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Formulation and evaluation of herbal pain reliving balm

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Abstract
Modern life is stressful, and tension headaches are one result of that stress. Cosmetics have great demand since ancient time, now a days, a focus has been shifted more towards derived cosmetic products. Not only cosmetic products, but also to the skin products due to their ease of application among all dermal drug delivery products, pain balm formulation are preferably used so as to get the faster local effect. Menthol is naturally occurring cyclic terpene alcohol of plant origin, which has been used since antiquity of medicinal purpose.
Its use in dermatology is ubiquitous, where it is frequently part of topical anti-pruritic, antiseptic, analgesic and cooling formulations. Despite its widespread use, it was only recently that the mechanism by which menthol elicits the same cool sensation as low temperature was elucidated upon, with the discovery of the TRPM 8 receptor. Although almost 5 years have passed since this receptor, many dermatologists are still unware of menthols underlying target.

Keywords: evaluation of herbal pain, dermatology is ubiquitous

Introduction

The pain balm works on the counter irritancy principal the where the instead of relieving the pain, the pain sensation is suppressed by causing the irritation to the point where formulation has been applied. the balm in common sense is defined as semisolid formulation (generally having medicament) and which is to be applied externally. Pain balm is such formulation that is intended to be used for the relief of mild to moderate rate pain [1].
Tension headaches are very common, affecting up to 78% of people. Unfortunately, there also among the most neglected and difficult types of head-ache to treat [2]. Menthol is a natural compound of plant origin known to produce cool sensation. Menthol is the cooling natural product and peppermint is widely used preparations for pain relief in sport injuries, arthritis and other painful conditions [3]. Camphor is a natural product derived from the wood of the tree Cinnamomum camphora, has a long history of use antiseptic, analgesic, antipruritic counter irritant and rubefacient [4]. Nowadays it is importance of drug administration via the skin for therapeutic effects has increased [5]. Camphor is highly volatile and readily absorbed through the skin. It acts as a rubefacient, (a substance which when rubbed causes redness due to dilation of blood vessels) produces a cool sensation and also acts as a mild local anesthetic.
In diagnostic test such as colonoscopies, it is essential to have bowel preparation before performing the procedure. Castor oil may be used in these types of procedures as it is effective in bowel evacuation. However, in these procedures patients typically have better results and satisfaction with other laxative such as sennosides, polyethylene glycol and other Bisacodyl [6] Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage [7].
Menthol is very soluble in alcohol, chloroform, ether and hexane and slightly soluble in water. Menthol is an alcohol that is found in mint oils and similar to peppermint, has a refreshing odour, white crystalline structure and cooling properties. Chemical formula of menthol C10H20O and molecular weight is 156.37g/mol. Menthol is found in many topical pain relief medications due to its counter irritant and local anaesthetic properties. The mechanism by which menthol is able to impart a cooling sensation when applied topically to the skin is well understood. Menthol in over the concentration has an excellence safety profile [8-11]. For the pharmaceutical purpose beeswax are used in drugs, pills, capsules, salve and ointments as consistency, binding agent, time release mechanism and carrier of drug [12].

Literature survey

1. Syed Safiullah Ghori, Md Ikram Ahmed (*et al.* 2015) Herbal medicine has been used since ancient era for many centuries. In today's life there is need for efficacious therapy for pain and inflammation. In the search for new therapeutic options, novel biomolecules of natural sources are to be investigated. Purpose of this study was to evaluate the analgesic and anti-inflammatory effects of OFCMT (Oily formulation of camphor, menthol and thymol).
One of the important and effective parts of herbal plants is essential oil and substances present in different parts of plants. Essential oils are components which are oil soluble that have effective smell and aroma and are separated by use of water and steam distillation and prepared by extraction with solvents and enzymatic hydrolysis. Menthol, the cooling natural product of peppermint, is widely used preparations for pain relief in sports injuries, arthritis, and other painful conditions. Thymol is a natural monoterpene phenol derivative cymene, isomeric with carvacrol, found in oil of thyme, and extracted from Thymus vulgaris and various other kinds of plants as a white crystalline substance of a pleasant aromatic odor and strong antiseptic properties.
2. Chatur Vibhavari M, Ghode Shweta P, Choudhari Pooja (*et al.* 2019) Cosmetics have great demand since ancient time. Now a days, a focus has been shifted more towards derived cosmetic products. Not only cosmetic products, but also to the skin products due to their ease of application. Among all dermal drug delivery products, pain balm

formulations are preferably used so as to get the faster local effect. The main aim of the present work was to formulate a pain balm containing paracetamol, a drug used in the treatment for relief of mild to moderate pain such as headache, toothache, backache etc. The paracetamol is considered to be safe at recommended dosage. Hence, in the current study the main focus was on the development of a pain balm using paracetamol so as to know the physical compatibility as well as the stability of the drug in the balm formulation and then to evaluate it with the basic primary characteristics.

3. Stefan Bogdanov (*et al*. 2009) Beeswax was used for making of figures and cult objects in ancient Egypt. In regions with stingless bees stingless-beeswax figures were made in different South American countries and in Australia16. Beeswax was an important ingredient of ancient seals 16. At the beginning pure beeswax was used and only later resin and colour were added. In ancient Egypt beeswax was used for writing tablets, the oldest known being from around 1300 BC16. The use of writing tablets continued until after the Middle Ages in Europe. The production and selling of beeswax and beeswax candles was a good business until the introduction of paraffin wax in the 19th century. Nowadays beeswax has lost its exclusiveness, but it remains the most expensive of all natural waxes.

Need and objectives

1. Need

Modern life is stressful and tension headaches are one result of that stress. Cosmetics have great demand since ancient time a focus has been shifted more towards derived cosmetic products. not only cosmetic products, but also to the skin products due to their ease of application among all dermal drug delivery products, pain balm formulation is preferably used so as to get the faster local effect.

Herbal balm is an ayurvedic formulation of powerful essential oils for quick relief from headaches, backache cold and in relieving pain by considering this point we are formulating herbal pain reliving Balm.

2. Objective

- To relieves the patients from muscle aches and joint pains.
- To Excellent Effect for headaches Patients.
- To treat the common cold as compare to other types of Products.
- To Relieves stress and promote relaxation.

Drug profile

1. Menthol

1.1 Scientific Name: *Hexahydrothymol.*

1.2 Synonym: Peppermint camphor.

1.3 Family: Lamiaceae.

1.4 Chemical constituents: Menthol (40.7%), Menthone (23.4%), menthyl acetate, 1,8 cineole limonine, beta pinene, a beta-caryophllene.

Fig 1: Menthol

Uses

1. Reduces spasm and pain caused by endoscopy.
2. In migraine headache.
3. 3.To treat nausea.

2. Castor oil

2.1 Scientific name: Ricinuscommunis.

2.2 Synonym: Ricinus oil.

2.3 Family: Euphorbiacea.

2.4 Chemical constituents: Triglyceride of ricinoleic acid 80%.

Fig 2: Castor oil

Uses
1. Castor oil is commonly used as the laxative.
2. Castor oil promote the wound healing.
3. Castor oil is a cathartic.

3. Camphor
3.1 Scientific name: Cinnamomum camphora.
3.2 Synonym: Alcanfor.
3.3 Family: Lauraceae.
3.4 Chemical constituents: D-camphor (51.3%), 1,8-cineole (4.3%), and alpha-terpineol.

Uses
1. Provide relief from cold cough, chest congestion, bronchitis and asthma.
2. Improves blood circulation and help to curb muscular and joint aches.
3. Powerful analgesic oil that produces a cooling sensation to numb pain and a warming sensation to increase circulation.

Fig 3: Camphor

4. Rosemary oil
4.1 Scientific name: Rosmarinus officinalis.
4.2 Synonym: Rosmarinus angustifolius Mill.
4.3 Family: Lamiaceae.
4.4 Chemical constituents: 1,8-cineol (38.5%), Camphor (17.1%), limonene (6.23%), camphene (6.00%) and linalool (5.70%)

Fig 4: Rosemary oil

Uses
1. Reduce pain and Inflammation.
2. Relieve Stress and Anxiety.
3. Treat respiratory problems.
4. Heal your skin.
5. Combat Gastrointestinal stress.

Excipient profile
1. Beeswax
1.1 Scientific name: *Ceraalba.*
1.2 Synonym: Yellow wax.
1.3 Family: Apidea.
1.4 Chemical constituents: Myricylpalmitate (80%), free cerotic acid (15%), melissic acid cerolein.

Uses
1. Used as antibacterial, antifungal.
2.It has anti-inflammatory and anti-allergic properties.

2. Betanin (from beetroot)
2.1 Scientific name: *Betacyanin.*
2.2 Synonym: Beet root
2.3 Family: Cactaceae.
2.4 Chemical constituents: water (87.1%), carbohydrate (7.6%), protein (1.7%), fat (0.1%), and betanin (0.03–0.06%).

Uses
1. Betanin can be used as a powerful antioxidant in the food industry in extract or powder form and is also applied as a natural pigment.
2. Betanin is used to color food and pharmaceutical products.

Plan of work
- **Literature Survey**

Literature survey was carried out by Goggle search, books and Different Research and review paper etc.

- **Collection of raw material**

All the material are collected from market and the natural material used in present study i.e., Menthol, Beeswax, Castor oil, rosemary oil, Camphor and Betanin were purchased from the market.

- **Methods of data collection**

Observation method of the data collection will be employed for the collection of data for the present dissertation work. Data on the Formulation and Evaluation of herbal pain reliving Balm will be collected from various standard journals and other sources like research literature databases such as Springer, Research Gate, Google scholar, Yahoo Gov and various ayurveda and herbal formulation book etc.

Plan of work

Table 1

Sr. No.	Activity	Tentative Time
1.	Literature survey	Throughout semester
2.	Selection of drug and excipients	2Week
3.	Procurement of drug and excipients	2Week
4.	Experimental work	2 Months
5.	Data completion, thesis writing, printing and binding	1 Month

Materials and methods

Table 2

Sr. No.	Ingredient's
1.	Menthol
2.	Beeswax
3.	Castor oil
4.	Rosemary oil
5.	Camphor
6.	Betanin (from beetroot)

Method of preparation

Weighing all the required herbal ingredients for herbal pain-relieving balm preparation were accurately weighed by using digital balance.

Weigh all the ingredients and blend menthol, beeswax, castor oil and Rosemary oil.

⇩

This mixture heat to 80^{0C} with stirring to melt the ingredients. Mix till homogenous.

⇩

Cool the content with 65^{0c} with continues mixing

⇩

Add the camphor at 60^{0c} and mix well.

⇩

Add the betanin to the above mixture with continuous stirring, till the uniform mixing

⇩

Fill the mixture into the container when hot

⇩

Allow to cool in the container and close it with tight lead.

Formula

1. Preparation of base

The menthol was dissolved in eucalyptus oil. The base for the balm prepared b fusion method was made suitable for incorporation of oils and drugs then cooled the hot melt stirring continuously.

2. Formulation of balm

At the temperature 400 c the menthol and eucalyptus oil mixture were dissolved in it with stirring. The drug was incoporated slowly with constant stirring till the uniform mass is obtained.

3. Container and Storage

Store in well closed mouth bottle at room temperature.

4. Direction for use

1. To be rubbed externally.
2. Rub gently on the skin with the help of finger.
3. Do not applied for dry skin.

5. Uses

1. It is used as Arthritis.
2. It is used as Backches.

Procedure for pain relieving balm application

In the first step the take pain relieving balm as per the requirement and in second step apply gently on the affected area. It helps to reduce headache, pains and sprains

Table 4

Sr. No.	Ingredients	Quantity Given	Quantity Taken	Uses
1.	Menthol	2.5gm	5.0gm	Counter irritant
2.	Beeswax	3.3gm	6.6gm	Base
3.	Castor oil	2.7gm	5.4gm	Anti-inflammatory
4.	Rosemary oil	0.4	0.8gm	It reduces pain and inflammation
5.	Camphor	0.6gm	1.2gm	Antiseptic
6.	Beetroot	0.5gm	1.0gm	It reduces the inflammation

Evaluation

Following evaluation parameters were preferred to ensure superiority of prepared pain-relieving balm.

1. Colour and odour

Colour and odour were examined by visual inspection.

2. Consistency

Smooth and no greeting is observed.

3. Spreadability

The test for spread ability was performed by applying the product on glass slide at room temperature repeatedly to observe uniformity in the formulation of protective layerand whether the stick fragmental deformed or broke during application for appropriate result.

4. Washability

This test is also used to check quality of balm. In this first of all we have to add small amount of balm which was applied on the hand. After that we have to washed with tap water.

5. No–irritancy

This is used to check the quality of materials as well as chemicals and whether it is harmful to skin / mucosal or not. First of all, we have to mark area on left hand (dorsal surface). After that we have to applied formulation of balm to that area and time was noted.

Then we have to leave formulation for few minutes by this we can checked for irritancy.

Advantages and disadvantages

Advantages

1. Avoidance of first pass metabolism.
2. Convenient and easy to apply.
3. Ability to deliver drug more selectively to a specific site.

2. Disadvantages

1. Skin irritation of contact dermatitis may occure due to the drug and / or excipients.
2. Poor permeability of some drug through the skin.

Result

In the presence of study, the pain balm of menthol was fomulated by using various excipients. The balm was then evaluated for the following physical parameters and was found to be satisfactory in terms of appearance and texture. It was easily spreadable with fingers without any roughness felt to touch. The smell of the balm was found to be characteristics. Only thing was the colour was faded as the natural colorant with origin of beetroot was incorporated.

The balm was dense with the optimized melting point. In general, oral or topical antibiotic formulation is used for the treatment of skin diseases. Traditional medicinal and aromatic plants are interesting and explore its various bioactive natural organic compounds for various treatments. In the last two decades, more research has been carried out towards the identification of the bioactive compound from medicinal plants and developing into drug for the various treatments

Table 5

Sr. No.	Parameter	Observation
1.	Colour and odour	Peach Colour and Pleasant odour
2.	Consistency	Smooth
3.	Spreadability	Easily Spreadable
4.	Washability	Easily washable
5.	Skin Irritation	No Skin Irritation
6.	Melting point	37.8°c

Conclusion

Frequency of intake the allopathic drugs for the treatment of acne vulgaris results to produce adverse side effects. Recently, herbal remidies are considered as safe as the synthetic one and herbal formulations are having growing demand in the global market.

Overall to conclude with, as the main objective of the study was to formulate and evaluate the basic physical parameter and stability check for pain balm containing menthol. We have attempted the same and the evaluation parameter results showed that, if the menthol formulated in the balm, remains stable. (The *in- vitro* studies are pending). The basic parameters were found to be within nomal range except the color variation. again, that can be improved by using the approved colorant. During this stability study of six months, the balm was found to be physically stable with all the basic characteristics. It had smooth and good consistency.

Still to perform the difusion study, the drug release study, animal study also the preformulation study since the menthol is the bcs class iv study our next motive would be to incoporate the suitable permeation enhancer, suitable and to check whether the release of drug can be increased, and the same study is being recommended further so as to know the effectively of the drug in balm formulation.

That is further research which is carried out so as to find the in *vitro* as well as *in vivo* characterisation hence the pain reducing activity can be notified.

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