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पेटेंट कार्यालय का एक प्रकाशन
PUBLICATION OF THE PATENT OFFICE

INTRODUCTION

In view of the recent amendment made in the Patents Act, 1970 by the Patents (Amendment) Act, 2005 effective from 01st January 2005, the Official Journal of The Patent Office is required to be published under the Statute. This Journal is being published on weekly basis on every Friday covering the various proceedings on Patents as required according to the provision of Section 145 of the Patents Act 1970. All the enquiries on this Official Journal and other information as required by the public should be addressed to the Controller General of Patents, Designs & Trade Marks. Suggestions and comments are requested from all quarters so that the content can be enriched.

(Shri Rajendra Ratnoo)
CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADE MARKS

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(71)**Name of Applicant :**
1)PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)
Address of Applicant :NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU, INDIA. ---------- ----------
Name of Applicant : NA
Address of Applicant : NA
(72)**Name of Inventor :**
1)DR.G.SRINIVASAN
Address of Applicant :PROFESSOR & HEAD, DEPARTMENT OF CHEMICAL ENGINEERING, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
2)DR. PRAVEEN KUMAR
Address of Applicant :PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
3)MR. M.G. KARTHI
Address of Applicant :ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
4)MR. M. PONMANIAN
Address of Applicant :ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
5)MS. S. PRAGATHI
Address of Applicant :ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
6)DR. S. KAILASH
Address of Applicant :PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
7)MRS. M. R. MAHALAKSHMI
Address of Applicant :ASSOCIATE PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
8)C. P. MURALI
Address of Applicant :ASSISTANT PROFESSOR, DEPARTMENT OF CHEMICAL ENGINEERING, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
9)MS. C. QUEEN SANTHOSHINI
Address of Applicant :STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
10)MR. T. PAVILAN
Address of Applicant :STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
11)MR. R. SRINIVASAN
Address of Applicant :STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------
12)MR. R RAMKUMAR
Address of Applicant :STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU. ---------- ----------

(57) Abstract :
The bioavailability of drugs delivered through transdermal patches are high as it doesn't meet first pass metabolism and gastrointestinal degradation which serves as the biggest trump card than other routes. The present invention is to combine three drugs namely diclofenac, methyl salicylate and capsaicin to develop transdermal patches. The process of developing transdermal patches in lab scale is evident and they are validated for the efficacy, safety, quality, and toxicity of the drugs in the developed transdermal patches. These formulated patches are qualitatively and quantitatively validated and characterized using UV-Visible spectroscopy. The formulated patches are expected to treat multiple analgesic complications.

No. of Pages : 17 No. of Claims : 1

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Government of India

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APPLICANT NAME	**PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)**
TITLE OF INVENTION	A HYBRID TRANSDERMAL PATCH
FIELD OF INVENTION	CHEMICAL
E-MAIL (As Per Record)	patent@allinnov.org
ADDITIONAL-EMAIL (As Per Record)	allinnovrnd@gmail.com
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Application Status	
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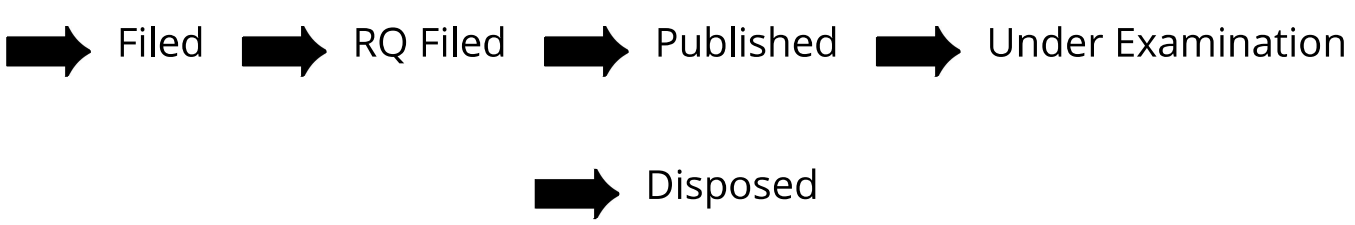

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FORM 1 THE PATENTS ACT, 1970 (39 of 1970) & THE PATENTS RULES, 2003 APPLICATION FOR GRANT OF PATENT [See sections 7,54 & 135 and rule 20(1)]	(FOR OFFICE USE ONLY) Application No.: ..... Filing Date: ..... Amount of Fee Paid: ..... CBR No.: ..... Signature: .....

1. APPLICANT(S):

Sr.No.	Name	Nationality	Address	Country	State
1	PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)	India	NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU, INDIA.	India	Tamil Nadu

2. INVENTOR(S):

Sr.No.	Name	Nationality	Address	Country	State
1	DR.G.SRINIVASAN	India	PROFESSOR & HEAD, DEPARTMENT OF CHEMICAL ENGINEERING, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
2	DR. PRAVEEN KUMAR	India	PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
3	MR. M.G. KARTHI	India	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY,	India	Tamil Nadu

			PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.		
4	MR. M. PONMANIAN	India	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
5	MS. S. PRAGATHI	India	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
6	DR. S. KAILASH	India	PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
7	MRS. M. R. MAHALAKSHMI	India	ASSOCIATE PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu

8	C. P. MURALI	India	ASSISTANT PROFESSOR, DEPARTMENT OF CHEMICAL ENGINEERING, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
9	MS. C. QUEEN SANTHOSHINI	India	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
10	MR. T. PAVILAN	India	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
11	MR. R. SRINIVASAN	India	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018,TAMIL NADU.	India	Tamil Nadu
12	MR. R RAMKUMAR	India	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS) NH-44, PAAVAI NAGAR, PACHAL,	India	Tamil Nadu

			NAMAKKAL -637 018,TAMIL NADU.		

3. TITLE OF THE INVENTION: A HYBRID TRANSDERMAL PATCH

4. ADDRESS FOR CORRESPONDENCE OF APPLICANT / AUTHORISED PATENT AGENT IN INDIA:
ALLINNOV R&D., INDIA PVT. LTD., #29B, BAIRAPPA COLONY, KRISHNAGIRI – 635001 TAMIL NADU, INDIA.

Telephone No.:
Fax No.:
Mobile No: 9790586194
E-mail: patent@allinnov.org

5. PRIORITY PARTICULARS OF THE APPLICATION(S) FILED IN CONVENTION COUNTRY:

Sr.No.	Country	Application Number	Filing Date	Name of the Applicant	Tilte of the Invention

6. PARTICULARS FOR FILING PATENT COOPERATION TREATY (PCT) NATIONAL PHASE APPLICATION:

International Application Number	International Filing Date as Allotted by the Receiving Office
PCT//	

7. PARTICULARS FOR FILING DIVISIONAL APPLICATION

Original (first) Application Number	Date of Filing of Original (first) Application

8. PARTICULARS FOR FILING PATENT OF ADDITION:

Main Application / Patent Number:	Date of Filing of Main Application

9. DECLARATIONS:

(i) Declaration by the inventor(s)

I/We ,DR.G.SRINIVASAN,DR. PRAVEEN KUMAR,MR. M.G. KARTHI,MR. M. PONMANIAN,MS. S. PRAGATHI,DR. S. KAILASH,MRS. M. R. MAHALAKSHMI,C. P. MURALI ,MS. C. QUEEN SANTHOSHINI,MR. T. PAVILAN,MR. R. SRINIVASAN,MR. R RAMKUMAR, is/are the true & first inventor(s) for this invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date: -----

(b) Signature(s) of the inventor(s): .....

(c) Name(s): DR.G.SRINIVASAN,DR. PRAVEEN KUMAR,MR. M.G. KARTHI,MR. M. PONMANIAN,MS. S. PRAGATHI,DR. S. KAILASH,MRS. M. R. MAHALAKSHMI,C. P. MURALI ,MS. C. QUEEN SANTHOSHINI,MR. T. PAVILAN,MR. R. SRINIVASAN,MR. R RAMKUMAR

(ii) Declaration by the applicant(s) in the convention country

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date: -----

(b) Signature(s) : .....

(c) Name(s) of the singnatory: PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)

(iii) Declaration by the applicant(s)

- **The Complete specification relationg to the invention is filed with this application.**
- **I am/We are, in the possession of the above mentioned invention.**
- **There is no lawful ground of objection to the grant of the Patent to me/us.**
- **I am/We are, the assignee or legal representative to true first inventors.**

10. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION:

Sr.	Document Description	FileName

I/We hereby declare that to the best of my/our knowledge, information and belief the fact and matters stated hering are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this(Final Payment Date): ----------

Signature: .....

Name: PREM CHARLES

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FORM 2

THE PATENTS ACT, 1970

(39 of 1970)

&

The Patent Rules, 2003

COMPLETE SPECIFICATION

(See sections 10 & rule 13)

1. TITLE OF THE INVENTION

A HYBRID TRANSDERMAL PATCH

2. APPLICANT(S)

NAME	NATIONALITY	ADDRESS
PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)	INDIAN EDUCATIONAL INSTITUTION	NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU, INDIA.

3. PREAMBLE TO THE DESCRIPTION

COMPLETE SPECIFICATION

The following specification particularly describes the invention and the manner in which it is to be performed

A HYBRID TRANSDERMAL PATCH

TECHNICAL FIELD

[0001] The present invention generally relates dermal patches and more particularly it describes the method of preparation of a hybrid transdermal patch for skin applications.

BACKGROUND OF THE INVENTION

[0002] Background description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

[0003] Transdermal route of drug administration is one of the common and frequently used drug delivery routes. Transdermal route has gained more attention in drug delivery due to its flexibility in palatability and convenience when compared to other routes. Administration of drug delivery through transdermal route is suitable, older, convenient, safe and economic way to deliver drugs at the site of action. There is chance of drug getting lost in different ways when it is administered through oral route which led to increase in the content of drug content in dosage forms. Toxic effects will also be produced in some routes of drug delivery. Deviation from Minimum Effective Concentration (MEC) caused by fluctuations in the blood concentration is a major drawback in normal drug delivery systems whereas it is necessary to maintain the MEC level in blood for a specified length of period to cure disease states. But transdermal drug delivery system, a novel drug delivery system may prompt release of drug and

maintenance of MEC. These kinds of systems target to specific site of action and controlling the rate of delivery.

[0004] Transdermal drug delivery is a discrete dosage form that deliver the drugs at controlled rate to the systemic circulation when applied to the intact skin. Dosages delivered through transdermal route include transdermal patches, transdermal gels which includes topical creams, moisturizers and like and there is a need for development of an efficient transdermal patch for administration of medicines during medical treatments.

[0005] As used in the description herein and throughout the claims that follow, the meaning of "a," "an," and "the" includes plural reference unless the context clearly dictates otherwise. Also, as used in the description herein, the meaning of "in" includes "in" and "on" unless the context clearly dictates otherwise.

[0006] In some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[0007] The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. "such as") provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0008] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member can be referred to and claimed individually or in any combination with other members of the group or other elements found herein. One or more members of a group can be included in, or deleted from, a group for reasons of convenience and / or patentability. When any such inclusion or deletion occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description of all groups used in the appended claims.

OBJECTS OF THE INVENTION:

[0009] The primary object of the present invention is to develop multicomponent transdermal patches using three different drugs with analgesic properties namely diclofenac, methyl salicylate and capsaicin.

[0010] Another object of the invention is to enhance the quick onset of action of the drug given through these patches

[0011] Yet another object of the invention is to reduce the dosing frequency and make the patient comfortable in taking the transdermal patches

[0012] Yet another object of the invention is to make the patches reliable to deliver drugs for various kinds of pain related complications

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The accompanying drawings are included to provide a further understanding of the present disclosure, and are incorporated in and constitute a part of this specification. The drawings illustrate exemplary embodiments of the present disclosure and, together with the description, serve to explain the principles of the present disclosure.

[0014] FIG. 1 illustrates an exemplary representation of the process flow for preparation of the transdermal patches.

[0015] FIG. 2 illustrates a pictorial representation of the process of preparing the patches.

DETAILED DESCRIPTION

[0016] The following is a detailed description of embodiments of the disclosure depicted in the accompanying drawings. The embodiments are in such detail as to clearly communicate the disclosure. However, the amount of detail offered is not intended to limit the anticipated variations of embodiments; on the contrary, the

intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present disclosure as defined by the appended claims.

[0017] In the following description, numerous specific details are set forth in order to provide a thorough understanding of embodiments of the present invention. It will be apparent to one skilled in the art that embodiments of the present invention may be practiced without some of these specific details.

[0018] Embodiments of the present invention include various steps, which will be described below. The steps may be performed by hardware components or may be embodied in machine-executable instructions, which may be used to cause a general-purpose or special-purpose processor programmed with the instructions to perform the steps. Alternatively, steps may be performed by a combination of hardware, software, and firmware and/or by human operators.

[0019] Various methods described herein may be practiced by combining one or more machine-readable storage media containing the code according to the present invention with appropriate standard computer hardware to execute the code contained therein. An apparatus for practicing various embodiments of the present invention may involve one or more computers (or one or more processors within a single computer) and storage systems containing or having network access to computer program(s) coded in accordance with various methods described herein, and the method steps of the invention could be accomplished by modules, routines, subroutines, or subparts of a computer program product.

[0020] The ensuing description provides exemplary embodiments only, and is not intended to limit the scope, applicability, or configuration of the disclosure. Rather, the ensuing description of the exemplary embodiments will provide those skilled in the art with an enabling description for implementing an exemplary embodiment. It should be understood that various changes may be made in the function and arrangement of elements without departing from the spirit and scope of the disclosure as set forth in the appended claims.

[0021] Specific details are given in the following description to provide a thorough understanding of the embodiments. However, it will be understood by one of ordinary skill in the art that the embodiments may be practiced without these specific details. For example, circuits, systems, networks, processes, and other components may be shown as components in block diagram form in order not to obscure the embodiments in unnecessary detail. In other instances, well-known circuits, processes, algorithms, structures, and techniques may be shown without unnecessary detail in order to avoid obscuring the embodiments.

[0022] Exemplary embodiments will now be described more fully hereinafter with reference to the accompanying drawings, in which exemplary embodiments are shown. These exemplary embodiments are provided only for illustrative purposes and so that this disclosure will be thorough and complete and will fully convey the scope of the invention to those of ordinary skill in the art. The invention disclosed may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Various modifications will be readily apparent to persons skilled in the art. The general principles defined herein may be applied to other

embodiments and applications without departing from the spirit and scope of the invention. Moreover, all statements herein reciting embodiments of the invention, as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents as well as equivalents developed in the future (i.e., any elements developed that perform the same function, regardless of structure). Also, the terminology and phraseology used is for the purpose of describing exemplary embodiments and should not be considered limiting. Thus, the present invention is to be accorded the widest scope encompassing numerous alternatives, modifications and equivalents consistent with the principles and features disclosed. For purpose of clarity, details relating to technical material that is known in the technical fields related to the invention have not been described in detail so as not to unnecessarily obscure the present invention.

[0023] Various terms as used herein are shown below. To the extent a term used in a claim is not defined below, it should be given the broadest definition persons in the pertinent art have given that term as reflected in printed publications and issued patents at the time of filing.

[0024] Transdermal patches refer to topical application that delivers drugs to healthy intact skin for localized treatment of tissues underlying the skin for a systemic therapy. Transdermal absorption occurs as a slow process of diffusion, which is driven by the concentration gradient between the high concentration in the delivery system and the prevailing zero concentration in the skin. Transdermal patches can be used to delivery wide range of potential drugs including steroids, anti-fungal, anti-bacterial,

interferon, local anesthetics and like. The main aim of the transdermal patches is to improve the release of less soluble drugs. As skin is the safest route for administration of drugs, these patches have the highest scope to provide the prolonged release of drugs into the systemic circulation. There is also research being undergoing to improve the safety and efficacy of the patches. Pros of transdermal patches are numerous, the important ones are a. Even for drugs with shortest half-life, these patches aid continuous release of active pharmaceutical ingredients (API) for longer time, b. Drug delivery through these patches overcomes the cons of administration of drugs through oral route (even for patients where administration of drugs orally is not possible) c. Transdermal patches do not meet the first pass metabolism and gastrointestinal degradation and hence the bioavailability of drugs delivered through transdermal patches are high (approximately 90%).

[0025] Transdermal patches will also have some cons as well. They are a. The size of the particle of drug should be less than 1000 Daltons, b. Penetration of the drug varies between various types of skin, c. There is a chance of occurrence of skin irritation and d. Limited to some of the drugs only.

[0026] The important components of a transdermal patch are: 1. Polymer Matrix: It is the backbone of transdermal drug delivery system. It controls the rate of release of drug from the patches. Always a polymer should be non-reactive and non-toxic. It should be cost effective. On storage, it should not decompose. Examples for polymer include polyvinylchloride, hydrin rubber, gelatin, shellac, cellulose derivatives. 2. Drug: The drugs are extremely the attractive portion of the patches. The drugs which extensively undergo first pass metabolism, those have narrow therapeutic index an

drugs with short half-life can be incorporated in the development of transdermal patches. 3. Permeation Enhancers: They enhance the therapeutic action of drugs by increasing the permeability of drugs into the stratum corneum. These enhance are of three types - lipophilic solvent, surface active agents and two component systems. Ex: DMSO 4. Release liners: They protect the patches during the times of storage and 5. Backing Laminates: These substances should have either low modulus or high flexibility. For instance, Vinyl polyethylene.

[0027] Transdermal Drug Delivery System (TDDS) is a method of applying drug formulation onto healthy skin for painless delivery of drugs. The first layer through which the drug initially penetrates is stratum corneum. And then it travels through the deeper layers of epidermis to dermis. The drug doesn't get accumulated in the dermal layer. The drug becomes available for systemic absorption via the dermal micro-circulation when it reaches the dermal layer.

[0028] The transdermal Patches of the present invention are developed by using diclofenac, methyl salicylate and capsaicin as active ingredients, chemicals such as polymers in particular ethyl cellulose, polyethylene glycol and solvents for instance, methanol. Development of multi-component transdermal patches is a process which requires less equipment and materials in the lab scale. The active ingredients namely diclofenac, methyl salicylate and capsaicin are selected. The excipients like ethanol as solvent, polyethylene glycol as plasticizer and ethyl cellulose as binder are also selected. The selected drugs and the excipients are dispersed uniformly in the solvent with continuous stirring. Then the mixture is to be sonicated to reduce the size of the particles using high frequency vibration. Centrifuging this mixture allows to separate

the particles based on their size and shape. The resulting mixture is poured in a petri dish which should be covered with inverted funnel. The petri dish is kept undisturbed for a day (24 hours) in room temperature. By slowly lifting the processed content from the petri dish, the transdermal patches are obtained. Then the transdermal patches are cut into the desired radius.

[0029] In formulation-1, gelatin used as a binder of 1g, glycerin as a plasticizer of 0.5ml and chloroform as a solvent for developing transdermal patches. In formulation-2 binder as a gelatin of 3g, glycerin as a plasticizer of 0.5ml and chloroform as a solvent of 10ml for making transdermal patches. In formulation-3 increase the concentration of gelatin of 5g, increase the concentration of glycerin 1ml and chloroform as a solvent of 10ml.In formulation-4 gelatin of 7g and glycerin as a plsticizer1.5g and solvent chloroform 10ml for developing patches. In formulation-5 gelatin is used as a binder of 9g, glycerin as a plasticizer of 2ml and chloroform is used as solvent of 10 ml for the development of patches.

[0030] These formulation forms a good patch after get drying of patches in room temperature for 24 hours. After removing the patches, it moves to the qualitative analysis like a weight uniformity, folding endurance, thickness of patch, amount of moisture content and moisture uptake for this formulation of patches are checked and these were the stabilized patches is obtained. The transdermal patches of using excipients were prepared successfully by using different concentrations of gelatin, glycerin, and chloroform by solvent evaporation method. The present work can further be proceeded by using active pharmaceutical ingredients and excipients for developing transdermal patches.

[0031] It should be apparent to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the scope of the appended claims. Moreover, in interpreting both the specification and the claims, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms "comprises" and "comprising" should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced. Where the specification claims refers to at least one of something selected from the group consisting of A, B, C ….and N, the text should be interpreted as requiring only one element from the group, not A plus N, or B plus N, etc. The foregoing description of the specific embodiments will so fully reveal the general nature of the embodiments herein that others can, by applying current knowledge, readily modify and/or adapt for various applications such specific embodiments without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation. Therefore, while the embodiments herein have been described in terms of preferred embodiments, those skilled in the art will recognize that the embodiments herein can be practiced with modification within the scope of the appended claims.

[0032] All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or

process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

[0033] The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0034] While the foregoing describes various embodiments of the invention, other and further embodiments of the invention may be devised without departing from the basic scope thereof. The scope of the invention is determined by the claims that follow. The invention is not limited to the described embodiments, versions or examples, which are included to enable a person having ordinary skill in the art to make and use the invention when combined with information and knowledge available to the person having ordinary skill in the art.

######DIGITALLY SIGNED########
PREM CHARLES I
REGISTERED PATENT AGENT INPA-3311
On Behalf of the Applicants

CLAIMS

We claim:

1. A hybrid transdermal patch, the process of preparation comprising the steps;

a plurality of drugs and excipients are selected for the process and mixed well using a stirrer;

at least one binder element is introduced to the mixture in order to completely emulate the mixture;

a process of sonication is applied to the mixture wherein the mixture is subject to sound energy towards agitate the particles;

the sonicated mixture is further centrifuged and dried in order to remove the excess moisture;

the formulated patches are then removed and characterized through ultraviolet treatment and tested for various parameters.

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PREM CHARLES I
REGISTERED PATENT AGENT INPA-3311
On Behalf of the Applicants

ABSTRACT

A HYBRID TRANSDERMAL PATCH

The bioavailability of drugs delivered through transdermal patches are high as it doesn't meet first pass metabolism and gastrointestinal degradation which serves as the biggest trump card than other routes. The present invention is to combine three drugs namely diclofenac, methyl salicylate and capsaicin to develop transdermal patches. The process of developing transdermal patches in lab scale is evident and they are validated for the efficacy, safety, quality, and toxicity of the drugs in the developed transdermal patches. These formulated patches are qualitatively and quantitatively validated and characterized using UV-Visible spectroscopy. The formulated patches are expected to treat multiple analgesic complications.

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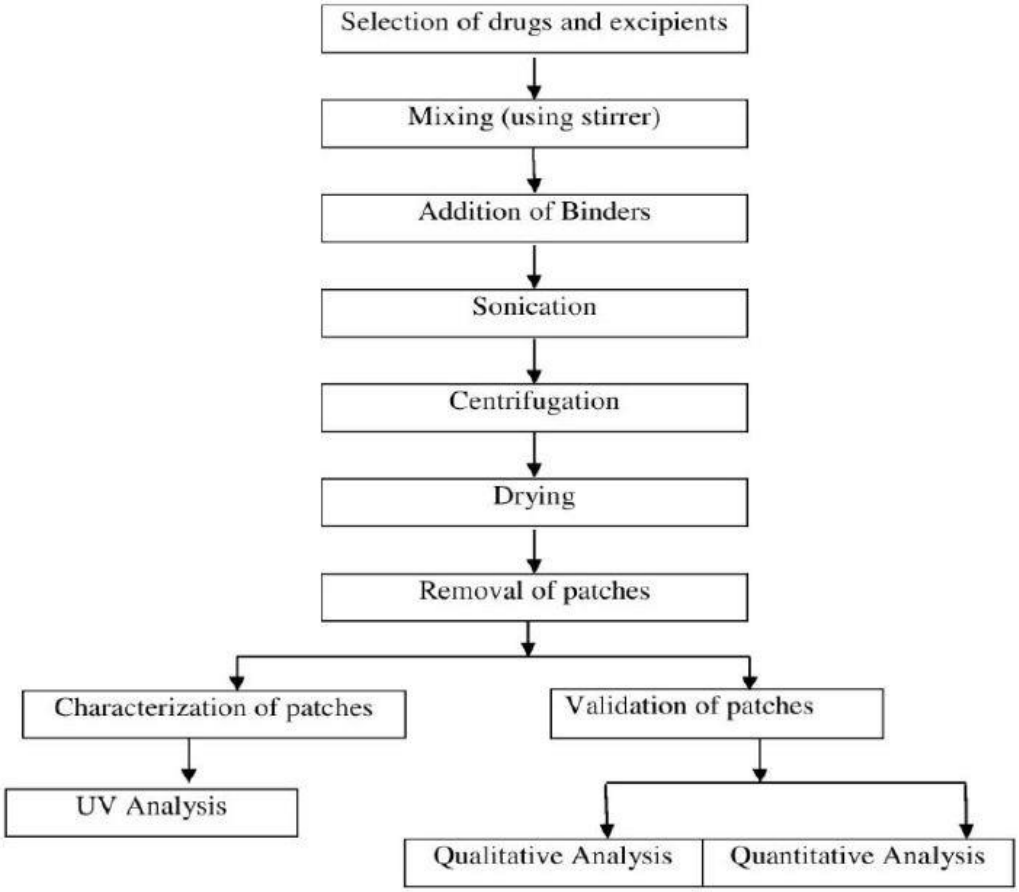

FIGURE 1

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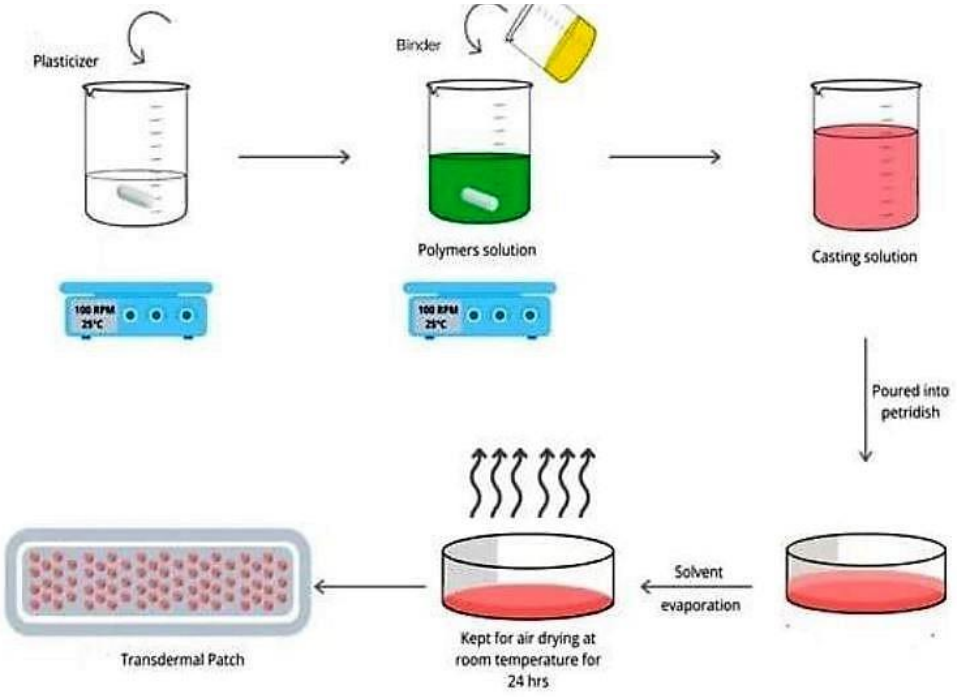

FIGURE 2

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On Behalf of the Applicants

FORM 3
THE PATENTS ACT, 1970
(39 of 1970)
and

THE PATENTS RULES, 2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

(See section 8; Rule 12)

I / We,

Name Of Applicants	Nationality	Address
PAAVAI ENGINEERING COLLEGE	INDIAN	NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL- 637 018, TAMIL NADU, INDIA.

hereby declares:-

(i) that I/We who have made this application No.: 202241007788 dated 14-02-2022; alone/jointly has made for the same / substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

NAME OF THE COUNTRY	DATE OF APPLICATION	APPLICATION NO.	STATUS OF THE APPLICATION	DATE OF PUBLICATION	DATE OF GRANT
—	—	—	—	—	—

(ii) that the rights in the application(s) has/have been assigned to

"NONE" and the rights are held with applicants only;

that I/We undertake that upto the date of grant of the patent by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application.

Dated This 15th day ofFeb,2022

Signature,
NAME: PREM CHARLES I(INPA 3311)
PATENT AGENT ON BEHALF OF THE APPLICANT(S)

To,
THE PATENT OFFICE, INTELLECTUAL PROPERTY BUILDING, BOUDHIK SAMPADA BHAVAN, GUINDY, CHENNAI- 600037 TAMIL

FORM 5
THE PATENTS ACT, 1970
(39 of 1970)
and

THE PATENTS RULES, 2003

DECLARATION AS TO INVENTORSHIP

[See section 10(6) and rule 13(6)]

1. NAME OF APPLICANT (S)	PAAVAI ENGINEERING COLLEGE (AUTONOMOUS)

hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my/our application numbered **202241007788** Dated **14thday ofFeb,2022** are

INVENTOR (S):

1	**a) Name:**	DR.G.SRINIVASAN
	b) Nationality:	INDIAN
	c) Address:	PROFESSOR & HEAD, DEPARTMENT OF CHEMICAL ENGINEERING, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU.
2	**a) Name:**	DR. PRAVEEN KUMAR
	b) Nationality:	INDIAN
	c) Address:	PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU.
3	**a) Name:**	MR. M.G. KARTHI
	b) Nationality:	INDIAN
	c) Address:	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL- 637 018, TAMIL NADU.
4	**a) Name:**	MR. M. PONMANIAN
	b) Nationality:	INDIAN
	c) Address:	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL- 637 018, TAMIL NADU.
5	**a) Name:**	MS. S. PRAGATHI
	b) Nationality:	INDIAN
	c) Address:	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL- 637 018, TAMIL NADU.
6	**a) Name:**	DR. S. KAILASH
	b) Nationality:	INDIAN
	c) Address:	PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU.
7	**a) Name:**	MRS. M. R. MAHALAKSHMI
	b) Nationality:	INDIAN
	c) Address:	ASSOCIATE PROFESSOR, DEPARTMENT OF FOOD TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU.

8	**a) Name:**	C. P. MURALI
	b) Nationality:	INDIAN
	c) Address:	ASSISTANT PROFESSOR, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE(AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL- 637 018, TAMIL NADU.
9	**a) Name:**	MS. C. QUEEN SANTHOSHINI
	b) Nationality:	INDIAN
	c) Address:	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL - 637 018, TAMIL NADU.
10	**a) Name:**	MR. T. PAVILAN
	b) Nationality:	INDIAN
	c) Address:	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018, TAMIL NADU.
11	**a) Name:**	MR. R. SRINIVASAN
	b) Nationality:	INDIAN
	c) Address:	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018, TAMIL NADU.
12	**a) Name:**	MR. R RAMKUMAR
	b) Nationality:	INDIAN
	c) Address:	STUDENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, PAAVAI ENGINEERING COLLEGE (AUTONOMOUS), NH-44, PAAVAI NAGAR, PACHAL, NAMAKKAL -637 018, TAMIL NADU.

Dated This 14thday ofFeb,2022

Signature,

NAME: PREM CHARLES I(INPA 3311)

PATENT AGENT ON BEHALF OF THE APPLICANT(S)

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY:-
-N.A-

To,

THE PATENT OFFICE, INTELLECTUAL PROPERTY BUILDING, BOUDHIK SAMPADA BHAVAN, GUINDY, CHENNAI- 600037 TAMIL