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Solubility of Essentials Oils by Non-alcoholic Agent

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Abstract: Solubility studies of essential oils (Spearmint oil, Peppermint, Anise oil and menthol) were carried out by using polyoxyethylene derivative of sorbitol fatty acid ester (Tween 80) in proportion of 1-2% weight/volume in Mouthwash (Gargle) dosage form with and without medicament at three different storage conditions. Results of preparations with Tween 80 were compared with preparations containing 20% weight/volume ethyl alcohol. Three sets of mentholated Mouthwash (Gargle) were formulated with and without medicinal agents (Potassium Nitrate 1% weight/volume and Sodium monofluorophosphate 1% weight/volume), using 0.15% weight/volume essential oils as flavoring agents. All formulations were kept in food grade transparent bottles at various temperatures for one-year i.e. at Refrigeration ($5\pm 1^{\circ}\text{C}$), at Room Temperature ($27.0\pm 1^{\circ}\text{C}$) and at Elevated Temperature ($45\pm 1^{\circ}\text{C}$). All these formulations were investigated and compared with each other with reference to clarity, pH, creaming and sedimentation. It was concluded that Tween 80 in a conc. of 2% weight/volume is much better compared to 20% weight/volume ethyl alcohol. It also helps to prevent sedimentation of active and inactive ingredients.

Key words: Essential oils, solubility non-alcoholic agents

Introduction

The word flavor refers to a mixed sensation of taste, touch, smell, sight and sound, all of which combine to produce an infinite number of gradations in perception of a substance. People are more sensitive to odor than flavor. The compounds used as flavoring agents vary considerably ranging from simple esters, alcohol, aldehyde and complex volatile oils. These are odoriferous bodies and are oily in nature but are not fats (Parry, 1922). These are obtained from natural sources through steam distillation or prepared synthetically (Bernthsen, 1941). Mostly they contain turpenes, which are constituted by head to tail union of isoprene units (Pinder, 1960). These are lighter than water and are insoluble in water (Pardeep, 2000). Therefore, they exhibit the phenomenon of creaming in aqueous formulation. In mouthwash dosage form, the flavours which are more pleasing to majority of people are associated with some physical or physiological nature and may contain counterirritants of spicy origin.

Mouthwash dosage form contains four types of excipients i.e. alcohol, surfactants, flavors and coloring agents (Tricca, 1988). Excipients in solution formulation controls their properties and performance (Crowley, 2001). Alcohol is used in a proportion of 10-20 % and surfactant (0.1-0.5%) for foaming and solubility. Flavors mostly used are peppermint, spearmint, aniseed oil and menthol to enhance organoleptic properties. For a successful formulation, the stability and interaction of excipients are important (Grvin, 2002).

In the light of above facts, in present investigation attempt was made to replace the use of alcohol by increasing the concentration of non-ionic surfactant because alcohol is narcotic, has side effects and its use in industry is under the supervision of Govt. Agencies. Therefore the use of alcohol may be avoided to taking into account its cost effectiveness and hazards.

Till 1950 it was a trial and error method for the selection of solubilizing agent (Griffin, 1949) In present study the selection of solubilizing agent was done on the basis of generalization that if a solute is soluble in alcohol or poly hydroxy alcohol and limited solubility in water, the addition of one or more hydroxy compound invariably improves its solubility in aqueous mixture and on Hydrophobic Lipophilic Balance (Griffin, 1954) and (Davies, 1957). A Polyoxyethylene derivative of sorbitol fatty acid ester polyoxyethylene sorbitan mono-oleate (Tween 80) having hydrophilic lipophilic balance 15 was selected as a solubilizing agent because the nonionic surfactants having HLB (10-18) act as solubilizing agents (James, 1978).

Materials and Methods

Potassium Nitrate (China), Sodium Monofluorophosphate, Sodium metabisulphite(China), Menthol, Spearmint oil, peppermint oil and Anise oil (China), Purified water and saccharine sodium (China), Polyoxyethylene sorbitane mono oleate (Tianjin Hengyi International Trade Co. China).

pH Meter WTW model 8120 Weilheim 1-OB manufacturer by Wissenschaft Technische Werkstatte West Germany, Refrigerator Dawlance Pakistan, Electric Oven Memmert 854 Schwabach west Germany, Bottles of Polyethylene terephthalate (PET), closures of Poly Propylene and Weighing balance Petit Balance Ohyo Balanco Corp. Kyoto Japan Serial No. 100327.

Preparation of non- medicated Formulations without any solubilizing agent

Three sets of sweet and preserved formulations were prepared, each containing one flavouring agent in a concentration 0.15% weight/volume and menthol 0.05% weight/volume without using ethyl alcohol and Tween 80.

Preparation of non-medicated Formulations with ethyl alcohol

Three sets of formulations were prepared using sweetening agent and preservative, each containing one flavouring agent in a concentration 0.15% weight/volume and menthol 0.05% weight/volume and in these preparations ethyl alcohol was used in a concentration of 20% weight/volume.

Preparation of medicated Formulations with ethyl alcohol

Three sets of formulations were prepared using sweetening agent and preservative, each containing one flavouring agent in a concentration 0.15% weight/volume and menthol 0.05% weight/volume. In these preparations ethyl alcohol was also used in a concentration (20% weight/volume). Potassium Nitrate and Sodium Monofluorophosphate were used each in a concentration of 1% weight/volume as medicinal agents.

Preparation of non- medicated Formulations with Tween 80

Three sets of formulations were prepared using sweetening agent and preservative, each containing one flavouring agent in a concentration 0.15% weight/volume and menthol 0.05% weight/volume. In these preparations Tween 80 was used in a concentration of 2% weight/volume.

Preparation of medicated Formulations with Tween 80

Three sets of formulations were prepared using sweetening agent and preservative, each containing one flavouring agent in a concentration 0.15% w v⁻¹ and menthol 0.05% w v⁻¹. In these preparations Tween 80 was used in a concentration of 2% weight/volume. Potassium Nitrate and Sodium Monofluorophosphate each in a concentration 1% weight/volume were used as medicinal agents.

All the above mentioned preparations were kept at various storage conditions as

Refrigerator	5±1 °C
Room Temperature	27±1 °C
Elevated Temperature	45±1 °C

Results and Discussion

The results of the studies of non-medicated formulations without any solubilizing agent are presented in Table 1. The formulations were turbid having phenomenon of creaming under all storage conditions. There was no sedimentation and pH remains unaltered (7.0).

Table 1: Non medicated Formulations without ethyl alcohol at different temperatures

Storage Time in Months and Temp.	Spearment oil				Peppermint oil				Aniseed oil			
	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed
5° C												
00	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
1	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
2	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
4	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
12	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
27° C												
00	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
1	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
2	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
4	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
12	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
45° C												
00	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
1	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
2	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
4	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-
12	7.0	-	+	-	7.0	-	+	-	7.0	-	+	-

Table 2: Non medicated Formulations with ethyl alcohol at different temperatures

Storage Time in Months and Temp.	Spearment oil				Peppermint oil				Aniseed oil			
	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed
5° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
27° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
45° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+

- = nil, + = yes, Cla. = clarity, Cream= creaming, Sed= Sedimentation

Table 3: Medicated Formulations with ethyl alcohol at different temperatures

Storage Time in Months and Temp.	Spearment oil				Peppermint oil				Aniseed oil			
	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed
5° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
27° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
45° C												
00	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
1	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
2	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
4	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+
12	7.0	-	+	+	7.0	-	+	+	7.0	-	+	+

Table 4: Non- Medicated Formulations with Tween 80 at different temperatures

Storage Time in Months and Temp.	Spearment oil				Peppermint oil				Aniseed oil			
	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed
5° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
27° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
45° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-

- = nil, + = yes, Cla. = clarity, Cream= creaming, Sed= Sedimentation

Table 5: Medicated Formulations with Tween 80 at different temperatures

Storage Time in Months and Temp.	Spearment oil				Peppermint oil				Aniseed oil			
	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed	pH	Clar	Cream	Sed
5° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
27° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
45° C												
00	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
1	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
2	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
4	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-
12	7.1	+	-	-	7.1	+	-	-	7.1	+	-	-

- = nil, + = yes, Cla. = clarity, Cream= creaming, Sed= Sedimentation

The results of studies carried out on non-medicated formulations having ethyl alcohol 20% weight/volume are presented in Table 2. The formulations exhibited turbidity, creaming and sedimentation under all storage conditions and similarly pH was not affected.

The results of medicated formulations having ethyl alcohol 20% weight/volume as solubilising agent are presented in Table 3. The formulations exhibited turbidity, creaming and sedimentation under all storage conditions and hence pH was also not affected.

The findings of the studies performed on non medicated formulations having Tween 80 are given in Table 4. All the formulations were stable with reference to pH, clarity, creaming and sedimentation at all storage conditions.

The findings of the studies performed on medicated formulations having Tween 80 are given in Table 5. All the formulations were stable with reference to pH, clarity, creaming and sedimentation at all storage conditions.

The present investigations showed that ethyl alcohol even up to 20% weight/volume is not sufficient to produce solubility of essential oils. Whereas Tween 80 in a conc. of 2% weight/volume is not only enough to solubilise essential oils but also prevent the sedimentation of active and inactive ingredients used in these investigations. The use of medicinal agents like potassium Nitrate 1% weight/volume and Sodium monofluorophosphate 1% weight/volume do not interfere physically with solubilising agent, which proved to be a stable formulation.

It is interesting to note that by using Tween 80 in a concentration of 2% weight/volume proved to be a good solubilising agent then ethyl alcohol and hence its use in the above formulations is also cost effective as compared to the ethyl alcohol.

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