ACSTM 2019
Asian Conference on Science, Technology & Medicine

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Kalam Sirisha
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December 10, 2018

**Subject:** *Invitation & Acceptance Letter - Oral Presentation*

Dear **Kalam Sirisha**,

We are pleased to inform you that Program Committee has approved your Abstract for **ORAL PRESENTATION** at ACSTM 2019 after a thorough peer review of your submitted research findings.

In this reference we cordially invite you to attend the 3rd Asian Conference on Science, Technology & Medicine to present your research entitled:

" *Design, Synthesis And Pharmacological Evaluation Of New Ciprofloxacin-Based Compounds As Chimeric Antitubercular Agents*"

**Note:** Approved abstracts will be published in the Conference Proceeding and will be indexed in Asian Digital Library, and IndexONE Database.

ACSTM aims to provide the platform that pays attention not only on the recent outstanding achievements in the field of Science, Technology and Medicine but also highlights the current trends and future needs.

We look forward for your participation in 3rd Asian Conference on Science, Technology & Medicine in Dubai.

With profound Regards,

Jean Ashley
Event Coordinator
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Vaagdevi College of Pharmacy Ramnagar, Hanamkonda

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ACSTM 2019

Asian Conference on Science, Technology & Medicine
3rd Conference | 12-14 February, 2019 | Dubai, U.A.E

# Certificate of Participation

This is to certify that

Dr. Kalam Sirisha

Vaagdevi College of Pharmacy, India

has presented a paper titled

Design, Synthesis and Pharmacological Evaluation of New Ciprofloxacin-Based Compounds as Chimeric Antitubercular Agents

**3rd Asian Conference on Science, Technology & Medicine**

Held on 12-14 February, 2019 at Carlton Palace Hotel, Deira Dubai, UAE

Vaagdevi College of Pharmacy Ramnagar, Hanamkonda

Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

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Kalam Sirisha
Professor, Vaagdevi College of Pharmacy,
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Warangal,India

November 17, 2018

**Subject:** *Travel Grant to attend ACSE/ACSTM 2019 in Dubai*

Dear **Kalam Sirisha**,

**Congratulations!** We are pleased to inform you that based on the scores of independent evaluation and funding review committee your **Travel Grant** to attend ACSE and ACSTM 2019 has been approved along with the submitted Abstract entitled " *DESIGN, SYNTHESIS AND PHARMACOLOGICAL EVALUATION OF NEW CIPROFLOXACIN-BASED COMPOUNDS AS CHIMERIC ANTITUBERCULAR AGENTS*" for **ORAL PRESENTATION**

With this Travel Grant award you are entitled to attend both conferences (3rd ACSTM and 6th ACSE Annual Conference) with one registration fee. The conferences will be hosted in Carlton palace Hotel, Deira Dubai during 12-14th February, 2019.

Approved abstracts will be published in the Conference Proceeding and will be indexed in Asian Digital Library, and IndexONE Database.

You are thereby requested to complete your registration process immediately.

We look forward to your valuable participation!

Regards,

Adam Vickers
Travel Grant Committee
ACSE/ACSTM

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# CENTRE FOR CO-OPERATION IN SCIENCE & TECHNOLOGY AMONG DEVELOPING SOCIETIES (CCSTDS)

(A Unit of Indian National Science Academy (INSA), New Delhi
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Prof.N.Sathyamurthy
Honorary Director

31 January 2019

DO\Lr \TF-III\2018-19

DR KALAM SIRISHA
ASSOCIATE PROFESSOR & HEAD
VAAGDEVI COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACEUTICAL CHEMISTRY
RAMNAGAR, HANAMKONDA
WARANGAL-506001, TELANGANA

Dear DR KALAM SIRISHA,

Sub: Travel support to attend 3RD ASIAN CONFERENCE ON SCIENCE, TECHNOLOGY & MEDICINE - 2019(ACSTM -2019), DEIRA, DUBAI during 12/02/2019 - 14/02/2019

We are extremely pleased to inform you that CCSTDS will provide financial assistance of Rs 15000/- which is subject to actual expenditures and receipts from all other sources whichever is less towards partial travel / registration / accommodation for attending the above meeting/conference. Please confirm your acceptance of this offer within 15 days from the date of this letter, failing which the award will be forfeited.

In the event you are not able to utilise this grant for various reasons even after confirming your acceptance, please do inform us immediately so that the money can be transferred to waitlisted awardees.

The actual amount will be paid only after your return from the Conference subject to submission of claim documents. The claim form for claiming the grant is available in our website www.ccstds.tn.nic.in under the page 'Download Forms'. The filled in claim form should be submitted to CCSTDS along with a copy of the following

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Your claim must be endorsed by the Head of the Institute / competent authority and should reach our office within 15 days after attending the conference/workshop/training programme. Your claim will be reimbursed to your institute bank account electronically.

The grant is however subject to the consideration that you have not availed such offer from CCSTDS (formerly CICS) during the last three years.

The grant is governed by Terms and Conditions (enclosed). The admissibility of the claim will be as per INSA/CCSTDS norms.

In order to avoid delay in reimbursement of your claim, please do ensure that the terms and conditions are strictly adhered to.

With kind regards.

Yours sincerely

(N SATHYAMURTHY)
Encl: As above

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**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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To

The Controller of Patents

The Patent Office at Chennai

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Principal
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Hanamkonda, Warangal-506 001

**FORM 2**

THE PATENTS ACT 1970

39 OF 1970

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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)**

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**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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Vaagdevi College of Pharmacy
Ramnagar, Hanamkonda

*Principal*
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Hanamkonda, Warangal-506 001

# 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

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 dibutylpthalate, 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 dibutylpthalate 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.

**[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 DESCRITION

**[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



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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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**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.



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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.

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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,
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Dated this 26th day of August 2022

Vaagdevi College of Pharmacy Ramnagar Hanamkonda

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## 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)


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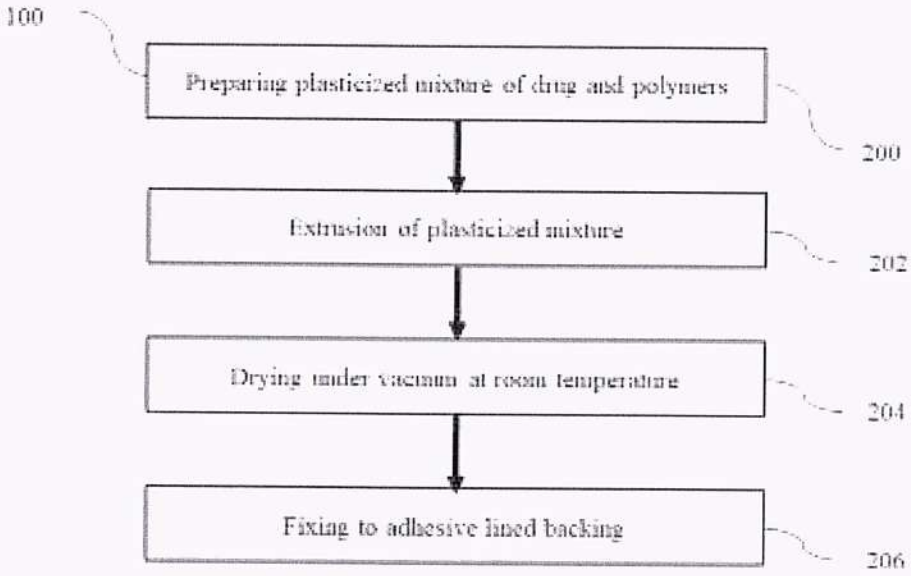


FIG. 2 illustrates a flowchart method of preparation of transdermal patch using biopolymer matrix containing dispersed drug.

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**FORM 2**

THE PATENTS ACT 1970

39 OF 1970

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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**

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## 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

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 dibutylpthalate, 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 dibutylpthalate 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



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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 DESCRITION

**[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



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(19) INDIA
(22) Date of filing of Application :17/09/2021

(21) Application No.202141042270 A
(43) Publication Date : 01/10/2021

(54) Title of the invention : An improved composition of a polyherbal extract with an improved neuroprotective effect

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| (51) International classification | :A23L 33/21 |
| (86) International Application No | :PCT// |
| Filing Date | :01/01/1900 |
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| (61) Patent of Addition to Application Number | :NA |
| Filing Date | :NA |
| (62) Divisional to Application Number | :NA |
| Filing Date | :NA |

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(57) Abstract :
The present invention relates to novel polyherbal extract (PHE) of three (Citrullus lanatus seeds, Cucumis sativus peel and Psidium guajava leaves) plant parts on cholinergic dysfunction and oxidative stress for the neuroprotective effect.

No. of Pages : 21 No. of Claims : 9



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(57) Abstract :
The present invention relates to novel Liquiritin extract of plant parts in treatment of Parkinson's disease with a neuroprotective effect.

No. of Pages : 16 No. of Claims : 6

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



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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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**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.



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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.

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## 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)



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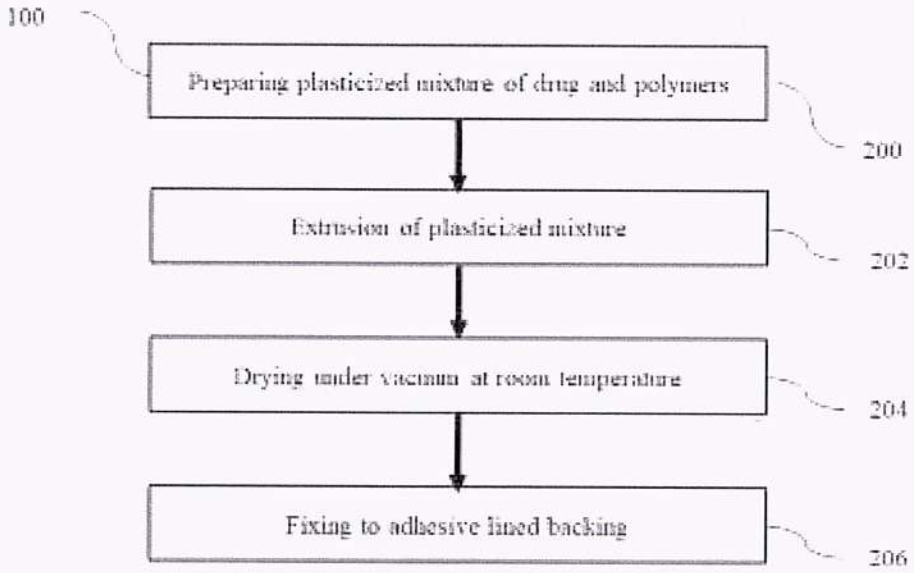


FIG. 2 illustrates a flowchart method of preparation of transdermal patch using biopolymer matrix containing dispersed drug.

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| **Type of Payment** | Stamps Non-Judicial<br>Sale of Non Judicial Stamps SoS | **TAX ID / TAN (If Any)** | |
| | | **PAN No.(If Applicable)** | |
| **Office Name** | PUNE A T O Stamps | **Full Name** | Dr Sateesh Kumar Vemula |
| **Location** | PUNE | | |
| **Year** | 2022-2023 One Time | **Flat/Block No.** | |
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