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Science behind the shelf life of Dr. JRK's Siddha products

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Abstract

Objective: Objective of the present study was to establish the role of phenoxyethanol for enhancing the shelf life of Siddha drugs. .

Methods: The method employed for preservative challenge study was used to achieve the above objective.

Results: Phenoxyethanol was proven to be effective against wide range of pathogens that affect the quality and stability of Siddha products. Further irrespective of the percentage of water activity phenoxyethanol was found to be effective.

Conclusion: Phenoxyethanol is safe and cost effective preservatives for various Siddha drugs and also it has broad spectrum anti - microbial activity.

Keywords: Phenoxyethanol, Antimicrobial activity, Shelf life, Siddha system

The present study deals with the science behind the prolonged shelf life and superiority of three Siddha drugs viz., Evefresh cream, Lippu ointment and Thee gel ointment. The findings show that phenoxyethanol is the preservative used in such products and it has broad spectrum activity. Further phenoxyethanol also work effectively in products with wide range of water activity. For the global acceptance of Siddha system of medicine phenoxyethanol holds the key.

Dr. JRK's Siddha Research and Pharmaceuticals has paid rich tribute to the ancient Siddha system of medicine by innovating and introducing wide range of Siddha products to the world at large. While introducing various Siddha drugs, the company has employed perfect strategy of connecting science with ancient Siddha tradition. Further the products are made in modern format in order to enhance the acceptance of Siddha system of medicine by the contemporary world.

Poor shelf life of herbal products is one of the predominant reasons likely limiting their global acceptance [1]. Therefore, enhancing the shelf life of herbal products and Siddha drugs is extremely important for the acceptance of the system as a whole [2].

Present study unravels the science of the three proprietary Siddha drugs of the company such as Evefresh cream, Thee gel ointment and Lippu ointment.

Thee gel ointment is composed of 80% water and hence is highly prone to microbial contamination. On the contrary the Lippu ointment is an oil dominant emulsion which is relatively resistant to contamination. The intelligent choice and wise use of phenoxy ethanol [3, 4] as the principal preservative by the company is the reason for the prolonged shelf life of the above mentioned Siddha drugs. The present study also reports the pan-antimicrobial effect of phenoxyethanol against wide range of microbes especially in two extreme ends of formulation art such as product with high water activity and product with greater percentage of oil.

For the present study, we have used three proprietary Siddha formulations such as Evefresh cream, Lippu ointment and Thee gel ointment of Dr. JRK's Siddha Research and Pharmaceuticals.

Preservative challenge study was done by using standard procedure [5]. In brief, the above products were formulated with the preservative- phenoxyethanol at 1%. 20 g of the creams were dispensed separately into nine sterilized containers in duplicate. The above set up was maintained separately for studying the preservative challenge against the three environmental isolates of *Escherichia coli, Staphylococcus aureus* and *Pseudomonas aeruginosa*. Similarly the entire experiment was done for the respective creams without preservative.

The bacterial cultures viz.,

E. coli- a total of 35055 cells of *E.coli* were used as inoculum for testing the efficacy of preservative in all the three products such as Evefresh cream, Lippu ointment and Thee gel ointment.

S. aureus- a total of 95139 cells of *S. aureus* was used as inoculum for testing the efficacy of preservative in all the three products such as Evefresh cream, Lippu ointment and Thee gel ointment.

P. aeruginosa- a total of 16309 cells of *P. aeruginosa* was used as inoculum for testing the efficacy of preservative in all the three products such as Evefresh cream, Lippu ointment and Thee gel ointment.

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All the containers were incubated at room temperature. After 7, 14 and 28 d of incubation, 0.1 g of the cream was collected aseptically from all the containers allocated for different species of microbes and were dispensed separately in 100 ml of sterilized distilled water. 0.1 ml of the sample was plated onto nutrient agar plate in duplicate and incubated for 24 h. Counting of the number of CFU's of the respective organisms that were grown in the respective plates in duplicates was done and from the above value the average was arrived.

Irrespective of the differences in the formulation of Lippu, Evefresh and Thee gel the % reduction of all the three organisms was constant by 28th day and which was ranging from 98 to 99 (table 1).

The above % of reduction was almost constant for all the three organisms irrespective of the inoculum size.

On the contrary an up-steep growth of all the microbes was observed in creams that contain no preservative (table 2).

Table1: Percentage reduction of microbes by phenoxyethanol

Organism	Products	% Reduction (mean) vis-à-vis time (The values arrived from initial load)			
		Inoculum size/no of cells	Day 7	Day 14	Day 28
Staphylococcus aureus	Evefresh	95139	21746 (78%)	13591 (86%)	135 (99%)
	Lippu		16309 (83%)	10873 (89%)	135 (99%)
	Thee gel		16309 (83%)	10873 (89%)	135 (99%)
Escherichia coli	Evefresh	35055	13591 (62%)	5496 (85%)	135 (99%)
	Lippu		13591 (62%)	8154 (77%)	135 (99%)
	Thee gel		10873 (69%)	8154 (77%)	135 (99%)
Pseudomonas aeruginosa	Evefresh	16309	8154 (51%)	5436 (67%)	271 (98%)
	Lippu		10873(34%)	8154 (51%)	135 (99%)
	Thee gel		10873 (34%)	5436 (67%)	135 (99%)

Table 2: The growth pattern of microbes in products devoid of phenoxyethanol

Organism	Products	% increase (mean) vis-à-vis time from the initial load			
		Inoculum size	Day 7	Day 14	Day 28
Staphylococcus aureus	Evefresh	95139	97858 (3%)	157660 (40%)	>200000
	Lippu		100576 (6%)	141350 (33%)	>200000
	Thee gel		106012 (11%)	13 3195 (29%)	>200000
Escherichia coli	Evefresh	35055	38055 (8%)	100576 (66%)	>200000
	Lippu		57083 (39%)	116886 (71%)	>200000
	Thee gel		51647 (33%)	146787 (77%)	>200000
Pseudomonas aeruginosa	Evefresh	16309	29301 (45%)	141350 (89%)	>200000
	Lippu		27182 (41%)	78830 (80%)	>200000
	Thee gel		40774 (61%)	108737 (86%)	>200000

The present study has clearly established that Dr. JRK's Siddha Research & Pharmaceuticals is extremely prudent and scientific in choosing the right preservative for enhancing the shelf life of time tested Siddha drugs.

We have chosen three Siddha products such as Evefresh cream, Lippu ointment and Thee gel purely because of the formulation idiosyncrasy. Irrespective of the water activity of different creams, the preservative has indeed resisted the preservative challenge and has reduced the population of the three pathogenic organisms to 98 to 99%. Further the varied sizes of inoculum of different organisms also showed equal susceptibility to the preservative. This shows the pan-antimicrobial activity of phenoxyethanol. Earlier findings also concur to our present observation [6].

Most of the Siddha products are formulated with herbs [7]. The herbs are largely processed by certain traditional methods [8]. How such traditional methods would ensure the herbs free of all microbes is unclear. This possibility might limit the shelf life of Siddha products and thus affecting their acceptance [9].

In order to enhance the global acceptance of Siddha system of medicine, the company has identified a universal preservative to enhance the shelf life of wide range of Siddha products. The careful choice of the preservative by the company is the secret science behind the products of Dr.

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JRK's Siddha Research and Pharmaceuticals. The Siddha system certainly requires such renovation to make it contemporary and effective.

The organisms such as *E. coli, S. aureus* and *P. aeruginosa* were used to challenge the preservative. These organisms assume great significance due to their ubiquitous presence in water and air as well as in human infections and further they also contribute greatly to the spoilage of various Siddha drugs as common contaminants [10]. Nevertheless, the findings clearly show that the phenoxyethanol is the best preservative for Siddha drugs.

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