overall range of motion and physical health. Based on previous research and clinical expertise concerning musculoskeletal issues, the formulation most likely contains substances focused at lowering inflammation while improving joint health. Throughout their pregnancy, pregnant women frequently experience a range of discomforts and musculoskeletal disorders. Hormonal changes, weight increase, and changed posture can cause these problems, which can include joint stiffness, muscle strain, back discomfort, and pelvic pain. Many women might not talk about these discomforts, though, until they seriously impair their quality of life or everyday activities. In order to support the well-being of mothers during pregnancy, it is imperative that these issues be addressed proactively [2]. In the Indian population, low back pain (LBP) and migraines were the main cause of years lived with disability, according to the 2013 Global Burden of Diseases (GBD) assessment. People of all ages and professions have low back discomfort, which has a substantial negative impact on the number of disability-adjusted life years (DALYs) lost [3]. Prevalence of rheumatic and musculoskeletal diseases (RMSD) in 310 cases and controls was 42.58%; 95% CI: 37.08–48.08 and 31.61%; 95% CI: 26.43–36.79, respectively. Rheumatic musculoskeletal (RMS) pain was marked by 194 individuals. Knee was the most common site of pain (33.4%) [4]. Pharmaceuticals are a crucial component of treatment, as they offer a vast array of diverse medications, including opioid analgesics, phytopharmaceuticals, proton pump inhibitors, and non-steroidal anti-inflammatory drugs (NSAIDS) that can be used in conjunction with other medications. Because they have less systemic side effects and are well-liked by patients, topical medications are likewise well-liked. In addition, among the drugs utilized for intra-articular OA therapy include glucocorticoids and hyaluronic acid formulations [5]. As everyone knows, using analgesic drugs excessively to manage pain might have unfavourable repercussions. According to this study, 66% of the respondents had negative pharmaceutical side effects, with an average of 4.6 ± 3.3 per person. Unsurprisingly, there were associations found between the quantity of analgesics (prescription and over-the-counter) used and the quantity of side effects reported [6]. In recognition of its many medicinal uses, the genus Curcuma has been used for a long time; it has about 133 species globally [7]. Existing literature indicates that *Curcuma longa* may be a promising therapeutic agent for osteoarthritis, potentially surpassing the benefits of NSAIDs [8]. Hence, our clinical trial aimed to establish the safety and efficacy of Pain Relief and Joint Mobility tablet in mitigating joint pain and mobility issues.

MATERIALS AND METHODS

Study Design

An Open-label, single-arm, safety study was conducted on 32 individuals. One tablet of Pain Relief and Joint Mobility was given twice daily after meals for 30 days and a total of thirty-two subjects enrolled and completed the study.

A clinical validation of safety and effectiveness of Pain Relief & Joint Mobility tablet study conducted on male and female participants. Subjects were recruited at the study centre i.e. Lokmanya Medical Research Centre & Hospital, Pune, India. The study was approved by the Institutional Ethics Committee (IEC) Lokmanya Medical Research Centre. The trial was registered on the Clinical Trial Registry of India (CTRI) website **(CTRI/2024/03/064117 [Registered on: 14/03/2024])**. The compositions of the investigational products are depicted in Table 1.

Table 1: Investigational product and standard of care product composition

Name of Ingredient	Scientific Name	Quantity
Sunthi ext.	*Zingiber officinale*	50 mg
Haldi ext.	*Curcuma longa*	350 mg
Shallaki ext. -BOSPUR	*Boswellia serrata*	150 mg
Yograj Guggul Powder	Generic Ayurvedic Formulation	250 mg
Maharasnadi Kwatha ext.	Generic Ayurvedic Formulation	250 mg

Inclusion criteria

Healthy male and female individuals aged between 25 to 60 years (both inclusive) were included in the study. A subject experiencing self-reported joint pain with a minimum pain rating of 4/10 (VAS) for at least the past 30 days, if the subject is a known case of osteoarthritis, it will be noted in CRF and subgroup analysis can be performed. Subjects must demonstrate their willingness to participate in the study and comply with its procedures by signing a written informed consent. Subjects are willing to follow up.

Exclusion criteria

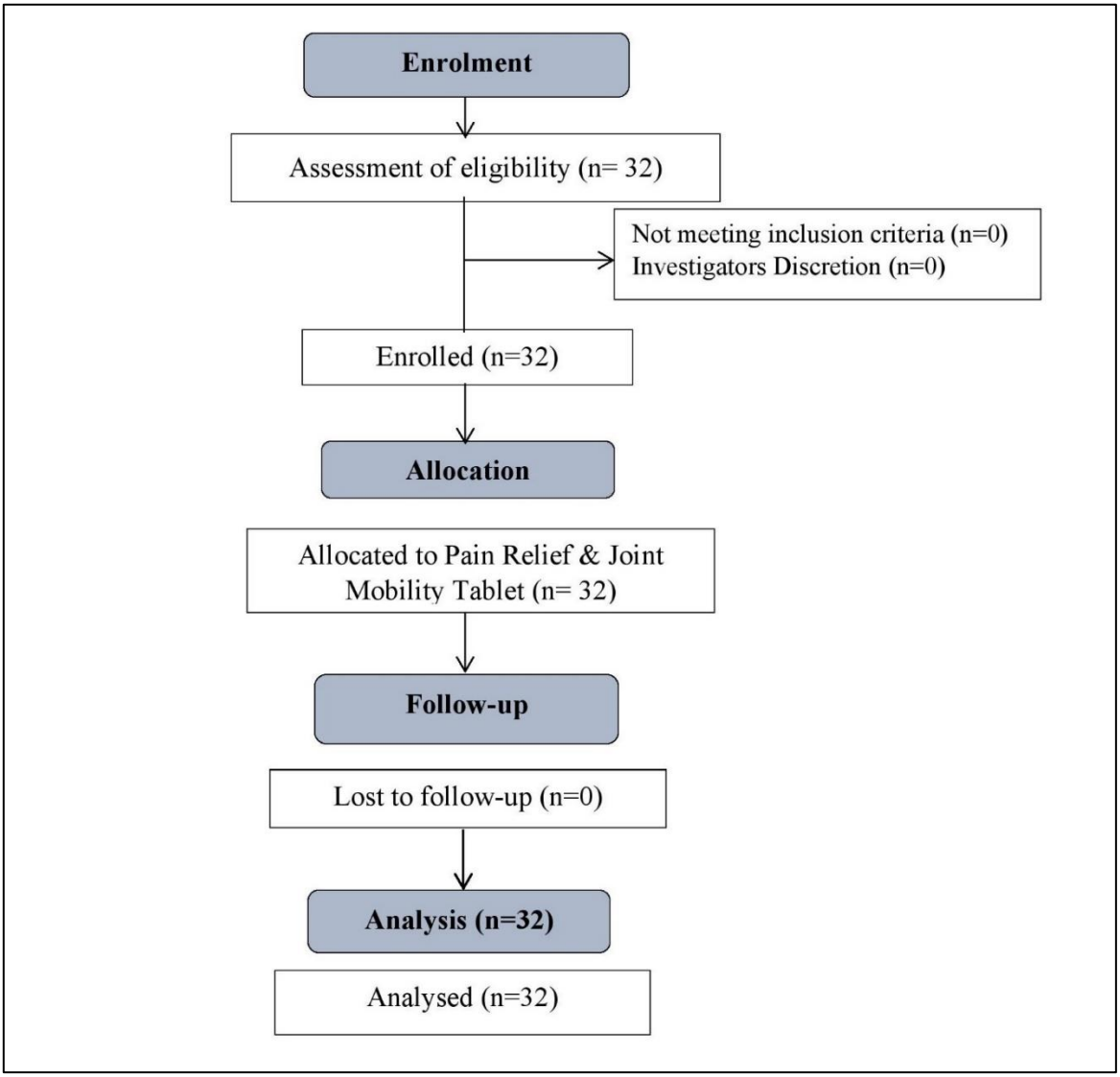
Subjects were excluded from the study if they met any of the following criteria: women of childbearing potential not using adequate contraception, pregnant or lactating women, individuals with a history of substance abuse, heavy alcohol use, or smoking, those with neurological conditions, or those who had undergone recent surgeries. Additionally, participants with comorbidities, those using anti-inflammatory medications, pain relievers, or dietary supplements, or those with any other condition deemed unsuitable by the investigator were excluded. Non-degenerative or other joint diseases (such as rheumatoid arthritis, gout, recent joint trauma, or joint infection) were also exclusion criteria. Individuals who were incapacitated or unable to perform self-care activities, those undergoing ongoing treatment with anticoagulants, hydantoin, lithium, steroids, methotrexate, or colchicine, or those with evidence of renal, hepatic, hematopoietic diseases, or severe cardiac insufficiency were not eligible. Further exclusions included individuals with congestive heart failure, those who had used Ayurvedic or complementary and alternative medicine (CAM) therapies in the past 3 months, or those who had received intra-articular steroid or hyaluronic acid treatments in the last 3 or 9 months, respectively. Participants who had an indication of OA knee surgery or had undergone arthroscopy of either knee in the past year were also excluded.

Methodology

This study was an open-label, single-arm, safety study wherein each subject received a single dose of CSYM-5 tablets daily after meal twice a day for 30 days. 32 subjects were enrolled in the study. The consolidated standards of reporting trials (CONSORT) flow of the entire study are depicted in Fig 1. There were no subject dropouts from the study. All thirty-two subjects received CSYM-5 tablets daily after meal twice a day and completed the study. The duration of treatment is considered from the enrolment to the day 30 visit of the subject. After confirming their eligibility for the study, subjects were enrolled in the study, and during the screening/baseline visit, the subject's demographic details were recorded. Medical history and demographic data including sex, age, body weight (kg), and height (cm), habits were recorded. Each subject underwent a complete general clinical and physical examination. After confirming their eligibility for the study, subjects were enrolled in the study. Assessment of changes in compliance, clinical,

vital parameters, and tolerability of the investigational product, adverse events were evaluated from baseline to end of the study. Assessment of changes in CBC, LFT, and RFT parameters, Assessment of change in WOMAC score, and Pain VAS score were evaluated at screening and end of the study.

Figure 1: CONSORT flow diagram of the study



Statistical Analysis

Analysis of haematological and biochemical parameters, vitals, and WOMAC questionnaire was done using a dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Analysis of VAS was done by Wilcoxon signed rank test (within the group). The normality of the study data was calculated by the Kolmogorov-Smirnov Test. Adverse events were reported as a number of events observed during the study period. Statistical analysis has been done by using SPSS.

RESULTS

Demographic Characteristics

All thirty-two participants (17 males and 15 females) successfully completed the study. The average age of the subjects was 51.06 ± 7.61 years. Male participants had an average weight of 67.06 kg, a height of

161.06 cm, and a BMI of 25.69 kg/m². Female participants had an average weight of 67.60 kg, a height of 156.93 cm, and a BMI of 27.49 kg/m². These values fall within clinically acceptable ranges. These demographic details are summarized in Table 2. All participants in the study reported being non-drinkers and non-smokers (Table 2).

Table 2: Demographic Details

Parameter	Male Mean ± SD (n=17)	Female Mean ± SD (n=15)	P Value
Average Age (Years)	52.06 ± 8.26	49.93 ± 6.90	0.439
	51.06 ± 7.61		
Anthropometric Parameters			
Height (cm)	161.06 ± 9.22	156.93 ± 9.22	0.216
Weight (kg)	67.06 ± 11.61	67.60 ± 10.16	0.890
BMI (kg/m²)	25.69 ± 2.83	27.49 ± 3.72	0.132

All Parameter Data Was Analyzed Using the Independent Student T-Test at P-Value < 0.05.

Haematological and biochemical investigations

There were no clinically significant changes in the assessed blood parameters between the screening and day 30-time points. All haematological, liver function, and kidney function values remained within the normal reference ranges throughout the 30-day study period, with no statistically significant differences observed in the mean values or standard deviations (Table 3).

Table 3: Assessment of haematological and biochemical investigation

Haematological and Biochemical Investigation Parameters				
Parameters	**Screening**	**Day 30**	**P value**	**Reference Range**
Hematological Parameters				
White Blood Cell Count	7139.69 ± 1558.48	7581.25 ± 2420.00	0.165	4000 - 11000 cell/cu.mm
Red Blood Cell Count	4.60 ± 0.50	4.79 ± 0.53	0.192	4.7 - 6.0 mil/cu.mm
Hemoglobin	13.33 ± 1.57	13.09 ± 1.37	0.160	Female: 11.6 - 15 gm/dL & Male: 13.2-16.6 gm/dL
Hematocrit (PCV)	41.06 ± 4.02	40.10 ± 4.75	0.411	42 - 52 %
Mean Corpuscular Volume	88.15 ± 7.97	87.39 ± 8.34	0.666	78 - 100 fL
Mean Corpuscular Hemoglobin	28.99 ± 2.78	28.25 ± 3.26	0.317	27 - 31 pg
Mean Corpuscular Hemoglobin Concentration	32.58 ± 1.14	32.39 ± 0.92	0.490	32-36 gm/dL
Platelet Count	276.84 ± 76.42	300.56 ± 81.74	0.157	150 - 450 10^3/u

Neutrophils	56.25 ± 6.93	56.84 ± 7.30	0.752	40 - 75 %
Lymphocytes	35.13 ± 6.57	36.56 ± 6.99	0.437	20 - 40 %
Monocytes	5.03 ± 1.58	4.88 ± 1.24	0.667	2-10 %
Eosinophils	3.34 ± 0.83	3.31 ± 0.82	0.841	1-6 %
Basophils	0.00 ± 0.00	0.00 ± 0.00	1	0-1 %
Liver Function				
Protein Total	6.76 ± 0.39	6.83 ± 0.53	0.577	6.0 - 8.3 g/dL
Albumin	4.19 ± 0.23	4.23 ± 0.42	0.670	3.2 - 5.5 g/dL
Globulin	2.56 ± 0.39	2.60 ± 0.40	0.741	1.8 - 3.6 g/dL
A/G Ratio	1.69 ± 0.37	1.68 ± 0.43	0.771	1.2 - 2.2
Bilirubin Total	0.59 ± 0.29	0.57 ± 0.19	0.831	0.1-1.2 mg/dL
Bilirubin Direct	0.17 ± 0.11	0.18 ± 0.10	0.911	0-0.4 mg/dL
Bilirubin Indirect	0.41 ± 0.22	0.40 ± 0.19	0.768	0.1-0.8 mg/dL
Aspartate Transaminase	28.97 ± 13.20	29.31 ± 9.42	0.830	49 U/ L
Alanine Transaminase	31.32 ± 15.09	31.19 ± 12.36	0.947	49 U/ L
Alkaline Phosphatase	142.59 ± 56.64	140.06 ± 53.06	0.634	80 - 306 U/ L
Kidney Function				
Urea	23.38 ± 7.09	25.65 ± 10.55	0.222	10-50 mg/dL
Creatinine	0.85 ± 0.17	0.82 ± 0.34	0.423	Female:0.6-1.4 & Male:0.7-1.4 mg/dL
Uric Acid	4.95 ± 1.37	4.96 ± 1.17	0.888	3.0 to 7.2 mg/dL

Data Is Represented as Mean ± S.D. Analysis Was Done Using the Dependent Student T-Test (Within A Group) And Wilcoxon Signed Rank Test (Within A Group). Significant at P< 0.05.

Assessment of vital signs

The analysis of the vital sign parameters revealed a statistically significant decrease in diastolic blood pressure (p=0.0075) and body temperature (p=0.0133) from the screening to day 30 time points. However, there were no statistically significant changes observed in systolic blood pressure, heart rate, or respiratory rate over the 30-day study period. These findings suggest that the intervention had a modest but statistically significant effect on lowering diastolic blood pressure and body temperature in the study participants, while the other vital sign measures remained stable (Table 4). All thirty-two subjects were compliant and showed excellent tolerability to the investigational product.

Table 4: Assessment of Vital Signs

Vitals Parameters			
Parameters	**Screening**	**Day 30**	**P value**
Systolic Blood Pressure (mmHg)	119.16 ± 3.76	116.09 ± 8.68	0.107
Diastolic Blood Pressure (mmHg)	78.19 ± 5.00	74.19 ± 5.46	0.007*
Heart Rate (BPM)	74.41 ± 2.88	73.28 ± 2.39	0.107

Body Temperature (ºF)	97.48 ± 0.46	97.05 ± 0.78	0.013*
Respiratory Rate (Breaths per minute)	20.16 ± 0.81	19.97 ± 1.06	0.423

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at p< 0.05.

Assessment of adverse events

The adverse events observed during the study are presented in Table 5. Out of the 32 participants, a total of 4 subjects (12.5%) experienced at least one adverse event. The most commonly reported adverse events were headache, fever, and heartburn. For each adverse event, the number of subjects affected and the corresponding rescue medication used are shown. AE's observed was not related to the investigational product.

Table 5: Adverse Events Observed in the Study

Adverse Events	**No (N=32)**	**Rescue Medication**
Headache	2	Aspirin
Heartburn	1	Pantoprazole
Fever	1	Paracetamol
Total No. of Events	**3**	-
Total No. of subjects (%)	**4 (12.5%)**	-

Assessment of WOMAC Score

The WOMAC questionnaire comprises three subscales: pain, stiffness, and physical function. Each question or activity is assessed on a difficulty scale ranging from 0 (None), 1 (Slight), 2 (Moderate), 3 (Very), and 4 (Extremely), with higher scores indicating greater difficulty and poorer function. The total score for each subscale is obtained by summing the response scores for that subscale. Improvement is reflected as a reduction in the score.

After 30 days of treatment, significant reductions were observed across all subscales of the WOMAC assessment.

Specifically, the pain score decreased by 32.42%, indicating a significant alleviation of pain. Likewise, the stiffness score decreased significantly by 34.12%, demonstrating a notable improvement in stiffness symptoms. Additionally, there was a significant decrease of 34.76% in the physical function score, suggesting enhanced physical function following the treatment period (Table 6).

Table 6: Assessment of WOMAC Score

Assessment of WOMAC Score				
Domain	**Screening**	**Day 30**	**% change**	**P value**
Pain	9.53 ± 1.50	6.44 ± 1.29	32.42	< 0.001
Stiffness	4.22 ± 1.07	2.78 ± 0.97	34.12	< 0.001
Physical Function	34.44 ± 2.86	22.47 ± 2.60	34.76	< 0.001

Data Is Represented as Mean ± S.D. Analysis Was Done Using a Dependent Student T-Test (Within The Group) And A Wilcoxon Signed Rank Test (Within The Group). Significant at P< 0.05.

Assessment of Pain VAS Score

The visual analogue scale (VAS) for pain assessment is a 10-point scale ranging from 0 (no pain) to 10 (severe pain), with higher scores indicating greater pain intensity. Analysis of the VAS pain scores indicated a statistically significant decrease, showing a 27.51% improvement in self-reported pain intensity throughout the 30-day study period (Table 7).

Table 7: Assessment of Pain VAS Score

Assessment of VAS Pain Score (% change)			
Domain	**Screening**	**Day 30**	**P value**
VAS Pain Score	5.78±0.66	4.19±0.82 (27.51)	< 0.001

Data Is Represented as Mean ± S.D. Analysis Was Done Using the Wilcoxon Signed Rank Test (Within The Group). Significant at P< 0.05.

DISCUSSION

Subsequently a 30-day treatment period, a study assessed the safety and effectiveness of Pain Relief & Joint Mobility tablets in a cohort of thirty-two subjects. The examination of the vital sign indicators showed that, between the screening and day 30 time periods, there was a statistically significant drop in both body temperature (p=0.0133) and diastolic blood pressure (p=0.0075). The safety of the intervention was indicated by haematological and biochemical examinations, which showed no clinical changes. After the trial, our analysis of the blood parameters over the 30-day period showed consistent results. Between the first screening and the evaluation on day 30, there were no statistically significant changes in the data related to haematological, hepatic, or renal function. All measured parameters stayed within normal reference limits for the course of the study, demonstrating the stability of these important health indicators. A statistical analysis supported the overall consistency and safety of the intervention with respect to these physiological variables by confirming that mean values and standard deviations did not demonstrate any significant variations from baseline to endpoint [9]. Four patients (12.5%) out of the 32 participants had at least one adverse event. The adverse events that were reported the most frequently were heartburn, fever, and headache. The number of patients impacted by each adverse event and the related rescue treatment are displayed. The reported adverse events have nothing to do with the experimental product. our research was related to its findings of earlier studies [10]. Significant drops have been observed across all WOMAC assessments subscales following a 30-day course of therapy, more specifically, there was an evident decrease in pain, as the pain score declined by 32.42%. Similarly, the stiffness score dropped noticeably by 34.12%, indicating a considerable reduction in the symptoms associated with stiffness. Furthermore, the physical function score showed an alarming decline of 34.76%, indicating improved physical function after the recovery period [8]. In accordance with the visual analogue scale (VAS), participants experienced a statistically significant drop in pain intensity throughout the period of the 30-day study. The VAS, offering a range of 0 (no pain) to 10 (severe pain), showcased a substantial decrease in pain levels of 27.51%. This drop demonstrates an important enhancement in alleviating pain throughout every phase of the trial, confirming the successful outcome of the intervention in reducing the participants' pain symptoms [11]. The incorporation of multiple medicinal products in the pain relief and joint mobility tablet, among them Maharasnadi Kwatha Ext., Haldi Ext. (*Curcuma longa*), Shallaki Ext. (*Boswellia serrata*), Yograj Guggul Powder (a generic form), and Sunthi Ext. (*Zingiber officinale*), underscores their

potential beneficial interactions. Due to their well-known anti-inflammatory effects, turmeric (*Curcuma longa*) and ginger (*Zingiber officinale*) can help alleviate discomfort in joints by bringing down inflammation. Ayurveda has long employed *boswellia serrata*, sometimes known as Shallaki Ext., for its analgesic and anti-inflammatory properties, which further promote joint health. likewise, because Yograj Guggul Powder and Maharasnadi Kwatha Ext. are both traditional Ayurvedic formulations designed to encourage joint mobility as well as decrease stiffness, they presumably aid all aspects of joint support [12]. The conclusions of this investigation emphasize the significance of an upgraded pain relief and joint mobility tablet as an efficient adjuvant for relieving joint pain, in particular for patients who have recently received a medical diagnosis. The study underlines the tablet's safety profile and substantial efficacy as opposed to conventional therapy techniques by concentrating on this specific group of people. This shows that in addition to providing efficient pain relief, the tablet enhances joint mobility, which may improve the overall quality of life for people dealing with early-stage joint disorders. Treatment with this product offers Stable haematological and biochemical profiles and no adverse events associated with the product point to the safety and well-tolerated nature of Pain Relief & Joint Mobility tablets, according to study results. The body temperature, WOMAC scores, pain VAS scores, diastolic blood pressure, and mild but statistically significant changes all support the tablets' likely efficacy in improving joint mobility while minimizing pain.

CONCLUSION

The study evaluated the safety and efficacy of Pain Relief & Joint Mobility tablets in a cohort of thirty-two participants over 30 days. Haematological and biochemical investigations demonstrated no clinically significant changes from baseline to endpoint, indicating the safety of the intervention. Furthermore, vital sign assessments revealed a modest yet statistically significant decrease in diastolic blood pressure and body temperature. Despite some adverse events reported, they were not attributed to the investigational product, suggesting good tolerability. Importantly, significant improvements were observed in WOMAC scores and pain VAS scores, highlighting the potential efficacy of Pain Relief & Joint Mobility tablets in alleviating pain and improving physical function.

ACKNOWLEDGMENTS

The authors would like to acknowledge the research team and the back-office team involved in the research work. We would like to acknowledge the support of Mprex Healthcare Pvt. Ltd., Pune, Maharashtra as a clinical research organization for this trial.

FUNDING

Investigational product Herbolab India Pvt. Ltd., Mumbai- 400072, India

CONFLICT OF INTEREST

Dr. Kriti Soni and Dr. Sachin Mulik are part of Herbolab India Pvt. Ltd. Other author declare no conflict of interest.

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