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Ramnagar Dist. Hanamakonda- 506001, (T.S)

S.No.	Name of the research project/ endowment	Name of the Principal Investigator/Co-investigator	Year of Award	Amount Sanctioned	Duration of the project	Name of the Funding Agency	Type (Government/non-Government)
1	Dental insert	Dr. Y. Shravan Kumar	2020-2021	50,000		VIPRA	NON-GOVERNMENT
2	Flubiprofen tablets formulation with improved release properties	Dr E. Venkateshwarulu	2020-2021	50,000		VIPRA	NON-GOVERNMENT
3	For research Work	Dr.Adukondalu	2020-2021	100,000	2yrs	VIPRA	NON-GOVERNMENT



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MTR Form Number-6



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Office Name	PUNE A T O Stamps			Full Name	Dr Sateesh Kumar Vemula					
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Yashwantrao Chavan College of Pharmacy
Warangal, Warangal-506 001

FORM 26
THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003

**FORM OF AUTHORIZATION OF A PATENT AGENT IN A MATTER
OR PROCEEDING UNDER THE ACT**

[See sections 127 and 132; rule 135]

We, **Dr. Sateesh Kumar Vemula**, Nationality: Indian, Address: Department of Pharmaceutics, MAK College of Pharmacy, Moinabad, Ranga Reddy, Telangana, India 501504, **Dr. Bhaskar Daravath**, Nationality: Indian, Address: Department of Pharmaceutics, GITAM School of Pharmacy, GITAM Deemed to be University, Rudraram, Patancheru, Sangareddy, Hyderabad, Telangana, India 502329; **Dr. Venkateshwarlu Eggadi**, Nationality: Indian, Address: Department of Pharmacology, Vaagdevi College of Pharmacy, Kishanpura, Hanamkonda, Telangana, India, 506001; **Dr. Sridhar Babu Gummadi**, Nationality: Indian, Address: Department of Medicinal Chemistry, Sri Shivani College of Pharmacy, Mulugu Road, Warangal, Telangana, India, 506006, **Rajendra Kumar Jadi**, Nationality: Indian, Address: Department of Pharmaceutics, Anurag University, Ghatkesar, Medchal, Telangana, India, 500088, **Dr. Pradeep Bodake**, Nationality: Indian, Address: Department of Pharmaceutics, Jijamata College of Pharmacy, Sarati, Indapur, Pune, Maharashtra, India, 413103, **Peta Sudhakar**, Nationality: Indian, Address: Department of Pharmacology, St Pauls College of Pharmacy, Turkayamjal, Ranga Reddy, Telangana, India, 501510, **Dr. Md. Ashaduz Zaman**, Nationality: Indian, Address: Department of Pharmaceutics, Scamewo Institute of Pharmaceutical Sciences. Shastrinagar, Dr. B. R. Ambedkar Road, Goalpara, Assam, India, 783121, **Dr. Kiran Thadkala**, Nationality: Indian, Address: Department of Pharmaceutics, MRM College of Pharmacy, Chintapallyguda, Ibrahimpatnam, Rangareddy, Telangana, India, 501510, **Matsyagiri Lenkalapally**, Nationality: Indian, Address: H.No.3-56, Vangapally Yadagirigutta, Yadadri Bhongir Telangana, India, 508116, do hereby authorize Ms. Sanchita Tewari, Registered Patent Agent (IN/PA-2711) and Mr. Prabhakar Ramabhilash Sharma, Registered Patent Agent (IN/PA-4122), both having address at THIRDIP Intellectual Property Services LLP, 15 A, 4th Floor, City Vista, Suite



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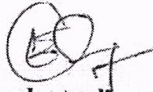
Dr. Sateesh Kumar Vemula

Department of Pharmaceutics, MAK College of Pharmacy, Moinabx, Sangareddy, Telangana, India, 501504



Dr. Bhaskar Daravath

Department of Pharmaceutics, GITAM School of Pharmacy, GITAM Deemed to be University, Rudraram, Patancheru, Sangareddy, Hyderabad, Telangana, India, 502329



Dr. Venkateshwarlu Eggadi

Department of Pharmacology, Vaagdevi College of Pharmacy, Kishanpura, Hanamkonda, Telangana, India, 506001



Dr. Sridhar Babu Gummadi

Department of Medicinal Chemistry, Sri Shivani College of Pharmacy, 1/1, Nuggu Road, Warangal, Telangana, India, 506006

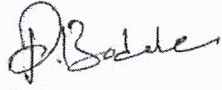


Rajendra Kumar Jadi

Department of Pharmaceutics, Anurag University, Ghatkesar, Medchal, Telangana, India, 500088

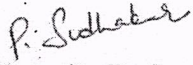


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Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001



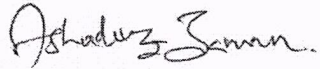
Dr. Pradeep Bodake

Department of Pharmaceutics, Jijamata College of Pharmacy, Sarati, Indapur
Pune, Maharashtra, India, 413103



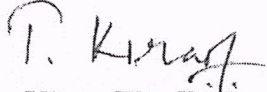
Peta Sudhakar

Department of Pharmacology, StPauls College of Pharmacy, Turkayamjal, Rangareddy,
Telangana, India, 501510



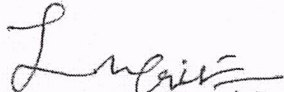
Dr. Md. Ashaduz Zaman

Department of Pharmaceutics, Scamewo Institute of Pharmaceutical Sciences,
Shastrinagar, Dr. B. R. Ambedkar Road, Goalpara, Assam, India, 783121



Dr. Kiran Thadkala

Department of Pharmaceutics, MRM College of Pharmacy, Chintapallyguda,
Ibrahimpatnam, Rangareddy, Telangana, India, 501510



Matsyagiri Lenkalapally

H.No.3-56, VangapallyYadagirigutta, YadadriBhongir Telangana, India, 508116



Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

To
The Controller of Patents
The Patent Office at Chennai



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Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001



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

**METHOD FOR PREPARATION OF TRANSDERMAL DRUG DELIVERY
SYSTEM WITH NATURAL BIOPOLYMER MATRIX**

2. APPLICANTS (S)

NAME	NATIONALITY	ADDRESS
MD Parveen	INDIAN	Assistant Professor, Department of Pharmaceutics, Max Institute of Pharmaceutical Sciences, Velugumatla- 507318, Khammam, Telangana, India
Dr.S N Koteswara Rao G	INDIAN	Vice Principal & Professor, Head -Dept. of Pharmaceutics, KL College of Pharmacy, Koneru Lakshmaiah Education Foundation Deemed to be University, Vaddeswaram, Guntur , Andhra Pradesh.





Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

Dr.Ch. Anil Kumar	INDIAN	Assistant Professor, University College of Pharmaceutical Science, Satavahana University, Karimnagar Telangana, India-505001
Dr. Adukondalu Devandla	INDIAN	Associate Professor, Vaagdevi College of Pharmacy, Ram Nagar, Hanamkonda, Warangal, Telangana, India-506001
Neha Kumari	INDIAN	Sri Sai College of Pharmacy, Badhani, Pathankot, Punjab -145001
Sumit Kaushik	INDIAN	Faculty of Pharmacy, Raja Balwant Singh Engineering Technical Campus, Bichpuri Agra
Pooja Bharti	INDIAN	Assistant Professor Agra Public Pharmacy College Artoni Agra
Fazlu Rehman	INDIAN	Associate Professor Department of Pharmaceutics, Global college of Pharmacy, Hyderabad, Telangana, India
Yashveer Bhardwaj	INDIAN	Assistant Professor, Career Point University, Hamirpur, Himachal Pradesh

3. PREAMBLE TO THE DESCRIPTION

COMPLETE SPECIFICATION

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



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METHOD FOR PREPARATION OF TRANSDERMAL DRUG DELIVERY SYSTEM WITH NATURAL BIOPOLYMER MATRIX

TECHNICAL FIELD

[0001] The present disclosure relates to a method of preparation and particularly it relates to transdermal drug delivery systems with natural biopolymer matrix.

BACKGROUND

[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 drug delivery systems (TDDS), otherwise called patches are dosage forms that convey medication into the bloodstream through the patient's skin. The transdermal drug delivery route consists of a discrete pharmaceutical dosage structure that when applied across unbroken skin, conveys a desired drug through the outer layers of the skin to the subcutaneous tissue from where the drug can be absorbed into the blood for distribution across the body. Such TDDS can take multiple forms, such as medicated plasters, usually available in bulk and used for localized release of pain medications at fractures and broken bones; as well as transdermal patches which are medicated adhesive patches that are placed on skin to deliver a time release dose of medication through skin for treating a systemic illness. The transdermal therapeutic system is of particular clinical significance for prevention and long-term treatment of chronic diseases like Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis, Dysmenorrhea, Acute Gout and Pain; as well as being commonly used for delivery of nicotine as an aid for smokers who are trying to quit. The present invention relates to the method of preparation of such transdermal patch systems.

[0004] Transdermal drug delivery enjoys several advantages over other routes of administration. It is an efficient and convenient method for conveyance of medications without first pass metabolism at steady predictable rates. It is useful for delivery of



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Vardhni College of Pharmacy
Hannamkonda, Warangal-506 001

medications that may cause gastrointestinal distress or other unpleasant effects like vomiting or loose bowels when administered orally. It is also easy to administer and terminate while providing steady plasma concentrations of even short half-life drugs or drugs with narrow therapeutic window over long periods of time.

[0005] Polymers are the backbone of TDDS, which control the discharge of the drug from the device. Polymer matrixes are often prepared by dispersion of drug in liquid or solid-state synthetic polymer base. Polymers utilized in TDDS should have biocompatibility and chemical compatibility with the drug and other components of the system like penetration enhancers and PSAs. Additionally, they ought to provide consistent and effective delivery of a drug throughout the product's intended time period and will be of safe status.

[0006] Several system designs have been used in development and fabrication of TDDSs. The systems that have been introduced in market can be classified into following types – Matrix type, Reservoir type, Membrane matrix hybrid, Micro reservoir type and Drug in adhesive type. Matrix type systems consist of a drug reservoir made out of a polymer matrix in which the drug is uniformly dispersed by dissolving the drug and polymer in a common solvent. The insoluble drug should be homogenously dispersed in hydrophilic or lipophilic polymer. The required quantity of plasticizer like dibutylphthalate, triethylcitrate, polyethylene glycol or propylene glycol and permeation enhancer is then added and mixed properly. The medicated polymer formed is then molded into sheets or shapes with defined surface area and controlled thickness, followed by evaporation of the solvent to render the matrix solid. Commonly used polymers for matrix are cross linked polyethylene glycol, eudragits, ethyl cellulose, polyvinylpyrrolidone and hydroxypropyl methylcellulose (HPMC). Advantages of matrix patches include absence of dose dumping, direct exposure of polymeric matrix to the skin and no interference of adhesive with drug absorption.

[0007] Various methods exist for preparation of the TDDS – These involve different modes of casting the drug reservoir system. Methods such as the Solvent Casting method, Asymmetric TPX membrane method, Round Teflon Method, Mercury substrate method, IPM membrane method, EVAC membrane method, Aluminum based adhesive film method



and Hot melt extrusion process are widely known, well studied and understood by persons knowledgeable in the field of medicated TDDS manufacture.

[0008] Efforts have been made in the related prior art to provide different processes of making transdermal drug delivery patches. Research literature by Jamakandi et al. from 2009 [*Jamakandi, V. G., Mulla, J. S., Vinay, B. L., & Shivkumar, H. N. (2009). Formulation, Characterisation, and Evaluation of matrix type transdermal patches of Anti-hypertensive Drugs. Drug. Del, 1-7.*] discloses use of different polymeric grades of Hydroxyl Propyl Methyl Cellulose (HPMC) for the development of transdermal drug delivery system of Nicorandil, an Antianginal drug. Prepared matrix type patches were evaluated for his or her physicochemical characterization accompanied by in-vitro evaluation.

[0009] Another research paper by Wokovich et al. from 2016 [*Wokovich, A. M., Prodduturi, S., Doub, W. H., Hussain, A. S., & Buhse, L. F. (2006). Transdermal drug delivery system (TDDS) adhesion as a critical safety, efficacy and quality attribute. European Journal of Pharmaceutics and Biopharmaceutics, 64(1), 1-8.*] provides synopsis of the on kinds of transdermal delivery system, their anatomy, the role of adhesion failure modes and how adhesion may be measured to boost transdermal adhesive performance.

[0010] A research paper by Mandal Sonjoy et al. from 2011 [*Sonjoy, M., Thimmasetty, J., Ratan, G. N., & Kilarimath, B. H. (2011). Formulation and evaluation of carvedilol transdermal patches. International Research Journal of Pharmacy, 2(1), 237-248.*] discloses methods to produce and evaluate matrix type transdermal formulations containing carvedilol with various ratios of hydrophilic (HPMC) and hydrophobic polymeric (Eudragit RS100) combinations plasticized with glycerin and dibutylphthalate by the solvent evaporation technique. Aftereffect of surfactant (PEG-400 and Tween 80) and permeation enhancers (DMSO and DMF) were studied.

[0011] PCT patent WO2014145484 discloses device for measurement and monitoring of a subject simultaneously with transdermal or transmucosal delivery of a therapeutic agent at a contact site with the subject's skin includes a transdermal sensor adapted and configured



to detect a specific indicator that is either the therapeutic agent itself or a biomarker that is affected by the therapeutic agent, a therapeutic-agent-containing formulation for passive or active transdermal drug delivery, wherein the formulation includes a dermo-adhesive agent to adhere the underside of the sensor housing unit to the skin, and a separate circumferential self-adhesive patch can be adapted and configured to hold the sensor and its housing unit firmly to the skin at the contact site for multiple days.

[0012] Similar US patent US20090259176 reveals a transdermal patch system configured as a patch or pump assembly may be placed into contact upon a skin surface to transport drugs or agents transdermally via any number of different mechanisms such as microporous membranes, microneedles, in-dwelling catheters, etc. The assembly may enclose or accommodate a reservoir configured as an elongate microchannel to contain the drug or agent suspended in a fluid vehicle. The reservoir may also be fluidly coupled via microchannels to transport the drugs into or against an underlying skin surface as driven or urged via a pump and controlled by an electronic control circuitry which may be programmed to affect any number of treatment regimens.

[0013] All such prior arts employ artificial or chemically modified polymers and microfluidic reservoir systems to store drugs for transdermal delivery. This increases the cost of producing the TDDS and places the burden on the buyer of the final product.

[0014] Therefore, the present disclosure overcomes the above-mentioned problem associated with the traditionally available methods or systems, any of the above-mentioned inventions can be used with the presented disclosed technique with or without modification. All publications herein are incorporated by reference to the same extent as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies. Accordingly, 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.



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[0015] 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.



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OBJECTS OF THE INVENTION

[0016] It is an object of the present disclosure is to provide a method to produce a transdermal drug delivery system with biopolymer matrix derived from Flaxseed Mucilage (FSM).

SUMMARY

[0017] The present disclosure relates to a method of preparation of a biopolymer matrix based transdermal drug delivery patch consisting of the system containing the drug containing patch affixed to an adhesive backing for application on skin.

[0018] In this further system, the patch contains the drug dispersed in a biopolymer matrix consisting of Flaxseed Mucilage (FSM) and Hydroxypropyl methylcellulose (HPMC) copolymer and a plasticizing agent such as Polyethylene Glycol (PEG).

[0019] In the present invention, the method for employing low-cost biopolymer derived from commonly available flaxseed for use in transdermal patch formulation is described.

[0020] In this method further comprises of preparation of plasticized biopolymer-drug mixture and the formulation of patch by solvent casting method.

[0021] One should appreciate that although the present disclosure has been explained with respect to a defined set of functional modules, any other module or set of modules can be added/deleted/modified/combined, and any such changes in architecture/construction of the proposed systems are completely within the scope of the present disclosure. Each module can also be fragmented into one or more functional sub-modules, all of which also completely within the scope of the present disclosure.

[0022] Various objects, features, aspects and advantages of the inventive subject matter will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures in which like numerals represent like components.



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BRIEF DESCRIPTION OF THE DRAWINGS

[0023] 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.

[0024] FIG. 1 illustrates a flowchart for preparation of plasticized biopolymer matrix containing dispersed drug.

[0025] FIG. 2 illustrates a flowchart method of preparation of transdermal patch using biopolymer matrix containing dispersed drug.

[0026] FIG. 3 depicts the typical construction of matrix type transdermal patch

[0027] It should be noted that the figures are not drawn to scale, and the elements of similar structure and functions are generally represented by like reference numerals for illustrative purposes throughout the figures. It should be noted that the figures do not illustrate every aspect of the described embodiments and do not limit the scope of the present disclosure.

[0028] Other objects, advantages, and novel features of the invention will become apparent from the following detailed description of the present embodiment when taken in conjunction with the accompanying drawings.



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DETAILED DESCRIPTION

[0029] 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. As the detailed description is concerned various stages are included in embodiments of the present invention, which will be detailed below. The stages can be carried out along with statistical data and by machine-executable instructions, which can be used to direct a general-purpose or special-purpose processor to carry out the procedures. If the specification states a component or feature "may", "can", "could", or "might" be included or have a characteristic, that particular component or feature is not required to be included or have the characteristic.

[0030] Aspects of the present disclosure relate to method of preparing a transdermal drug delivery system with natural biopolymer matrix. It is inferred that the foregoing description is only illustrative of the present invention, and it is not intended that invention be limited or restrictive thereto. Many other specific embodiments of the present invention will be apparent to one skilled in the art from the foregoing disclosure. All substitutions, alterations and modifications of the present invention which comes within the scope of the following claims are to which the present invention is readily susceptible without departing from the spirit of the invention. The scope of the invention should therefore be determined not with reference to appended claims but along with the full scope of equivalents to which such claims are entitled.

[0031] Thus, for example, it will be appreciated by those of ordinary skill in the art that the diagrams, schematics, illustrations, and the like represent conceptual views or processes illustrating systems and method embodying this invention. Those of ordinary skill in the art further understand that the exemplary processes, method, and/or pharmaceutical components described herein are for illustrative purposes and, thus, are not intended to be limited to any particular named.



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[0032] 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.

[0033] 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.

[0034] In an embodiment of the present disclosure, FIG. 1 illustrates the method of producing the plasticized polymer-drug matrix wherein said method comprises of firstly, preparing Flaxseed mucilage (FSM) by boiling whole flaxseed in water at medium to low heat uncovered till the mixture turns thick & glossy and white streaks are observed. Said solution is then filtered and stored under refrigeration.

[0035] In an embodiment of the present disclosure, FIG. 1 illustrates the method wherein said method comprises of secondly, preparing the drug and polymer/copolymer mixture by combining the drug such as Naproxen sodium (NS) in suitable solvent such as oleic acid with the polymer & copolymer (FSM and another polymer such as HPMC) and mixing till uniformly dispersed and free of lumps.

[0036] In an embodiment of the present disclosure, FIG. 1 illustrates the method wherein said method comprises of thirdly plasticizing the mixture by addition of polymeric solvent such as Polyethylene Glycol and mixing till homogenous and allowing to stand for 2 hours to exclude any trapped gasses.

[0037] In another embodiment of the present invention, FIG. 2 illustrates the method of producing the transdermal patch using plasticized biopolymer-drug matrix wherein said



method comprises of firstly extruding the plasticized mixture on a clean flat support surface into a layer of uniform thickness and sheet of known shape and surface area.

[0038] In another embodiment of the present invention, FIG. 2 illustrates the method of producing the transdermal patch using plasticized biopolymer-drug matrix wherein said method comprises of secondly drying the extruded sheet under vacuum at room temperature till it is solid and flexible without the support surface after which it may be stored in a desiccator in foil packing.

[0039] In another embodiment of the present invention, FIG. 2 illustrates the method of producing the transdermal patch using plasticized biopolymer-drug matrix wherein said method comprises of thirdly affixing the dried patch to an adhesive lined backing which consists of an impermeable layer and an absorbent layer along with adhesive on the area intended for skin contact.

[0040] One aspect of the present invention is the method is the relative low cost of FSM over conventional polymers used for TDDS matrix formulations – Flaxseeds are cheap, widely available even in rural regions and extraction of mucilage does not require any specialized equipment. Therefore, this method reduces the overall cost of materials for TDDs manufacture, thereby allowing cheaper final product to be made available to the public as well as larger profit margins on the finished product.

[0041] 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.

[0042] Thus, the scope of the present disclosure is defined by the appended claims and includes both combinations and sub-combinations of the various features described



Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

hereinabove as well as variations and modifications thereof, which would occur to persons skilled in the art upon reading the foregoing description.

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Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

I/We Claim:

1. A method of preparation of a patch for transdermal drug delivery, wherein the method comprises the steps of:
 - preparing of a plasticized mixture containing the drug in a biopolymer matrix;
 - extruding of the plasticized mixture as a thin film onto clean, flat support substrate surface of suitable size;
 - drying of the extruded mixture under vacuum at room temperature; and
 - affixing of dried film onto adhesive lined backing to be used as a patch suitable for application on skin.
2. The method of preparation of a patch for transdermal drug delivery as claimed in claim 1, wherein the plasticized mixture consists of:
 - the drug quantity intended for delivery in a suitable solvent, such as Naproxen sodium (NS) (250mg) in 0.5ml oleic acid;
 - the biopolymer flaxseed mucilage (FSM), prepared by boiling whole flax seed in aqueous solution till mucilage is extracted;
 - the polymer Hydroxypropyl methylcellulose (HPMC E15); and
 - the plasticizer Polyethylene glycol (PEG 400) (15% v/w of total dry polymer weight).
3. The plasticized mixture as claimed in claim 2, wherein the total weight of the polymers (FSM + HPMC) is 30 mg for 250mg NS and the ratio of FSM:HPMC can range between 1:5 and 5:1 by weight.
4. The plasticized mixture as claimed in claim 2, wherein the plasticizer is added after the drug and polymers have been mixed till homogenous and care taken to avoid any lumps in homogenization process.



5. The method of preparation of a patch for transdermal drug delivery as claimed in claim 1, wherein the plasticized mixture is allowed to stand for 2 hrs prior to extrusion to exclude any entrapped air.
6. The method of preparation of a patch for transdermal drug delivery as claimed in claim 1, wherein the extruded film on support substrate is dried in a vacuum oven at room temperature till the film is solid and flexible without the support, after which it may be stored in a desiccator after packing in foil.
7. The method of preparation of a patch for transdermal drug delivery as claimed in claim 1, wherein the adhesive lined backing consists of an impermeable layer with and absorbent layer coated with adhesive designed to stick temporarily to human skin and provide integrity and structural support to the drug containing matrix film during its use.



Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

No.789 Fountain Road, Kharadi, Pune Maharashtra 411014 India, to act on our behalf in connection with filing, prosecution and maintenance of our Indian patent application in respect of inventions related to “**FLURBIPROFEN TABLET FORMULATION WITH IMPROVED RELEASE PROPERTIES** ” and any foreign patent corresponding to the said invention including PCT application and requests that all notices, requisitions and communication relating thereto may be sent to such person at the below mentioned address unless otherwise specified.

We hereby revoke all or any previous authorization, if any made, in respect of same matter or proceeding.

We hereby assent to the action already taken by the said person in the above matter.

Address of service

THIRDIP Intellectual Property Services LLP,
15 A, 4th Floor, City Vista, Suite No.789,
Fountain Road, Kharadi, Pune, Maharashtra, 411014 India

Dated this 26th day of August 2022



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Principal
Veerdevi College of Pharmacy
Warangal, Warangal-506 001

ABSTRACT

METHOD FOR PREPARATION OF TRANSDERMAL DRUG DELIVERY SYSTEM WITH NATURAL BIOPOLYMER MATRIX

The present disclosure relates to a method of preparing of matrix-dispersion type transdermal drug delivery system using biopolymer derived from flaxseed *Linum usitatissimum*. Transdermal patches of naproxen sodium were prepared with flaxseed mucilage in combination with hydroxyl propyl methyl cellulose (HPMC).



(FIG. 2 will be the reference figure)



Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

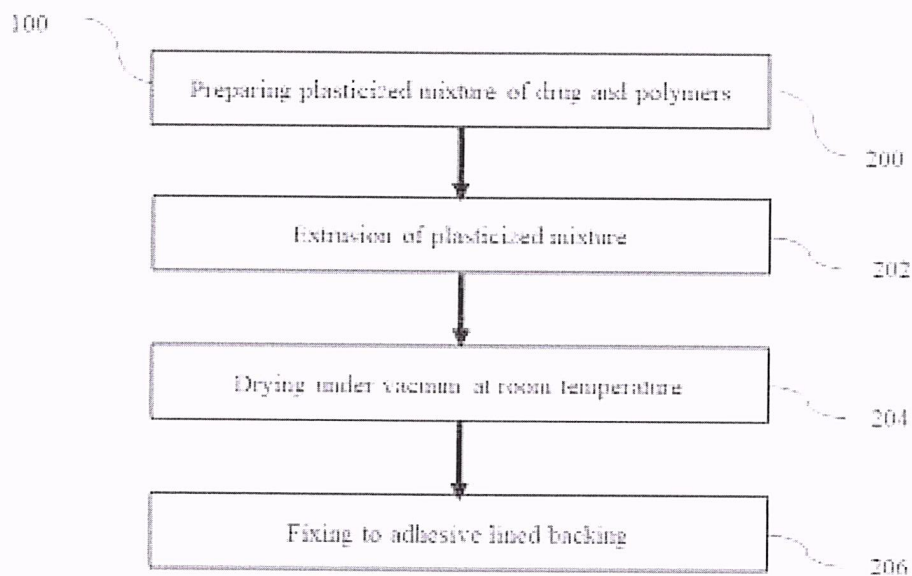


FIG. 2 illustrates a flowchart method of preparation of transdermal patch using biopolymer matrix containing dispersed drug.



Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001