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Formulation and Evaluation of Basic Parameters and Stability Check for Pain Balm Containing Paracetamol

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Abstract
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.(1) The paracetamol is considered to be safe at recommended dosage.(2) 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. Also, it was formulated with the intension of using it locally to get the pain relief from cracked heals as well as cracked lips. Formulation of pain balm was done using simple base, oils, natural colour and flavoring agents and then can be evaluated for their resistance to temperature variations, pleasant flavor, and soothes the skin during application. Formulated pain balm was then evaluated for the very basic parameters. (3)

Keywords
Paracetamol, balm, formulation and evaluation of primary characteristics.

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INTRODUCTION:
Paracetamol is popularly in demand over the counter pain reliever and widely used as an antipyretic. The drug is bitter in taste and that why was thought of converting it into pain balm formulation. Pain balm is such formulation that is intended to be used for the relief of mild to moderate pain. The balm in common sense is defined as a semisolid formulation (generally having medicament) and which is to be applied externally.

The pain balm works on the counter irritancy principle where the instead of relieving the pain, the pain sensation is suppressed by causing the irritation to the point where the formulation has been applied. (4) Here, the formulation has been formulated with the intension of use mainly on the cracked areas as

well as cracked lips and to minimize the pain due to winter seasonal injury.

The present study was done with the idea of formulation of pain balm by incorporating the paracetamol into the base so as to utilize it as an anti-inflammatory analgesic for the treatment in acute pain which is usually experienced during winter season especially in case of cracked heels as well as cracked lips also for headache as it is the safe drug in the NSAID category. (5)

For the formulation of pain balm, the basic objective was to incorporate paracetamol in base form and formulate it into balm and to evaluate the same in terms of basic characterization parameters, so that can be used in as above stated conditions. (6) The skin permeability of paracetamol also other biopharmaceutical parameters is to be considered and to be studied later.

Delivery of Drug via Topical route:

Topical preparations are used for the localized effects at the site of their application by virtue of drug penetration into the underlying layers of skin or mucous membranes. The main advantage of topical delivery system is to bypass first pass metabolism Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption, like pH changes, presence of enzymes, gastric emptying time are

other advantage of topical preparations. Topical drug delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders (e.g. acne) or the cutaneous manifestations of a general disease (e.g. psoriasis) with the intent of confining the pharmacological or other effect of the drug to the surface of the skin or within the skin. Topical activities may or may not require intracutaneous penetration or deposition (7, 8). Topical drug delivery systems include a large variety of pharmaceutical dosage form like semisolids, liquid preparation, sprays and solid powders. Most widely used semisolid preparation for topical drug delivery includes gels, creams and ointments.

Mechanism of Action:

Acetaminophen, also known as paracetamol, is a nonsteroidal anti-inflammatory drug with potent antipyretic and analgesic actions but with very weak anti-inflammatory activity. When administered to humans, it reduces levels of prostaglandin metabolites in urine but does not reduce synthesis of prostaglandins by blood platelets or by the stomach mucosa. Because acetaminophen is a weak inhibitor in vitro of both cyclooxygenase (COX)-1 and COX-2, the possibility exists that it inhibits a so far unidentified form of COX, perhaps COX-3. In animal studies, COX enzymes in homogenates of different tissues vary in sensitivity to the inhibitory action of acetaminophen. This may be evidence that there are 2 isoforms of the enzyme. Recently, a variant of COX-2 induced with high concentrations of nonsteroidal anti-inflammatory drugs was shown to be highly sensitive to inhibition by acetaminophen. Therefore, COX-3 may be a product of the same gene that encodes COX-2, but have different molecular characteristics found in COX-1. This is important in understanding why some drugs, especially those with large sulfur-containing side groups, are more selective for the COX-2 isoform. (09,10)

MATERIALS AND METHODS:

Materials: Coco butter, glycerin, honey, menthol, colorant betaine obtained from beet root, bees wax, orange oil.

Methods: Preparation of balm:

Formulation-

a) Preparation of base: The menthol was dissolved in orange oil. The base for the balm was prepared by fusion method and was made suitable for incorporation of oils and drugs and then cooled the hot melt by stirring continuously. (11)

b) Preparation of balm: At the temp 40°C, the menthol and orange oil mixture was dissolved in it with stirring. The drug was incorporated slowly with constant stirring till the uniform mass is attained.

Container and Storage: Store in a well-closed wide mouth bottle at room temperature.

Category: Intended to be used as an analgesic

Direction for use:

1. To be rubbed externally
2. Rub gently on the skin with the help of finger.
3. Do not apply on open skin or cuts.

Formula:

Sr.No	Ingredients	Quantity	Purpose
1.	Paracetamol	10mg/Ml	Analgesic
2.	Coco butter	5.6gm	Base
3	Beeswax	3gm	Base
4.	Honey	1ml	Smoothening agent
5	Menthol	0.2gm	Counter irritant
6.	Orange oil	0.1gm	Aroma
7	Betanin(from beet root)	QS	Colorant

RESULT AND DISCUSSION:

In the present study, the pain balm of paracetamol was formulated 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 characteristic. Only, thing was the color was faded as the natural colorant with the origin of beet root was incorporated. The texture remained same as that of formulation on first day, was found to be smooth and consistent. The balm was dense with the optimized melting point.

Sr. No.	Parameter	Inference
1	Appearance	Smooth
2	Colour	Peach Colour
3	Odour	Pleasant
4	Spread ability	Easily Spreadable
5	Skin Irritation	No Skin Irritation
6	pH	5.6
7	Texture	Smooth
8	Density	1.45 gm/cm^3
9	Melting point	37.8^{O}C
10	Stability	Stable for 6 months and further study is carried out

Table: 1: Physical Evaluation parameters:

TIME PERIOD	Fresh	One Month	Three Months	Six Months
PHYSICAL STATUS OF FORMULATION				

Table 2: The Physical changes occurred in Pain Balm during 6 Months

STABILITY STUDY:

For this formulation the stability study was carried out over a period for six months by keeping the formulations at normal room temperatures so as to check the basic physical parameters such as the physical appearance, pH value, and rheological properties which is the basic objective of this study.

CONCLUSION:

Overall to conclude with, as the main objective of the study was to formulate and evaluate the basic physical parameters and stability check for pain balm containing Paracetamol. We have attempted the same and the evaluation parameters results showed that, if the paracetamol is formulated in the balm, remains stable. (The *in-vitro* studies are pending) The basic parameters were found to be within normal 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 diffusion study, the drug release study, animal study also the preformulation study

Since the paracetamol is BCS class III drug, our next motive would be to incorporate the suitable permeation enhancer, suitable permeation enhancer, in the optimum amount and to check whether the release of the drug can be increased, and the same study is being recommended. The animal study is also planned further recommended further so as to know the effectivity of the drug in balm formulation. That is the further research Which is to be carried out so as to find the in-vitro as well as in-vivo characterization hence the pain reducing activity can be notified.

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