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Research Article

ASSESSMENT OF EFFICACY AND SAFETY OF DR.ORTHO CAPSULES IN MANAGING MUSCULOSKELETAL DISORDERS: A PHASE IV POST-MARKETING SURVEILLANCE STUDY

Shreya Verma[1], Amrish Verma[1], Jaspal Singh[1], Hasan Ali Ahmed[2], Lokesh Holagundi[3]*

[1]Divisa Herbals Pvt. Ltd. E4E-E4J, 4th Floor, Block-B, Plot No.-70, Godrej Eternia, Industrial Area, Phase 1, Chandigarh, India.

[2]Xplora Clinical Research Services Pvt. Ltd., #252, 13th Cross, Wilson Garden, Bangalore, Karnataka, India.

*[3]Health India Hospital, #7, 6th Cross, Tavarekere Main Road, Chikka Adugodi, Bangalore, Karnataka, India.

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ABSTRACT

Objectives: This study aimed to evaluate the potential efficacy and safety of Dr. Ortho capsules in managing various musculoskeletal conditions, including knee pain, joint stiffness, arthritis, bulky shoulders, joint inflammation, acute sports injuries, strains, and sprains. **Methods:** The study was a single centric, open-label, non-randomized, post-marketing surveillance study involving 120 subjects. Subjects were selected based on inclusion and exclusion criteria. The study assessed changes in pain intensity and disability levels after the administration of Dr. Ortho capsules, employing the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI), respectively. Additionally, safety was evaluated through physical examinations, vital sign monitoring, and laboratory safety parameters. **Results:** The study revealed significant reductions in pain intensity and disability levels among the participants. Pain intensity, as measured by VAS, decreased significantly ($p < 0.0001$) from a mean score of 4.84 at baseline (day 1) to 0.38 at the end of the study (day 30). Disability levels, indicated by ODI, significantly improved ($p<0.0001$) from a mean score of 14.73% at baseline to 1.88% at the end of the study. There were no reported adverse events during the study, and all safety parameters remained within normal ranges. **Conclusion:** The findings of the study suggest that Dr. Ortho capsules may offer effective relief for individuals with musculoskeletal conditions, reducing pain intensity and improving functional abilities. The absence of adverse events and the maintenance of normal safety parameters indicate the safety of Dr. Ortho capsules for human consumption.

INTRODUCTION

Musculoskeletal conditions are prevalent and often debilitating health issues affecting millions of individuals worldwide. These conditions encompass a wide array of disorders, including osteoarthritis, rheumatoid arthritis, gout, ankylosing spondylitis, and more. These are characterized by inflammation, pain, and restricted joint mobility, typically arising from a complex interplay of genetic, environmental, and immunological factors.[1] These conditions not only lead to physical discomfort but also significantly impact on individual's quality of life. Consequently, patients suffering from arthritis, knee pain, joint stiffness, and related musculoskeletal ailments actively seek therapeutic solutions to alleviate their discomfort. Understanding the complex mechanisms behind joint pain and inflammation is crucial for the development of successful treatments. Joint pain often arises from nerve and tissue irritation around the joint, while inflammation is a natural response to injury or infection. In the context of arthritis, chronic inflammation can harm joint cartilage and surrounding tissues, prompting exploration of the anti-inflammatory and analgesic properties of medicinal plants.[2]

In recent years, there has been growing interest in exploring alternative and complementary therapies, such as Ayurveda, to address these conditions. Ayurveda, a traditional system of medicine

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that originated in India thousands of years ago, emphasizes the use of natural remedies and medicinal plants to promote holistic health and well-being without causing harmful side effects.[3] Dr. Ortho capsules are formulated using a blend of medicinal plant extracts, each with purported anti-inflammatory and analgesic properties.[4] These extracts include *Pluchea lanceolata* (*Rasna*), *Trigonella foenum-graecum* (*Methi*), Shunthi extract, *Boswellia serrata* (*Sallaki*), *Commiphora mukul* (*Guggulu*), *Shilajit*, *Withania somnifera* (*Asvagandha*), and *Strychnos nux vomica* (*Kuchla*). For instance, *P. lanceolata* traditionally combats joint swelling in arthritis and acts as a nerve tonic.[5] *T. foenum-graecum* seeds exhibit both anti-inflammatory and antioxidative properties,[6,7] while Shunthi is renowned for its anti-inflammatory activity.[8] *B. serrata* extracts hold potential for managing osteoarthritis and improving joint function.[9] *C. mukul* addresses a range of conditions, including inflammation, gout, and rheumatism.[10] *Shilajit* possesses antioxidant, anti-inflammatory, immunomodulatory, and anti-arthritic potentials,[11] and *W. somnifera* demonstrates effectiveness as an analgesic, anti-inflammatory, and chondroprotective agent, addressing both rheumatoid and osteoarthritis.[12,13] *S. nux vomica* seeds are used in Ayurvedic and Unani formulations for pain, inflammation, and rheumatism.[14]

In light of those promising findings, a rigorous clinical study was conducted to evaluate the efficacy and safety of Dr. Ortho capsules in managing various musculoskeletal conditions. This open-label, non-randomized, observational study sought to provide valuable insights into the clinical use of Dr. Ortho capsules in diverse patient populations suffering from joint pain, stiffness, arthritis, and related complaints.

MATERIAL AND METHODS

Study Participants and Selection Criteria

Participants for the study were enrolled from the outpatient orthopedic department (OPD) at Health India Hospital, Bangalore. The sample size was determined without statistical considerations, and a total of 120 eligible subjects voluntarily participated in the study. Participants who were between 18 to 80 years old and had problems like knee and joint pain, arthritis, sports injuries, strains, sprains, chronic arthritis, and back pain were included in this study. Participants also agreed to take part, provide informed consent, and avoid similar medications during the study.

Exclusion criteria included individuals who had undergone recent surgery or took part in another clinical trial within 30 days of screening. Pregnant and breastfeeding women were not included. Participants with significant cardiovascular, respiratory, hepatic, renal diseases, congenital disorders, or any major health issues, as well as those with known allergies to any ingredient of the study products, or pre-existing systemic or genetic disorders, were also not eligible for participation in this study.

Study Interventions

The "Dr. Ortho" capsule is a polyherbal product comprising extracts from various Ayurvedic plants, including *P. lanceolata* (rasna), *T. foenum-graecum* (*Methi*), *Shunthi* extract, *B. serrata* (*Sallaki*), *C. mukul* (guggul), *Shilajit*, *W. somnifera* (*Aswagandha*), and *S. nux vomica* (*Kuchla*). This product (Figure 1) is currently available in the Indian market as an oral capsule designed for the management of various inflammatory conditions. It is specifically formulated to address issues such as arthritis, acute sports injuries, knee pain, joint inflammation, muscle and joint stiffness, strains and sprain.

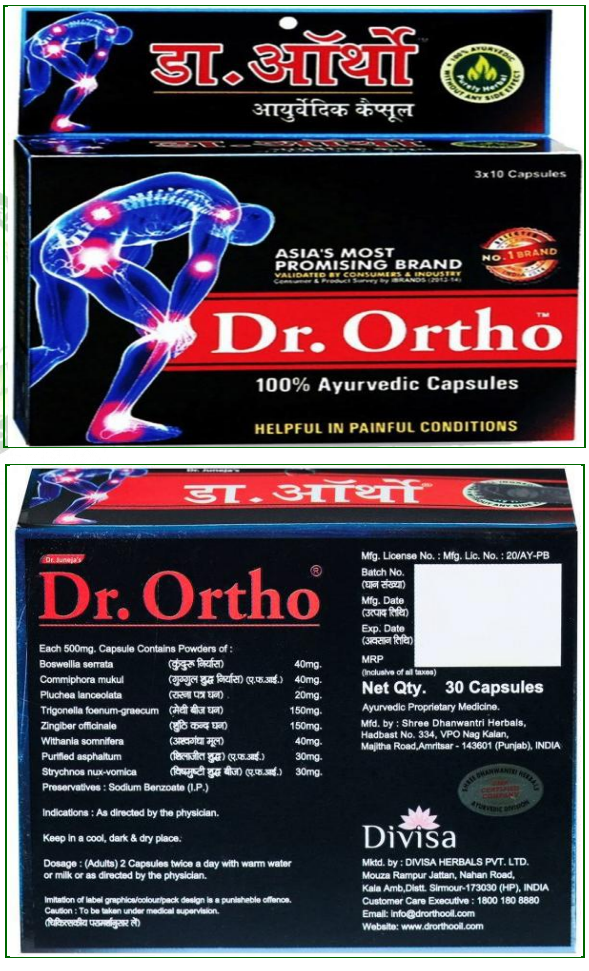

Figure 1: Dr. Ortho Capsules

Study Design

The study was a single centric, open-label, non-randomized, post-marketing surveillance study involving 120 subjects. A total of 120 eligible subjects, who met the inclusion criteria, were enrolled in this study. The study involved four visits, including one telephonic follow-up. During the screening visit on day

0, subjects were assessed based on inclusion and exclusion criteria, and informed consent was obtained. During the screening visit (day 0), all eligible subjects underwent a physical examination, and their vital signs were assessed. Subjects were then instructed to take Dr. Ortho capsules (500mg) twice daily for a period of 30 days, along with warm water or milk. On day 15, a telephonic follow-up was conducted to monitor subjects' general well-being, concomitant medications, and adverse effects. The final assessment of the subjects was performed at the end of the study (day 30).

Outcomes Measures

Assessments of pain intensity

In this study, pain assessments were carried out at two evaluation points: at the visit 1 (day 0) and at the end of the study (day 30). Pain intensity was measured using the Visual Analog Scale (VAS), a validated method offering a scale from 0 (representing "No Pain") to 10 (representing "Worst Possible Pain") with intermediate values indicating different levels of pain (1-3 = Mild pain, 4-6 = moderate pain, and 7-9 = severe pain). Subjects marked the VAS line to reflect their current pain intensity.

Assessments of Oswestry Disability Index (ODI)

Oswestry Disability Index (ODI) assessments are vital in evaluating functional disability for individuals recuperating from low back pain.[15] It is the gold standard offering a percentage score that categorizes disability levels across ten everyday activities including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sexual activity, social engagement, and travel. Each activity was scored from 0 (minimal disability) to 5 (highest disability). The total score, ranging from 0 to 50 (0-4=no disability, 5-14=mild disability, 15-24=moderate disability, 25-34=severe disability, and 35-50= complete disability), was converted into a percentage, with 0% indicating no disability and 100% indicating the highest disability level.

Assessment of safety

Safety assessments involved recording all adverse events (AEs) and serious adverse events (SAEs) along with their severity and their possible correlation to the study drug. Vital signs, such as body temperature, heart rate, respiratory rate, pulse rate, and blood pressure, were monitored to evaluate the effects of the investigational product on fundamental physiological functions. Additionally, haematology, liver function tests, and kidney function tests were conducted to gain insight into any potential drug-related impacts on blood components and vital organs.

Ethical Consideration

The study was conducted at Health India Hospital (Bangalore, India) from 08 Mar 2023 to 12 Sep 2023 in full compliance with the Declaration of Helsinki, ICMR ethical guidelines for biomedical research, and ICH guidelines for Good Clinical Practice (GCP). The study protocol was approved by the ACE Independent Ethics Committee (Protocol No: SBS/DIV/002/2022) and was prospectively registered with the Clinical Trials Registry - India (ID: CTRI/2023/03/050809) dated 17 Mar 2023. The study objectives and procedures were clearly explained to all participants, and prior to their enrolment, each patient provided a signed, dated, written informed consent.

Statistical Analysis

Descriptive statistics was used to describe the characteristics of the study subjects. The data was presented as the arithmetic mean, standard deviation (SD), percentages, and minimum and maximum values. A statistical comparison between screening and end-of-study data was conducted using a sample t-test. A p-value≤0.05 was considered to be statistically significant.

RESULTS

Demographics

A total of 121 subjects were screened and among them, 1 individual did not meet the inclusion criteria. Finally, 120 subjects were enrolled in this study. The mean age of the subjects was 37.22±13.37 years, with a minimum age of 18 years and a maximum age of 72 years. Of the participants, 69 (57.5%) were male, while 51 (42.5%) were female. The average weight and height of the subjects were 65.21±8.21kg and 163.19±9.48cm, respectively.

Pain Intensity

The VAS was used to evaluate pain levels at the screening (day 0) and at the end of the study (day 30). On day 1, the mean VAS score was 4.84 ± 1.31, which significantly reduced to 0.38 ± 0.58 at the end of the study. The mean change in VAS score from screening to the end of the study was highly significant ($p< 0.0001$), exhibiting a mean difference of 4.458 and a 95% confidence interval between 4.28 and 4.64 (Figure 2).

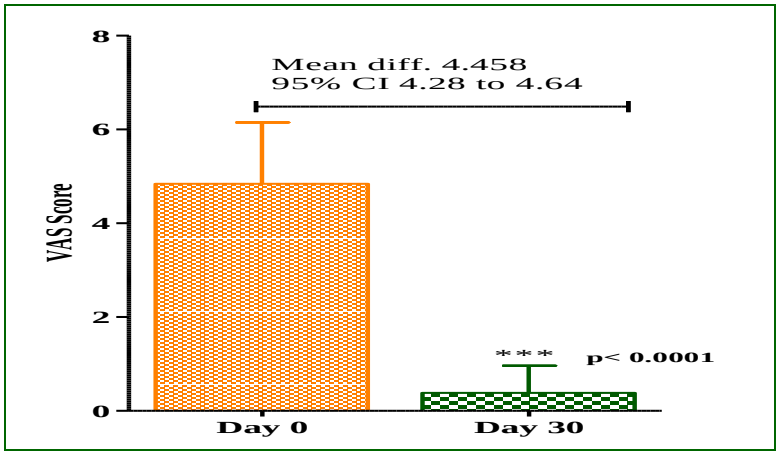

Figure 2: Mean change in VAS score from day 0 (screening) to day 30 (end of the study). Statistical analysis was performed to compare the VAS scores between day 0 and day 30 using a paired t-test (*P < 0.0001).**

Oswestry Disability Index (ODI)

The ODI was employed to assess disability levels of the subjects at the screening (day 0) and at the end of the study (day 30). At the screening visit, the mean ODI score was 14.73 ± 3.64, signifying an overall disability of 29.45 ± 7.28%. This established the initial disability status of the study population, serving as a reference for monitoring changes in disability levels throughout the study. At the end of the study, the mean ODI score significantly decreased to 1.88 ± 3.15 with an overall disability of 3.30 ± 6.33%, indicating reduced disability levels among participants. The comparison of ODI scores between the screening visit and the end of the study visit demonstrated a highly significant difference (P < 0.0001) with a mean difference of 12.83 [95% CI 12.24 to 13.41]. Additionally, there was a significant reduction in the overall disability percentage (P < 0.0001) with a mean difference of 25.65% [95% CI 24.48 to 26.82], underscoring the impact of Dr. Ortho capsule on the subjects' disability levels (Table 1).

Table 1: Mean change in functional abilities and overall disability scores from screening to end of the study (n=120)

Disability	Visit 1 (Day 0) (mean ± SD)	Visit 4 (Day 30) (mean ± SD)	Mean diff.	95% CI	P value
Pain intensity	1.99 ± 0.82	0.46 ± 0.85	1.525	1.371 - 1.679	< 0.0001***
Personal care	1.16 ± 0.73	0.23 ± 0.77	1.367	1.193 - 1.540	< 0.0001***
Lifting	1.46 ± 0.75	0.71 ± 1.44	0.750	0.494 - 1.006	< 0.0001***
Walking	1.31 ± 0.75	0.22 ± 0.61	1.092	0.933 - 1.251	< 0.0001***
Sitting	1.38 ± 0.81	0.0 ± 0.0	1.383	1.237 - 1.530	< 0.0001***
Standing	1.53 ± 0.80	0.03 ± 0.37	1.492	1.336 - 1.647	< 0.0001***
Sleeping	1.40 ± 0.73	0.05 ± 0.31	1.350	1.210 - 1.490	< 0.0001***
Social life	1.43 ± 0.71	0.0 ± 0.0	1.433	1.306 - 1.561	< 0.0001***
Travelling	1.28 ± 0.71	0.03 ± 0.26	1.250	1.115 - 1.385	< 0.0001***
Employment/home making	1.33 ± 0.69	0.05 ± 0.34	1.283	1.157 - 1.410	< 0.0001***
ODI score	14.73 ± 3.64	1.88 ± 3.15	12.83	12.24 - 13.41	< 0.0001***
Overall disability (%)	29.45 ± 7.28	3.30 ± 6.33	25.65	24.48 - 26.82	< 0.0001***

Note: A paired t-test was employed to statistically compare the screening data with the data obtained at the end of the study (***P < 0.0001).

Safety

Physical Examination

Throughout the study, all participants underwent thorough physical examinations, including evaluations of general appearance, head and neck, ear, nose, throat, respiratory system, cardiovascular system, gastrointestinal system, musculoskeletal system, neurological system, and lymphatic/lymph nodes. No abnormalities were identified during the screening or final examinations.

Vital Signs

Vital signs, including body temperature, pulse rate, respiratory rate, systolic and diastolic blood pressure, were evaluated at screening (visit 1) and at end of the study (visit 4). The changes in vital signs from screening were as follows: body temperature from 36.83 ± 0.48 to 36.54 ± 3.07°C, pulse rate from 80.33 ± 8.67 to 78.48 ± 6.02 bpm, respiratory rate from 16.72 ± 2.48 to 16.47±1.95 bpm, systolic blood pressure from 114.74 ± 6.66 to 116.76 ± 7.51 mmHg, and diastolic blood pressure from 75.08 ± 6.49 to 76.53±6.40 mmHg (Figure 3). Subsequent analysis revealed no significant changes in these parameters at the end of the study, and all parameters remained within the normal range.

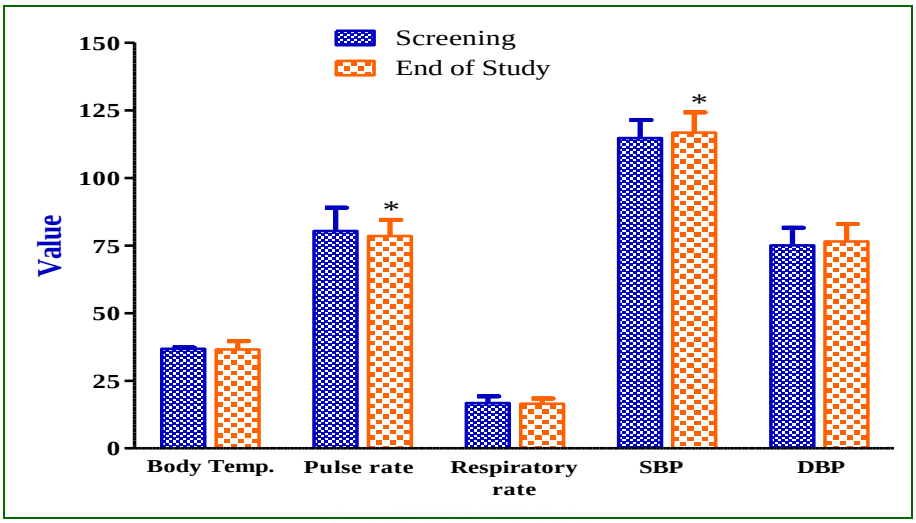

Figure 3: Mean change in vital signs from screening to end of the study (n=120). Statistical comparison between screening and end-of-study data was conducted using a paired t-test (*P < 0.05)

Laboratory Safety Parameters

Laboratory safety assessments, including renal function, liver function, and haematological parameters are presented in Table 2. All parameters were within normal ranges both at screening visit and at the end of the study. There were no statistically significant changes (except basophil) in the mean scores of the parameters between the two evaluation points.

Table 2: Mean differences in renal function, liver function, and haematological parameters between screening visit and end of the study (n=120)

Parameters	Screening (mean ± SD)	End of the study (mean ± SD)	Mean diff.	p-value
SGPT, U/L	21.95 ± 11.24	21.77 ± 9.57	0.183	0.874
Serum creatinine, mg/dl	0.77 ± 0.24	0.75 ± 0.20	-0.065	0.941
Haemoglobin, g/dl	13.96 ± 2.08	14.09 ± 2.19	-0.128	0.298
RBC, million/mm^3	5.06 ± 0.57	5.13 ± 0.67	-3.709	0.310
Haematocrit (PCV) %	42.23 ± 5.69	42.69 ± 6.34	-0.362	0.334
Platelet count, lakhs/mm^3	2.84 ± 0.69	2.92 ± 0.51	-0.080	0.240
Total WBC, cell/mm^3	9394.17 ± 2423.53	9527.50 ± 2215.83	-133.3	0.618
Lymphocytes, %	33.70 ± 6.99	32.64 ± 8.32	1.058	0.242
Eosinophils, %	4.13 ± 2.49	4.20 ± 2.32	0.012	0.970
Monocytes, %	6.75 ± 2.38	7.10 ± 2.49	-0.354	0.218
Neutrophils, %	54.77 ± 8.32	55.29 ± 8.69	-0.518	0.613
Basophils, %	0.85 ± 0.39	0.68 ± 0.30	-1.648	< 0.0001***

Note: Statistical comparison of screening data vs end of the study was performed by paired t-test (***P < 0.0001)

Adverse effects

Based on data collected from the 120 subjects who completed the study, no adverse events were reported throughout the entire study duration.

DISCUSSION

The study investigated the potential efficacy and safety of Dr. Ortho capsules in managing various musculoskeletal conditions, such as knee pain, joint stiffness, arthritis, bulky shoulders, joint inflammation,

acute sports injuries, strains, and sprains. The findings revealed significant reductions in both pain intensity and disability levels among the study participants, highlighting the potential efficacy of Dr. Ortho capsules in addressing a range of musculoskeletal ailments. The considerable decrease in pain intensity, as demonstrated by a marked decline in mean VAS scores, suggests the capacity of Dr. Ortho capsules to alleviate discomfort linked to conditions such as arthritis, joint stiffness, and sports injuries. Furthermore, the substantial reduction in disability levels, as indicated by the decreased ODI scores, underscores the efficacy of Dr. Ortho capsules in improving the functional abilities and overall quality of life of the individuals. These observations align with the purported anti-inflammatory and analgesic properties attributed to the herbal constituents found in Dr. Ortho capsules.

Studies have shown that *P. lanceolata* exhibits anti-inflammatory effects by suppressing pro-inflammatory mediators like cytokines and prostaglandins and modulating signalling pathways such as NF-κB and MAPK pathways.[16] It also possesses analgesic properties by influencing neurotransmitter pathways that modulate pain signalling.[5] *T. foenum-graecum* extracts have been found to mitigate inflammation and oxidative stress, which may contribute to their effectiveness in alleviating pain.[6,7] Extensive research has unveiled the multifaceted biological activities of ginger, encompassing antioxidative, anti-inflammatory, anti-microbial, anticancer, neuroprotective, cardiovascular protective, respiratory protective, antiobesity, antidiabetic, antinausea, and antiemetic properties. Notably, *Shunthi* is renowned for its anti-inflammatory activity.[8] Gingerols also act as potential pain relievers by modulating pain receptors and pathways.[19] *B. serrata* is known for its boswellic acids, which inhibit pro-inflammatory enzymes, including 5-lipoxygenase and cyclooxygenase, reducing the production of inflammatory mediators like leukotrienes and prostaglandins.[20,21] This anti-inflammatory action has shown clinical efficacy in managing conditions such as arthritis.[22] *C. mukul*, which contains guggulsterones as its principal bioactive compounds, has anti-inflammatory properties by reducing inflammatory markers like TNF-α, IL-1β, IL-6, and enzymes such as COX-2.[23] *Shilajit* exhibits anti-inflammatory properties by modulating pro-inflammatory cytokines and inhibiting the expression of inflammatory mediators.[11] *W. somnifera* contains withanolides with potent anti-inflammatory properties, reducing inflammation by modulating pathways such as NF-κB, JAK/STAT, and PPARγ. *S. nux-vomica* has traditionally been associated with anti-inflammatory properties.[14] Hence, the synergistic action of key bioactive constituents, including gingerol, boswellic acids, guggulsterones, and withanolides, modulates multiple inflammatory mediators and pathways, potentially supporting the anti-inflammatory and analgesic properties of Dr. Ortho capsules for musculoskeletal conditions.

The safety assessments confirmed the absence of any discernible abnormalities in physical examinations, along with the consistent maintenance of normal vital signs and laboratory safety parameters throughout the study period. Moreover, the absence of adverse events during the study highlights the safety profile of Dr. Ortho capsules for human consumption.

CONCLUSION

In conclusion, the study demonstrates the potential efficacy of Dr. Ortho capsules in managing various musculoskeletal conditions, supported by reductions in pain intensity and disability levels. The absence of adverse events and the maintenance of normal vital signs and laboratory parameters highlights the excellent safety profile of Dr. Ortho capsules. However, the limitations in study design warrant further investigation through randomized, double-blind, placebo-controlled trials to provide stronger evidence for its clinical use.

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***Address for correspondence**
Dr. Lokesh Holagundi
Health India Hospital,
Tavarekere Main Road, Chikka Adugodi, Bangalore, India.
Email: loksdoc@gmail.com