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Novel Film Forming Spray from Tea Tree Leaves with Special Emphasis on Development, Formulation and Evaluation

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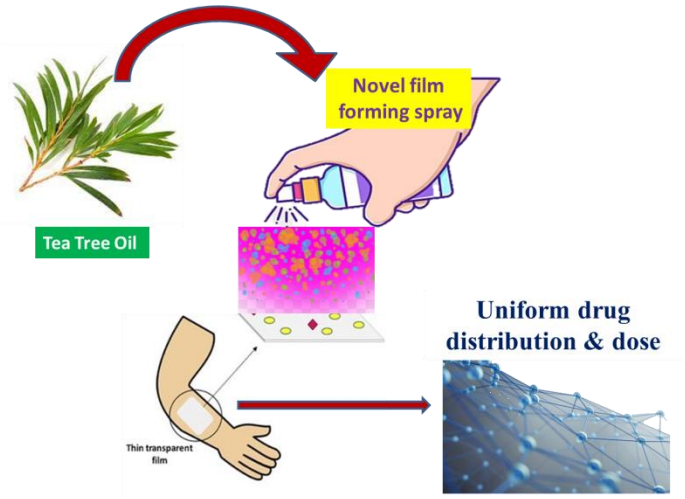
ABSTRACT

The dictum of this study was to develop topical film forming spray having tea tree oil which might increase wound healing. Film-forming sprays supply several benefits compared to standard topical preparations as a result of they will give uniform drug distribution and dose, increased bioavailability, lower incidence of irritation, continuous drug unleash, and accelerated wound healing through wet management. Film-forming sprays comprises polymers and excipients that improve the characteristics of preparations and enhance the soundness of active substances. every style of chemical compound and excipient can turn out films with completely different options. Therefore, the varied sorts of polymers and excipients and their analysis standards ought to be examined for the event of alot of best kind of film-forming spray. The chosen literature enclosed analysis on formulation and analysis of film forming spray victimization polymers and plasticizers as film-forming matrices for potential medical use. This text discusses the categories and concentrations of polymers and excipients, sprayer varieties, evaluations, and significant parameters in decisive the sprayability and film characteristics. Ultimately we have a tendency to conclude that the developed film forming spray formulations were clear, sleek and versatile in physical look. The analysis studies were conferred ability to evaporate speedily on applies, hydrogen ion concentration becomes like that of traditional skin offered of lower skin irritation. Spray is a lot of convenient to use, may be applied simply therefore improve patient acceptance and compliance.

Keywords: Tea Tree leaves, Melaleuca alternifolia, Novel film forming spray, topical drug delivery



INTRODUCTION

Injuring the skin increases the risk of infection by damaging the protective layer. This can further cause systemic infections and increase the level of complications1 Local routes of drug delivery, targeting systemic or local effects, offer several benefits, including avoidance of first-pass metabolism, low pH and enzymatic

effects in the gastrointestinal tract, and large available surface areas2–8. To improve the therapeutic effect or pharmacokinetic profile, topically administered drugs are generally prepared in dosing systems such as patches, gels, lotions, creams, ointments, or sprays9-11. Complementary and alternative medicines such as tea tree oil (Melaleuca) have become more and more popular over the last few decades. This essential oil has been used in Australia for almost 100 years and is now used worldwide as a pure oil and as an active ingredient in a variety of products. The main uses of tea tree oil in the past have benefited from the antiseptic and anti-inflammatory properties of the oil. This review summarizes recent developments in understanding the antibacterial and anti-inflammatory activity of oils and their ingredients, as well as their clinical effects. Review specific mechanisms of antibacterial and anti-inflammatory effects and briefly explain the toxicity of oils12. Many complementary and alternative medicines have become more popular in recent decades. Efforts to validate their use have led to increased investigation of their putative therapeutic properties in vitro and, in some cases, in vivo. One such product is tea tree oil (TTO). It is a volatile essential oil derived primarily from the native Australian plant Melaleuca alternifolia. TTO is used primarily due to its antibacterial properties and is included as an active ingredient in many topical formulations used in the treatment of skin infections. It is available in stores in Australia, Europe and North America and is sold as a treatment for a variety of illnesses. Tea tree oil is composed of terpenoids and may be beneficial to the skin. Tea tree oil for the skin has benefits such as anti-inflammatory, antifungal and preservatives. Tea tree oil is composed primarily of terpene hydrocarbons, primarily monoterpenes, sesquiterpenes, and related alcohols. Terpen is a volatile aromatic hydrocarbon and is considered a polymer of isoprene with the chemical formula C5H8. Using tea tree oil on the skin has several benefits. It helps treat certain skin conditions, such as acne, itching, and oily skin. It can also promote wound healing.[9]

METHODS

Tree tea leaves were collected from the local market of Chinchwad, Pune.

Optimization of excipients for film forming spray: Optimization of spray formulation includes selection and study of solvent systems, polymers, plasticizers, and other adjuncts such as methyl salicylate, menthol, and concentrations. The effect of the spray on the appearance was visually observed and applied to the skin and better aids were selected for the next attempt.[6-8]

Selection of solvent system: Tea tree oil is soluble in organic alcohol solvents, immobilizer oil, paraffin oil and propylene glycol. It is not soluble in water. Water and ethanol were used as solvents in varying concentrations. Selected solvents such as water and ethanol are safe and these common solvents are used in topical solutions and preparations.[7]

Selection of type and concentration of polymer: PVPK30 and HPMCE5 were selected to test their ability to spray to form a film of tea tree. As shown in Table 1, the various film-forming polymers were PVPK30 and HPMCE3 at different concentrations of 1.0, 2.0, 3.0, 4.0, and 5.0% by weight. Apply a film-forming spray to the skin. The polymer was selected based on the physical properties of the film. Focus on film thickness, smooth, clear white spots on the surface, and quick-drying.[11]

TABLE 1. Preparation of film forming spray using various type and concentration of polymers

Ingredients	**Formulation (%w/w)**									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
HPMC E5	1.0	2.0	3.0	4.0	5.0	-	-	-	-	-
PVP K30	-	-	-	-	-	1.0	2.0	3.0	4.0	5.0
Ethanol	49.5	49.0	48.5	48.0	47.5	49.5	49.0	48.5	48.0	47.5
Water	49.5	49.0	48.5	48.0	47.5	49.5	49.0	48.5	48.0	47.5

Selection of the type of plasticizers:

Propylene glycol (PG) and polyethylene glycol 400 (PEG 400) were selected to study their spray-forming flexibility. The various plasticizers are propylene glycol and PEG 400 at a concentration of 1.0% by weight as shown in Table 2. Apply the film forming spray to the skin. Polymers are selected based on the physical properties of the film. Focus on fragile film and white spot on the surface.

Ingredients	**Formulation w/w**			**Function**
	F1	F2	F3	
PVP K30	3.0	3.0	0	Film forming agent
HPMC E5	-	-	2.0	Film forming agent
Propylene glycol	1.0	-	-	Plasticizer
Polyethylene glycol 400	-	1.0	1.0	Plasticizer
Methyl salicylate	3.0	3.0	3.0	Active ingredient
Menthol	1.0	1.0	1.0	Active ingredient
Tea tree oil	0.02	0.02	0.02	Active ingredient
Purified water	37.98	37.98	37.98	Solvent
Ethanol	54.0	54.0	54.0	Solvent

Preparation of film forming spray : The spray changed into organized with the aid of using easy answer method. First the polymeric answer device changed into made with the aid of using dissolving polymers in ¾th amount of water and stirring the usage of magnetic stirrer. Tea tree oil changed into dissolved in ethanol and introduced right into a polymeric answer. Then the plasticizer changed into introduced and changed as much as very last weight with water. After screening the excipients (polymers and plasticizers) in formulation, the topical movie forming sprays from Tea tree have been developed, introduced different elements along with methyl salicylate and menthol as counterirritant that each dissolved in ethanol, combined properly to absolutely formulation.

Evaluation of film forming spray formulations.

Physical characteristics: *Tea tree* film forming spray were set separately at room temperature (30±2 °C) for 0, 7, 14 and 28 days, lucidity of solution, film thickness development and white spot on surface were recorded by visual observation.

Evaporation time: Film forming spray droplets were spread on a bagasse paper that is suspended at a sensitive balance in a fume hood. Weight loss of the bagasse solvent/paper liquid is measured as a function of time as the solvent evaporates using analytical elements balance.

Volume per spray: The following quantifiable tests for the spray formulations were also performed. Average weight per dose is a vital quantitative parameter to be evaluated. Ten sprays were actuated into a glass beaker where on analytical balance and then calculated volume per spray.

pH : About 20 ml of film forming spray solution was taken in a 30 mL glass beaker. The pH was determined using digital pH meter. The measurement of pH of each formulation was done in triplicate and mean values were calculated. pH was determined at every 0, 7, 14 and 28 days.

RESULT:

Preparation of film forming spray.

The physical appearances of all film forming spray formulation F1-F3 were pure clear. Tea tree oil was dissolved in ethanol showed a clear solution, and acceptable formulations were F1 (PVP K30 as polymer, PG as plasticizer), F2(PVP K30 as polymer**,** PEG400 as plasticizer) and F3(HPMC E5 as polymer, PEG400 as plasticizer). Spray solution was stored in a well-litted tight container with spray pump as shown in Figure 1**.** The evaluation of film forming spray formulations were presented in Table 3. and Table 4.

F1 **F2** **F3**

Figure 1. Physical appearances of film forming spray formulation (F1, F2 and F3),

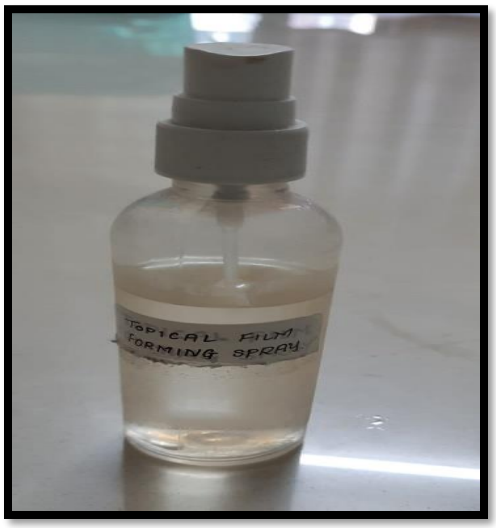


Figure 2: Topical film forming spray

Table 3: Physical appearances of film forming spray formulation

Formulation	Days			
	0 day	7 days	14 days	28 days
F1	Clear, thin film,smooth	clear, thin film, smooth	clear, light yellow solution, thin film, smooth	clear, light yellow solution, thin film,smooth
F2	Clear, thin film,smooth	clear, thin film, smooth	clear, thin film, smooth	clear, thin film,smooth
F3	Clear, thin film, smooth, white spot	clear, thin film, smooth, white spot	clear, light yellow solution, thin film, smooth, white spot	clear, light yellow solution, thin film, smooth, white spot

Table 4: Evaluation of film forming spray formulation

Formulation	Evaluation					
	Evaporation Time (second)	Volume per Spray (g)	pH			
F1	18.61	0.11	5.17	5.32	5.78	5.81
F2	27.78	0.11	6.40	6.38	6.40	6.40
F3	14.72	0.11	5.09	5.18	5.45	5.67

DISCUSSION

The selected solvents were highly purified water and ethanol. Both solvents were safe, less expensive and common solvents used in solution preparations. Water attainable with homogenous and clear solution. All the polymers were entirely dissolved in water. In instance of ethanol, Tea tree oil in ethanol was found clear. Water part and ethanol part were mixed, the mixture gave clear (F1,F2,F3). After 14 days, F1 and F3 were changed a little too light yellow clear in appearance. The upshot of solvent on evaporation time was recorded. It was established that ratio of 37.08 : 54.00 (water : ethanol) was the most appropriate solvent system ratio for spray formulations due to its capability to evaporate rapidly on application (<30 sec) at the surface of skin.

The film forming polymers: PVP K30 and HPMC E5 were selected for inspection of uniform thick film formation. The PVP (polyvinylpyrrolidone) K30 is a hygroscopic, amorphous polymer in nature. It is are miscible in water and organic solvents. As the concentration of PVP K30 was augmented from 1% to 5 % by weight, the viscosity was progressively amplified. With a higher value polymer concentration, the resultant gel formed was more viscous in nature and the tightness of the swollen hydrogel network was also increased. Compared with the other polymers, HPMC E5 increased from 1.0% to 5.0% by weight, the viscous was gradually enlarged, at concentration 3.0-5.0% by weight depicted white spots. Spray formulations F1 and F2 were formulated using PVP K30 ,1.0 to 5.0% by weight, PVP K30 at 3.0% by weight exhibited thin film, smooth and clear that shaped satisfactory films. Formulations F3 was articulated using HPMC E5 1.0 to 5.0%% by weight, HPMC E3 at 2.0% by weight fashioned acceptable films. All formulations F1-F3 were signposted slow drying films. Therefore, the formulations were established to increase rate of drying time by varies concentration of solvent.

The formulations F1-F3 were primed to examine the result of different plasticizers. Propylene glycol and PEG 400 were nominated for exploration of their flexibility of spray formulation using 1.0% by weight. The results depicted that similar of film appearance, clear film, and smooth surface and not to breakdown. F1-F3 gave clear solutions while after 14 days F1 and F3 offered light yellow solution those compose of PVP K30 as polymer and detected a wobbly of pH. F2 gave clear solution and denoted white spot after applied. Film forming sprays were developed by added methyl salicylate and menthol as counterirritant for synergistic Tea tree oil activities. Methyl salicylate and menthol were added produce heating and cooling sensation after application of spray (time around 5 min). The films on skin could be easily washed off with water. Comparing the physical characteristics of films, evaporation time and pH, formulation F2 was found to be better as compared to other formulations.

CONCLUSION

Melaleuca alternifolia composed of terpenoids. Tea Tree oil for the skin may have the following benefits like anti-inflammatory, anti-fungal, antiseptic. It may also promote wound healing activity.The topical film forming spray is one of formulations are medicines that reduce the sensation of pain in the area to which applied. The method of preparation of film forming spray was simple. The developed film forming spray formulations were clear, smooth and flexible in physical appearance. The evaluation studies were presented ability to evaporate rapidly on applies, pH becomes similar to that of normal skin offered of lower skin irritation. Spray is

more convenient to use, can be applied easily thus improve patient acceptance and compliance.

Conflict of Interest

All the authors declare no conflict of interest.

Contribution

All the authors in this paper heve equal contribution.

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