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Shree Dhootapapeshwar Limited

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Preface

With the rising popularity of Ayurved system of medicine worldwide, the need for generation of scientific evidence has also increased. Evidence in Ayurved needs to be generated through standardization of medicines and evaluation of their safety, efficacy, and probable mode of action. As a 152-year-old enterprise, **Shree Dhootapapeshwar Limited** feels extremely honoured to be associated with eminent organisations in India and abroad to work in cognizance for contribution towards **Evidence Based Ayurved**. Through our collaborations with institutes like Indian Institute of Technology (Mumbai), Seth G S Medical College and KEM Hospital (Mumbai), National Institute of Research in Reproductive and Child Health (Mumbai), D Y Patil Ayurved University (Navi Mumbai), National Institute of Ayurveda (Jaipur), Parul Ayurved University (Vadodara), KAHER's Shri B M Kankanawadi Ayurveda Mahavidyalaya (Belagavi, Karnataka), and Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM's NMIMS (Mumbai), we could successfully generate evidence on **characterization, safety, efficacy, and probable mode of action** of our classical and proprietary products. Reputed scientific journals have already published some of the evidence we generated through our collaborations.

Some of our unique work includes the studies on the potential of *Vasant Kusumakar Rasa*, in the management of type 2 diabetes complication and chondroprotective potential of *Vishesha Shodhit Guggul (Commiphora wightii)*. We are in process of collaborating with more institutes to generate more evidence on Ayurved products and Ayurved treatment protocols. This booklet is our small attempt to highlight some of our research work on standardization, preclinical, and clinical safety and efficacy.

Thank you

Sincerely yours,



Dr. Mukesh B Chawda

Senior Manager - Medical Services

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Effectiveness of Medhasagar Rasa® in Combating Aging-Associated Mild Neurocognitive Disorder: An Open-Label, Exploratory, Interventional Clinical Trial

Cite as:

Shetty, Suhas & Ramachandran, Aswini & Chawda, Mukesh & Narvekar, Sangam & Nalawade, Megha & Sharma, Mohit & Seetharaman, Rajmohan. (2024). Effectiveness of Medhasagar Rasa® in Combating Aging-Associated Mild Neurocognitive Disorder: An Open-Label, Exploratory, Interventional Clinical Trial. Cureus. 10.7759/cureus.69561.

Publication Year:

2024

Collaborating Institute(s):

Karnatak Lingayat Education Academy of Higher Education and Research's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, Shahpur, Belagavi - 590 003, Karnataka.

ABSTRACT:

Introduction: With the rising prevalence of neurocognitive disorders (NCDs) among the aging population, particularly in conditions like mild cognitive impairment (MCI), which often precedes dementia, there remains a significant gap in effective pharmacological interventions. This has generated interest in exploring alternative therapies to manage symptoms and enhance cognitive function in the aging population. The primary objective of this study was to evaluate the effect of Medhasagar Rasa® on cognitive functions, daily functioning, and quality of life in participants with aging-associated mild neurocognitive disorder using the Montreal Cognitive Assessment (MoCA) Scale, Ayurvedic Manasabhava Scale, and Brief Cognitive Rating Scale (BCRS).

Methods: This open-label, interventional study at Karnatak Lingayat Education (KLE) Ayurveda Hospital, Belagavi, Karnataka, involved 32 screened participants, with 30 completing the study. Participants aged 50-70 years with MoCA scores of 18-25 received Medhasagar Rasa (2 tablets at bedtime, provided by M/s. Shree Dhootapapeshwar Limited, Mumbai, India) for 60 days. Assessments occurred at baseline and every 15 days until day 60.

Results: Thirty participants were recruited for the study after screening, all of whom completed the study. The median total MoCA score at baseline (visit one) was 20, which significantly improved to 25 by visit five (day 60±3) ($p<0.001$), indicating enhanced cognitive performance. The BCRS scores also showed significant improvement, with the median score decreasing from 12 to 7.5 ($p<0.001$) over 60 days. Anxiety symptoms were significantly reduced, with Hamilton Anxiety Rating Scale (HAM-A) scores dropping from 14 to 7 ($p<0.001$), while the Pittsburgh Sleep Quality Index (PSQI) scores indicated improved sleep quality, reducing from 9.5 to 7 ($p<0.001$). The Ayurvedic Manasabhava Scale also demonstrated a significant reduction in intensity (14 to 6; $p<0.001$) and frequency (13.5 to 6; $p<0.001$). Clinical Global Impression (CGI) scores showed stable illness severity, sustained global improvement, and consistent therapeutic efficacy. No adverse events were reported, and vital parameters remained normal throughout the study. Compliance with the medication was over 80%, and no significant changes were observed in laboratory values.

Conclusion: Medhasagar Rasa effectively enhanced cognitive functions and alleviated anxiety and sleep disturbances in aging-related mild neurocognitive disorder, offering a promising therapeutic option.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 1902674
Medhasagar Rasa



A Randomized Study of Myostaal® Liniment as an Add-On Therapy for Muscle Strengthening in Cases of Knee Osteoarthritis

Cite as:

Deshpande S,
Deshpande V, Bhatt N,
Dhanavade B, Toshikane
H, Kulkarni BG,
Chawda M, Nalawade
M, Seetharaman R. A
Randomized Study of
Myostaal® Liniment as
an Add-On Therapy for
Muscle Strengthening in
Cases of Knee
Osteoarthritis. Cureus.
2024 Aug
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PMID: 39347318;
PMCID: PMC11429852.

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2024

Collaborating Institute(s):

Khemdas Ayurved
Hospital, Parul Institute
of Ayurved and
Research and Parul
Ayurved Hospital, Parul
Institute of Ayurved,
Parul University,
Vadodara – 391 760,
Gujarat.

ABSTRACT:

Introduction: Knee osteoarthritis (OA) is a prevalent degenerative musculoskeletal condition, affecting approximately 277 million people worldwide, with significant impacts on mobility, especially in women and obese patients, and an increasing incidence among Indians aged 30 to 50 years. The primary objective was to evaluate the knee muscle-strengthening effect of Myostaal® liniment (Solumiks Herbaceuticals Limited, Mumbai, India) as an add-on to physiotherapy for 90 days compared to physiotherapy alone in participants with knee OA. Secondary objectives included assessing changes in the total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, WOMAC Subscale scores, Six-Minute Walk Test (6MWT) distance, Single Leg Stance Test (SLST) duration, Visual Analogue Scale (VAS) score, and the number of adverse events from baseline to Day 90 between the two groups.

Methods: Seventy participants were randomly allocated to Group A (Myostaal® liniment plus physiotherapy) or Group B (physiotherapy alone) for 90 days, with Myostaal® liniment applied twice daily in Group A. Data were recorded in Case Report Forms (CRFs) and analyzed using parametric tests for within-group comparisons (one-way ANOVA or Friedman test) and non-parametric tests (Mann-Whitney test) for between-group comparisons, with significance set at $p < 0.05$.

Results: The knee muscle strength (index knee) in Group A (test medication group) was significantly greater compared to Group B (standard treatment group) at Visit 3 ($p < 0.05$; Day 60 ± 3) and Visit 4 ($p < 0.001$; Day 90 ± 3). For the non-index (other) knee, a statistically significant increase in knee muscle strength was observed ($p < 0.001$ at Day 90 ± 3) solely in Group A. A notable reduction in total WOMAC score was seen in Group A from Visit 2 ($p < 0.01$; Day 30 ± 3) onward, compared to Visit 1 (Day 0). The scores at Visit 3 ($p < 0.001$; Day 60 ± 3) and Visit 4 ($p < 0.001$; Day 90 ± 3) were significantly lower than those at Visit 2 (Day 30 ± 3).

Conclusion: The local application of Myostaal® liniment through massage as an adjunct to a physiotherapy regimen, improved knee muscle strength in participants with knee OA, leading to an enhancement in joint functionality. Additionally, Myostaal® liniment provided superior pain relief as an add-on therapy.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070225
Myostaal Liniment



Pharmacological Evaluation of Vasant Kusumakar Rasa in High Fat Diet and Streptozotocin-Induced Diabetic Retinopathy in Rats

Cite as:

Alok Singh, Mukesh B. Chawda and Yogesh A. Kulkarni
 Journal of Pharmacology and Experimental Therapeutics June 2024, 389 (S3) 402; DOI: <https://doi.org/10.1124/jpet.402.914200>

Publication Year:

2024

Collaborating Institute(s):

Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM's NMIMS, Department of Pharmacology, V.L. Mehta Road, Vile Parle (West), Mumbai - 400 056, Maharashtra.

ABSTRACT:

Diabetic retinopathy is one of the important microvascular complications of diabetes. Vasant Kusumakar Rasa (VKR) is a promising herbo-mineral preparation from Ayurveda, a traditional system of medicine for the management of diabetes. The present study was designed to evaluate the efficacy of Vasant Kusumakar Rasa in type II diabetic retinopathy in rats. Type II diabetes was induced in *Sprague Dawley* rats by using a high-fat diet and a single dose of streptozotocin at 35 mg/kg, *i.p.* After confirmation of diabetes induction, the rats were treated with two doses of VKR (28 mg/kg and 56 mg/kg, *p.o.*) for 16 weeks. At the end of the study, various biochemical and oxidative stress parameters were assessed. Moreover, an electroretinogram (ERG) of all animals was recorded to study retinal physiology. In addition to this, the expression of key proteins MMP-2, MMP-9, and VEGF, was studied. Histopathological study of retinal tissue was also performed using hematoxylin and eosin staining. The administration of VKR at both doses, 28 and 56 mg/kg, exhibited a significant reduction in glucose, glycosylated hemoglobin, and insulin levels when compared to the diabetic control group. Furthermore, the higher dose of VKR, 56 mg/kg, notably decreased the elevated levels of aldose reductase and sorbitol dehydrogenase after the 16-week treatment period. VKR at both doses demonstrated a remarkable ability to prevent the changes in 'a' and 'b' wave amplitude and latency, thus preserving retinal function in comparison to the diabetic control group. Additionally, oxidative stress, a key player in the progression of diabetic retinopathy, was considerably reduced in diabetic animals following 16 weeks VKR treatment. Notably, the expression levels of MMP-2, MMP-9, and VEGF were decreased in the VKR-treated diabetic animals. These findings indicate the significant therapeutic effects of Vasant Kusumakar Rasa in the management of type II diabetic retinopathy.



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Vasant Kusumakar Rasa

Cardioprotective Effects of 'Vasant Kusumakar Rasa,' a Herbo-metallic Formulation, in Type 2 Diabetic Cardiomyopathy in Rats

Cite as:

Singh AD, Chawda MB, Kulkarni YA. Cardioprotective Effects of 'Vasant Kusumakar Rasa,' a Herbo-metallic Formulation, in Type 2 Diabetic Cardiomyopathy in Rats. Cardiovasc Toxicol. 2024 Sep;24(9):942-954. doi: 10.1007/s12012-024-09891-0. Epub 2024 Jul 18. PMID: 39023814.

Publication Year:

2024

Collaborating Institute(s):

Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM's NMIMS, Department of Pharmacology, V.L. Mehta Road, Vile Parle (West), Mumbai - 400 056, Maharashtra.

ABSTRACT:

Diabetic cardiomyopathy (DCM) is one of the serious complications of type 2 diabetes mellitus. Vasant Kusumakar Rasa (VKR) is a Herbo-metallic formulation reported in Ayurveda, an Indian system of medicine. The present work was designed to study the effect of VKR in cardiomyopathy in type 2 diabetic rats. Diabetes was induced by feeding a high-fat diet (HFD) for 2 weeks followed by streptozotocin (STZ) administration (35 mg/kg *i.p.*). VKR was administered orally at dose of 28 and 56 mg/kg once a day for 16 weeks. The results of the study indicated that VKR treatment significantly improved the glycemic and lipid profile, serum insulin, CK-MB, LDH, and cardiac troponin-I when compared to diabetic control animals. VKR treatment in rats significantly improved the hemodynamic parameters and cardiac tissue levels of TNF- α , IL-1 β , and IL-6 were also reduced. Antioxidant enzymes such as GSH, SOD, and catalase were improved in all treatment groups. Heart sections stained with H & E and Masson's trichrome showed decreased damage to histoarchitecture of the myocardium. Expression of PI3K, Akt, and GLUT4 in the myocardium was upregulated after 16 weeks of VKR treatment. The study data suggested the cardioprotective capability of VKR in the management of diabetic cardiomyopathy in rats.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 0900144
Vasant Kusumakar Rasa

Vasant Kusumakar Rasa

Neuroprotective effects of nanogold-based Ayurveda medicine *Suvarna Bhasma* against rotenone-induced Parkinson's-like model

Cite as:

Biswas S, Chawda M, Gudi R, Bellare J. Neuroprotective effects of nanogold-based Ayurveda medicine *Suvarna Bhasma* against rotenone-induced Parkinson's-like model. *J Ayurveda Integr Med.* 2024 Jan-Feb;15(1):100854. doi: 10.1016/j.jaim.2023.100854. Epub 2023 Dec 24. PMID: 38145607; PMCID: PMC10767266.

Publication Year:

2024

Collaborating Institute(s):

Indian Institute of Technology,
Department of
Chemical Engineering,
Powai, Mumbai -
400 076, Maharashtra.

ABSTRACT:

Background: Neurodegenerative diseases have been one of the major concerns for human health. Genetic and environmental factors are believed to be responsible for neuronal diseases such as Parkinson's disease, Alzheimer's disease, and Huntington's disease. It is difficult to restore normal nervous function after neurodegeneration; hence, prevention could be the best strategy against these diseases. Ayurvedic medicines such as *Suvarna Bhasma* (SB) have enormous potential to treat these neurological diseases.

Aim: The aim of this study is to examine the protective effect of SB against rotenone-induced Parkinson's-like model in zebrafish.

Materials and methods: In this study, we induced Parkinson's-like disease model in zebrafish by inducing it with rotenone (7 µg/L). We examined the behavioural, proteomics and dopamine alterations of rotenone induced zebrafish of SB pre-treated group as compared to the control group.

Results: The behavioural experiments showed that due to rotenone exposure, Parkinson's-like behavioural abnormality was induced in zebrafish. However, because of SB treatment, this behavioural abnormality was reduced. The proteomics study of zebrafish brains clearly showed that the SB-treated group was not significantly affected due to rotenone exposure. However, in the SB non-treated group, expression of nine proteins that are linked to Parkinson's disease (gene name: *sncg*, *ywhae1*, *ywhah*, *uchl1*, *ywhaba*, *psma6a*, *ywhab1*, *ywhaqb*, and *ywhabb*) were differentially expressed after rotenone exposure. Finally, prevention of dopamine alteration in SB-treated fish brains confirmed the protective action of SB against rotenone-induced Parkinson's-like model in zebrafish.

Conclusions: This study finds that *Suvarna Bhasma* has neuroprotective effects against Parkinson's-like disease model.



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SDS Monograph No. 0900014
Suvarna Bhasma



Evaluation of Effects of Swamala (Fortified *Chyawanprash*) on Immunity and Quality of Life in Healthy Human Volunteers: An Open Labelled, Randomized, Controlled Exploratory Study.

Cite as:

Kurle Dnyaneshwar G, Marathe Padmaja A, Narvekar Sangam S, Nalawade Megha L, Chawda Mukesh B, Parhe Ajinkya et al, (2023). Evaluation of Effects of Swamala (Fortified Chyawanprash) on Immunity and Quality of Life in Healthy Human Volunteers: An Open Labelled, Randomized, Controlled Exploratory Study. Journal of Cardiovascular Disease Research 14(7):607-618.

Publication Year:

2023

Collaborating Institute(s):

D.Y. Patil Deemed to be University, School of Ayurveda, Nerul, Navi Mumbai - 400 706, Maharashtra.

ABSTRACT:

Background: The immune system defends against invading pathogenic microorganisms and cancer. Ayurved interventions can restore immune functions. Swamala is an ayurvedic formulation containing *Chyawanprash* fortified with processed gold, silver, mica, coral, iron, etc. The study was planned to assess the effect of Swamala on immune functions and Quality of Life in healthy volunteers.

Methods: A prospective, randomized, open-label, parallel arm, single-centre exploratory clinical study was conducted involving thirty-two healthy volunteers. They were randomly assigned to the Swamala Group (n=21) or Control Group (n=11) after conducting haematological, biochemical, X-ray, ECG, urine routine & immunological (IgG, TNF- α , CD4 cell count, anti-COVID antibody) investigations along with Quality of Life (QoL) assessment. Participants in the Swamala group were instructed to consume two teaspoonfuls (10 grams) of Swamala twice daily for 90 days. Control group participants did not receive any treatment. Weekly follow-up was done by means of telephonic interviews, and blood investigations were repeated after 45 & 90 days.

Results: Swamala group showed significant improvement in CD4 cell count, neutrophils, platelets & quality of life scores, and significant reduction in TNF- α levels & eosinophil counts during the subsequent follow-up visits ($p < 0.05$). Incidence of general illness (80% vs. 35%), and absenteeism (30% vs. 0) were higher in the control group during the treatment period. The control group showed significant decrease in IgG levels and an increase in CRP levels during follow-up ($p < 0.05$); no such variations were observed in the Swamala group. However, all the changes observed were within the physiological range. Swamala was found to be well-tolerated and safe.

Conclusion: The current exploratory pilot study findings suggest that Swamala possesses potential immunostimulant and anti-inflammatory properties.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070009
Swamala Compound



Swamala Compound

A Pilot, Open-Label, Proof-of-Concept Study To Evaluate the Efficacy and Safety of Asthiposhak® Tablets in Participants Suffering From Asthikshaya or Osteopenia

Cite as:

Kumar K, Godatwar P, Sharma S, Narvekar S, Nalawade M, Chawda MB, Verma P, Seetharaman R, Tripathi RK. A Pilot, Open-Label, Proof-of-Concept Study To Evaluate the Efficacy and Safety of Asthiposhak® Tablets in Participants Suffering From Asthikshaya or Osteopenia. *Cureus*. 2023 Jul 14;15(7):e41862. doi: 10.7759/cureus.41862. PMID: 37581133; PMCID: PMC10423404.

Publication Year:
2023

Collaborating Institute(s):

National Institute of Ayurveda, Madhav Vilas Palace, Jorawar Singh Gate, Amer Road, Jaipur – 302 002, Rajasthan.



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ABSTRACT:

Introduction: Both osteoporosis and osteopenia are prevalent public health concerns worldwide and can lead to debilitating bone fractures. This study aimed to assess the efficacy of Asthiposhak® Tablets in individuals with Asthikshaya (osteopenia) by measuring changes in the bone mineral density (BMD) score before and after the intervention, specifically between visit 1 (baseline) and visit 8 (after 180 days of treatment).

Methods: The single-arm study involved the screening of participants for Asthikshaya (osteopenia) using baseline investigations, which included a bone mineral density (BMD) assessment through a dual-energy X-ray absorptiometry (DEXA) scan. A total of 36 participants were enrolled in the study, who took two Asthiposhak Tablets three times a day with lukewarm water, for a period of 180 days. Safety assessments, along with evaluations of BMD (DEXA Scan), Ayurvedic Symptom Score, and serum biochemical markers, were conducted through blood investigations. Efficacy and safety data were analyzed using 'intention-to treat' analysis. Descriptive statistics were used to express data in percentages, mean \pm SD, or median (IQR). Data at different intervals were compared using paired t-tests or Wilcoxon signed-rank tests. One-way analysis of variance (ANOVA) with Bonferroni correction tested the significance between visits for the Ayurvedic Symptom Score, and Friedman's two-way analysis of variance by ranks measured differences in vital parameters. The significance level used was $p < 0.05$.

Results: Out of the initially recruited 36 participants, 30 successfully completed the study, consisting of 12 males and 18 females, with an age range of 40 to 70 years and a mean age of 51.33 years. After 180 days of treatment with Asthiposhak Tablets, a statistically significant ($p < 0.05$) improvement in hip and spine BMD (T-score) was observed. Additionally, significant reductions in the mean Total Ayurvedic Symptom Score were noted at both 90 and 180 days of treatment compared to day 0. Moreover, the levels of bone-specific alkaline phosphatase and osteocalcin, serum bone markers, showed statistically significant ($p < 0.05$) reduction after 180 days of treatment compared to day 0. Importantly, all safety variables, including laboratory investigations, remained within the normal range following the 180-day treatment with Asthiposhak Tablets.

Conclusion: Asthiposhak Tablets exhibited significant efficacy in enhancing both BMD (T-score) and Ayurvedic Symptom Score, thereby substantiating their osteoprotective potential in individuals with Asthikshaya (osteopenia). Furthermore, the tablets were found to reduce the levels of biochemical markers, such as serum bone specific alkaline phosphatase and osteocalcin, suggesting their anti-resorptive action.



Asthiposhak Tablets

A Pilot, Prospective, Randomized-Controlled Study to Evaluate the Efficacy and Safety of Arsha Hita™ in the Treatment of Anal Fissures

Cite as:

B J G, K R S, Shetty SK, Rao PN, Narvekar S, Nalawade M, Chawda MB, Chitnis KR, Seetharaman R, Tripathi RK. A Pilot, Prospective, Randomized-Controlled Study to Evaluate the Efficacy and Safety of Arsha Hita™ in the Treatment of Anal Fissures. Cureus. 2023 Apr 13;15(4):e37531. doi: 10.7759/cureus.37531. PMID: 37193430; PMCID: PMC10182782.

Publication Year:

2023

Collaborating Institute(s):

Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, P.B. No.164, B.M. Road, Thanniruhalla, Hassan – 573 201, Karnataka.

ABSTRACT:

Introduction: Anal fissures are tears in the anal canal that cause pain, bleeding, and spasms. They can be treated with non-operative options such as sitz baths, local anesthetics, topical nitrates, oral fiber, and calcium channel blockers, but some patients require surgery. Topical nitrates have side effects such as severe headaches, while topical calcium channel blockers can cause itching. There is a need to explore alternative treatments with fewer side effects. This proof-of-concept pilot study aimed to compare the efficacy and safety of a combination of Arsha Hita™ tablets and ointment (Shree Dhootapapeshwar Limited, Mumbai Maharashtra, India) (test treatment) with a combination of lidocaine 1.5% w/w + nifedipine 0.3% w/w cream for local application and Isabgol powder (6 g) orally as an active comparator (standard treatment), which is the standard treatment of anal fissures as per the Association of Colon and Rectal Surgeons of India (ACRSI) guidelines.

Methodology: This study was a single-center, prospective, randomized-controlled study conducted in Karnataka, India. Participants were screened for anal fissures and randomized to receive either standard treatment (Group A) or test treatment (Group B) for 14 days, and were re-evaluated after two, four, and six weeks. The study assessed signs and symptoms related to anal fissures, such as pain post-defecation on Visual Analog Scale (VAS), bleeding per anus grading, wound healing grade, stool consistency, and stool frequency. Compliance, inter-current illness, and concomitant therapy were noted at each visit. The study used independent sample t-tests to compare variables at baseline and chi-square or Fisher's exact tests to compare the number/proportion of participants achieving primary and secondary endpoints. Mann-Whitney U test was used to compare median composite scores at baseline and Visit 4, and Friedman's two-way analysis of variance was used to compare median composite scores across the four visits ($p < 0.05$ was considered significant). Descriptive analysis was used to assess VAS, bleeding, and healing grades.

Results: The study included 53 participants with anal fissures, of which 25 out of 27 allocated in Group A (two dropouts) received standard treatment, and all 26 allocated in Group B received Arsha Hita treatment. At the end of the study, 11 participants in Group B achieved a 90% reduction in composite scores compared to only three patients in Group A ($p < 0.05$). Both groups showed improvement in pain on defecation, severity of bleeding, healing of anal fissure wound, and participant's and physician's global impression score. Group B had significantly better results in terms of VAS score, resolution of per-anal bleeding, and physician's global impression score ($p < 0.05$). There were no adverse events in either group during the six-week treatment period.

Conclusion: The pilot study provides evidence that the combination of Arsha Hita tablets and Arsha Hita ointment may be more effective and safer for treating anal fissures than the standard treatment. The test treatment group experienced greater pain relief, complete resolution of per-anal bleeding, and better global impression scores than the standard treatment group. These findings suggest the need for further research through larger, randomized controlled trials to determine the efficacy and safety of Arsha Hita in treating anal fissures.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 0702564
Arsha Hita Tablets



Assessment of Chronic Toxicity of an Ayurvedic Herbo-Metallic Formulation Rasaraj Rasa in Wistar Rats

Cite as:

Waghmare CS, Bidve SR, Gudi RV, Nalawade ML, Chawda MB. Assessment of Chronic Toxicity of an Ayurvedic Herbo-Metallic Formulation Rasaraj Rasa in Wistar Rats. J Pharmacopuncture. 2022 Dec 31;25(4):354-363. doi: 10.3831/KPI.2022.25.4.354. PMID: 36628344; PMCID: PMC9806152.

Publication Year:

2022

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Objectives: This study aimed to assess the adverse effects of Rasaraj Rasa tablets after repeated oral administration for 180 days in Wistar rats.

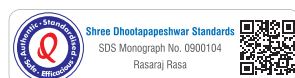
Methods: Wistar rats were divided into five groups, of which three were treated with 54, 162, and 270 mg/kg body weight of Rasaraj Rasa, respectively, which correspond to one, three, and five times the proposed human therapeutic dose, for 180 days consecutively. The fifth group (satellite) also received 270 mg/kg body weight of Rasaraj Rasa for 180 days. Body weight and food intake were measured weekly. At the end of the study, all rats were sacrificed, and their blood, serum, and organs were collected and examined using hematology, serum biochemistry, gross pathology, and histopathology tests. In contrast, the satellite group was kept for 4 weeks after treatment.

Results: No significant treatment-related toxicological findings were observed in the clinical features, body weight, laboratory findings, and pathological findings of the high-dose treated groups, when compared to those of the control group.

Conclusion: The no-observed-adverse-effect-level for Rasaraj Rasa in Wistar rats is set at 270 mg/kg body weight.



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A prospective, single centre, open label, single arm pilot study to evaluate the efficacy and safety of Amlapitta Mishran Suspension in participants with endoscopic gastritis

Cite as:

Shetty YC, Koli PG, Lahoti M, Kulkarni S, Rajput P, Chawda MB. A prospective, single centre, open label, single arm pilot study to evaluate the efficacy and safety of Amlapitta Mishran Suspension in participants with endoscopic gastritis. J Ayurveda Integr Med. 2022 Oct-Dec;13(4):100664. doi: 10.1016/j.jaim.2022.100664. Epub 2022 Nov 24. PMID: 36436294; PMCID: PMC9700308.

Publication Year:

2022

Collaborating Institute(s):

Suyash Hospital, A Unit of Suyash Institute of Medical Science Pvt. Ltd. Kota Gudhiyari Road, Behind Hotel Piccadily, Raipur – 492 001, Chhattisgarh.



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ABSTRACT:

Background: Endoscopic gastritis is associated with symptoms of gastritis, along with endoscopic findings. Amlapitta Mishran has multiple active components that act via various mechanisms in patients with gastritis symptoms. We planned to conduct this study to find out the efficacy and safety of Amlapitta Mishran in patients with endoscopic gastritis.

Objectives: To find out efficacy of Amlapitta Mishran in patient with endoscopic gastritis.

Materials and methods: This study was an open-label, prospective, single-center study. Thirty participants were recruited, and Amlapitta Mishran Suspension was given for 30 days. Blood investigations for safety were performed at baseline (Visit 1), on Visit 3 and Visit 4. Endoscopy was performed at baseline and Visit 4, and stomach erosion score was recorded. Amlapitta Symptom Rating Scale score, Postprandial Distress Syndrome (PPDS) score, and Epigastric Pain Syndrome (EPS) score were efficacy endpoints.

Results: Out of the 30 participants recruited, 28 participants completed the study. The median age of participants in the study was 26.50 years. A statistically significant ($P < 0.05$) reduction was seen in endoscopy score at Visit 4 as compared to baseline (Visit 1) by Wilcoxon Signed Rank test. Amlapitta Symptom Rating Scale score, PPDS score, EPS score also exhibited significant reduction ($P < 0.05$) at Visit 3 and Visit 4 as compared to baseline by Friedman's test with post hoc analysis. No statistically significant reduction was seen in these scores from Visit 3 to Visit 4, except for the EPS score. At the end of Visit 4, 18 (64%) participants had an endoscopy score of 1 (no erosions). At the end of Visit 4, $\geq 50\%$ improvement was seen in Amlapitta Symptom Rating Scale score in 27 (96%) participants, PPDS score improved by $\geq 50\%$ in 25 (89%) participants, and EPS score improved by $\geq 50\%$ in 26 (93%) participants. All safety variables including laboratory investigation were within the normal range in all visits.

Conclusion: Amlapitta Mishran Suspension effectively reduced endoscopic gastritis scores in the participants and reduced the symptoms of gastritis measured by the Amlapitta Symptom Rating Scale, PPDS, and EPS scores with no adverse events.



Shree Dhootapapeshwar Standards
 SDS Monograph No. 070003
 Amlapitta Mishran Suspension



Evaluation of chronic toxicological profile of herbo-mineral formulations: Shwaskas Chintamani Rasa and its marketed formulation namely Kas Shwas Hari Rasa

Cite as:

Waghmare CS, Bidve S, Gudi RV, Yadav S, Chawda MB, Nalawade ML. Evaluation of chronic toxicological profile of herbo-mineral formulations: Shwaskas Chintamani Rasa and its marketed formulation namely Kas Shwas Hari Rasa. J Ayurveda Integr Med. 2022 Jul-Sep;13(3):100615. doi: 10.1016/j.jaim.2022.100615. Epub 2022 Sep 8. PMID: 36088824; PMCID: PMC9471453.

Publication Year:

2022

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Background: Shwaskas Chintamani Rasa (SKC) and Kas Shwas Hari Rasa (KSH) are the Ayurvedic herbo-mineral formulations. These Ayurvedic formulations contain heavy metals which is the reason of concern and might bring up the safety issue.

Objective: This research article is aimed to study chronic toxicity of SKC and KSH for safety aspect in Wistar rats.

Material and method: A study group of 220 healthy rats were divided into six groups. These rats were administered with SKC and KSH formulations where both the formulations were administered for 180 consecutive days. SKC was administered at doses of 58 mg/kg (equivalent to therapeutic dose i.e. TD), 145 mg/kg (2.5 TD), 290 mg/kg (5 TD) and KSH was administered at dose of 58 mg/kg (TD). According to OECD guideline 452, the effect of these formulations was examined on hematology, serum biochemistry and histopathology of various organs.

Results: Both the formulations did not produce any signs or symptoms of treatment related toxicity in both male and female Wistar rats at therapeutic dose (TD), 2.5 times TD and 5 times TD.

Conclusion: Based on these findings, the NOAEL (No observed adverse effect level) for test formulations SKC and KSH tablets in male and female wistar rats concluded to be preclinically safe.



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Cardioprotective effect of Hrudroga Chintamani Rasa in isoproterenol induced cardiotoxicity in male Sprague Dawley rats

Cite as:

Laddha, A.P., Chawda, M.B. & Kulkarni, Y.A. Cardioprotective effect of Hrudroga Chintamani Rasa in isoproterenol induced cardiotoxicity in male Sprague Dawley rats. J Diabetes Metab Disord (2022). <https://doi.org/10.1007/s40200-022-01012-4>.

Publication Year:

2022

Collaborating Institute(s):

Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, SVKM's NMIMS, Department of Pharmacology, V.L. Mehta Road, Vile Parle (West), Mumbai 400 056, Maharashtra.

ABSTRACT:

Purpose: Ayurvedic system, a traditional medicinal system has mentioned a preparation Bruhat Vata Chintamani Rasa (Suvarnayukta) for management of heart diseases. Hrudroga Chintamani Rasa (HCR) is a formulation containing Bruhat Vata Chintamani Rasa and a few additional ingredients having beneficial effects in heart diseases. The present study was designed to investigate the cardioprotective activity of the Hrudroga Chintamani Rasa in isoproterenol (ISO)-induced myocardial infarction in rats.

Methods: Male Sprague Dawley rats were treated with HCR at a dose of 56.16 and 112.32 mg/kg for 30 days. Animals received ISO (85 mg/kg. s.c.) on 28th and 29th day at an interval of 24 h.

Result: Disease control animals treated with HCR at a dose of 56.16 mg/kg and 112.32 mg/kg to rats showed a significant reduction in elevated levels of aspartate aminotransferase (AST), lactate dehydrogenase (LDH), and creatine phosphokinase MB (CK-MB), and prevented loss of depleted antioxidant enzymes from the cardiac tissue. ISO-altered electrocardiogram pattern and haemodynamic parameters were also brought about to normal by treatment with HCR. HCR treatment also improved the levels of 5' adenosine monophosphate-activated protein kinase (AMPK) and Silent information regulator 1 (SIRT1) which have potent role in antioxidant defence mechanism. Histopathological findings also showed HCR treatment prevented cardiac tissue from damage.

Conclusion: HCR treatment showed a significant cardioprotective effect in ISO-induced cardiotoxicity in rats probably because of the potent antioxidant activity.



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Shree Dhootapapeshwar Standard
SDS Monograph No. 1902594
Hrudroga Chintamani Rasa



Hrudroga Chintamani Rasa

Characterization of Copper-based ayurved medicine Tamra bhasma produced by various manufacturers and its pharmacokinetic profiling in Wistar rat

Cite as:

Waghmare C. S., Bidve S.,
Gudi R. V., Chawda M.
B., Yadav S. (2022).
Characterization of
Copper-based Ayurved
Medicine Tamra bhasma
produced by various
manufacturers and its
Pharmacokinetic
profiling in Wistar rat.
International Journal of
Ayurvedic
Medicine,13(2),487-494.

Publication Year:

2022

Collaborating Institute(s):

Shree Dhootapapeshwar
Ayurvedic Research
Foundation (SDARF),
Panvel,
Navi Mumbai - 410 206,
Maharashtra.

ABSTRACT:

Background: Tamra bhasma (TB) is copper based herbo-metallic preparation which is used extensively by Ayurvedic practitioners. Tamra bhasma is endorsed for different disorders of liver, abdominal pain, heart disease, colitis, tumors, anemia, loss of appetite, tuberculosis, as well as eye problems.

Objective: Our aim is to characterize 5 commercial TB preparations from 5 different manufacturers by using modern scientific techniques and to study there bioavailability in Wistar rat.

Materials and Methods: Tamra bhasma was characterized by X-ray diffraction (XRD), Scanning electron microscope (SEM), Energy Dispersive X-ray analysis (EDAX), Nanoparticle tracking analyzer (NTA), Inductively coupled plasma optical emission spectroscopy (ICP-OES). Bioavailability of Tamra bhasma was studies using non compartmental rat model with daily dose of 6.45 mg/kg according to their body weight.

Results: The colour of one of the TB preparation was different from other 4 TB samples. The chemical phase and particle size is significantly different for all the 5 TB's. Pharmacokinetic model confirms difference in various PK parameters such as peak concentration (C_{max}), half-life ($t_{1/2}$) and terminal elimination slope (λ_z) for all 5 TB's. TB-A showed highest C_{max} (82.21 mg/L), whereas TB-E showed lowest C_{max} (48.69 mg/L). The highest bioavailability of TB is may be due to specific chemical moiety and morphology. Based on XRD and elemental analysis, it was found that manufacturing route followed for one of the preparation is not as per ayurvedic text reference.

Conclusions: The morphology as well as chemical phase of the five TB's studied were different from each other, which might be responsible for different pharmacokinetic profiles in Wistar rat model.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 020019
Tamra Bhasma



Tamra Bhasma

Phytochemical and elemental profiling and standardization of some ayurveda medicines used in COVID-19 Pandemic

Cite as:

Priyanka Patil, Madhuree Gawhankar, Shivcharan Bidve, R V Gudi and Atul Lavand. Phytochemical and elemental profiling and standardization of some Ayurveda Medicines used in COVID-19 Pandemic. Int. J. Res. Ayurveda Pharm. 12(4),2021

Publication Year:

2021

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.



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ABSTRACT:

Tribhuvankirti Rasa is a herbo-mineral Ayurvedic medicine regularly used to treat different types of fever. It has antipyretic and analgesic activities. It is an effective medicine for the common cold, flu and other Vata kapha problems. Laghumalini Vasanta is also Ayurvedic medicine, used to treat chronic fever and effective in pitta disorders. Ministry of AYUSH, Government of India also recommended these medicines to prevent the severe conditions of Cov-2 infection. Review of literature suggested that phytochemical and elemental characterization parameters of Tribhuvankirti Rasa and Laghumalini Vasant are not reported. The objective of this study is to report phytochemical and elemental profiling and to standardize Tribhuvankirti Rasa (TKR) and Laghumalini Vasant (LMV) to confirm quality and purity. Tribhuvankirti Rasa and Laghumalini Vasant evaluated for phytochemical and elemental parameters by HPTLC and ICP-OES respectively. HPTLC analysis confirms LMV contains Piperine and TKR contains Piperine and 6-Gingerol. The solvent systems toluene: ethyl acetate (7: 3) v/v for Piperine & Hexane: Ethyl acetate: Formic acid (4 : 6 : 0.1) v/v for 6-Gingerol were optimized. ICP-OES analysis confirms presence of Zn in LMV and Hg in TKR. HPTLC and ICP-OES methods were validated successfully for Tribhuvankirti Rasa and Laghumalini Vasant. The characterization and method validation parameters presented in this paper may serve as standard reference for quality control analysis of Tribhuvankirti Rasa and Laghumalini Vasant.



Shree Dhootapapeshwar Standards
SDS Monograph No. 0800234
Tribhuvankirti Rasa



Tribhuvankirti Rasa

Evaluation of anti-osteoporotic activity of Asthiposhak Tablets in ovariectomized rats

Cite as:

Mrinal Sanaye,
 Bhavna Bora,
 Mukesh Chawda &
 Viprav Kshirsagar.
 Evaluation of
 anti-osteoporotic
 activity of Asthiposhak
 Tablets in
 ovariectomized rats.
 IJPSR, 2021; Vol.
 12(6):3498-3507.

Publication Year:
 2021

Collaborating Institute(s):

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ABSTRACT:

Osteoporosis is a condition that makes the bones porous, fragile, and prone to fractures. Although it is very prevalent in elderly people, it is more common in women, especially after menopause. The present study aimed to evaluate the effect of Asthiposhak Tablets on their anti-osteoporotic activity in ovariectomized (OVX) rats. Thirty-two female albino Wistar rats were randomly divided into four groups (n=8). Group 1 served as sham-operated control. Group 2 rats were ovariectomized (OVX) and served as a negative control. Group 3 received raloxifene (5.4 mg/kg i.p.) and served as the standard control, and Group 4 received Asthiposhak (405 mg/kg p.o.) and served as treatment control. After 60 days of ovariectomy, animals were treated with Asthiposhak for the next 45 days. At the end of the study, femur bone length, weight, bone ash calcium level, and bone mineral density (BMD) were estimated. The levels of serum alkaline phosphatase (ALP), calcium, and phosphorous, and bone histopathology were also evaluated. OVX-induced increased serum ALP, calcium, and phosphorous levels were significantly attenuated in Asthiposhak-treated rats. Asthiposhak treatment significantly prevented an OVX-induced increase in body weight. The calcium content in bone ash was significantly increased on Asthiposhak treatment indicating remineralization of bones. OVX-induced decrease in BMD was significantly reversed in Asthiposhak-treated animals. Femur bone histopathology revealed increased trabecular thickness and decreased osteoclast formation in Asthiposhak-treated animals. Asthiposhak exhibited a significant anti-osteoporotic effect in the experimental model of OVX-induced osteoporosis in rats. These results indicate Asthiposhak can be beneficial in postmenopausal osteoporosis.



Shree Dhootapapeshwar Standards
 SDS Monograph No. 0702594
 Asthiposhak Tablets



Asthiposhak Tablets

Evaluation of the effect of an ayurvedic formulation Myostaal Forte tablets on chondroprotective biomarkers in an experimental model of osteoarthritis in rats

Cite as:

Shetty YC, Singh VK, Manjesh PS, Vetrivel Babu Nagarajan, Patil P, Chawda M, Rege NN, Evaluation of the effect of an ayurvedic formulation Myostaal Forte tablets on chondroprotective biomarkers in an experimental model of osteoarthritis in rats, Phytomedicine Plus, Volume 1, Issue 3, 2021, 100082, ISSN 2667-0313, <https://doi.org/10.1016/j.phyplu.2021.100082>.

Publication Year:
2021

Collaborating Institute(s):

Seth G. S. Medical College & K.E.M Hospital, Department of Pharmacology & Therapeutics, Parel, Mumbai - 400 012, Maharashtra.

ABSTRACT:

Background: Osteoarthritis is a chronic progressive disease commonly affecting the hip and knee joints. Although many drugs are available and afford symptomatic relief, their side effects pose limitations to their continuous use. **Introduction:** Myostaal forte (MF) is a poly herbal Ayurvedic formulation that has shown protection against damage to the chondrocyte layer on histopathological examination in previous studies. But biomarkers which are indicative of chondroprotection have not been assessed. So, the present study was planned to reconfirm the protective effect of MF in osteoarthritic rats by histopathology and create a more substantial evidence by assessing the levels of Cartilage oligomeric matrix protein (COMP) and matrix metalloproteinase-13 (MMP-13). **Methods:** 32 rats were divided into four groups (n = 8 each group); sham control (SC), disease control (DC), positive control (PC) and a MF group. Behavioural tests were compared from baseline to 7th day, 14th day, 21st day and on 28th day. Histopathology and bone markers were compared on the 28th day. $p < 0.05$ was considered as statistically significant. Analysis of Variance (ANOVA) with post hoc Tukey's test was used for parametric data. Non-parametric data was analysed using Kruskal Wallis test with post hoc Dunn's test. **Results:** On measurement of locomotor activity, number of squares crossed was significantly higher in MF group when compared to DC group & there was a significant decrease in the immobility time in MF group when compared DC group. Number of falls on Rota rod test was significantly lower in MF group when compared to DC on day 28. Hot Plate Analgesimeter showed no significant difference in the MF group compared to DC group but over the period of time till day 28, the latency time to lick hind paw was higher in the MF group compared to DC group. In histopathology grading, the scores in MF group were significantly reduced compared to DC group. MMP-13 levels and COMP levels in MF group were significantly decreased as compared to the DC and were statistically significant ($p < 0.05$). **Conclusion:** Myostaal Forte has shown antiarthritic effect by virtue of its chondroprotective action.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070250
Myostaal Forte Tablets



Myostaal Forte Tablets

Physicochemical variation in nanogold based ayurved medicine Suvarna Bhasma produced by various manufacturers lead to different *in vivo* bioaccumulation profiles

Cite as:

Biswas S, Chawda M, Thakur K, Gudi R, Bellare J. Physicochemical Variation in Nanogold-Based Ayurved Medicine Suvarna Bhasma Produced by Various Manufacturers Lead to Different *in vivo* Bioaccumulation Profiles. J Evid Based Integr Med. 2021 Jan-Dec;26: 2515690X211011064. doi: 10.1177/2515690X211011064. PMID: 33906452; PMCID: PMC8743929.

Publication Year:

2021

Collaborating Institute(s):

Indian Institute of Technology, Department of Chemical Engineering, Powai, Mumbai - 400 076, Maharashtra.

ABSTRACT:

Suvarna Bhasma (SB) is a gold particle-based medicine that is used in Ayurved to treat tuberculosis, arthritis and nervous diseases. Traditionally, the Ayurved preparation processes of SB do exist, but they are all long, tedious and involve several steps. Due to this, there is a possibility of bypassing the necessary Ayurved processes or non-adherence to all steps or use of synthetic gold particles. Our aim is to characterize 5 commercial SB preparations from 5 different manufacturers. A comparative physicochemical, pharmacokinetic (PK) and bioaccumulation study was carried out on all the 5 SB preparations. The general appearance such as color and texture of these 5 samples were different from each other. The size, shape and gold concentration (from 32-98 wt%) varied among all the 5 SBs. The accumulation of ionic gold in zebrafish and gold concentration profiles in rat blood were found to be significantly different for all the 5 SBs. Non-compartmental PK model obtained from the concentration-time profile showed significant differences in various PK parameters such as peak concentration (C_{max}), half-life ($t_{1/2}$) and terminal elimination slope (λ_z) for all the 5 SB preparations. SB-B showed the highest C_{max} (8.55 $\mu\text{g/L}$), whereas SB-D showed the lowest C_{max} (4.66 $\mu\text{g/L}$). The dissolution of ionic gold from SBs in zebrafish tissue after the oral dose had a 5.5-fold difference between the highest and lowest ionic gold concentrations. All the 5 samples showed distinct physicochemical and biological properties. Based on characteristic microscopic morphology, it was found that 2 preparations among them were suspected of being manufactured by nonadherence to the mentioned Ayurved references.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 0900014
Suvarna Bhasma



Suvarna Bhasma (Premium)

An evaluation of the efficacy, safety, and tolerability of Abhraloha compared with oral Ferrous Ascorbate on Iron Deficiency Anemia in women: A randomized controlled, parallel-group, assessor-blind clinical trial

Cite as:

Gajbhiye S, Koli PG, Harit M, Chitrakar M, Bavane V, Chawda M. An Evaluation of the Efficacy, Safety, and Tolerability of Abhraloha Compared With Oral Ferrous Ascorbate on Iron Deficiency Anemia in Women: A Randomized Controlled, Parallel-Group, Assessor-Blind Clinical Trial. Cureus. 2021 Apr 7;13(4):e14348. doi: 10.7759/cureus.14348. PMID: 33972905; PMCID: PMC8104902.

Publication Year:

2021

Collaborating Institute(s):

D.Y. Patil Deemed to be University, School of Ayurveda, Nerul, Navi Mumbai - 400 706, Maharashtra.

ABSTRACT:

Background and objective: Iron deficiency anemia (IDA) is a common condition in women for which ferrous ascorbate (FA) is often prescribed, which can lead to multiple side effects. Abhraloha is an Ayurvedic medicine that has been used for decades in India to treat IDA. In this study, we aimed to evaluate the efficacy and safety of Abhraloha with regard to change in hemoglobin (Hb) levels as compared to the standard treatment using FA in participants with IDA. **Materials and methods:** We conducted a single-center, pragmatic, prospective, randomized, active-controlled, two-arm, parallelgroup, assessor-blind study to evaluate the efficacy and safety of Abhraloha with regard to change in Hb levels as compared to the standard treatment using FA in participants suffering from IDA. The eligible participants were randomized and were advised to take either Abhraloha (two tablets twice a day) or FA (one tablet twice a day) for eight weeks; they were asked to follow up after 14 days for re-evaluation. On visit 1 and during the study period, the physician assessed the participants on the Pandurog scale and subjective variables. Descriptive statistics were used with unpaired T-test/Mann-Whitney U test for comparison between the groups. The Wilcoxon signed-rank test was used for within-group analysis, and the chi-square test/Fisher's exact test was employed for categorical data. **Results:** Based on our findings, Abhraloha tablets significantly increased all the variables including the Pandurog scale after eight weeks of treatment. Abhraloha reduced total iron-binding capacity (TIBC) and peripheral smear lymphocyte (PSL), which is consistent with an improvement in IDA. There was a statistically significant increase in Hb, red blood cell (RBC) count, packed cell volume (PCV), mean corpuscular volume (MCV), and mean corpuscular hemoglobin (MCH) in the Abhraloha group as compared with the FA group at eight weeks. The Abhraloha group also exhibited a statistically significant improvement in all the subjective variables. Abhraloha was found to be safe and well-tolerated among the participants. **Conclusions:** Abhraloha possesses hematinic activity and it improves all the blood indices. It is associated with significantly fewer adverse effects compared to oral iron therapy, which proves that it can be safely used for the treatment of IDA.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 0700014
Abhraloha Tablets



The effect of Madhumeha Kusumakar Rasa - an ayurved medicine - in insulin resistance

Cite as:

Kavishwar S, Sanaye M, Nair M, Chawda M, Kshirsagar V, Kulkarni YA. The effect of Madhumeha Kusumakar Rasa - an Ayurved medicine - in insulin resistance. J Complement Integr Med. 2021 Jul 15;19(2):353-363. doi: 10.1515/jcim-2021-0090. PMID: 34265886.

Publication Year:

2021

Collaborating Institute(s):

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Maharashtra.

ABSTRACT:

Objectives: Madhumeha Kusumakar Rasa (MKR) is an Ayurved formulation having a strong pharmacological base for diabetes management. This study aimed to validate MKR's efficacy in dexamethasone-induced insulin resistance (IR).

Methods: Albino Wistar rats were divided into four groups. Group 1 served as the normal control, Group 2 received dexamethasone 1.5 mg/kg (i.p.), Group 3 received dexamethasone and metformin 200 mg/kg (p.o.), and Group 4 received dexamethasone and MKR 236 mg/kg (p.o.). Animals were evaluated for serum glucose levels and glucose tolerance, serum insulin, Homeostatic model assessment of insulin resistance (HOMA-IR), Homeostatic model assessment of insulin sensitivity (HOMA-IS), fasting glucose to insulin ratio (FGIR), and lipid parameters. Pancreas, liver, and kidneys were evaluated for reduced Glutathione (GSH) and Malondialdehyde (MDA) levels. These tissues were also evaluated for histopathological changes.

Results: MKR showed significant improvement in serum glucose and glucose tolerance, serum insulin and HOMA-IR, HOMA-IS, and FGIR. It also showed a significant improvement in lipid parameters as compared to the dexamethasone-treated group. It prevented depletion of GSH levels and elevation in MDA levels. These effects were supported by histopathological analysis.

Conclusions: MKR treatment significantly attenuated dexamethasone-induced IR. This study validates the mechanism of the anti-diabetic potential of MKR.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 1902614
Madhumeha Kusumakar Rasa



Madhumeha Kusumakar Rasa

Physicochemical characterization of Suvarna Bhasma, its toxicity profiling in rat and behavioural assessment in zebrafish model

Cite as:

Biswas S, Dhumal R, Selkar N, Bhagat S, Chawda M, Thakur K, Gudi R, Vanage G, Bellare J. Physicochemical characterization of Suvarna Bhasma, its toxicity profiling in rat and behavioural assessment in zebrafish model. J Ethnopharmacol. 2020 Mar 1;249:112388. doi: 10.1016/j.jep.2019.112388. Epub 2019 Nov 12. PMID: 31730889.

Publication Year:
2020

Collaborating Institute(s):

Indian Institute of Technology,
Department of Chemical Engineering, Powai, Mumbai - 400 076, Maharashtra.



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ABSTRACT:

Ethnopharmacological relevance: Suvarna Bhasma is a gold-based Ayurved medicine that has a wide range of therapeutic indications like tuberculosis, diabetes mellitus, rheumatoid arthritis and nervous diseases. Suvarna Bhasma is also used in Suvarnaprashana, an Ayurved advocated therapy being practised to improve immunity in children. **Aim of the study:** To augment traditional understanding, here we present an evidence-based study on Suvarna Bhasma regarding its physicochemical properties, toxicity and efficacy. **Materials and methods:** Suvarna Bhasma was characterised by physicochemical characterization techniques such as scanning electron microscope (SEM), transmission electron microscopy (TEM), X-ray diffraction (XRD) and atomic emission spectroscopy (ICP-AES). Toxicity of Suvarna Bhasma was studied in Holtzman rats with daily oral dose from 3 mg/kg (therapeutic dose, TD) up to 30 mg/kg (10 TD) body weight for 90 days. Behavioural study, such as motor and geotactic behaviour were examined in zebrafish model to find out any sign of neurotoxicity or behavioural changes due to Suvarna Bhasma administration. **Results:** Suvarna Bhasma has two types of gold particles, large ones (~60 μm) having irregular shapes, and nanosized spherical particles (starting from ~10 nm), the latter coated with Fe, Si, O, P and Na. XRD study revealed that all the peaks of Suvarna Bhasma match well with pure gold (face centred cube) with crystallites size 45 ± 2.8 nm. In rat studies, some change in biochemical parameters such as urea, creatinine and alanine aminotransferase (ALT) was observed mainly at the higher therapeutic dose; however, those parameters were within the normal range. There were no significant macroscopic as well as microscopic treatment-related alteration observed, in any of the organs and tissues evaluated. In zebrafish behavioural study, the motor parameters of Suvarna Bhasma treated fish showed normal behaviour analogous to the vehicle control group. Interestingly, the geotactic behaviour showed anxiolytic effects of Suvarna Bhasma as evidenced by the time spent in the upper zone, and average swimming height. The anxiolytic effects persisted for more than 30 days after withdrawing the Suvarna Bhasma treatment. **Conclusions:** Suvarna Bhasma contained spherical gold nanoparticles. It was nontoxic in rat model at the does tested. Suvarna Bhasma has anxiolytic effects in zebrafish behavioural model.



Shree Dhootapashwar Standards
SDS Monograph No. 0900014
Suvarna Bhasma



Suvarna Bhasma (Premium)

Physicochemical characterization and antimicrobial properties of Mahamanjishthadi Kadha: An Ayurvedic formulation

Cite as:

Kapil Thakur, P. Mini Mol, Madhuree Gawhankar, Himanshu Gupta, Priyanka Patil and Mansee Thakur. Annals of Phytochemistry 9(1): 78-90, 2020. DOI: <http://dx.doi.org/10.21276/ap.2020.9.1.9>

Publication Year:

2020

Collaborating Institute(s):

MGM School of Biomedical Sciences, MGMIHS, Kamothe-410206, Navi Mumbai, Maharashtra, India.
Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Skin infections are common throughout the world. With high infectivity amongst skin pathogens, approximately 300 million people are affected worldwide. The increasing rate of failure of chemotherapeutics and antibiotic resistance exhibited by pathogenic microbial infectious agents, has increased the use of Ayurvedic medicines. This study aims to standardize an Ayurvedic formulation, Mahamanjishthadi kadha and to evaluate its antimicrobial properties against skin infection, causing pathogens. Physicochemical analysis such as organoleptic tests, pH, alcohol content, Brix and Specific gravity was done. Phytochemical screening was performed for various bioactive compounds. Heavy metals, aflatoxins and microbial load were checked for contaminants. Chromatographic analysis was performed to estimate lupeol, ellagic acid and gallic acid, using high performance thin layer chromatography (HPTLC). Antimicrobial activity was determined against five common pathogens causing skin infections, using well-diffusion method. Organoleptic tests confirmed brown color and characteristic odor of self generated alcohol with bitter and astringent taste. Phytochemical screening showed the presence of alkaloids, steroids, triterpenoids, tannins, phenolic compounds, saponins and flavonoids. HPTLC analysis confirmed the presence of lupeol, ellagic acid and gallic acid. Heavy metals, aflatoxins and microbial load were found within the permissible limit. Antimicrobial study showed the formulation could inhibit growth of *Staphylococcus aureus*, *Candida albicans*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis* and *Escherichia coli*. The study presented has completely characterized the formulation will serve as reference to develop quality control profile of Mahamanjishthadi kadha and help in validating therapeutic efficacy of this formulation.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 100009
Mahamanjishthadi Kadha



Mahamanjishthadi Kadha

Assessment of immunomodulatory potential of an ayurvedic formulation, Nirocil Syrup in Wistar rats

Cite as:

Ghadigaonkar, Dinesh; Chawda, Mukesh & Thakur, Kapil. (2020). Assessment of immunomodulatory potential of an ayurvedic formulation, Nirocil Syrup in Wistar rats. Asian Journal of Pharmaceutical and Clinical Research. 154-158. 10.22159/ajpcr.2020.v13i10.38826.

Publication Year:

2020

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Objective: This study aims to assess the immunomodulatory potential of an Ayurvedic formulation, Nirocil syrup, in Wistar rats.

Methods: The experiments were conducted on Wistar rats with prior approval from the Institutional Animal Ethics Committee. Nirocil syrup was administered for 6 weeks to experimental animals. Parameters such as hemagglutination titer, histopathology of immunological organs, complete blood count, differential leukocyte count, and immunological paw edema were recorded and compared with controlled (untreated) and becozinc treated groups.

Results: Nirocil treated group significantly enhanced the antibody titer in comparison to the control group. The results are supported by the increase in blood lymphocyte count and antigenic stimulation in immunological organs (spleen). Nirocil syrup enhanced antibody formation and suppressed the immunological edema in experimental animals.

Conclusions: The study concludes that the Ayurvedic formulation Nirocil syrup has immunopotentiating activity.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070228
Nirocil Syrup



Nirocil Syrup

Standardization of ayurvedic formulation “Arjunarishta” in terms of physicochemical, spectroscopy and chromatographic techniques

Cite as:

Thakur KS, Patil P and
Gawhankar M:
Standardization of
ayurvedic formulation
“Arjunarishta” in terms
of physicochemical,
spectroscopy and
chromatographic
techniques. Int J Pharm
Sci & Res 2020; 11(12):
6237-42. doi: 10.13040/
IJPSR.0975-8232.11(12).
6237-42.

Publication Year:

2020

Collaborating Institute(s):

Shree Dhootapapeshwar
Ayurvedic Research
Foundation (SDARF),
Panvel,
Navi Mumbai -
410 206, Maharashtra.



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ABSTRACT:

Objective: Arjunarishta is an important Ayurvedic formulation with chief ingredient Arjuna (*Terminalia arjuna*), which is excellent “Hrudya” Dravya. It nourishes & strengthens heart muscles & promotes cardiac functioning by regulating blood pressure and cholesterol level. This study aims to established quality parameters for standardization of Ayurvedic formulation “Arjunarishta” on the basis of various techniques viz. Physico-chemical screening, Chromatography & IR Spectroscopy.

Method: Conventional analysis such as Organoleptic tests, pH, Alcohol content, Brix, and Specific gravity was done. Chromatographic analysis was performed to estimate Arjungenin, Ellagic acid, and Gallic acid using High-Performance Thin Layer Chromatography (HPTLC). IR fingerprint was done using Fourier transform infrared (FT-IR) spectrometer.

Result: The above analysis showed the pH of tested formulation ranges between 3.0-5.0, Brix 25-30%, and Alcohol content 6-10% v/v. Organoleptic tests confirmed characteristic odor of self-generated alcohol with sweet, astringent & slightly bitter taste. HPTLC analysis confirmed the presence of Arjungenin, Ellagic acid, and Gallic acid. FT-IR reveals unique transmittance spectra in the range of 4000 - 600 cm^{-1} .

Conclusion: This study can be used for qualitative evaluation of Arjunarishta in terms of modern parameters, which may help in the authenticity of the drug and to compile suitable information for the better utility and safe use of this formulation in therapeutics.



Shree Dhootapapeshwar Standards
SDS Monograph No. 100001
Arjunarishta



Evaluation of hypolipidemic activity of Arogyavardhini and Zpter Tablet in cholesterol-rich high fat diet (HFD) induced hyperlipidemia in Wistar rats

Cite as:

Ghadigaonkar, D. D.;
 Chawda, M. B.;
 Thakur, K. S.;
 Kushwah, P. K.
 Evaluation of
 hypolipidemic activity
 of Arogyavardhini and
 Zpter Tablet in
 cholesterol-rich high fat
 diet (HFD) induced
 hyperlipidemia in
 Wistar rats. Int J Pharm
 Pharm Sci;2019 Jun;
 11(6):1-5, doi:10.22159/
 ijpps.2019v11i6.30805.

Publication Year:

2019

Collaborating Institute(s):

Shree Dhootapapeshwar
 Ayurvedic Research
 Foundation (SDARF),
 Panvel, Navi
 Mumbai - 410 206,
 Maharashtra.



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ABSTRACT:

Objective: The present research work aims to evaluate the hypolipidemic activity of arogyavardhini and zpter tablet in high fat diet (HFD) induced hyperlipidemia in wistar rats.

Methods: Wistar rats were divided in 5 groups. The normal control group received standard pellet diet. The HFD group received HFD rich in cholesterol. The HFD+Arogyavardhini group received HFD rich in cholesterol along with Arogyavardhini treatment. The HFD+zpter group received HFD rich in cholesterol along with zpter treatment. The standard Control group received HFD rich in cholesterol and treatment with Atorvastatin. Serum Lipid profile estimation and histopathological estimations done at end treatment. Group means were compared with Analysis of Variance (ANOVA) followed by Tukey's post-hoc analysis ($P < 0.05$).

Result: HFD group shows significant ($P < 0.05$) increase in total cholesterol (TC) levels (207.15 mg/dl) and triglyceride (TG) levels (223.83 mg/dl) when compared with standard pellet fed rats (TC=151.05 mg/dl and TG=164.67 mg/dl). Treatment with Arogyavardhini significantly ($P < 0.05$) reduces the increased levels of TC (160.123 mg/dl) and TG (189.5 mg/dl) in hyperlipidemic rats. Treatment with Zpter significantly ($P < 0.05$) reduces the increased levels of TC (163.89 mg/dl) and TG (193.167 mg/dl) in hyperlipidemic rats, which is comparable to standard treatment atorvastatin (TC= 155.81 mg/dl, TG=180.33 mg/dl).

Conclusion: The observations in this study suggest that, herbal formulations arogyavardhini and zpter have the potential to overcome hyperlipidemia.



Shree Dhootapapeshwar Standards
 SDS Monograph No. 0800044
 Arogyavardhini



Qualitative evaluation and impact of Vishesh Shodhana process on Guggul (*Commiphora mukul*)

Cite as:

Thakur KS, Patil P and Gawhankar M:
Qualitative evaluation and impact of Vishesh Shodhana process on Guggul (*Commiphora mukul*). *Int J Pharm Sci & Res* 2018; 9(10): 4243-47. doi: 10.13040/IJPSR.0975-8232.9(10).4243-47.

Publication Year:

2018

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF),
Panvel,
Navi Mumbai - 410 206,
Maharashtra.



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ABSTRACT:

ABSTRACT: Objective: Guggulu is one of the important dravya (drug) used in Ayurvedic formulations since ancient time which means “Protection against diseases”. Ashuddha guggulu has physical and chemical impurities which need to be eliminated before using in formulation by shodhana. The present study was conducted to evaluate and compare the effect of different shodhana processes i.e. Samanya shodhana and Vishesh shodhana on properties of guggul by employing various physicochemical and chromatographic methods.

Method: Physicochemical screening was done by evaluating ash, Acid Insoluble Ash (AIA), Loss on Drying (LOD), Water Soluble Extractive (WSE), Alcohol Soluble Extractive (ASE) and Ethyl acetate Soluble Extractive (EASE). Chromatographic analysis was performed to estimate guggulsterone (E and Z) content and to confirm the presence of ellagic acid and gallic acid, tinosporaside and diosgenin after shodhana with Triphala kwath, Gulvel kwath and Dashmool kwath respectively, using High Performance Thin Layer Chromatography (HPTLC).

Result: The Physico-chemical studies showed decrease in LOD, Ash and AIA content and increase in extractive values such as ASE and EASE of guggul after shodhana process. The HPTLC analysis showed no significant change in guggulsterone (E and Z) content in guggul after shodhana process. The peak of ellagic acid and gallic acid, tinosporaside and diosgenin was observed in Triphala shodhit Guggul, Gulvel shodhit Guggul and Dashmool Shodhit Guggul respectively.

Conclusion: This study helps to understand the effect of Vishesh shodhana on the efficacy of drug. In this study, we established qualitative profile of Vishesh Shodhit Guggul in terms of physicochemical parameters and phytochemical content by HPTLC.

Standardization of an ayurvedic drug - Madhumeha Kusumakar Rasa by HPTLC

ABSTRACT:

Madhumeha Kusumakar Rasa (MKR) is an Ayurvedic medicine having ingredients of Vasantkusumakar Rasa, Shuddha Shilajeet, Jasad Bhasma, Extract of Mamajjaka (*Enicostemma littorale*), Haridra (*Curcuma longa*), Amalaki (*Emblica officinalis*) and Guduchi (*Tinospora cordifolia*) indicated for complications of madhumeha (Diabetes). The purpose of this work was to develop and validate HPTLC method for quantification of marker compound Swertiamarin which is expressed in formulation through one of its major ingredient (Pradhan dravya) Mamajjaka (*Enicostemma littorale*). The formulation was subjected to methanol extractions and extracted samples were applied on TLC plate precoated with Silica Gel 60GF254. The detection and quantification was performed at a wavelength of 240 nm. The method validation was carried out as per ICH guidelines. Calibration curve plotted was found to be linear in the range of 200 – 900 ng. The linear regression equation was found to be $Y = 3.50 X + 670.5$, while correlation coefficient (r^2) was 0.9996 with high reproducibility and accuracy. LOD and LOQ were found to be 67.8 and 205.6 ng respectively. Madhumeha Kusumakar Rasa samples MKR-1, MKR-2 and MKR-3 were found to contain Swertiamarin 15.08 mg/tab, 14.95 mg/tab and 14.30 mg/tab respectively. This method was thus found to be linear, precise and accurate for quantitative determination of Swertiamarin in MKR.

Cite as:

Thakur, K.S.,
 Pimpalkar, P.,
 Gawhankar, M., &
 Gudi, R. (2017).
 Standardization of an
 ayurvedic drug -
 Madhumeha
 Kusumakar Rasa by
 HPTLC.IAMJ: Volume 5;
 Issue 1; January- 2017.

Publication Year:

2017

Collaborating Institute(s):

Shree Dhootapapeshwar
 Ayurvedic Research
 Foundation (SDARF), Panvel,
 Navi Mumbai - 410 206,
 Maharashtra.



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Shree Dhootapapeshwar Standards
 SDS Monograph No. 1902614
 Madhumeha Kusumakar Rasa



Madhumeha Kusumakar Rasa

Preparation and characterization of Suvarna Bhasma Parada Marit

Cite as:

Kapil Thakur,
 Ramacharya Gudi,
 Mahesh Vahalia,
 Shekhar Shitut, Shailesh
 Nadkarni. Preparation
 and characterization of
 Suvarna Bhasma Parada
 Marit. Journal of
 Pharmacopuncture
 2017;20[1]:036-044

Publication Year:

2017

Collaborating Institute(s):

Shree Dhootapapeshwar
 Ayurvedic Research
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 Panvel,
 Navi Mumbai -
 410 206, Maharashtra.



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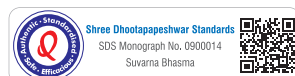
ABSTRACT:

Objectives: The goal of this study was to characterize Suvarna Bhasma Parada Marit by using the Ayurvedic test parameters, physico-chemical tests, and various instrumentation techniques.

Methods: Suvarna Bhasma, an Ayurvedic formulation manufactured as per Bharat Bhaishajya Ratnakar 5/8357 (BBR), has been studied using various instrumentation techniques: X-ray diffraction (XRD), scanning electron microscopy (SEM), energy dispersive X-ray analysis (EDAX), laser particle size distribution (PSD) analysis, fourier transform infrared spectroscopy (FT-IR), and atomic absorption spectroscopy (AAS), and physico-chemical parameters, such as the loss on drying (LOD), loss on ignition (LOI), and acid insoluble Ash (AIA) were determined. In addition, Ayurvedic tests, such as Rekhapurnatva (enterable in the furrows of the fingers), Varitaratwa (floatable over water), Nirdhoomta (smokeless), Dantagre Kach-Kach (gritty particle feeling between the teeth), were performed.

Results: The XRD study showed Suvarna Bhasma to be crystalline in nature and to contain more than 98% gold. The mean size of the gold crystallites was less than 10 microns, and the morphology was globular and irregular. Suvarna Bhasma contains gold as its single and major element, with EDAX and FT-IR spectra showing that it is more than 98% pure gold. The moisture content (LOD) is less than 0.5%, the LOI is less than 2%, and the AIA is not less than 95%. The Ayurvedic tests, as specified above, helped to confirm the quality of Suvarna bhasma prepared as per the text reference (BBR).

Conclusion: This chemical characterization of Suvarna Bhasma performed in this study by using modern instrumentation techniques will be helpful in understanding its pharmacological actions and will help in establishing quality protocols and specifications to substantiate the safety, efficacy & quality of Suvarna Bhasma.



Suvarna Bhasma (Premium)

Quality standardization of a traditional ayurvedic formulation Panchamrut Loha Guggul Tablet

ABSTRACT:

Panchamrut Loha Guggul is herbo mineral ayurvedic preparation indicated in treatment of cervical spondylitis, neuromuscular conditions, Gridhrasi (Sciatica), pain in waist and knees, and other Vata vyadhi (diseases caused by aggravated Vata dosha). The present research work was conducted to standardize Panchamrut Loha Guggul Tablets on the basis of Physico chemical screening, Elemental analysis, Chromatographic and IR spectroscopic study. Physico-chemical screening was done by evaluating Ash, Acid insoluble ash (AIA), Loss on Drying (LOD), Water Soluble Extractive (WSE) and Alcohol Soluble Extractive (ASE). The Atomic Absorption Spectrophotometric method (AAS) was applied to determine the Iron (Fe), Silver (Ag) and Copper (Cu) content. Chromatographic analysis was performed to estimate Guggulsterone (E & Z) content using High Performance Thin Layer Chromatography (HPTLC). The chemical fingerprint was taken by using Fourier transform infra red spectroscopy (FT-IR). The Physico-chemical studies showed Ash content less than 50%, AIA less than 25%, LOD less than 6%, WSE more than 25% and ASE more than 15%. FT-IR reveals unique transmittance spectra in the range of 4000-600 cm^{-1} . Iron (Fe), Silver (Ag) and Copper (Cu) content found to be more than 20 mg/tab, 10 mg/tab and 1.5 mg/tab respectively. The HPTLC analysis showed the Guggulsterone (E & Z) content more than 0.50 mg/tab. This study will help to develop quality control profile for Panchamrut Loha Guggul Tablet for future reference in determining the quality of Panchamrut Loha Guggul Tablets.

Cite as:

K S Thakur, Priyanka Patil, Madhuree Gawhankar, Shivcharan Bidve, R V Gudi. Quality standardization of a traditional ayurvedic formulation Panchamrut Loha Guggul Tablet. Int. J. Res. Ayurveda Pharm. 8 (4), 2017

Publication Year:

2017

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.



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Panchamrut Loha Guggul

Optimization and validation of microwave digestion method for determination of Copper (Cu) and Iron (Fe) in an classical ayurvedic medicine- Arogyavardhini

Cite as:

Thakur K.S, Shivcharan Bidve, Priyanka Patil, Madhuree Gawhankar, Maral A.B, Khare R.V. Optimization and validation of microwave digestion method for determination of Copper (Cu) and Iron (Fe) in an classical ayurvedic medicine- Arogyavardhini.) Int. J. Res. Pharm. Sci., 8(3), 298-303.

Publication Year:

2017

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

The main objective of this study was to optimize and validate an efficient microwave digestion method for determination of Copper (Cu) and Iron (Fe) in Arogyavardhini sample. The samples were digested in Aquaregia (a mixture of HNO₃ and HCl - 1:3) for Copper (Cu) and HCl for Iron (Fe) with closed vessel microwave digestion system. The digested samples were subjected to Atomic absorption spectrophotometer for determination of Copper (Cu) and Iron (Fe). The method validation was carried out as per ICH guidelines and can be adopted for the routine analysis of Copper (Cu) and Iron (Fe). The method was validated for precision, accuracy, linearity, limit of detection and limit of quantification. The optimized method showed good regression ($r^2 = 0.9997$). The limit of detection and limit of quantification were found to be 0.02 PPM and 0.05 PPM for Copper (Cu) and 0.28 PPM and 0.83 PPM for Iron (Fe) respectively. Accuracy of the method was checked by recovery study of three different levels with the average percentage recovery of 99.76% for Copper (Cu) and 104.66% for Iron (Fe).



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Shree Dhootapapeshwar Standards
SDS Monograph No. 0800044
Arogyavardhini



Clinical Study

Efficacy and safety evaluation of Myostaal Forte, a polyherbal formulation, in treatment of Knee Osteoarthritis: A randomised controlled pilot study

Cite as:

Tripathi RK, Vaidya PH, Raote S, Desai MM, Chawda MB, Uchil D, Rege NN. Efficacy and safety evaluation of Myostaal Forte, a polyherbal formulation, in treatment of Knee Osteoarthritis: A randomised controlled pilot study. J Clin of Diagn Res.2017; 11(10):FC06-FC10. <https://www.doi.org/10.7860/JCDR/2017/27644/10759>

Publication Year:

2017

Collaborating Institute(s):

Seth G. S. Medical College & K.E.M Hospital, Department of Pharmacology & Therapeutics and Department of Orthopedics, Parel, Mumbai - 400 012, Maharashtra.

ABSTRACT:

Introduction: Myostaal Forte, a proprietary poly-herbal formulation, is mixture of nine herbal plant extracts which possess analgesic, anti-inflammatory and chondroprotective properties. **Aim:** A prospective, randomised, active controlled, 2-arm, parallel group, assessor blind study was planned to evaluate clinical efficacy and safety of Myostaal Forte in patients of knee osteoarthritis. **Materials and Methods:** Idiopathic knee osteoarthritis cases as per American College of Rheumatology (ACR) clinical criteria were screened and recruited. A total of sixty patients were assigned to receive Myostaal Forte TDS (n=30) or Paracetamol 650 mg TDS (n=30) for six weeks. Naproxen was rescue analgesia. Modified Western Ontario and McMaster Universities Arthritis Index (WOMAC), Visual Analogue Scale (VAS), global assessment scores determined by orthopaedic physician at baseline, two, four, six weeks and telephonically at eight weeks. Safety was assessed through laboratory investigations at baseline and six weeks, adverse events and tolerability. Data were expressed as Mean \pm SD and analysed by Chi-square and unpaired t-test. p<0.05 was considered significant. **Results:** Myostaal Forte and Paracetamol showed significant reduction in osteoarthritis disease activity. Myostaal Forte produced significant improvement compared to Paracetamol, in the pain, stiffness and physical function from baseline to eight weeks (p<0.05). Significant reduction in WOMAC pain score was seen within two weeks in Myostaal Forte group (p<0.05), but not in Paracetamol group. From baseline to two weeks, the pain severity reduced in 8/8 patients in Myostaal Forte group, whereas in 4/8 patients in Paracetamol group. After treatment cessation at six weeks, symptomatic relief was sustained over two weeks in Myostaal Forte group, whereas in Paracetamol, relapse of pain and physical disability occurred within two weeks (p>0.05). No significant adverse events, changes in the laboratory parameters and excellent compliance to treatment were seen in both the groups. **Conclusion:** Earlier onset analgesic effect with sustained chondroprotection after treatment cessation makes Myostaal Forte, a safe and effective alternative for treatment of knee osteoarthritis.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070250
Myostaal Forte Tablets



Myostaal Forte Tablets

Genotoxic and Mutagenic activity of Suvarna Bhasma

Cite as:

Nilakash Selkar, Sharad Bhagat, Mukesh Chawada, Mahesh K Vahalia, Anand Puranik and Geeta Vanage. Genotoxic and Mutagenic activity of Suvarna Bhasma. Toxicology International, Sept-Dec 2016 / Vol-23/Issue-3, 221-228. DOI: 10.22506/ti/2016/v23/i3/146714

Publication Year:

2016

Collaborating Institute(s):

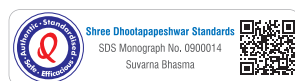
National Centre for Preclinical Reproductive and Genetic Toxicology, ICMR-National Institute for Research in Reproductive and Child Health, J. M. Street, Parel, Mumbai - 400 012, Maharashtra.

ABSTRACT:

Genetic toxicity and mutagenicity of Suvarna Bhasma (SB), an Ayurvedic drug, was determined using a battery of tests. The results of *in-vivo* Micronucleus assay and COMET assay did not reveal any significant increase in % Micronucleus frequency (MN) in bone marrow cells of mice and DNA damage in blood lymphocytes respectively after the oral administration of SB at various concentrations (3,-30 mg/kg bw) in treated animals as compared to vehicle control in either sex. The *in-vitro* chromosome aberration (CA) assay carried out with and without metabolic activation at different concentrations of SB in human lymphocyte culture did not cause any effect on structural or numerical chromosome aberrations. Suvarna Bhasma did not induce any mutagenic activity in presence and absence of S9 fractions in Ames assay employing three strains of salmonella typhimuriumTA98, TA100 and TA102. These results demonstrated that Suvarna Bhasma preparation evaluated in this study is not genotoxic and mutagenic at the concentrations tested under the experimental conditions.



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Suvarna Bhasma (Premium)

Confirmation and optimization of Bhavana Vidhi in Tribhuvankeerti Ras - An ayurvedic formulation

Cite as:

KS Thakur, Mukesh Chawda,
Nitin Mundhe, Priyanka
Pimpalkar, Madhuree
Gawhankar and RV Gudi.
Confirmation and optimization
of Bhavana Vidhi in
Tribhuvankeerti Ras - An
Ayurvedic formulation. J
Pharmacogn Phytochem
2016;5(6):205-213.

Publication Year:

2016

Collaborating Institute(s):

Shree Dhootapapeshwar
Ayurvedic Research Foundation
(SDARF), Panvel,
Navi Mumbai - 410 206,
Maharashtra.

ABSTRACT:

The present study carried out to analyze the effect of bhavana in standardisation of Tribhuvankeerti Ras. An attempt has also been made to correlate the analytical test results with the efficacy study. The standardization of Tribhuvankeerti Ras was carried out using HPTLC and FT-IR. Also, the therapeutic efficacy of Tribhuvankeerti Ras was carried out on Swiss albino mice. The HPTLC fingerprint profile depicts the presence of all three bhavana dravyas Tulasi Ras, Adrak Ras and Dhatura Ras. The result showed that all the bhavanas in Tribhuvankeerti Ras formulation has exactly same R_f values as they had in alone and FT-IR analysis confirms unique transmittance peak in range of 4000 cm⁻¹ to 600 cm⁻¹. The pharmacological result elaborates the anti-pyretic effect of Tribhuvankeerti Ras in mice. The HPTLC and FT-IR methods developed for confirmation of bhavana dravyas in Tribhuvankeerti Ras will help in establishing the specifications and need for presence of bhavana dravyas.



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Tribhuvankeerti Rasa

Evaluation of wound healing activity of Radona® Tablet in Wistar rats

ABSTRACT:

Wound healing is an important aspect in surgical procedures. Only antibiotics and local management may not be sufficient for proper wound healing. Skin care has always been the strength of Ayurveda and management of wounds has been described in depth in Ayurvedic texts. This study was aimed to evaluate the wound healing potential of Radona® Tablets in the excision and incision model in Wistar Rats. 36 Wistar Rats of either sex weighing around 150-200 g were divided equally for excision and incision models. Animals in each model were divided into three groups of 6 animals per each viz. Normal control (1 ml/kg, p.o.), Radona® Tablet (648 mg/kg, p.o.) and Soframycin (1% w/w, topical). The test drug was administered for 21 days in excision model and for 9 days in incision model. In excision model, a wound area of about 250 mm² and about 2 mm in depth was studied by tracing the raw wound area on the subsequent days 1, 4, 8, 12, 16 and 21 on graph paper for wound contraction. The scar area and time for complete epithelization was also evaluated. In incision model, on 10th day the tensile strength was measured. The results showing p values < 0.05 were considered significant and all values are expressed as mean ± S.E.M. Significant decrease in epithelization period (p<0.05 and p<0.01), scar width (p<0.05 and p<0.01) and wound contraction (p<0.05 and p<0.01) on 21st day in excision model and significant increase in tensile strength (p<0.05 and p<0.01) in incision model was observed in treated groups (Radona® Tablet and Soframycin) as compared to control group. The result suggests that Radona® Tablet has significant wound-healing activity nearly equal to standard Soframycin ointment.

Cite as:

Mundhe, Nitin.
(2015). Evaluation of
Wound Healing
Activity of Radona®
Tablets in wistar rats.
International Journal
of Pharmaceutical
Sciences Review and
Research. 31. 8.

Publication Year:

2015

Collaborating Institute(s):

Shree
Dhootapapeshwar
Ayurvedic Research
Foundation
(SDARF), Panvel,
Navi Mumbai -
410 206,
Maharashtra.



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Shree Dhootapapeshwar Standard
SDS Monograph No. 070237
Radona Tablets



Radona Tablets

Efficacy and safety of a polyherbal formulation in hemorrhoids

Cite as:

Tripathi RK,
Bolegave SS, Shetty PA,
Uchil DA, Rege NN,
Chawda MB, Rege SA.
Efficacy and safety of a
polyherbal formulation
in hemorrhoids. J
Ayurveda Integr Med.
2015 Oct-
Dec;6(4):225-32. doi:
10.4103/0975-
9476.172382. PMID:
26834421; PMCID:
PMC4719482.

Publication Year:

2015

Collaborating Institute(s):

Seth G. S. Medical
College & K.E.M
Hospital, Department of
Pharmacology &
Therapeutics and
Department of Surgery,
Parel, Mumbai - 400 012,
Maharashtra.

ABSTRACT:

Background: The medical management of hemorrhoids should include an integrated approach. This integrated approach can be achieved by polyherbal formulations containing anti-inflammatory, styptics, analgesics, and laxative effect which reduce inflammation, pain, and bleeding, and increase gastro-intestinal motility and soften stools. One such polyherbal kit is “Arshkeyt™, a 7 day kit,” which consists of oral tablets and powder along with topical cream.

Objective: Efficacy and safety of Arshkeyt™, a 7 day kit, a marketed polyherbal formulation was evaluated in comparison with conventional therapy practiced in surgery outpatient departments.

Materials and Methods: Patients (n = 90) with hemorrhoids were randomly allocated to receive either Arshkeyt™ or standard therapy (combination of oral Isabgul powder and 2% lidocaine gel) for 14 days. Assessment on the basis of rectal symptoms and proctoscopic examination was done on day 0, 7, and 14 to derive a “composite score” which ranged from 0 to 25 by a blinded evaluator. The primary endpoint was number of patients achieving composite score 0 at the end of therapy (day 14). Inter-group analysis was done using Chi-square test.

Results: On day 14, the composite score of 0 was achieved in 15 patients of Arshkeyt™ group versus 6 patients receiving standard therapy. The symptoms and signs which showed significant improvement in Arshkeyt™ group compared to standard treatment group were the tenesmus (visual analog score) (P = 0.047), anal sphincter spasm (P = 0.0495) and a decrease in the grade of hemorrhoids (P = 0.0205) on day 14. Arshkeyt™ was also more beneficial in case of bleeding hemorrhoids as compared to nonbleeding hemorrhoids (P < 0.05). The incidence of adverse drug reactions in both groups was comparable and no patient required any treatment for the same.

Conclusion: “Arshkeyt™, a 7 day kit,” was effective in the treatment of hemorrhoids and had a good safety profile.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070258
Arshkeyt™ Tablets



Arshkeyt, a 7 day kit

Anti-ulcer activity of Plantacid® Suspension in Wistar rats: A pilot study

Cite as:

Mukesh B Chawda,
Nitin A Mundhe, Venu
Gopal Jonnalagadda,
Kapil S Thakur, MK
Vahalia, Shekhar S
Shitut. Anti-ulcer
activity of Plantacid®
Suspension in Wistar
rats: A pilot study. J
Pharmacogn
Phytochem
2015;4(4):175-178.

Publication Year:

2015

Collaborating Institute(s):

Shree Dhootapapeshwar
Ayurvedic Research
Foundation (SDARF),
Panvel,
Navi Mumbai -
410 206,
Maharashtra.

ABSTRACT:

Background: The main intent of this study is to evaluate the antiulcer activity of Plantacid® suspension on non-steroidal anti-inflammatory drugs (NSAID's) -induced ulcers in the rat model.

Methods: 24 Wistar Rats weighing around 180-200g were fasted for 12 hours before the study and arbitrarily divided into 4 groups of 6 animals each. The 4 groups were: Vehicle (1 ml/kg, p.o), indomethacin (100 mg/kg, p.o), Plantacid® suspension (2.7 ml/kg, p.o), and Ranitidine (100 mg/kg, p.o) groups respectively. The treatment was given 60 minutes before the administration of indomethacin. Effect of Plantacid® suspension was studied by calculating the ulcer score, total number of ulcers, ulcer index and percentage inhibition. The results showing p values <0.05 were considered significant and all values are expressed as mean ± S.E.M.

Results: Significant decrease in ulcer score ($p < 0.05$), total number of ulcers ($p < 0.0001$), ulcer index ($p < 0.001$), and % inhibition of ulcer was reduced by 82.06%, and 90.04 % in Plantacid® suspension and Ranitidine treated groups respectively, as compared to the indomethacin group.

Conclusion: The results indicate that Plantacid® suspension has showed antiulcer activity in experimental animals and corroborates Ayurvedic use of Plantacid® suspension in gastric ulcers.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070232
Plantacid Suspension



Plantacid Suspension

Evaluation of structural, chemical characterisation and safety studies of Samagandhak Kajjali, an Indian traditional ayurvedic drug

Cite as:

K.S. Thakur , Mahesh K. Vahalia, Venu Gopal Jonnalagadda, Khare Rashmi, Shailesh D. Nadkarni, R.V. Gudi, Shekhar S. Shitut. Evaluation of structural, chemical characterisation and safety studies of Samagandhak Kajjali, an Indian traditional ayurvedic drug. J Pharmacogn Phytochem 2014;2(6):57-67.

Publication Year:

2014

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Ayurveda, literally means "science of life" and it is practised over 5000 years back onwards. In Ayurveda, several compounds of Mercury (Parada) and Sulphur (Gandhaka) are extensively used in Ayurvedic therapeutics for a wide variety of ailments and conditions. Kajjali is one such compound which is the most predominant amongst them. Kajjali, an Indian traditional drug has been used in the treatment of various disorders. In our study, processing and chemical characterization of this drug using various techniques, viz. X-ray diffraction (XRD), Scanning electron microscopy (SEM), X-ray photoelectron spectroscopy (XPS), Particle size analyzer, Thermo-gravimetry analysis (TGA), and Energy dispersive X-ray fluorescence (EDXRF) have been reported. In the perspective of safety concerns In vitro bovine shrimp assay and Osmotic fragility test also have been performed. XRD pattern of preparation delineates its cubic and hexagonal form with 2θ position at 23.08, 26.42, 27.76, 28.80, 30.46, 31.25, 43.78, 51.86, and 54.30 with d-spacing of 3.83, 3.37, 3.21, 3.09, 2.93, 2.86, 2.06, 1.76 and 1.68 Å respectively. SEM photomicrograph of Samagandhak Kajjali particles shows the appearance of particles of 10 μm and less than 5 μm size particles i.e. Upto 0.237 μm in size. Drug contains Mercury in the Mercury Sulphide (HgS) form with free Sulphur and associated with organic contents, whereas EDAX showed the presence of Hg (49.4 %), S (48.70 %), Zn (12.39 ppm), P (0.67%) and Selenium (0.04 ppm) in the final preparation of Kajjali. There is no significant ($p < 0.05$) difference in the In vitro toxicity and Osmotic fragility of control group with treated ones. These findings help in understanding the therapeutic value, safety aspect and standardization of Ayurvedic drug- Kajjali. Though the metallic Mercury is known to be toxic to the biological system, no compelling evidence has been put forth to suggest any toxic effects of Kajjali. By observing the results of structural and chemical characterisation of the study, clearly delineates in crystal view manner of its safety concern.



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Evaluation of safety and efficacy of Maa-Lact in lactating Holtzman rats

Cite as:

Dhumal, Rohit & Selkar, Nilakash & Chawda, M.B. & Thakur, Kapil & Vahalia, M.K. & Gopal, Venu & Vanage, Geeta. (2014). Evaluation of safety and efficacy of Maa-Lact in lactating Holtzman rats. Asian Pacific Journal of Reproduction. 3. 8–12. 10.1016/S2305-0500(13)60177-3.

Publication Year:

2014

Collaborating Institute(s):

National Centre for Preclinical Reproductive and Genetic Toxicology, ICMR-National Institute for Research in Reproductive and Child Health, J. M. Street, Parel Mumbai - 400 012, Maharashtra.

ABSTRACT:

Objective: To evaluate the safety & efficacy of Maa-Lact granules for its galactogogue activity in Holtzman rats and its effect on suckling pups.

Methods: Group I rats were treated as control, group II and III rats were treated with 500 mg/kg, 1 000 mg/kg of Maa-Lact granules for 21 days. Weekly body weights of dams and pups were collected, litter survivability for 22 days and ocular blood samples were collected on 1st day of parturition and 21st day of post parturition for the estimation of prolactin levels. On 21st day blood samples were collected from retro-orbital sinus for haematological and biochemical estimations. On the same day of weaning rats were sacrificed and subjected to necropsy and individual organ weights were recorded

Results: No significant difference in weekly food weight consumption, body weights between control & treated groups with normal clinical signs. There is no mortality in dams through the study period with no significant difference in pups weights. The percentage mortality in pups was 14.43 %, 14.07 %, and 13.42% in group I, group II and group III, respectively. The histopathological finding has shown that treated groups have less convulsion and adipose tissue deposition along with increase in length and branching of lactiferous duct and alveolar size.

Conclusion: Based on above results, it can be concluded that Maa-Lact possesses significant galctogogue activity.



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Abrogation of carbon tetrachloride (CCl₄) induced hepatotoxicity by Arogyavardhani in Wistar rats

Cite as:

Gopal, Venu & Selkar, Nilkash & Vemula, Sampath & M.B.Chawda, & Thakur, Kapil & Shitut, Shekhar. (2014). Abrogation of carbon tetrachloride (CCl₄) induced hepatotoxicity by arogyavardhani in wistar rats. Asian Journal of Pharmaceutical and Clinical Research. 07. 183-185.

Publication Year:

2014

Collaborating Institute(s):

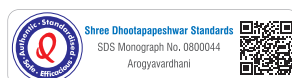
Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

From long back Arogyavardhani, a herbo-mineral preparation is used in the affections of liver & spleen disorders as an ayurvedic preparation. The present study was aimed to evaluate the hepatoprotective effect of Arogyavardhani in carbon tetrachloride (CCl₄) induced liver damage in wistar rats. In the present study Arogyavardhani A (65 mg/kg, p.o) and Arogyavardhani B (65 mg/kg, p.o) were used to screen the hepatoprotective activity. Hepatotoxicity was induced by the CCl₄ (3 ml/kg, p.o), and silymarin (50 mg/kg, p.o) was taken as a standard. Biochemical parameters like serum glutamate oxaloacetate transaminase (SGOT), serum glutamate pyruvate trasaminase (SGPT), alkaline phosphatase (ALP), total bilirubin and direct bilirubin levels were estimated. Histopathological examination of liver samples were also done. CCl₄ treated groups showed the elevated levels of biochemical parameters like SGOT, SGPT, ALP, total bilirubin, and direct bilirubin levels. In-case of Arogyavardhani treated groups significantly (p<0.01) prevented this hepatotoxicity. Histopathological examinations revealed the post-treatment of Arogyavardhani exhibited the protection of liver tissue from CCl₄ induced hepatotoxicity. The observed results strongly support the hepatoprotective activity of Arogyavardhani against CCl₄ induced hepatotoxicity.



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Evaluation of the chondroprotective effect of an ayurvedic formulation Myostaal Forte tablet in experimental model of osteoarthritis in rats

Cite as:

"Lahkar M, Chawda MB, Selkar NA, Allakonda L. Evaluation of the Chondroprotective Effect of an Ayurvedic Formulation Myostaal Forte Tablet in Experimental Model of Osteoarthritis in Rats. Int J Sci Stud 2014;2(6):37-41."

Publication Year:

2014

Collaborating Institute(s):

Gauhati Medical College and Hospital,
Department of Pharmacology and
National Institute of Pharmaceutical
Education and Research,
Guwahati - 781 032,
Assam.

ABSTRACT:

Background: Osteoarthritis is one of the prevalent and degenerative disorders of the joints that causes significant pain and functional disability. It is a disease in which not only the articular cartilage of the synovial joint is affected, but also the adjacent bone, ligaments, capsule, synovial membrane, and even peri-articular muscles are distressed.

Purpose: The purpose was to evaluate the chondroprotective effect of the formulation on the monosodium iodoacetate (MIA) induced arthritis in rats.

Materials and Methods: Osteoarthritis was induced in rats by giving a single intra-articular injection of 1 mg MIA. Three groups viz. normal group, control group, and a test group were used to study the chondroprotective effect of myostaal forte in MIA induced osteoarthritis in rats. Each group had eight animals of either sex. Four animals from each treatment group were sacrificed and examined for the histopathological examinations on 14th day of treatment and remaining on the 28th day of treatment.

Results: In the Myostaal forte treated group, the chondrocytes were present up to 50% and no synovial proliferation was observed which shows the protective effect of myostaal forte against chondrocytes damage. The swelling in the knee of the myostaal forte treated group was found significantly lower.

Conclusions: Myostaal forte has chondroprotective effect and palliates the inflammation and discomfort of the osteoarthritis.



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Shree Dhootapapeshwar Standard
SDS Monograph No. 070250
Myostaal Forte Tablets



Myostaal Forte Tablets

Acute and sub-chronic toxicity (90-Day) study of Swamala (SWA)[®] in Wistar rats

Cite as:

Nilakash, S. & Jonnalagadda, G. & Chawda, M.B. & Thakur, Kapil & Vahalia, M.K. & Shitut, S.S.. (2014). Acute and sub-chronic toxicity (90-Day) study of Swamala (SWA)[®] in Wistar rats. Pharmaceutical Sciences. 20. 52-60.

Publication Year:

2014

Collaborating Institute(s):

Shree Dhootapapeshwar
 Ayurvedic Research
 Foundation (SDARF),
 Panvel,
 Navi Mumbai - 410 206,
 Maharashtra.

ABSTRACT:

Background: Swamala (SWA)[®] is an Ayurvedic proprietary product used in the treatment of general debility and in immune-compromised conditions. Despite its usefulness, there is no published data on toxicity profile of SWA[®].

Objective: The main objective of the present study was to evaluate safety of SWA[®] in an acute and 900 day repeated dose toxicity study in Wistar rats.

Methods: SWA[®] at the doses of 0, 3, 6, and 15 g/kg was administered for 90 consecutive days. Body weights and feed consumption were recorded and analyzed. At termination of the study rats were sacrificed and observed for gross pathological changes. All organ parts were collected, weighed and preserved for histopathological examination and blood was collected from retro-orbital sinus for clinical biochemical analysis.

Results: After 90 days of oral administration SWA[®] did not show any gross toxicological signs and histopathology also when compared with normal. All animals in Group IV showed significant increase in body weight as compared to that of control group animals. No mortality was observed throughout the period.

Conclusion: Finally, it was concluded that SWA[®] having no toxico-pathological effects at a dose of 15 g/Kg which is equivalent to five times the therapeutic dose administered orally for 90 days.



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Shree Dhootapapeshwar Standards
 SDS Monograph No. 070009
 Swamala Compound



Swamala Compound

Efficacy and safety of a herbo-mineral ayurvedic formulation 'Afrodet Plus®' in male rats

Cite as:

Dhumal R, Vijaykumar T, Dighe V, Selkar N, Chawda M, Vahlia M, Vanage G. Efficacy and safety of a herbo-mineral ayurvedic formulation 'Afrodet Plus®' in male rats. J Ayurveda Integr Med. 2013 Jul;4(3):158-64. doi: 10.4103/0975-9476.118706. PMID: 24250145; PMCID: PMC3821190.

Publication Year:
2013

Collaborating Institute(s):

National Centre for Preclinical Reproductive and Genetic Toxicology, ICMR-National Institute for Research in Reproductive and Child Health, J. M. Street, Parel, Mumbai - 400 012, Maharashtra.

ABSTRACT:

Background: Reverse pharmacology for drug development has been highly productive and cost-effective in recent past as it is based on the documented therapeutic effects of plants in ancient texts. Afrodet Plus® is formulated for the treatment of male infertility, which contains ancient herbo-minerals. Its efficacy and safety are validated through this animal study in reverse pharmacology mode.

Objectives: This study was undertaken to evaluate efficacy and safety of an Ayurvedic formulation Afrodet Plus® in adult male rats.

Materials and Methods: Twelve male rats (Holtzman) between 8 and 10 weeks of age were randomly selected and animals were assigned to a control and two treatment groups. Dosing was performed daily. Various parameters such as weekly body weight, hematology, serum testosterone levels, epididymal sperm count, and efficiency of Daily Sperm Production (DSP) were evaluated.

Results: It was found that epididymal sperm count had significantly increased in both low-dose (+27.39%) and high-dose (+40.5%) groups as compared to control group. The DSP also showed an increase of 43.7% at high dose of 180 mg/kg body weight as compared to the control group. An increase in sperm motility and especially progressive motility was observed when evaluated by Computer Assisted Semen Analyzer. Histological evaluation of testicular tissue for spermatogenic index revealed that the index had increased in treatment group as compared to control group.

Conclusion: This study revealed that oral administration of Afrodet Plus® resulted in significant increase in DSP in the testis along with increase in epididymal sperm count and progressive motility as compared to control group without producing any treatment-related adverse effects. These findings provide the documentary evidence that the use of Afrodet Plus® at 90 and 180 mg/kg body weight is effective and safe for the treatment of male infertility especially to improve sperm count and progressive motility.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070200
Afrodet Plus Capsules



Afrodet Plus Capsules

Sub-chronic safety evaluation of ayurvedic immunostimulant formulation 'immuforte' in rats in reverse pharmacology

Cite as:

Dhumal R, Patil P, Selkar N, Chawda M, Vahlia M, Vanage G. Sub-chronic safety evaluation of ayurvedic immunostimulant formulation 'immuforte' in rats in reverse pharmacology. *Toxicol Int.* 2013 Jan;20(1):87-94. doi: 10.4103/0971-6580.111543. PMID: 23833443; PMCID: PMC3702133.

Publication Year:

2013

Collaborating Institute(s):

National Centre for Preclinical Reproductive and Genetic Toxicology, ICMR-National Institute for Research in Reproductive and Child Health, J. M. Street, Parel, Mumbai - 400 012, Maharashtra.

ABSTRACT:

Objective: The present study was undertaken to determine target organ safety of "Immuforte" to establish relationship between dose or exposure and response and also to identify potential parameters for monitoring adverse effects of "Immuforte" in clinical studies, if any. **Materials and methods:** A total of 40 males and 40 females were randomly assigned to the four groups, namely group I (vehicle control; gum acacia), group II (120 mg/kg BW of Immuforte in gum acacia), group III (360 mg/kg BW of Immuforte in gum acacia), and group IV (600 mg/kg BW of Immuforte in gum acacia) consisting of 10 males and 10 females in each group. Additionally, a recovery group (600 mg/kg BW of Immuforte in gum acacia) containing 5 males and 5 females was included. **Results:** The results showed significant decrease in percent lymphocyte count of high and mid dose groups as compared to control group. The percent neutrophil counts in all the three treated groups of male and female rats were found to be significantly higher than that of control group ($P < 0.05$). In females MCV values in low dose and mid dose were significantly higher as compared to control ($P < 0.05$). The males from low dose group showed significant decrease in total serum protein, globulin, electrolytes, direct bilirubin, creatinine levels, whereas in mid dose group along with albumin, globulin. A significant decrease in AST and cholesterol was observed. In females, significant decrease was observed in total protein and globulin of low dose and mid dose of Immuforte-treated rats ($P < 0.05$). Though few hematological and biochemical parameters were different from control group, no dose related response was observed and further, all these values were comparable with historical control data of the colony. Terminal body weight, organ weight, gross, and histopathology did not reveal any toxicity-related any adverse effects. Heavy metal analysis of the blood samples collected from terminally sacrificed animals did not show presence of heavy metals viz. lead (Pb), mercury (Hg), cadmium (Cd), and arsenic (As). **Conclusion:** The results of the present study demonstrated that Immuforte does not cause any observable toxicity at doses used in the study when administered for the period of 90 days and is safe for the human use and thus, Immuforte could be used safely for therapeutic use in humans.



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Antiulcer activity of Amlapitta Mishran suspension in rats: A pilot study

Cite as:

Vemula SK, Chawada MB, Thakur KS, Vahalia MK. Antiulcer activity of Amlapitta Mishran suspension in rats: A pilot study. *Anc Sci Life*. 2012 Oct;32(2):112-5. doi: 10.4103/0257-7941.118551. PMID: 24167338; PMCID: PMC3807954.

Publication Year:

2012

Collaborating Institute(s):

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Navi Mumbai - 410 206, Maharashtra.

ABSTRACT:

Context: Amlapitta Mishran suspension is a poly herbal ayurvedic formulation, which has been traditionally used for acidity and gastric ulcers.

Aim: The aim of this study is to evaluate the antiulcer activity of Amlapitta Mishran on non-steroidal anti-inflammatory drugs (NSAID's) -induced ulcers in the rat model.

Subjects and Methods: The antiulcer activity of Amlapitta Mishran was investigated on indomethacin (100 mg/kg) NSAID's induced ulcers in rats. Effect of two different doses of Amlapitta Mishran was studied by calculating the total number of ulcers, ulcer index and percentage inhibition.

Statistical Analysis Used: Data was analyzed by the Student's t-test ($P < 0.05$).

Results: Amlapitta Mishran treated rats have shown significant ($P < 0.0001$) decrease in the total number of ulcers and ulcer index and significant increase in % inhibition of ulcers as compared with positive control group.

Conclusion: The results indicate that Amlapitta Mishran has showed a dose dependent antiulcer activity in experimental animals and confirms ayurvedic use of Amlapitta Mishran in gastric ulcers.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070003
Amlapitta Mishran Suspension



Amlapitta Mishran Suspension

Therapeutic profile of an ayurvedic formulation Ashotone in dysfunctional uterine bleeding (D.U.B.)

Cite as:

Shringi M, Galvankar P,
Vaidya R, Shankari K, Butt
M, Joshi B, et al.
Therapeutic profile of an
ayurvedic formulation
Ashotone in dysfunctional
uterine bleeding (DUB).
Indian Practitioner
2000;53:193-8.

Publication Year:

2000

Collaborating Institute(s):

Bharatiya Vidya Bhavan's
Swami Prakashananda
Ayurvedic Research Centre,
JVPDS, 13th North South
Road, Juhu,
Mumbai - 400 049,
Maharashtra.

ABSTRACT:

Tablet Ashotone® with *Saraca indica* as the main ingredient was studied for the control of dysfunctional uterine bleeding (DUB). This multicentric study was conducted in 30 patients of DUB drawn from three participating centres. The preparation was found to be effective in 18 patients i.e. 81.8% out of 22 patients of ovulatory DUB. In 6 cases of anovulatory DUB there was no response with short term treatment. Response to the treatment was judged by the total number of sanitary pads used and number and size of clots passed during bleeding episode in pretreatment and three treatment cycles. A significant reduction in the number of sanitary pads was observed in the 1st cycle and continued through the 3rd cycle ($p < 0.001$; paired 't' test). The duration or number of days of bleeding was also reduced in all treatment cycles ($P < 0.02$; $P < 0.01$; $P < 0.05$). In ovulatory DUB cases cyclicity was maintained and irregular bleeding or spotting did not occur. None of the women had significant side effects and none discontinued the treatment for the same. Only 4 out of 30 cases had minor transient gastrointestinal complaints in the form of mild abdominal pain and discomfort.

Additional observations showed relief of dysmenorrhoea and premenstrual tension syndrome in two cases each.



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Shree Dhootapapeshwar Standards
SDS Monograph No. 070205
Ashotone Tablets



Ashotone Tablets

Manufacturers of **Authentic, Standardised, Safe & Efficacious** Ayurved Formulations



आयुर्वेद श्रेष्ठता के १५० से अधिक वर्ष



ISO Certificate



GMP Certificate



- A successful tradition of manufacturing Ayurved medicine for over 150 years.
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- Certified Drug Testing Laboratory with Modern Technology.
- CCSEA certified Animal House for Safety and other Pharmacological studies.
- Research and Development unit registered with DSIR
- Manufactures more than 350 Granthokta, Standardised and Safe Ayurved Medicines.
- All medicines standardised on Ayurved and Modern Parameters.
- First Ayurved Company in the world which has provided QR code on product label to view Quality Monograph available on website.
- Continuous efforts towards establishing Safety of Bhasma and Rasaushadhi.
- Availability of medicines in India, Srilanka, Nepal etc.
- Collaboration with eminent institutions such as NIA – Jaipur, KEM – Mumbai, IIT – Mumbai, Parul University, Gujarat for successful completion of experimental and clinical trials.

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