SUMMARY OF SCIENTIFIC STUDIES/PUBLICATIONS
Dear Doctors and Scientists,

Dr. JRK's Siddha Research and Pharmaceuticals Pvt Ltd is stepping into the 25th successful year in business with the support and encouragement of the medical practitioners and the scientific fraternity.

We began our journey of introducing clinically effective and well researched products in 1992 with a single product- Dr. JRK's 777 oil – a formulation that made a positive global impact in the way Psoriasis is managed. It was perhaps amongst the first Siddha medicinal products to have been through an extensive set of Scientific and clinical studies.

Since then we have constantly working on evolving a number of research products from the Siddha system in various therapeutic areas substantiating their safety, efficacy and mechanisms of action on par with global expectations and standards. Over the years these studies have been published in journals of international repute.

With increased thrust on research and strengthening of our team the numbers of such publications have seen a quantum jump in the recent years and we see that being taken to new heights. We have summarized all the studies done on the Proprietary Siddha medicines in the current edition. We sincerely hope these studies help in better understanding of the products and their clinical efficacy.

Recently we have done Toxicological studies on Psoriasis products Dr. JRK's 777 oil and PSOROLIN ointment which are probably first of its kind in proprietary range.

We have also done clinical trials registered in CTRI, co-culture studies to understand the exact mechanism and need for dual drug therapy with Tolenorm in Vitiligo conditions.

As would be evident from the studies, all our products are well researched and their efficacy and mechanism well understood. We shall be happy to have your feedback and in case you wish to have further information on any of the studies please feel free to contact our personnel.

Thank you and we are looking forward for your continued support and encouragement for all our research based products.

Sincerely yours
Rajagopal JK
Director

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<table>
<thead>
<tr>
<th>Product</th>
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<tr>
<td>Psorolin® Oil</td>
<td>For Psoriasis</td>
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<tr>
<td>Psorolin® Ointment</td>
<td>For Psoriasis</td>
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<tr>
<td>Psorolin®</td>
<td>For Psoriasis, Dry skin &amp; Vitiligo</td>
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<tr>
<td>pesin® Capsules</td>
<td>Augmentive therapy for Psoriasis</td>
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<tr>
<td>aforte® Capsules</td>
<td>Augmentive therapy for Psoriasis</td>
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<tr>
<td>Lumina® Oil</td>
<td>For Dandruff &amp; Scalp Psoriasis</td>
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<tr>
<td>tole norm® Oil</td>
<td>For Vitiligo</td>
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<td>caratol®e Capsules</td>
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<td>Bekay® Capsules</td>
<td>For Hepato protection &amp; Augmentive therapy for Vitiligo</td>
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<td>Lippu® Oil</td>
<td>For Dry skin, Allergic skin &amp; Eczema</td>
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<td>Lippu® Ointment</td>
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<tr>
<td>g7® Capsules</td>
<td>For Allergic skin disorders &amp; Augmentive therapy for dry skin</td>
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<tr>
<td>Thee® gel</td>
<td>For Ulcers in diabetic skin, First degree burns, Cuts &amp; wounds</td>
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<tr>
<td>dano®</td>
<td>Anti-dandruff Oil</td>
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<tr>
<td>KESH RAKSHA® Oil</td>
<td>For Hair fall &amp; Premature greyning</td>
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<tr>
<td>KESH RAKSHA® Gel</td>
<td>For Hair damage &amp; Hair fall</td>
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<tr>
<td>Eve® fresh Pimple Cure Cream Paste</td>
<td>For Hyperpigmentation &amp; Post pimple marks</td>
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<td>Eve® fresh</td>
<td>For Pimples/Acne</td>
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<td>S.I.V.A® Herbal Drops</td>
<td>Strengthens Immune system for Psoriasis, Vitiligo &amp; Dry skin</td>
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<td>S.I.V.A® Herbal Tonic</td>
<td>For Paediatric Immune Boosting</td>
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<td>Dolowhite® Emulsion</td>
<td>For Chronic Pain</td>
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<tr>
<td>DoloBalm® Pain Balm</td>
<td>For Acute muscular pain &amp; Head ache</td>
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<tr>
<td>Micro KU®</td>
<td>For Viral Fever, Pain &amp; Adjuvant in Dengue and Chikungunya Fevers</td>
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* Proprietary Siddha Medicine
Certificates

Dr. JRK's Siddha Research and Pharmaceuticals Pvt Ltd

Summary of Scientific Studies/Publications

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Since circadian rhythm influences the pathogenesis of Psoriasis, the findings of the present study necessitate the combination therapy that includes Psorolin oil & Psorolin ointment in the management of Psoriasis.

Psorolin oil is effective in inhibiting keratinocyte proliferation. Psorolin ointment is effective in inhibiting elastase enzyme. Psorolin oil & Psorolin ointment are effective in inhibiting the proliferation and differentiation of keratinocytes in a non-cytotoxic manner.

Psorolin ointment and Psorolin oil were studied for:
1. Cell proliferation inhibition of the keratinocytes assay
2. Cytotoxicity by LDH and Tryphan blue exclusion
3. Elastase inhibition assay

Though monotherapy with Dr. JRK’s 777 oil and Psorolin ointment is effective, combination therapy (which is a part of 1-3-2 topical treatment for Psoriasis from Dr. JRK’s Siddha) shows greater effectiveness and hence inevitable for the management of Psoriasis.

A prospective, double blind, randomized, two arm, placebo controlled study to evaluate the efficacy, safety and tolerability of two proprietary herbal medicines as mono therapy and as combination therapy in adult subjects with moderate to severe Psoriasis was conducted on 42 patients for 12 weeks.

Group A: Dr. JRK’s 777 oil
Group B: Psorolin ointment.
Group C: Dr. JRK’s 777 oil and Psorolin ointment.

Improvement in PASI (Psoriatic Area Severity Index) score for combination therapy was 80% as against 50% each for mono therapy with Dr. JRK’s 777 oil and Psorolin ointment.
Physician’s Global Assessment (PGA) score for combination therapy was 4.57 as against 3.64 and 3.21 for Dr. JRK’s 777 oil and Psorolin ointment respectively.
Tolenorm oil and Tolenorm ointment (Dual Drug therapy) were found to be ideal topical agents in the treatment of all types of Vitiligo.

- 60% of patients showed faster repigmentation within 8 weeks treatment in group C, whereas in group A & B it takes 10-11 weeks for repigmentation.
- Many patients reported that both oil and ointment were user-friendly and there is no reports of burning or stinging following the topical application.

Dual Drug therapy of Tolenorm oil and Tolenorm ointment in the treatment of Vitiligo shows greater repigmentation than the individual treatment.

A clinical study was done at the Department of Dermatology, in a tertiary care hospital, Chennai. Study design was open label. 30 patients were selected for the study between the age group 14-70 years. Duration - 3 months.

- Group A - 10 patients were administered monotherapy with Tolenorm oil alone.
- Group B - 10 patients were administered only Tolenorm ointment
- Group C - 10 patients were advised to use combination of Tolenorm oil followed by Tolenorm ointment.

The patients were observed on the progress of their clinical symptoms over the study period.

Safety, Efficacy and Tolerability of Topical Tolenorm Oil and Tolenorm Ointment in Vitiligo Management- 2015.

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<td>• 60% of patients showed faster repigmentation within 8 weeks treatment in group C, whereas in group A &amp; B it takes 10-11 weeks for repigmentation. • Many patients reported that both oil and ointment were user-friendly and there is no reports of burning or stinging following the topical application. • Dual Drug therapy of Tolenorm oil and Tolenorm ointment in the treatment of Vitiligo shows greater repigmentation than the individual treatment.</td>
<td>Tolenorm oil and Tolenorm ointment (Dual Drug therapy) were found to be ideal topical agents in the treatment of all types of Vitiligo.</td>
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<td>Why is Dual Therapy for Vitiligo Essential? Scientific Proof from Co-culture Experiment.</td>
<td>The role of Tolenorm oil and Tolenorm ointment in up regulating tyrosinase activity, melanogenesis and melanocyte stimulation was studied to establish the unique therapeutic value of both Tolenorm oil and Tolenorm ointment when used in combination.</td>
<td>• Combination therapy significantly increased the dendrite formation and transfer of melanosomes to keratinocytes when compared to monotherapy.</td>
<td>Dual Drug therapy is essential for repigmentation, transfer of pigment to keratinocytes and restrict the disease progression.</td>
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Why is Dual Therapy for Vitiligo Essential?
Scientific Proof from Co-culture Experiment.

- Combination therapy significantly increased the dendrite formation and transfer of melanosomes to keratinocytes when compared to monotherapy.

Dual Drug therapy is essential for repigmentation, transfer of pigment to keratinocytes and restrict the disease progression.
### Dr. JRK's 777 Oil and Psorolin Oil Proven to be Non-Rancid and Safe

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<td>Rancid Oil: The Hidden Villain of Psoriasis. Aruna V.*, Gayathri Rajagopal. Research and Reviews: Journal of Unani, Siddha and Homeopathy, ISSN: 2394-1960 (online), Volume 2, Issue 2 p-22-25, STM Journals 2015.</td>
<td>Rancidity is an indicator of spoilage of oils. The oils with high acid value are extremely harmful. In order to establish the rancidity (Acid value) Dr. JRK's 777 oil vis-a-vis various Ayush products available in the market were evaluated.</td>
<td>• Acid value indicates the rancidity of oil which was extremely low at 1.5 and 1.0 for Dr. JRK's 777 oil and Psorolin oil which was far below the approved acid value of 7 as per BIS. Most of the branded oils sold in the market showed acid value above 50.</td>
<td>The oil chosen by the clinician for the treatment of Psoriasis should not be just based on the herbs Wrightia tinctoria, Psoralea corylifolia etc. but it should be free of rancidity. If oils are not prepared properly by following the basic tenets of the ancient Siddha system, oils can become rancid and can be harmful to psoriatic patients. Dr. JRK's 777 oil &amp; Psorolin oil are proven to be non-rancid and safe to use.</td>
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### Safety of Metals as Drug

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<td>A Unique Insight on Detoxification and Inactivation of Metal Toxicity in Herbal-Metal Preparations in Siddha System. Aruna V.*, Gayathri Rajagopal. Research and Reviews: Journal of Unani, Siddha and Homeopathy, ISSN: 2394-1960 (online). Volume 2, Issue 2 p-13-17, STM Journals 2015.</td>
<td>Metal chelating property of various time tested Siddha herbs such as Phyllanthus emblica, Embelia ribes, Elettia cardamomum, Withania somnifera, Coriocarpus epigaeus, Centella asiatica, Celastrus paniculatus, Smilax chinensis, Psoralea corylifolia, Solanum trilobatum and Indigofera aspalathoides were studied individually.</td>
<td>• Most of the plants showed metal chelating effect irrespective of plant parts used, suggesting their role in inactivating metal toxicity. • Use of these herbs in various metal preparations duly justifies their significant role in chelating and inactivating the unprocessed metals if present and their associated toxicity.</td>
<td>The study shows that metal toxicity is significantly decreased if the drug is fortified with the right choice of metal chelating herbs. Dr. JRK’s Siddha employs the right use of Siddha tenets in the choice of ingredients and modern approach in ensuring safety of drugs.</td>
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### Proof on safety of Dr.JRK's 777 oil and Psorolin ointment as per global standards (Toxicology studies)

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<tr>
<td>OECD 406</td>
<td>Skin Sensitization in Guinea pig</td>
<td>2.5 % (v/v) of product in distilled water was selected for intradermal injection. Un diluted product was selected for topical application. 2-mercaptobenzothiazole was used as positive control.</td>
<td>Did not produce skin sensitization effect after 24hrs and 48hrs of removal of the patch</td>
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<tr>
<td>OECD 405</td>
<td>Effect on Mucus membrane</td>
<td>Products were tested on New Zealand white rabbits to determine the degree of irritation on single dose in mucus membrane- vaginal route.</td>
<td>Did not produce mucus membrane irritation</td>
<td></td>
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<tr>
<td>OECD 476</td>
<td>In vitro Mammalian cell gene mutation test- Chinese hamster ovary K1 cell line</td>
<td>Products were tested to determine the relative cloning and absolute cloning efficiency. Benzopyrine at 6 µg/ml was used as positive control. S9 metabolic activator was also used.</td>
<td>Did not show any mutagenic effect</td>
<td></td>
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<tr>
<td>OECD 471</td>
<td>Bacterial reverse mutation test using S. typhimurium and E.coli WP2 uvr A</td>
<td>Products were tested at different concentration (0.1 to 5.0µl/ plate) 2- aminoanthracene – positive control S9 fraction metabolic activator was used.</td>
<td>Did not show any mutagenic effect on all four strains of S. typhimurium and E.coli</td>
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Dr. JRK's 777 oil and Psorolin ointment – proven to be safe based on the tests done as per OECD (Organization for Economic Cooperation and Development) guidelines for toxicity studies

1. Clinically effective
2. Well understood mechanism of action, safety re-established.
### Proof on safety of Dr. JRK's 777 oil and Psorolin ointment as per global standards (Toxicology studies)

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<td>OECD 474</td>
<td>Mammalian erythrocyte Micronucleus testing Swiss albino mice</td>
<td>Effect of oral administration of products at various doses was given to assess the bone marrow toxicity (micronucleus-suppression of polychromatic to total erythrocyte ratio (P/E)). Dose- 2.5 and 5.0 ml Mitomycin used as positive control.</td>
<td>Did not produce toxic effect on bone marrow and total polychromatic/erythrocyte ratio (P/E).</td>
<td>Dr. JRK’s 777 oil and Psorolin ointment – proven to be safe based on the tests done as per OECD (Organization for Economic Cooperation and Development) guidelines for toxicity studies.</td>
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| OECD 408    | Acute lethal dose | 90 days repeated administrations of various doses of products were tested in wistar rats to determine its acute lethal dose. | No change in the visceral organs and histological parameters was observed even in the animals that received high dose. | 1. Clinically effective  
2. Well understood the mechanism of action, safety re-established. |
| OECD 421    | Reproduction developmental toxicity screening | The reproductive toxicity was assessed in wistar rats by orally feeding the products with drug prior to, during and post mating. | Mother rats did not produce reproduction and developmental toxicity. Pups did not reveal any abnormalities either at reproductive and histological level. | |

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Dr.JRK’s 777 Oil

Dr.JRK’s 777 oil was formerly known as 777 oil

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| “Efficacy of 777 oil (Wrightia tinctoria) in the Treatment of Psoriasis”       | 30 patients with chronic plaque Psoriasis were taken for study at Kilpauk Medical College and Hospital, Chennai to evaluate the efficacy of coded 777 oil (Wrightia tinctoria) in the treatment of Psoriasis for 8 weeks. Patients were advised to apply 777 oil twice daily and they were assessed weekly. | • 29.4% patients showed 100% improvement              | 1. 777 oil is found to be clinically effective, non toxic and convenient to use.  
2. No side effects were observed within the short observation period. |
| “Comparative Study of Topical Calcipotriol and 777 oil in the Treatment of Psoriasis”, Dr. H.K. Kar, Dr. V. Jain, Dr. Raj Narayan, “National conference of Indian Association of Dermatologists, Venerologists & Leprologists (January 1997). | To compare the efficacy of 777 oil and Calcipotriol in the treatment of Psoriasis as topical application.  
Group A: 25 patients selected for a 12 week study (16 M and 9 F) with Calcipotriol (CPT) on right side of the body and 777 oil on left side of the body for 12 weeks study.  
Group B: 4 patients with CPT right side and coconut oil left side.  
Group C: 6 patients with 777 oil right side and coconut oil left side. | • BEFORE TREATMENT:  
- PASI CPT side – 5.4 to 41.4 (mean score 19.5)  
- 777 oil side – 5.6 to 42.5 (mean score 19.8)  
- AFTER TREATMENT: Average decrease in value of PASI score  
  CPT side – 17.7(90.8%) PASI for 777 oil side – 18.3 (91.1%) | 1. From the PASI score decline, it can be seen that 777 oil is as effective as Calcipotriol.  
2. There were no side effects and hypercalcemia observed in the patients with the usage of 777 oil.  
3. Erythema, thickness and scaling had been reduced significantly.  
4. Hypercalcemia is a well known side effect in the long-term use of Calcipotriol. |
| “Herbal Treatment (Siddha) for Psoriasis” Dr.J.R.Krishnamoorthy et al “Journal of Research in Ayurveda and Siddha” (December 1998) Vol. IX, No.3 & 4. | 30 cases were taken for follow up study for a period of 6 months with 777 oil treatment. Histopathological findings with periodic biopsy and photography before and after treatment was done. Grading of epidermal and inflammatory changes was noted. | • After treatment with 777 oil there was marked reduction in parakeratosis.  
- Diminished heights of rete ridges is seen.  
- Reduction in the number of inflammatory cells.  
- Out of 30 cases, 1 patient showed recurrence after 4 years.  
- 18 patients showed recurrence after 3 years.  
- 6 patients showed recurrence after 2 years.  
- 5 patients showed recurrence after 1 year. | 1. Majority of the patients showed no recurrence even after 2 years.  
2. 777 oil helps in postponing recurrence of Psoriasis. Severity of the lesions was very much minimised in all cases.  
3. Disappearance of scales, erythema, papular & macular lesions is highly significant. |
1. 777 oil was found to be clinically effective, safe and without any toxicity in all cases patients. No adverse reaction was noted.

- 8 patients had 100% improvement
- 4 patients had 75% improvement
- 18 patients had 50% improvement.

30 patients with chronic plaque Psoriasis were taken up study for at King George hospital, Vishakapatnam, Andhra Pradesh, India.

"Efficacy of Topical Application of 777 Oil (Wrightia tinctoria) in the Treatment Of Psoriasis", Dr.P.Lakshmi, Dr.G.Rathnakumari. Clinical trial done at King George Hospital, Vishakapatnam, India.

1. The effect of 777 oil and Psorolin ointment was proven to be growth inhibitory and not cytotoxic in nature, hence 777 oil is very safe and effective in controlling the cell multiplication of HaCaT cells.

2. 777 oil and Psorolin ointment can be used continuously for long-term treatment of Psoriasis.

777 oil effectively reduces the keratinocyte multiplication both in vitro and in vivo assay.

**Title of Study**

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</table>
| "Efficacy of Topical Application of 777 Oil (Wrightia tinctoria) in the Treatment Of Psoriasis" | 30 patients with chronic plaque Psoriasis were taken up study for at King George hospital, Vishakapatnam, to evaluate the efficacy of 777 oil in the treatment of Psoriasis for a period of 12 weeks. Four criteria- degree of scaling, plaque thickness, itching and erythema were taken up for assessment of the improvement. Patients were advised to apply the drug twice daily and assessed on a weekly basis. | - 8 patients had 100% improvement  
- 4 patients had 75% improvement  
- 18 patients had 50% improvement. | 1. 777 oil was found to be clinically effective, safe and without any toxicity in all cases patients.  
2. No adverse reaction was noted. |
| Effect of 777 Oil and Psorolin Ointment In The Multiplication Of HaCaT (human Keratinocytes) By MTT Assay" | HaCaT (Immortal Human Keratinocyte) cells were grown in Dulbecco’s Modified Eagle’s Medium (DMEM). HaCaT cells were seeded on 24 well tissue culture plate CO2 with 90% cell density and incubated overnight in CO2 and treated with 777 oil and Psorolin ointment at varying concentrations. The rate of multiplication of the cells in treated versus untreated conditions was studied by MTT assay. | 777 oil at 2.8 mg/ml inhibits the growth and proliferation of HaCaT cells by 50% i.e., IC50 (Inhibition Concentration) is 2.8 mg/ml. Psorolin ointment at 6.3 mg/ml inhibits the growth and proliferation of HaCaT cells by 50% i.e., IC50 (Inhibition Concentration) is 6.3 mg/ml. | 1. The effect of 777 oil and Psorolin ointment was proven to be growth inhibitory and ‘not cytotoxic’ in nature, hence 777 oil is very safe and effective in controlling the cell multiplication of HaCaT cells.  
2. 777 oil and Psorolin ointment can be used continuously for long-term treatment of Psoriasis. |
| “Effect of 777 Oil in Keratinocyte Proliferation Inhibition by In Vitro and In Vivo Methods" | To evaluate the efficacy of 777 oil using cell line based assay (in vitro) and animal study (in vivo study). In vitro assay : Keratinocytes cell line using MTT assay was done to study the effect of 777 oil vs Methotrexate in keratinocyte multiplication inhibition. In vivo assay : In Guinea pig, hyperproliferation was induced and 777 oil was applied topically. the level of keratinisation was studied by kinetics of cell division. | - In vitro assay: 777 oil at concentration of 1 to 2.5 microgram/ml inhibited about 60% of cell proliferation.  
- 777 oil above 2.5 microgram/ml inhibited 60 % of cell proliferation. Methotrexate at 2 microgram/ml inhibited only 24% of cell proliferation.  
- In vivo assay: The kinetics of cell division in the case of 777 oil treated was high when compared to untreated. | 777 oil effectively reduces the keratinocyte multiplication both in vitro and in vivo assay. |
Dr. JRK’s 777 Oil

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| Secret of Dr. JRK’s 777 Oil - Pharmacognostic and Cell Culture Revelation | The metabolites profile of *Wrightia tinctoria* leaf with reference to their age (young, matured and senescent) was studied by TLC (Thin-Layer Chromatography) and HPTLC (High-Performance Thin-Layer Chromatography) derivatization. Further, the difference between the young and matured leaf was tested by anatomical and pharmacognostic means. | • The profile of Dr. JRK’s 777 oil matched fully with the TLC & HPTLC profile of young *Wrightia tinctoria* leaf.  
• The quantitative and qualitative abundance of metabolites was found to be higher in young leaf.                                                                                      | The findings suggest that the careful selection of raw materials, unique processing and standardization of the same followed by the company and that’s why Dr. JRK’s 777 oil is unique and therapeutically effective for the management of Psoriasis. Dr. JRK’s 777 oil is the first, original Siddha research product with single herb *Wrightia tinctoria* for Psoriasis. |

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PESIN Capsules

Title of Study | Brief Methodology | Key Findings/Conclusion | Significance/Relevance to Product
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"Immunomodulatory Properties of Siddha Drugs- Pesin & S.I.V.A Herbal Drops". Dr.J.R. Krishnamoorthy and S. Ranganathan Journal of Research in Ayurveda & Siddha Vol-24, No1-2 Jan-jun 2003. | T-helper cell-mediated immunity impairment in animal model (rabbit) was created using drugs like cyclosporine, cyclophosphamide & Fk506 and the Pesin was co-administered. 1. The drug combination was administered orally for a period of 30 days. 2. In the test animals, the drug was co-administered everyday along with immunosuppressive drugs. 3. The T-helper cell levels were checked at regular time interval. | • An increased T-helper cell proliferation was recorded in animals treated with Pesin  
• Despite the type of immunosuppressive drugs used, the effect of Pesin on T-helper cell proliferation was significant. | Pesin capsules is an ideal drug for the treatment of various immunosuppressive disorders. |
“Therapeutic Efficacy of Pesin and the Role of Metal Moiety in Increasing The Bioavailability and Efficacy of the Drug - A Pilot Study” Dr. JR Krishnamoorthy et al, Journal Of Indain Medicine and Homeopathy, Vol.3 Oct - Dec 2003. | The present study is focussed on the herbo-mineral combinations and their therapeutic advantage over herbal combinations alone while treating certain chronic illness or certain specific disorders. 6 New zealand white rabbits were grouped into 3 groups with 2 rabbits each. All the three groups of the animals, the drug Prednisolone administered orally at 5mg/kg body wt/day. On the third day of Prednisolone administration, treatment with the herbo-metal drug was started.  
Group A animals – Pesin was administered at 5mg/kg body weight/day.  
Group B animals – Only Linga chendooram was administered at 5mg/kg body weight per day.  
Group C animals – Only the Herbal moiety in the Pesin was administered. | • Co-administration of the Pesin has counteracted with Prednisolone and maintained the T-cell levels in both animals.  
• However the effect of Pesin can be seen only after 10 days of administration.  
• When the Herbal moiety alone co-administered with Prednisolone did not affect the immunosuppressive effect of Prednisolone.  
• By 30th day, the T-cell levels dropped down to zero.  
• When the Linga chendooram alone was co-administered with the Prednisolone, the immunosuppressive effect of Prednisolone was unaltered. | 1. Pesin capsule is therapeutically effective in immunosuppressive conditions.  
2. The metal moiety in Pesin capsules increases the bioavailability & immuno-boosting nature. |
1. The effect of Methotrexate was not affected by Pesin capsules & S.I.V.A Herbal drops administration.

2. There is no drug interaction in co-administration of Pesin capsules & S.I.V.A Herbal drops with Methotrexate.

The mitotic activity in the test and control group was observed. No statistical significant difference between mean of Pesin treated and control was observed.

The nuclear activity in test and control group was similar with 0.023% difference.

Co-administration of Pesin capsules & S.I.V.A Herbal drops along with Methotrexate did not induce any antagonistic drug-drug interaction.

To study Pesin capsule & S.I.V.A Herbal drops combination therapy for antagonistic drug-drug interaction.

8 Albino rabbits were used, divided into each groups of 4 each, GROUP A&B. Both the groups Methotrexate was administered at a dose of 0.3mg as single dose for 7 days. Group B animals , combination of Pesin & S.I.V.A was administered at 20 mg single dose for 7 days. At 7th day , mitosis level in the keratinocytes were determined using mitosis tracer and monoclonal antibody using ELISA. The rate of nuclear activity determined by tunnel assay.

The study confirms the high degree of accuracy in the distribution and homogeneity of all herbal ingredients in Pesin. The findings also confirms the standardization and perfection in the manufacturing process used by the company. (The company employs the same techniques for all the capsules manufactured). The findings also highlights the assured clinical efficacy of Pesin.

<table>
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| “Effect of Pesin and S.I.V.A Herbal Drops Combination in Methotrexate Induced Mitosis Inhibition”. | To study Pesin capsule & S.I.V.A Herbal drops combination therapy for antagonistic drug-drug interaction. 8 Albino rabbits were used, divided into each groups of 4 each, GROUP A&B. Both the groups Methotrexate was administered at a dose of 0.3mg as single dose for 7 days. Group B animals, combination of Pesin & S.I.V.A was administered at 20 mg single dose for 7 days. At 7th day, mitosis level in the keratinocytes were determined using mitosis tracer and monoclonal antibody using ELISA. The rate of nuclear activity determined by tunnel assay. | • The mitotic activity in the test and control group was observed. No statistical significant difference between mean of Pesin treated and control was observed.  
• The nuclear activity in test and control group was similar with 0.023% difference.  
• Co-administration of Pesin capsules & S.I.V.A Herbal drops along with Methotrexate did not induce any antagonistic drug-drug interaction. | 1. The effect of Methotrexate was not affected by Pesin capsules & S.I.V.A Herbal drops administration.  
2. There is no drug interaction in co-administration of Pesin capsules & S.I.V.A Herbal drops with Methotrexate. |

Use of Powder Microscopy in the Validation of Polyherbal Churnum: Pesin


The scope of powder microscopy in the evaluation of homogeneity and uniform dispersal of different herbal powders in the Churnum Pesin. Further, the thin layer chromatographic analysis was performed for individual ingredients present in Pesin and the product as a whole.

• The unique characteristic of each herb in pesin was identified and their relative abundance was established through microscope.  
• TLC profile also confirms the presence of the individual herbal ingredients in the total mix.  

The study confirms the high degree of accuracy in the distribution and homogeneity of all herbal ingredients in Pesin. The findings also confirms the standardization and perfection in the manufacturing process used by the company. (The company employs the same techniques for all the capsules manufactured). The findings also highlights the assured clinical efficacy of Pesin.
A-forte shows greater dissolution in acidic pH and hence is not desirable to be given either before food or in empty stomach as it may cause gastric irritation. However, *Phyllanthus emblica* creates acidic micro-environment when the drug is administered post food and ensures greater release. The use of A-forte after food as recommended by the company is scientific as revealed by the study finding.

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| Stomach Mimicry of A-Forte for Pharmacokinetic Insight | The release of A-forte in different pH conditions were studied in order to understand its pharmacokinetic dynamics. The release pattern was measured by spectrophotometry. A-forte capsule released under different conditions were studied by Thin-Layer Chromatography (TLC). | • The rate of dissolution of A-forte capsules was high in the pH of 2.  
• The right choice of the excipient - *Phyllanthus emblica* was made to give the acidic environment for better elusion.  
• The chemical property of herbal actives were not influenced by the pH. *Phyllanthus emblica* provides the right environment for greater dissolution when the drug is given post food and also does not induce. | A-forte shows greater dissolution in acidic pH and hence is not desirable to be given either before food or in empty stomach as it may cause gastric irritation. However, *Phyllanthus emblica* creates acidic micro-environment when the drug is administered post food and ensures greater release. The use of A-forte after food as recommended by the company is scientific as revealed by the study finding. |
Psorolin medicated bathing bar

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| Presence of Free Form of Kumari Thailam and Indrajava Thailam in Psorolin Medicated Bathing Bar as Reason for its Clinical Use. | The retention of quantity and efficacy of Wrightia tinctoria oil (Indrajava thailam) and Aloe vera oil (Kumari thailam) in Psorolin medicated bathing bar was evaluated by the following methods  
1. Presence of extractable ‘free oil’.  
2. Analytical and TLC characterization of ‘free oil’. | • The free oil present in Psorolin medicated bathing bar was found to be 10% and the free oil matched with characteristics of Kumari thailam and Indrajava thailam irrespective of the age of the Psorolin medicated bathing bar (shelf life). | Free state of the oils (Indrajava and Kumari thailam) and its well preserved chemical characteristics clearly suggest that ingredients with therapeutic value are available in sufficient quantities. The above findings supports the treatment value of Psorolin medicated bathing bar in the treatment of Psoriasis. |

Aruna V, Amruthavalli G.V., Gayathri Rajagopal.  
Research and Reviews: Journal of Unani, Siddha and Homeopathy ISSN: 2394-1960(online).  
Volume 2, Issue 1, STM Journals 2015.
# Lumina herbal shampoo

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<tr>
<td>‘Quick Kill Effect’ of a Herbal Shampoo Versus Contact time, Janani S, Gayathri Rajagopal Journal of Applied Cosmetology. Vol. 33, 1-7 (Jan/June -2015).</td>
<td>The quick kill effect (QKE) of the ingredients used in herbal shampoo were tested individually against Candida albicans cells. The cells treated with varying concentrations of the extracts and incubated for different time points were studied with methylene blue. The number of live versus dead cells was ascertained against the concentration and treatment time of the respective extracts.</td>
<td>• The quick kill effect of these herbal extracts suggests their outstanding value in wash-off products like shampoo as potent anti-fungal agents. Most of the anti-dandruff shampoo preparations despite having effective anti-fungal agent show poor efficacy mainly due to short contact time.</td>
<td>The superiority of Lumina herbal shampoo which is formulated with unique herbal extracts with their quick kill effect on microorganisms. The study also justifies the claim that Lumina can be used to treat Psoriasis, scalp scales and dandruff.</td>
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### Tolenorm Oil & Ointment

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<tr>
<td>“Efficacy of Topical Application of Tolenorm Oil/Ointment in the Treatment of Vitiligo”, G. Ravichandran, M. Jayaraman. Dermavision beyond 2000. Presented in IADVL (2000) Bangalore. Clinical study done at Government Stanely Medical College, Chennai. Total number of patients - 50 Vitiligo patients for 1 year 20- Focal vitiligo 15- Generalized vitiligo 8- Segmental vitiligo 5- Acral vitiligo 2- Lip vitiligo Apply Tolenorm Oil/Ointment on the depigmented region once a day and expose to sunlight.</td>
<td>• Repigmentation in 6-8 weeks  • Near complete repigmentation seen in segmental &amp; focal vitiligo is 9-10 months.  • Generalised vitiligo showed 50-60% repigmentation.</td>
<td>1. Tolenorm - single topical agent was found to be very effective. 2. Nature of repigmentation - uniform, smooth and complete. 3. Topical Tolenorm- management of extensive cases of Vitiligo.</td>
<td></td>
</tr>
<tr>
<td>“Clinical Experimental Research Study on Certain Herbal, Mineral and Metal Compounds Used in Siddha Medicine – For Management of Venpadai – Vitiligo”, Krishnamoorthy J.R., Ranganathan S, &quot;Journal of Research in Ayurveda and Siddha&quot; (June 2001) Vol. XXII, No. 1-2, 1-11. The clinical efficacy of herbal formulations in the treatment of Vitiligo. Trial 1- Tolenorm oil for topical application only. Trial 2- Tolenorm oil topically and Caratol-E capsules orally. Trial 3- Tolenorm oil topically, Bekay capsules orally. The extent of re-pigmentation was recorded periodically. Trial 4- 2 mm epidermal punch from non-vitiligo skin was collected and grafted on to the vitiligenous tissue. After graft acceptance, Tolenorm was applied.</td>
<td>• Trial 1- Repigmentation of 65-70% observed (Tolenorm alone)  • Trial 2- Repigmentation of 75-90% observed (Tolenorm + Caratol-E)  • Trial 3- Repigmentation of 60-70% observed (Tolenorm + Bekay)  • The pigmentation from the periphery of the grafted skin to the vitiligenous region in a centripetal manner was observed in Tolenorm treated region where as in control site, the pigmentation was very insignificant.</td>
<td>The combination therapy of Tolenorm oil and Caratol-E capsules is ideal for the treatment of Vitiligo.</td>
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<td>“Study on the Clinical Efficacy of Tolenorm Oil/Ointment as Topical Agent in the Treatment of Vitiligo- Clinical Trial Report.” Kilpauk Medical College &amp; Hospital, Chennai. Dr. S. Gomathy, Dr. Jayakumari jeevan, Dr. Dhanalakshmi UR, presented in IADVL(2005), New Delhi. Evaluation of Tolenorm in 170 Vitiligo patients for 3 years (children 13, females 63 and male patients 94) was done. The usage instructions include Sun exposure for 5 minutes after application of Tolenorm.</td>
<td>• Early pigmentation of 25% was observed in 42% of patients in 12 weeks treatment.  • During 2nd year, repigmentation of 75% was observed in 71% of patients.  • Complete repigmentation of 90% was observed in 62% of patients by 3rd year.</td>
<td>1. Tolenorm as single topical agent was found to be very effective in the treatment of Vitiligo. 2. The nature of repigmentation was uniform, smooth and complete. 3. No side effects/Skin sensitivity reactions was observed in any of 170 patients.</td>
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* This document/booklet is meant for use by registered medical practitioner, hospital or laboratory only. *
**Title of Study** | **Brief Methodology** | **Key Findings/Conclusion** | **Significance/Relevance to Product**
--- | --- | --- | ---
“Study on the Effect of Tolenorm and Carotol-E in Melanogenesis in Cultured Melanocytes”, Dr. Krishnamoorthy J.R., Gokulshankar S. | Tolenorm and Carotol-E capsules - Siddha proprietary formulations are used by the clinicians for the treatment of Vitiligo. Clinical studies have shown both Tolenorm and Carotol-E are effective in the treatment of Vitiligo. The present study was conducted to establish whether these drugs affect the TrP1 & TrP2 as well as pre-transcriptional stage of melanogenesis. | • Dose dependent activity of Tolenorm in melanin production was observed in B16F10 cell line.  
• Increased level of melanin synthesis of 70% was observed when the cell line was treated with 20 microgram of Tolenorm.  
• Carotol-E slightly increased the melanogenesis when combine with Tolenorm in B16 cell line.  
• An increase of melanin synthesis at 115 times was observed with Tolenorm treatment as against untreated control.  
• Treatment group shows 140 times increase in Tyrosinase activity as against untreated control.  
• Tolenorm effectively increased mRNA expression and TrP1 and TrP2 indicating the event to be at transcriptional level.  
• Treated with DOPA solution and dark DOPA melanin bands were observed , Tolenorm increased DOPA activity by 160 times.  
• The prolonged incubation of 72 hours, the cells with Tolenorm showed increased tyrosinase(120%), TrP1 and TrP2 specific proteins.  
1. Tolenorm and Carotol-E are safe, effective medication for the treatment of Vitiligo.  
2. They significantly increased the melanin synthesis. |
“Involvement of Tolenorm – A Siddha Proprietary Medicine in the Regulatory Mechanism of Melanogenesis Both at Transcriptional and post Transcriptional levels”. Dr. J.R. Krishnamoorthy, Dr. S. Ranganathan, Dr. M.S. Ranjith. NIMA’S Clinician, Vol-1, Jan 2008. | The following assays were used in the study  
1. B16F10 murine melanoma cells in cell lysate.  
2. Tyrosinase assay was performed.  
3. On mRNA specific to TrP1 (Tyrosinase-related protein 1) and TrP2 (Tyrosinase-related protein 2).  
4. DOPA chrome assay was performed.  
5. Protein expression specific to COOH termini of TrP1 and TrP2. | • An increase of melanin synthesis at 115 times was observed with Tolenorm treatment as against untreated control.  
• Treatment group shows 140 times increase in Tyrosinase activity as against untreated control.  
• Tolenorm effectively increased mRNA expression and TrP1 and TrP2 indicating the event to be at transcriptional level.  
• Treated with DOPA solution and dark DOPA melanin bands were observed , Tolenorm increased DOPA activity by 160 times.  
• The prolonged incubation of 72 hours, the cells with Tolenorm showed increased tyrosinase(120%), TrP1 and TrP2 specific proteins.  
1. Tolenorm alter the levels of TrP1 and TrP2 as they play a critical role in melanin biosynthesis.  
2. The reactivity of DOPA staining consistent with the protein levels seen in western blot suggest that Tolenorm alter mRNA levels for melanogenic enzymes.  
3. Tolenorm alters the process of melanogenesis both at transcriptional and post transcriptional level.
## Caratol-E capsules

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Trial 1- Tolenorm oil for topical application only.  
Trial 2- Tolenorm oil topically and Caratol-E capsules orally.  
Trial 3- Tolenorm oil topically, Bekay capsules orally. The extent of re-pigmentation was recorded periodically.  
Trial 4- 2 mm epidermal punch from non-vitiligo skin was collected and grafted on to the vitiligenous tissue. After graft acceptance, Tolenorm was applied. | • Trial 1- Repigmentation of 65-70% observed (Tolenorm alone)  
• Trial 2- Repigmentation of 75-90% observed (Tolenorm + Caratol-E)  
• Trial 3- Repigmentation of 60-70% observed (Tolenorm + Bekay)  
• The pigmentation from the periphery of the grafted skin to the vitiligenous region in a centripetal manner was observed in tolenorm treated region where as in control site, the pigmentation was very insignificant. | The combination therapy of Tolenorm oil, Caratol-E capsules and Bekay capsules is ideal for the treatment of Vitiligo. |
| “Study on the Effect of Tolenorm and Caratol-E in Melanogenesis in Cultured Melanocytes”, Dr. JR Krishnamoorthy. Gokulshankar S. | Tolenorm and Caratol-E capsules - Siddha proprietary formulations are used by the clinicians for the treatment of Vitiligo. Clinical studies have shown both Tolenorm and Caratol-E are effective in the treatment of Vitiligo. The present study was conducted to establish whether these drugs affect the TrP1 & TrP2 as well as pre-transcriptional stage of melanogenesis. | • Dose dependent activity of Tolenorm in melanin production was observed in B16 cell line.  
• Increased level of melanin synthesis of 70% was observed when the cell line was treated with 20 microgram of Tolenorm.  
• Caratol-E slightly increased the melanogenesis when combine with Tolenorm in B16 cell line. | 1. Tolenorm and Caratol-E are safe, effective medication for the treatment of Vitiligo.  
2. They significantly increased the melanin synthesis. |
**Bekay capsules**

**Hepatoprotective Effect of Bekay against CCl4-Animal Model Study.**

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| Hepatoprotective Effect of Bekay against CCl4-Animal Model Study.              | Carbon tetrachloride (CCl4) was used to damage the hepatic cells in three groups of animals  
Group 1: Normal animals  
Group 2: CCL4 alone treated animals  
Group 3: CCl4 + 30 mg Bekay treated animals  
Liver enzyme levels were measured in all the three groups which is an indicator of the extent of hepatic damage in the animals. | • Treatment with Bekay capsules brought down the level of liver enzymes such as ALT, AST, ALP, LP and Bilirubin to normal. (Group 3 animals)  
• Treatment with Bekay capsules increased the level of liver enzymes such as TSP, SOD, CAT, GSH, GLY and GPX to normal. (Group 3 animals) | The study proves that Bekay capsules offers excellent hepato protection and improves liver functioning for effective Vitiligo treatment.                                                                                     |
## G7 capsules

### Summary of Scientific Studies/Publications

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| "Herbal Solutions for Allergy". Dr.J.R. Krishnamoorthy. Journal of Indian Medicine & Homeopathy. April-June 2002. | G7 Capsule was evaluated for its efficacy in the management of allergic disorders by 1. In vitro study: Isolation of peritoneal mast cells from peritoneal cavity of female BalB-C mice after injecting with spores of Aspergillus niger. mast cells were treated with various concentration of G7 capsules. The amount of histamines released from G7 treated & untreated cells were quantified using radio labeled antihistamines & counting by Scintillation chamber. Protease estimated spectrophotometrically at 280nm. 2. In vivo: Dust inhalation study G7 was orally adminstred to animal 1hr prior to challenge with standard allergens & evaluation of mast cell degranulation inhibiting property of G7. | • Mast cells contribute to a great extent to hypersensitive problems.  
• The ingredients of G7 viz. Phyllanthus emblica, Smilax chinensis, Withania somnifera etc., have been known to have strong anti allergic activity & block degranulation of mast cell & other granulocytes confirmed by both in vitro & in vivo. | G7 capsule is very effective in management of allergy related problems & significantly block the degranulation of mast cell. |
| "Effective Management of Allergy by a Siddha Preparation- In Vitro Study" Dr. JR.Krishnamoorthy , Ranjith MS, Gokulshankar S, Sumitra R, Ranganathan S ,Mohanty BK. Egyptian dermatology online Journal, Vol. 7 No 1,1, June 2011. | An in vitro study was conducted to evaluate the effect of G7 in the following 1.Effect of G7 in inhibition of histamine release from mast cells.  
2.Effect on release of IL1α and IL8 from keratinocyte culture.  
3.Reduction on histamine induced skin reactions. | • The histamine release from cultured mast cells lowered with increase dose of G7.  
• The release of IL1α was highly suppressed by G7 at 100 micro gram concentration.  
• G7 effectively supressed the release of IL 8 by keratinocytes when irradiated with UV or induced by PMA (Pharbol-12 - myristate 13-acetate) | 1. G7 capsule is effective in retarding the mast cell degranulation event, which is evident from the recorded lower quantity of histamine released in vitro.  
2. It shows the effect of G7capsule in controlling the participation of keratinocytes and in turn reduction of key interleukins in the allergic and inflammatory process. |
| "Effect of Topical Application of G7 in Reducing Histamine Induced Skin Reactions-A Preliminary Study". Journal of Medicina plants & Research Vol.5 (10), pp.2104-2106,4 June,2011. | The effect of G7 as topical preparation in reducing histamine induced wheel and flare reaction was studied in human volunteer. Substance P was used as positive control. Histamine was prick tested on G7 pre-treated skin in the volar forearm. The extent of erythema, oedema and itching were scored. | The erythema (wheel & flare reaction) was totally absent at G7 pre-treated site. Further, dose-dependent effect was also observed. | G7 capsule is very effective in the management of allergic & inflammatory disorders of the skin by controlling the release of histamine. |
### S.I.V.A Herbal drops

**Title of Study**


- "Effect of Pesin and S.I.V.A Herbal Drops Combination in Methotrexate induced Mitosis Inhibition".


**Brief Methodology**

- Subsequently the effect of S.I.V.A Herbal drops in phagocyte mediated immunity was studied by in vitro & in vivo. The isolated peritoneal phagocytes were pre-treated with S.I.V.A Herbal drops and later were infected with fungal spores of Candida albicans and Aspergillus niger.

- To study Pesin capsule & S.I.V.A Herbal drops combination therapy for antagonistic drug-drug interaction.

- Psoriatic patients are divided in to two groups with 7 patients in each. Group A patients were administered with S.I.V.A Herbal drops alone. Group B group patients were asked to apply 777 oil topically & oral administration of S.I.V.A Herbal drops.

**Key Findings/Conclusion**

- Significant increase in the level of phagocytosis of fungal spores was recorded in S.I.V.A Herbal drops treated macrophages.

- The kinetics of phagocytosis was recorded to be 4hrs in S.I.V.A Herbal drops treated groups whereas in control 7 hrs.

- Spore germination inside the phagocytes & cell death of the macrophages was significant in case of untreated cells as against test & it was confirmed by tryphan blue exclusion technique.

- The mitotic activity level in keratinocytes were determined using mitosis tracer and monoclonal antibody using ELISA. The rate of nuclear activity determined by tunnel assay.

- The mitotic activity of both test and control groups was observed.

- No statistical significant difference between mean of Pesin capsules & S.I.V.A Herbal drops treated and control was observed.

- The nuclear activity in Test and control group was similar with 0.023% difference.

- Co-administration of Pesin capsules & S.I.V.A Herbal drops along with Methotrexate did not induce any antagonistic drug-drug interaction.

- Significant reduction in number of days required for resolution of symptoms of Psoriasis was observed in patients under combination therapy of oral S.I.V.A Herbal drops with the topical 777 oil.

**Significance/Relevance to Product**

- S.I.V.A Herbal drops is an ideal drug for the treatment of various immunosuppressive disorders.

- 1. The effect of Methotrexate was not affected by Pesin capsules & S.I.V.A Herbal drops administration.

- 2. There is no drug interaction in co-administration of Pesin capsules & S.I.V.A Herbal drops with Methotrexate.

- The study findings clearly demonstrates that combination therapy of S.I.V.A Herbal drops along with topical 777 oil helps in management of Psoriasis effectively.
### Title of Study: Immuno Protective Effect of S.I.V.A Herbal Drops in Animals Challenged with Candida albicans

**Brief Methodology:**
- 9 rabbits were divided into 3 groups viz., A, B & C.
- To all the 3 groups of animal were administered with prednisolone for 7 days, in group B treated with S.I.V.A Herbal drops.
- A- Untreated group
- B- S.I.V.A Herbal drops treated group
- C-Control group.
- After 8 days, the animals were challenged with Candida albicans through intravenous route and the second challenge done on day 10. The animals were tested for various findings like clinical, histopathological & culture.

**Key Findings/Conclusion:**
- High immuno protective effect of S.I.V.A Herbal drops was observed.
- The clinical findings such as pyrexia, dyspnea, shivering, ataxia were not observed only in the S.I.V.A treated group B.
- Mortality (death) rate nil.
- The histopathological findings showed the haemorrhages in the viscera, necrotic foci etc were observed in the group A & C where as S.I.V.A Herbal drops (B) treated groups remains normal.
- The blood & faecal matter negative for Candida albicans in Group B animals. (S.I.V.A. treated)

**Significance/Relevance to Product:**
- S.I.V.A Herbal drops offers sufficient immune protection for treatment of fungal infections.

### Title of Study: Efficacy, Tolerability and Compatibility of S.I.V.A Herbal Drops as an Immunomodulator in Skin Infections of Microbial Origin (Candidiasis and Dermatophytosis)

**Brief Methodology:**
- Group A patients- treated only with antifungal drugs.
- Group B patients- S.I.V.A Herbal drops co-administered with standard anti fungal drugs.

**Key Findings/Conclusion:**
- Near complete reduction in itching was observed under treatment with oral S.I.V.A Herbal drops in combination with standard antifungal drugs when compared to treatment with standard antifungal drugs alone.
- Symptomatic & mycological cure achieved much faster with the combination therapy of S.I.V.A Herbal drops along with antifungal drugs.

**Significance/Relevance to Product:**
- Immunomodulatory effect of S.I.V.A Herbal drops plays a significant role in the quick recovery from fungal infections.

### Title of Study: Efficacy, Tolerability and Compatibility of S.I.V.A Herbal Drops as an Adjuvant Immunomodulator in Pediatric Upper Respiratory Tract Infections

**Brief Methodology:**
- Two groups (each with 10 patients) of pediatric age group(1-10 yrs), with upper respiratory tract infections were selected.
- Group A was given drugs like anti-congestants, anti-histamines, anti-inflammatory and antibiotics for 3 weeks. Group B was given S.I.V.A Herbal drops - 5 drops orally once a day with honey or hot water along with other routine allopathic drugs for a period of 3 weeks.

**Key Findings/Conclusion:**
- Average number of days for resolution of the disease
  - Group A patients - 24.7 days
  - Group B patients - 21.5 days
- Group B patients showed a significant reduction in their vitals (Temperature, Respiratory Rate, Pulse Rate) and lab values like ESR, WBC count, when compared to Group A.

**Significance/Relevance to Product:**
- 1. S.I.V.A Herbal drops was found to be safe and effective for the pediatric age group.
- 2. No serious adverse effects.
- 3. Reduction in the number of days required for resolution of the disease condition from the baseline.
## S.I.V.A Herbal tonic

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| “An Overview of Management of URTI and A Novel Approach Towards RSV Infection”, Dr. Krishnamoorthy J.R., Ranjith M.S., Gokulshankar S, Sumithra R, Ranganathan S, Mohanty BK and K. Babu. Respiratory diseases. Chapter 8. | 6 Juvenile chinchillas mice were grouped into 2 with 3 mice in each group. Group A - induced respiratory syncytial virus (RSV) alone, control group B - was treated previously with S.I.V.A Herbal tonic & then induced RSV virus. After 5 days of infection, animals were sacrificed & histopathological observation was done. | • The untreated animals showed signs of acute respiratory tract infection. Nasal fluids were abnormal. Histology of nasal area showed areas of hyper secretion.  
• S.I.V.A Herbal tonic treated animals remain normal and didn't show any signs of acute respiratory infection. | The study showed anti-viral and immunomodulatory effect of S.I.V.A Herbal tonic against RSV virus.                                                                                                                                 |

*This document/booklet is meant for use by registered medical practitioner, hospital or laboratory only.*
### Evefresh Cream & Evefresh Pimple Cure Cream Paste

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| “Effect of The Extract Combinations of Curcuma zedoaria & Aloe vera in Retarding Melanin Synthesis in Murine Melanoma Cells” | The extract combinations of Curcuma zedoaria & Aloe vera were tested for MELANOGENESIS & TYROSINASE ACTIVITY in B16F10 murine melanoma cells. Nearly 190% reduction in melanin synthesis was observed when cells treated with the extracts as against untreated control. Similarly the extracts also showed suppression of tyrosinase activity. | • Tyrosinase being the primary enzyme, plays major role in the oxidation of tyrosine to melanin.  
• The combination of extracts of the above plants are effective for the management of problems due to hyperpigmentation, skin darkening, tanning, post inflammatory pigmentation etc. | The blockage of tyrosinase enzyme with the use of Evefresh. A combination of the plant extracts in Evefresh cream offers dual benefit of skin lightening as well as sun protection. |
| “Extract combinations of Curcuma zedoaria and Aloe vera inhibit melanin synthesis and dendrite formation in murine melanoma cells” | Effect of the extract combinations on melanocytes was studied. | • The number and length of dendrites in extract treated melanocytes were significantly shorter when compared to untreated control.  
• The dendrites play a major role in transfer of melanocytes to keratinocytes.  
• The combination of extracts posses dual mechanism of regulating down the melanin synthesis & further transfer to skin. | The study proves combination Curcuma zedoaria & Aloe vera in the Evefresh cream offers great skin protection. |
| “Dermal Melanogenesis in Response to Combination of Curcuma zedoaria & Aloe vera- A Mexameter Based Evaluation” | Mexameter based study in 30 human volunteers was carried out for Evefresh cream to understand the clinical effect. A placebo cream was used for comparison. Volunteers were requested to apply Evefresh on right side of the fore arm and placebo on the left side of the fore arm for a period of 21 days. | • The periodic usage of cream positively correlated with the decreased level of melanin.  
• The reduction in melanin index was observed to be 3%, 5% and 14% for 7th, 14th & 21st day respectively.  
• In case of placebo, a steady increase in melanin index was noticed. | Curcuma zedoaria & Aloe vera are excellent natural agents that help in the treatment of problems associated with hyperpigmentation, skin tanning & improves complexion of skin. |

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*This document/booklet is meant for use by registered medical practitioners, hospital or laboratory only.*
### Adhesion and Arrest of Skin Microbes as Reason for Efficacy of a Pimple Cure Cream Paste (PCCP) – A Siddha Drug.

**V. Aruna, S. Janani, R. Gayathri, A. Abbas**


**Title of Study**

Adhesion and Arrest of Skin Microbes as Reason for Efficacy of a Pimple Cure Cream Paste (PCCP) – A Siddha Drug.

**Brief Methodology**

- **Evefresh Pimple Cure Cream Paste (Evefresh-PCCP)** was evaluated for its efficacy in controlling acne (pimple) both by in vitro and in-use conditions by the following methods:
  1. Study on the skin adhesion as a proof of microbial limit.
  2. Water resistance as a proof for sun protection by Mexameter.
  3. In-use evaluation of efficacy by acne sufferers.
  4. Combination treatment approach of EF-PCCP and Evefresh cream.

*EF-PCCP - Evefresh Pimple Cure Cream Paste.

**Key Findings/Conclusion**

1. Significant reduction in the microbial count was observed.
2. The cumulative % difference in erythema value decreased with increased dose of EF-PCCP.
3. 18/20 volunteers responded well to 4 week treatment. Complete remission of the symptoms and near complete remission of the post-inflammatory scars, reduction of superficial sebum, etc., were observed in all patients by 4th week.
4. The effect of EF-PCCP was further increased by combined use of Evefresh cream and further it was confirmed by the reduction in microbial load and sun protection effect.

**Significance/Relevance to Product**

Dual therapy with Evefresh Pimple cure cream paste and Evefresh cream is effective in the treatment of acne. The clinical findings show that combination therapy provides additional benefits such as improvement and glow in the skin tone, reduction of darkened skin around the neck and moisturization.
Kesh Raksha Gel / Oil

**Title of Study**


**Brief Methodology**

The hair growth enhancing property of Herbal oil (Kesh Raksha Oil) & Herbal cream (Kesh RakshaGel) was studied. In Guinea pig model, the total hair count technique was employed. Group 1- treated with oil; Group 2- treated with gel; topically tonsuring the flank regions both left and rights for treatment and control comparison. Duration of 9 days with single application per day either gel & oil. The total number of growing hairs was counted using magnifying hand lens at regular intervals (3, 6, 9 days) & compared with control. To confirm the possible mechanism of action, northern blotting was performed using shh gene.

**Key Findings/Conclusion**

- A significance increase in total number of hair grown & length in oil & gel treated areas was recorded from 3rd day of treatment.
- An increased mRNA Synthesis was recorded in dermal papillae cells of hair of animal treated with oil & gel.

**Significance/Relevance to Product**

Kesh Raksha Oil and Kesh Raksha Gel enhances the protein synthesis in the papillae cells specific for hair growth and thereby prolongs the anagen phase of the hair.

**Title of Study**


**Brief Methodology**

The hair growth promoting effect of Kesh Raksha Gel was studied in guinea pigs and Minoxidil was used as control. The hair growth initiation time and hair growth completion time were determined. Group 1 - Placebo gel Group 2 - Kesh Raksha Gel Group 3-2% Minoxidil Group 4- Untreated.

**Key Findings/Conclusion**

- Animals treated with Kesh Raksha Gel has reduced the hair growth completion time by 30% as against 53 % for 2 % Minoxidil.
- The placebo did not have any effect on hair growth completion.
- The texture of hair formed after treatment with the use of gel was soft, silky & shiny.

**Significance/Relevance to Product**

Kesh Raksha Gel has significant effect on promoting hair growth comparable to Minoxidil 2% solution. However long term side effects of use of Minoxidil is known to have multiple side effects that may be absent in the users of Kesh Raksha Gel. Further Kesh Raksha Gel ensures better texture of hair.

**Title of Study**


**Brief Methodology**

The effect of Kesh Raksha Gel was evaluated for hair damage repair and control through in vitro experiment. Pretreated hair with KR Gel and normal hair was subjected to hair damage. Hair damage was done by different means such as alkali treatment, bleach treatment, ironing.

**Key Findings/Conclusion**

- The findings compared with coconut oil usage in the same methodology.
- Repairs and controls hair damage.
- Strengthens the hair
- Decreases hair breakage
- Damage control and repairing effect of KR Gel is significant compared to coconut oil.

**Significance/Relevance to Product**

KR Gel is must for those who
- Use hair dye/hair colour
- Use shampoo/herbal hair wash powder
- Have frizzy/dry/dull hair
- Have dandruff
- Suffer from early stage of alopecia
- Use Minoxidil
They are all prone to have highly damaged hair, hence regular use of Kesh Raksha Gel will strengthen the hair and minimize hair breakage.
The present study reveals that extracts of *Wrightia tinctoria* and *Hibiscus rosa-sinensis* possess fungicidal activity and hence shall ensure that recurrence of dandruff is effectively prevented.

The study reveals that Dano - antidandruff oil is very effective against *Pityrosporum ovale* & helps in the management of dandruff.

The combination of extracts of *Wrightia tinctoria* and *Hibiscus rosa-sinensis* is effective against the clinical isolates of *Pityrosporum ovale* when tested by in vitro methods.

The combination of extracts of the above plants can be used for the treatment of dandruff.

Dano has broad spectrum antifungal activity and has antidandruff effect as proved by clinical evaluation.

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| “Anti-Pityrosporum ovale Activity of A Herbal Drug Combination of Wrightia tinctoria & Hibiscus rosa-sinensis”. Dr. JR.Krishnamoorthy, Ranganathan S. Indian Journal of Dermatology 2000; Vol 45 (3). | Anti-Pityrosporum ovale activity of herbal drug combination of *Wrightia tinctoria* & *Hibiscus rosa-sinensis* was tested in in-vitro against isolates of *Pityrosporum ovale*. | • The combination of extracts of *Wrightia tinctoria* and *Hibiscus rosa-sinensis* is effective against the clinical isolates of *Pityrosporum ovale* when tested by in vitro methods.  
• The combination of extracts of the above plants can be used for the treatment of dandruff. | The present study reveals that extracts of *Wrightia tinctoria* and *Hibiscus rosa-sinensis* possess fungicidal activity and hence shall ensure that recurrence of dandruff is effectively prevented. |
| “Dano: A Herbal Solution for Dandruff”. Dr. JR.Krishnamoorthy, Ranganathan S, Gokulshankar S, Ranjith MS, African Journal of Biotechnology Vol.5 (10), pp. 960-962, May 2006. | The MIC (Minimum Inhibitory Concentration) of Dano against *Pityrosporum ovale* was 30 mg/ml. Similarly the MIC of Dano for *Candida albicans* was 50mg/ml. Methylene blue reductase test confirms the antifungal effect of Dano antidandruff oil at sub-MIC level.  
In vivo study: Clinical and myological cure was observed in volunteers with dandruff on 4th and 8th days of use of Dano respectively. | Dano has broad spectrum antifungal activity and has antidandruff effect as proved by clinical evaluation. | The study reveals that Dano - antidandruff oil is very effective against *Pityrosporum ovale* & helps in the management of dandruff. |
Thee gel helps in cell migration & proliferation of fibroblast in the management of superficial wounds & burns.

In response to Thee gel treatment, an increased cell proliferation and cell migration was observed and the findings were comparable to EGF.

Cell migration assay on fibroblast 3T3 cells was conducted to study the wound healing effect Thee gel. For comparison a placebo and the Epidermal Growth Factor (EGF) were maintained. A scratch wound was created in the tissue culture plate and the level of cell migration in test and control plants were studied. The MTT assay was also performed to confirm the cell proliferation.

Thee gel helps in cell migration & proliferation of fibroblast in the management of superficial wounds & burns.

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