Office of the Controller General of Patents, Designs & Trade Marks
Department of Industrial Policy & Promotion,
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Government of India

(http://ipindia.nic.in/index.htm)

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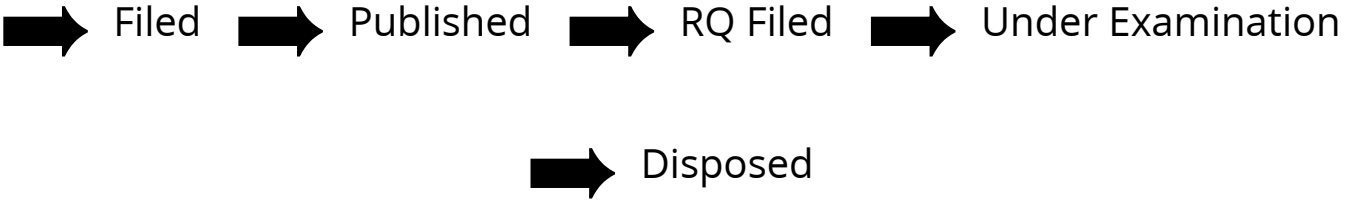
Application Details	
APPLICATION NUMBER	202121039262
APPLICATION TYPE	ORDINARY APPLICATION
DATE OF FILING	30/08/2021
APPLICANT NAME	1 . DR. SHUBHRAJIT MANTRY 2 . MS. SAYALI SAKHARAM HANDE 3 . DR. SUMIT ASHOK JOSHI 4 . DR. GANESH YOGIRAJ DAMA 5 . DR. SHRIRAM RAMESH PETHAKAR
TITLE OF INVENTION	TRANSDERMAL PATCH OF LOSARTAN POTASSIUM
FIELD OF INVENTION	CHEMICAL
E-MAIL (As Per Record)	vijay@patlex.in
ADDITIONAL-EMAIL (As Per Record)	vijay@patlex.in
E-MAIL (UPDATED Online)	
PRIORITY DATE	
REQUEST FOR EXAMINATION DATE	--
PUBLICATION DATE (U/S 11A)	10/09/2021

Application Status	
APPLICATION STATUS	Awaiting Request for Examination

			View Documents



In case of any discrepancy in status, kindly contact ipo-helpdesk@nic.in

पेटेंट कार्यालय
शासकीय जर्नल

OFFICIAL JOURNAL
OF
THE PATENT OFFICE

निर्गमन सं. 37/2021	शुक्रवार	दिनांक: 10/09/2021
ISSUE NO. 37/2021	FRIDAY	DATE: 10/09/2021

पेटेंट कार्यालय का एक प्रकाशन
PUBLICATION OF THE PATENT OFFICE

(12) PATENT APPLICATION PUBLICATION
(21) Application No.202121039262 A
(19) INDIA
(22) Date of filing of Application :30/08/2021
(43) Publication Date : 10/09/2021

(54) Title of the invention : TRANSDERMAL PATCH OF LOSARTAN POTASSIUM

(51) International classification	:A61K0009700000, C07D0403100000, A61K0031417800, C08L0033120000, A61K0009000000
(31) Priority Document No	:NA
(32) Priority Date	:NA
(33) Name of priority country	:NA
(86) International Application No Filing Date	:NA :NA
(87) International Publication No	: NA
(61) Patent of Addition to Application Number Filing Date	:NA :NA
(62) Divisional to Application Number Filing Date	:NA :NA

(71)**Name of Applicant :**
1)DR. SHUBHRAJIT MANTRY
Address of Applicant :Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune 410504, Maharashtra, India. Maharashtra India
2)MS. SAYALI SAKHARAM HANDE
3)DR. SUMIT ASHOK JOSHI
4)DR. GANESH YOGIRAJ DAMA
5)DR. SHRIRAM RAMESH PETHAKAR
(72)**Name of Inventor :**
1)DR. SHUBHRAJIT MANTRY
2)MS. SAYALI SAKHARAM HANDE
3)DR. SUMIT ASHOK JOSHI
4)DR. GANESH YOGIRAJ DAMA
5)DR. SHRIRAM RAMESH PETHAKAR

(57) Abstract :
The present invention is related to transdermal patch of Losartan potassium and the process of preparing the same. Transdermal patch of Losartan potassium are made by solvent casting method and useful for treating Hypertension.

No. of Pages : 22 No. of Claims : 6

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हि. एन. केदार
प्र.क्र. 3701028 तहसिल समोर, लातूर ।

FORM FOR AUTHORISATION OF A PATENT AGENT/OR ANY PERSON IN A MATTER OR PROCEEDING UNDER THE ACT

Power of Attorney by **Dr. Shubhrajit Mantry, Ms. Sayali Sakharam Hande, Dr. Sumit Ashok Joshi, Dr. Ganesh Yogiraj Dama** and **Dr. Shriram Ramesh Pethakar** in the name of **Vijaykumar Kashinath Shivpuje** of the address **Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India** in respect of the patent application filing and prosecution in India.

FORM 26

THE PATENTS ACT, 1970

(39 of 1970)

&

THE PATENT RULES, 2003

FORM FOR AUTHORISATION OF A PATENT AGENT/OR

ANY PERSON IN A MATTER OR PROCEEDING UNDER THE ACT

(See sections 127 and 132; rule 135)

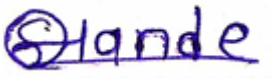
We

Name	Nationality	Address
Dr. Shubhrajit Mantry	Indian	Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India.
Ms. Sayali Sakharam Hande	Indian	Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India.
Dr. Sumit Ashok Joshi	Indian	Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India.
Dr. Ganesh Yogiraj Dama	Indian	Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India.
Dr. Shriram Ramesh Pethakar	Indian	Shramjivi Shikshan Prasarak Mandal's Shramjivi College of Pharmacy, Omerga, Dist: Osmanabad – 413606, Maharashtra, India.

hereby authorize **Vijaykumar Shivpuje (IN-PA 1096)** of the address **Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India** to act our behalf, as our agent, in connection with Granted patents and pending applications or any future cases, their renewals and maintenance, objections, oppositions, rectifications, cancellations, assignments and other matters and proceedings relating thereto and to receive all notices, requisitions and communications until further notice.

We further authorize our said agents to appoint any person or persons on our behalf to do all what is necessary in the matters and proceedings. We hereby revoke all previous authorizations, if any made, in respect of, same matter or proceeding.

Dated this 27th August 2021

Name	Signature
Dr. Shubhrajit Mantry	
Ms. Sayali Sakharam Hande	
Dr. Sumit Ashok Joshi	
Dr. Ganesh Yogiraj Dama	
Dr. Shriram Ramesh Pethakar	

To,

The Controller of Patent,

The Patent Office, at…**Mumbai**…

FORM 3 **THE PATENTS ACT, 1970** **(39 OF 1970)** **and** **THE PATENTS RULES, 2003** **STATEMENT AND UNDERTAKING UNDER SECTION 8** **[See section 8, rule 12]**	
1. Name of the applicant (s),	~~I/~~We **DR. SHUBHRAJIT MANTRY** Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India. **MS. SAYALI SAKHARAM HANDE** Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India. **DR. SUMIT ASHOK JOSHI** Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India. **DR. GANESH YOGIRAJ DAMA** Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India. **DR. SHRIRAM RAMESH PETHAKAR** Shramjivi Shikshan Prasarak Mandal's Shramjivi College of Pharmacy, Omerga, Dist: Osmanabad – 413606, Maharashtra, India. hereby declare,
2. Name, address and nationality of the joint applicant	(i) that ~~I/~~We have not made any application for the same/substantially the same invention outside India. **Or** (ii) ~~that I/We who have made this application No……dated ……alone/jointly with……made for the same/substantially same invention, application(s) for patent~~

		~~in the other countries, the particulars of which are given below:~~			
Name of the country	Date of application	Application No	Status of the application	Date of publication	Date of grant
N/A					
3. Name and address of the assignee		(iii) that the rights in the application(s) have been assigned to …… that I/~~We~~ undertake that upto the date of the grant of the patent by the Controller, I/~~We~~ would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application. Dated this 30th day of August 2021			
4. To be signed by the applicant or his authorized patent agent		Signature Digitally signed by,			
5. Name of the natural person who has signed		**VIJAYKUMAR SHIVPUJE** Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India.			
		To, The Controller of Patents, The Patent Office, at…**Mumbai**…			
Note: - Strike out whichever is not applicable					

FORM 1 THE PATENTS ACT, 1970 (39 of 1970) and THE PATENTS RULES, 2003 **APPLICATION FOR GRANT OF PATENT** **(See section 7, 54 & 135 and sub-rule (1) of rule 20)**	**(FOR OFFICE USE ONLY)**

	Application no:	
	Filing Date:	
	Amount of Fee Paid:	
	CBR No:	
	Signature:	
1. APPLICANT'S REFERENCE/ IDENTIFICATION NO. (AS ALLOTTED BY OFFICE)		

2. TYPE OF APPLICATION [Please tick (✓) at the appropriate category]

Ordinary (✓)		Convention ( )		PCT-NP ( )	
Divisional ( )	Patent of addition ( )	Divisional ( )	Patent of addition ( )	Divisional ( )	Patent of addition ( )

3 A. APPLICANT (S)

Name in full	**Nationality**	**Country of residence**	**Address of the applicant**	
DR. SHUBHRAJIT MANTRY	Indian	India	House No.	Sharadchandra Pawar College of Pharmacy
			Street	At: Dumbarwadi, Post : Khamundi, Tal: Junnar
			City	Pune
			State	Maharashtra
			Country	India
			Pin Code	410504
MS. SAYALI SAKHARAM HANDE	Indian	India	House No.	Sharadchandra Pawar College of Pharmacy
			Street	At: Dumbarwadi, Post :

				Khamundi, Tal: Junnar
			City	Pune
			State	Maharashtra
			Country	India
			Pin Code	410504
DR. SUMIT ASHOK JOSHI	Indian	India	House No.	Sharadchandra Pawar College of Pharmacy
			Street	At: Dumbarwadi, Post : Khamundi, Tal: Junnar
			City	Pune
			State	Maharashtra
			Country	India
			Pin Code	410504
DR. GANESH YOGIRAJ DAMA	Indian	India	House No.	Sharadchandra Pawar College of Pharmacy
			Street	At: Dumbarwadi, Post : Khamundi, Tal: Junnar
			City	Pune
			State	Maharashtra
			Country	India
			Pin Code	410504
DR. SHRIRAM RAMESH PETHAKAR	Indian	India	House No.	Shramjivi Shikshan Prasarak Mandal's Shramjivi College of Pharmacy, Omerga
			Street	Omerga, Dist. Osmanabad
			City	Osmanabad
			State	Maharashtra
			Country	India
			Pin Code	413606

3 B. CATEGORY OF APPLICANT [Please tick (✓) at the appropriate category]

Natural person (✓)	Other than natural person		
	Small entity ( )	Startup ( )	Others ( )

4. INVENTORS [Please tick (✓) at the appropriate category]

Are all the inventor(s) same as the applicant(s) named above?	Yes (✓)	No ()

If "NO", furnish the details of the inventor (s)		
5. TITLE OF THE INVENTION TRANSDERMAL PATCH OF LOSARTAN POTASSIUM		
6. AUTHORISED REGISTERED PATENT AGENT (S)	IN/PA No.	1096
	Name	VIJAYKUMAR SHIVPUJE
	Mobile No.	09768665354
7. ADDRESS FOR SERVICE OF APPLICANT IN INDIA	Name	MR. VIJAYKUMAR SHIVPUJE
	Postal address	Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India.
	Telephone No.	NA
	Mobile no.	+91 9768665354
	Fax No.	NA
	E-mail ID	vijay@patlex.in

8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION

Country	Application Number	Filing date	Name of the applicant	Title of the invention	IPC (as classified in the convention country)
N/A	N/A	N/A	N/A	N/A	N/A

9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)

International application number	International filing date
N/A	N/A

10. IN CASE OF DIVISIONAL APPLICATION, FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION

Original (first) application No.	Date of filing of original (first) application
N/A	N/A

11. IN CASE OF PATENT OF ADDITION, FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main application/patent No.	Date of filing of main application
N/A	N/A

12. DECLARATIONS

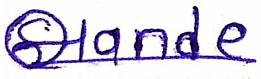
(i) Declaration by the inventor (s)

(In case the applicant is an assignee: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

~~I~~/We, the above mentioned inventor(s) ~~is~~/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein ~~is~~/are ~~my~~/our assignee or legal representative.

(a) Date: 30th August 2021

(b) Signature(s):



(c) Name(s): **DR. SHUBHRAJIT MANTRY** **MS. SAYALI SAKHARAM HANDE**

DR. SUMIT ASHOK JOSHI **DR. GANESH YOGIRAJ DAMA**

DR. SHRIRAM RAMESH PETHAKAR

(ii) Declaration by the applicant(s) in the convention country N/A

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

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

(a) Date:

(b) Signature(s):

(c) Name(s) of the signatory

(iii) Declaration by the applicant(s):

I/~~We~~, the applicant(s) hereby declare(s) that:-

- ~~I am~~/ We are in possession of the above-mentioned invention.
- The Complete/ ~~provisional~~ specification relating to the invention is filed with this application.
- ~~The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.~~
- There is no lawful ground of objection to the grant of the patent to me/us.
- ~~I am~~/ We are the true and first inventor(s).

○ ~~I am~~/ We are the assignee or legal representative of true & first inventors.

○ ~~The application or each of the applications, particulars of which are given in Paragraph-8 was the first application in convention country/countries in respect of my/our invention~~.

○ ~~I/We claim the priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/us or by any person from which I/We derive the title.~~

○ ~~My/Our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Paragraph-9.~~

○ ~~The application is divided out of my/our application particulars of which are given in Paragraph-10 and pray that this application may be treated as deemed to have been filed on _____ under section 16 of the Act.~~

○ ~~The said invention is an improvement in/or modification of the invention particulars of which are given in Paragraph-11.~~

13. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION

(a) Form 2

Item	Details	Fee	Remarks
Complete/ ~~provisional~~ specification)#	No. of pages (18)	1600	
No. of claim(s)	No, of claims (6) and no. of pages (2)		
Abstract	No. of pages (**1**)	0	
No. of drawing(s)	No. of drawings (2) and No. of pages (1)	N/A	N/A

In case of a complete specification, if the applicant desires to adopt the drawings filed with his provisional specification as the drawings or part of the drawings for the complete specification under rule 13 (4), the number of such pages filed with the provisional specification are required to be mentioned here.

(b) ~~Complete specification (in conformation with the international application)/ as amended before the International Preliminary Examination Authority (IPEA) as applicable (2 copies).~~

(c) ~~Sequence listing in electronic form~~

(d) ~~Drawings (in conformation with the international application)/ as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).~~

(e) ~~Priority document(s) or a request to retrieve the priority document(s) from DAS (Digital Access Service) if the applicant had already requested the office of first filing to make the priority document(s) available to DAS.~~

(f) ~~Translation of priority document/Specification/International Search Report/International Preliminary report on patentability.~~

(g) Statement and undertaking on Form 3

(h) Declaration of Inventorship on Form 5

(i) ~~Power of authority~~

(j)……

Total fee ☐ **1600** Rs. via e-payment.

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

Dated this 30th day of August 2021

Signature:

Name: **MR. VIJAYKUMAR SHIVPUJE**

Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India.

To,

The Controller of Patents

The Patent Office, at…**Mumbai**…

Note: -

* Repeat boxes in case of more than one entry.
* To be signed by the applicant(s) or by authorized registered patent agent otherwise where mentioned.
* Tick (✓)/ cross (x) whichever is applicable/ not applicable in paragraph-12.
* Name of the inventor and applicant should be given in full, family name in the beginning.
* Strike out the portion which is/are not applicable.
* For fee: See First Schedule;

COMPLETE SPECIFICATION

DR. SHUBHRAJIT MANTRY
SAYALI SAKHARAM HANDE
DR. SUMIT ASHOK JOSHI
DR. GANESH YOGIRAJ DAMA
DR. SHRIRAM RAMESH PETHAKAR

TOTAL SHEETS: 1
CURRENT SHEET: 1

Figure 1

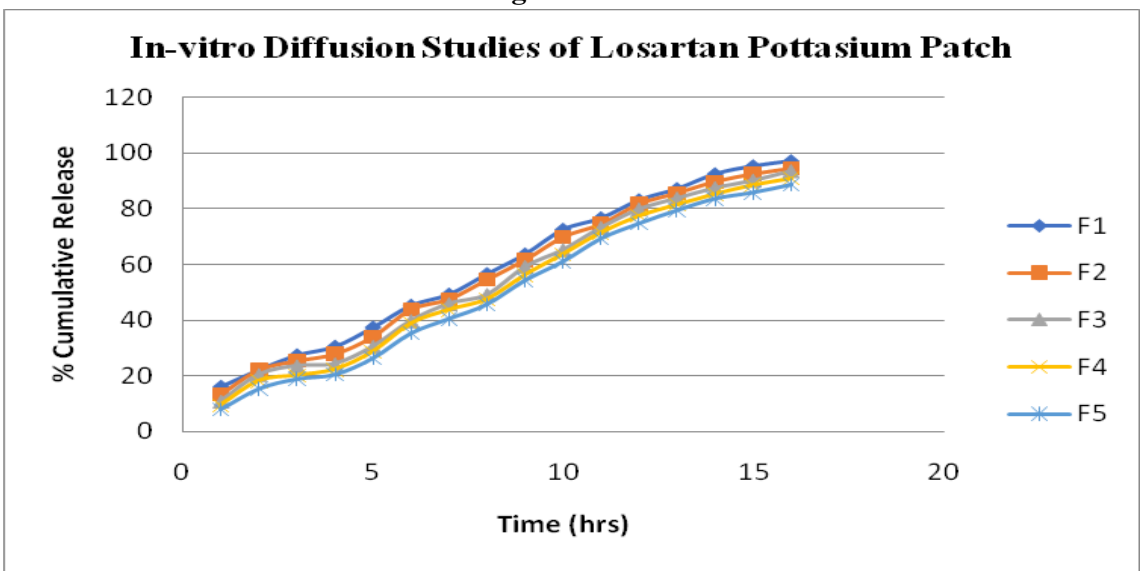
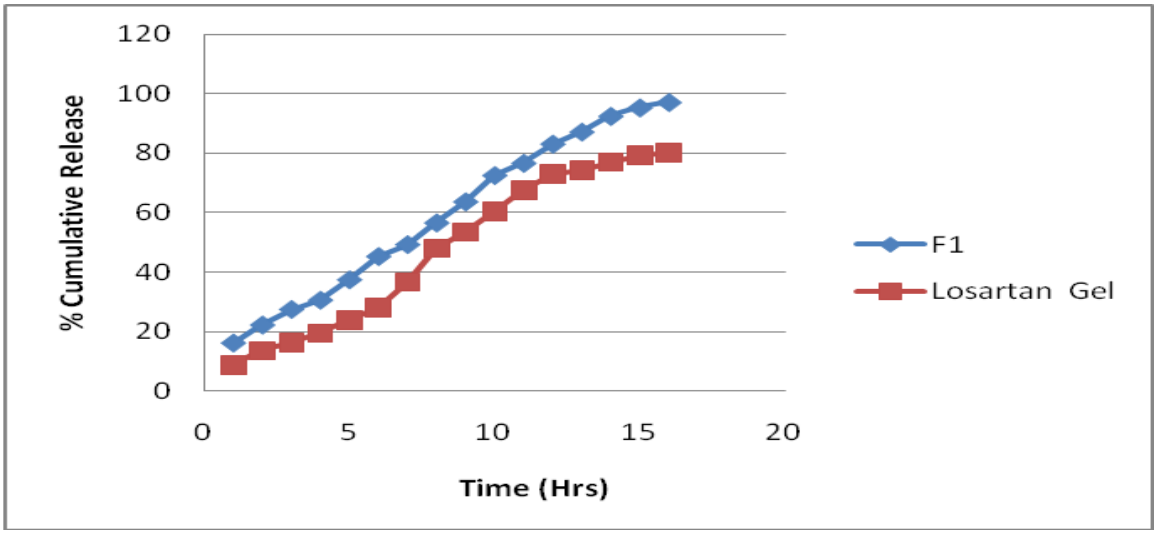


Figure 2



Dated this 30th August 2021

Digitally signed by,

Vijaykumar Shivpuje,

IN/PA 1096,

Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India

FORM 5

THE PATENTS ACT, 1970

(39 OF 1970) &

The Patents Rules, 2003

DECLARATION AS TO INVENTORSHIP

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

1. NAME OF THE APPLICANT (S)	**DR. SHUBHRAJIT MANTRY** **MS. SAYALI SAKHARAM HANDE** **DR. SUMIT ASHOK JOSHI** **DR. GANESH YOGIRAJ DAMA** **DR. SHRIRAM RAMESH PETHAKAR**

hereby declare that the true and first inventor(s) of the invention disclosed in the provisional specification filed in pursuance of ~~my~~/our application numbered _____ dated_____ ~~is~~/are **DR. SHUBHRAJIT MANTRY, MS. SAYALI SAKHARAM HANDE, DR. SUMIT ASHOK JOSHI, DR. GANESH YOGIRAJ DAMA** and **DR. SHRIRAM RAMESH PETHAKAR**

2. INVENTORS

INVENTOR (1)

(a) NAME: **DR. SHUBHRAJIT MANTRY**

(B) NATIONALITY: Indian

(C) ADDRESS: Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi, Post: Khamundi, Tal: Junnar, Dist: Pune – 410504, Maharashtra, India.

Dated this 30th August 2021

Signature: -

Name of the signatory: - **DR. SHUBHRAJIT MANTRY**

INVENTOR (2)

(a) NAME: **MS. SAYALI SAKHARAM HANDE**

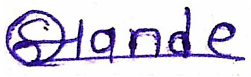
(B) NATIONALITY: Indian

(C) ADDRESS: Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi,

Post: Khamundi, Tal: Junnar, Dist: Pune – 410504,
Maharashtra, India.

Dated this 30th August 2021

Signature: -



Name of the signatory: - **MS. SAYALI SAKHARAM HANDE**

INVENTOR (3)

(a) NAME: **DR. SUMIT ASHOK JOSHI**

(B) NATIONALITY: Indian

(C) ADDRESS: Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi,
Post: Khamundi, Tal: Junnar, Dist: Pune – 410504,
Maharashtra, India.

Dated this 30th August 2021

Signature: -

Name of the signatory: - **DR. SUMIT ASHOK JOSHI**

INVENTOR (4)

(a) NAME: **DR. GANESH YOGIRAJ DAMA**

(B) NATIONALITY: Indian

(C) ADDRESS: Sharadchandra Pawar College of Pharmacy, At: Dumbarwadi,
Post: Khamundi, Tal: Junnar, Dist: Pune – 410504,
Maharashtra, India.

Dated this 30th August 2021

Signature: -

Name of the signatory: - **DR. GANESH YOGIRAJ DAMA**

INVENTOR (5)

(a) NAME: **DR. SHRIRAM RAMESH PETHAKAR**

(B) NATIONALITY: Indian

(C) ADDRESS:	Shramjivi Shikshan Prasarak Mandal's Shramjivi College of Pharmacy, Omerga, Dist: Osmanabad – 413606, Maharashtra, India. Dated this 30th August 2021 Signature: -  Name of the signatory: - **DR. SHRIRAM RAMESH PETHAKAR**

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

Not applicable.

4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)

~~I~~/We assent to the invention referred to in the above declaration, being included in the complete specification filed in pursuance of the stated application.

Dated this 30th August 2021.

Signature of the additional inventor(s) : -

Name: -

To, The Controller of Patent,
The Patent Office, at…**Mumbai**…

Form 2
The Patent Act 1970
(39 of 1970)
&
The Patent Rules, 2003
COMPLETE SPECIFICATION
(see section 10 and rule 13)

TITLE OF THE INVENTION

TRANSDERMAL PATCH OF LOSARTAN POTASSIUM

1. APPLICANT(S)

(a) NAME: DR. SHUBHRAJIT MANTRY
NATIONALITY: Indian
ADDRESS: Sharadchandra Pawar College of pharmacy, Dumbarwadi, Khamundi, Pune, Maharashtra, 410504, India

(b) SAYALI SAKHARAM HANDE
NATIONALITY: Indian
ADDRESS: Sharadchandra Pawar College of pharmacy, Dumbarwadi, Khamundi, Pune, Maharashtra, 410504, India

(c) DR. SUMIT ASHOK JOSHI
NATIONALITY: Indian
ADDRESS: Sharadchandra Pawar College of pharmacy, Dumbarwadi, Khamundi, Pune, Maharashtra, 410504, India

(d) DR. GANESH YOGIRAJ DAMA
NATIONALITY: Indian
ADDRESS: Sharadchandra Pawar College of pharmacy, Dumbarwadi, Khamundi, Pune, Maharashtra, 410504, India

(e) NAME: DR. SHRIRAM RAMESH PETHAKAR
NATIONALITY: Indian
ADDRESS: Shramjivi Shikshan Prasarak Mandal's Shramjivi College of Pharmacy,

Omerga, Dist. Osmanabad, Maharashtra – 413606, India
2. PREAMBLE TO THE DESCRIPTION
The following specification particularly describes the invention and the manner in which it is to be performed.

TRANSDERMAL PATCH OF LOSARTAN POTASSIUM

FIELD OF THE INVENTION

The present invention is related to the field of Transdermal drug delivery system and more particularly to Transdermal patch of Losartan Potassium.

BACKGROUND OF THE INVENTION

Drug delivery administered by the skin and attain a systemic effect of drug is called as transdermal drug delivery system. These are kind of dosage form which includes drug transport to reasonable epidermis and potentially dermal tissue of the skin locally therapeutic effect. While an exceptionally significant division of the drug is transported in systemic blood circulation. A transdermal dermal patch is characterized as a medicated adhesive patch which is set over the skin to deliver a particular dose of medication by the skin with a foreordained rate of release to reach into the circulation system.

Transdermal drug delivery system (TDDS) is a painless method of delivering drugs systemically by applying a drug formulation onto intact and healthy skin. The drug initially penetrates through the stratum corneum and then passes through the deeper epidermis and dermis without drug accumulation in the dermal layer. When drug reaches the dermal layer, it becomes available for systemic absorption via the dermal microcirculation. Transdermal drug delivery system has many advantages over other conventional routes of drug delivery. It can provide a non-invasive alternative to parenteral routes, thus circumventing issues such as needle phobia. A large surface area of skin and ease of access allows many placement options on the skin for transdermal absorption. Furthermore, the pharmacokinetic profiles of drugs are more uniform with fewer peaks, thus minimizing the risk of toxic side effects. It can improve patient compliance due to the reduction of dosing frequencies and is also suitable for patients who are unconscious or vomiting, or those who rely on self-administration. TDDS avoids pre-systemic metabolism, thus improving bioavailability. With reference to the use of the skin as a novel site for

vaccination strategies, this organ is known to be replete with dendritic cells in both the epidermal and dermal layers which play a central role in immune responses making TDDS an attractive vaccination route for therapeutic proteins and peptides.

A transdermal patch is an adhesively medicated skin patch used to deliver the doses into the bloodstream through the skin in a controlled manner. The system consists of several layers:

1. a backing layer to protect from the outside environment and water
2. a drug reservoir on a semipermeable membrane to control the release of the drug
3. an adhesive to glue onto skin
4. a liner to protect the patch and adhesive.

Advantages of Transdermal drug delivery system are:

1. Provides smooth plasma concentrations of a drug without fluctuations, for a long period.

2. Drug administration through skin avoids the pH variations seen with gastrointestinal transit.

3. Drug reaches the systemic circulation whilst avoiding first-pass hepatic metabolism.

4. Self- administration is possible.

5. Drug intake can be stopped at any point by simply removing the transdermal patch.

6. The simplified medication regimen leads to improved patient compliance and reduced side effects as well as inter and intra-patient variability.

7. Transdermal patches are noninvasive, avoiding the inconvenience of parenteral therapy.

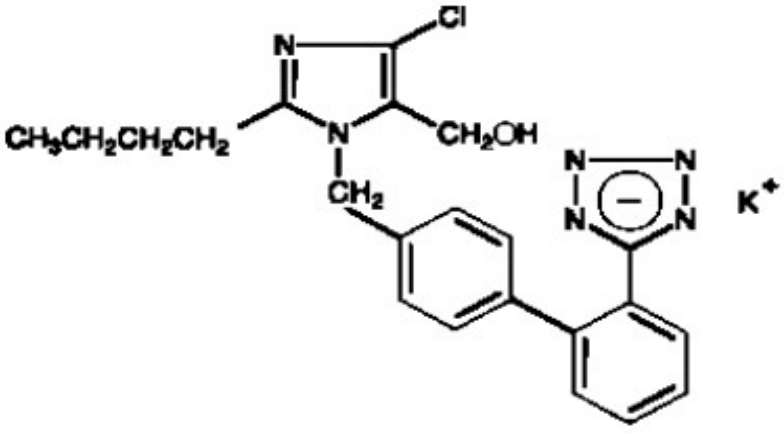
8. Equivalent therapeutic effect can be elicited with less amount of dose if given as a transdermal patch as compared to dose of same drug if given orally.

9. Comparable characteristics with intravenous infusion.

10. Increased bioavailability and reduced drug-drug interactions

Hypertension is defined as a systolic blood pressure that remains above 140 mm Hg or a diastolic pressure that remains above 90 mm Hg. Blood pressure is the force exerted by the blood against the walls of the arteries when being pumped by the heart and when the blood pressure is higher; more effort must be made by the heart to pump blood. Normal blood pressure in adults is 120 mm Hg when the heart beats (systolic tension) and 80 mm Hg when the heart relaxes (diastolic tension). Among antihypertensive drugs, losartan potassium (angiotensin II receptor blocker) is used as a first-line agent to treat hypertension without complications, hypertension in people with diabetes, heart failure, nephropathy, and left ventricular hypertrophy. It is also be used as a second-line agent in the treatment of congestive heart failure, systolic dysfunction, myocardial infarction, and coronary artery disease in those intolerant to angiotensin-converting enzyme inhibitors.

Losartan potassium, a nonpeptide molecule, is chemically described as 2-butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5- methanol monopotassium salt. Its empirical formula is C22H22ClKN6O, and its structural formula is:



COZAAR (Losartan potassium) is available as tablets for oral administration containing either 25 mg, 50 mg or 100 mg of losartan potassium and the following inactive ingredients: microcrystalline cellulose, lactose hydrous, pregelatinized starch, magnesium stearate, hydroxypropyl cellulose,

hydroxypropyl methylcellulose, titanium dioxide, D&C yellow No. 10 aluminum lake and FD&C blue No. 2 aluminum lake. COZAAR 25 mg, 50 mg and 100 mg tablets contain potassium in the following amounts: 2.12 mg (0.054 mEq), 4.24 mg (0.108 mEq) and 8.48 mg (0.216 mEq), respectively. 25 mg, 50 mg and 100 mg tablets contain potassium in the following amounts: 2.12 mg (0.054 mEq), 4.24 mg (0.108 mEq) and 8.48 mg (0.216 mEq), respectively.

Losartan is an angiotensin receptor blocker. Losartan is available as losartan potassium oral tablets as well as a combination tablet of losartan potassium and hydrochlorothiazide. Following oral administration, losartan is well absorbed (based on absorption of radiolabeled losartan) and undergoes substantial first-pass metabolism; the systemic bioavailability of losartan is approximately 33%. About 14% of an orally-administered dose of losartan is converted to the active metabolite. Mean peak concentrations of losartan and its active metabolite are reached in 1 hour and in 3-4 hours, respectively. While maximum plasma concentrations of losartan and its active metabolite are approximately equal, the AUC of the metabolite is about 4 times as great as that of losartan. A meal slows absorption of losartan and decreases its Cmax but has only minor effects on losartan AUC or on the AUC of the metabolite (about 10% decreased). A 50-80mg oral dose of losartan leads to a Cmax of 200-250ng/mL. Losartan is 98.6-98.8% protein bound and the active metabolite (E-3174) is 99.7% protein bound in serum. The terminal elimination half life of losartan is 1.5-2.5 hours while the active metabolite has a half life of 6-9 hours.

The inventors of the present invention have prepared transdermal patch of Losartan potassium providing sustained release of the drug and reducing multiple dosing and reducing side effects as less amount of drug is incorporated in transdermal patch as compared to conventional dosage form such as tablets which are currently available. The detailed invention is decribed as herein.

OBJECTIVE OF THE INVENTION

The main objective of the present invention is to provide transdermal patch of Losartan potassium.

Yet another objective of the present invention is to provide a process of preparing transdermal patch of Losartan potassium.

Yet another objective of the present invention is to provide transdermal patch of Losartan potassium for treating Hypertension.

SUMMARY OF THE INVENTION

Main embodiment of the present invention provides transdermal patch of Losartan potassium.

Another aspect of the present invention provides transdermal patch of Losartan potassium comprising:

i. 10 to 30 mg of Losartan potassium,
ii. 10 to 800 mg of Polymer,
iii. other pharmaceutical additives.

Another aspect of the present invention provides a process of preparing an transdermal patch of Losartan potassium by solvent casting method.

Another aspect of the present invention provides transdermal patch of Losartan potassium for treating Hypertension.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1: In Vitro Diffusion study of Losartan Potassium Transdermal Patch

Figure 2: Comparison study (In-vitro diffusion study) of Optimized F1Transdermal patch and Losartan Potassium Gel

DESCRIPTION OF THE INVENTION

The present invention is all about formulation of transdermal patch of Losartan potassium.

The term "comprising", which is synonymous with "including", "containing", or "characterized by" here is defined as being inclusive or open-ended, and does not exclude additional, unrecited elements or method steps, unless the context clearly requires otherwise.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. The term "a" and "an" refers to one or to more than one (i.e., to at least one) of the grammatical object of the article. The information provided in this document, and particularly the specific details of the described exemplary aspects, is provided primarily for clearness of understanding and no unnecessary limitations are to be understood from there.

Although the invention has been described with reference to specific embodiments, this description is not meant to be construed in a limiting sense. Various modifications of the disclosed embodiments, as well as alternate embodiments of the invention, will become apparent to persons skilled in the art upon reference to the description of the invention. It is therefore contemplated that such modifications can be made without departing from the spirit or scope of the present invention as defined.

Main embodiment of the present invention provides transdermal patch of Losartan potassium.

Another aspect of the present invention provides transdermal patch of Losartan potassium comprising:

i. 10 to 30 mg of Losartan potassium,
ii. 10 to 800 mg of polymer,
iii. other pharmaceutical additives.

As per another embodiment the active ingredient used is Losartan Potassium which is the potassium salt of losartan, a non-peptide angiotensin II receptor antagonist with antihypertensive activity.

As per another embodiment the other pharmaceutical additives may include penetration enhancer, plasticizer, solvent, backing laminates, release liner, pressure sensitive adhesive.

As per another embodiment the penetration enhancer is selected from dimethylsulfoxide (DMSO), ethanol, propylene glycol, polyethylene glycol, 2-Propanol, oleic acid, dimethylformamide, Lauric acid, Myristic acid, capric acid, Limonene, Menthol, Linalool, Carvacrol, dimethyl acetamide, isopropyl myristate, 2-Pyrrolidone, N-methyl-2-pyrrolidone, 1-decanol, 1-octanol, 1-hexanol, butane-1,2-diol, Urea, butylacetate, Cetyl lactate, sorbitan trioleate, sorbitan monopalmitate, cetyl trimethyl ammonium bromide, sodium lauryl sulphate, farnesol, carvone, menthone, nerolidol, Monoolein.

As per another embodiment the plasticizer is selected from Glycerine, Glycerine triacetate, Glyceryltributyrate, Propylene glycol, Polyethylene glycol, Dibutyl phthalate, Diethyl phthalate, Dibutyl sebacate, Diethyl sebacate, Oleil oleate, Sorbitol, Triethyl citrate, Tributhyl citrate, Diethyl tartarate, Polyethylene glycol 600, Polyethylene glycol 3350, Polyethylene glycol 400, Polyethylene glycol 200.

As per another embodiment the solvent is selected from Methanol, Ethanol, Isopropyl alcohol, Acetonitrile, ethyl acetate, chloroform, Acetone, dichloromethane, Toluene, Benzene, water.

As per another preferred embodiment, the present invention provides a transdermal patch of Losartan potassium comprising:

i. 10 to 30 mg of Losartan potassium,

ii. 10 to 800 mg of Polymer,
iii. 0.05 to 20 ml of Penetration enhancer,
iv. 0.1 to 30 ml of Plasticizer,
v. Solvent

As per another embodiment, the present invention provides a process of preparing transdermal patch of Losartan potassium comprising steps of:

1. Dissolving Losartan potassium in solvent to prepare a drug mixture,
2. Dissolving Polymers in solvent mixture to form a polymer mixture,
3. Mixing drug mixture and polymer mixture thoroughly to obtain a solution,
4. Adding permeation enhancers and plastisizers to the solution of step 3 and mixing thoroughly to obtain uniform solution,
5. Casting films by pouring the uniform solution on desired size flat Teflon plates or glass petridish or any desired flat plate and allowing to evapourate the solvent to obtain transdermal patch.

As per another embodiment, the present invention provides transdermal patch of Losartan potassium for treating Hypertension.

The invention is illustrated by the following examples which are not meant to restrict the scope of the invention in any manner.

EXAMPLES

Example 1: Composition and process of Preparing Transdermal Patch

Table 1 – Composition of Losartan Potassium transdermal patch

Sr. no.	Ingredient	F1	F2	F3	F4	F5
1	Losartan Potassium	20 mg	20 mg	20 mg	20 mg	20 mg
2	HPMC (E50)	40 mg	80 mg	120 mg	160 mg	200 mg
3	Ethyl Cellulose	700 mg	660 mg	620 mg	580 mg	540 mg
4	DMSO	0.1 ml	0.1 ml	0.1 ml	0.1 ml	0.1 ml

5	Dibutyl Phthalate	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
6	Methanol: Acetonitrile (1:1)	10 ml	10 ml	10 ml	10 ml	10 ml

Drug loaded polymer patches were prepared by solvent evaporation technique. The polymer in different ratios was dissolved in methanol: Acetonitrile (1:1). Losartan Potassium was dissolved in methanol and than added in polymer solution and mixed thoroughly to obtain a solution. DMSO as a penetration enhancer and Dibutyl Phthalate as a Plasticizer was added and mixed to form a uniform solution. Films were casted by placing this solution on desired size flat Teflon plates allow to evapourate the solvent for 24 hrs.

Example 2: Evaluation Of characterization of Transdermal Patch

1. Determination of thickness of the film: The thickness of Transdermal patch of Losartan potassium was determined by measuring the thickness of the whole patches. The average thickness of Transdermal patch of Losartan potassium was determined at four points using vernier calliper. The thickness of the transdermal patches varied from 0.22 mm which indicate that all the prepared patches was of the nearly uniform thickness

2. Folding endurance: A strip of specific area was cut and repeatedly folded at the same place till it broke. The number of times the Transdermal patch could be folded at the same place without breaking gave the value of the folding endurance. Folding endurance test result indicated that the patches did not break and maintained their integrity with general skin folding when applied and it measures the ability of the patch withstand rupture. Folding endurance of all the patches was found to be varied in between 57±2.9.

3. Uniformity of weight: The prepared patcheswere dried at 60°C for 4 hrs. before testing. A specified area of patch was cut in different parts of the patches and weight in digital balance. The average weight and standard deviation values

calculated from the individual weights. The patches were found to have uniformity of weight and it was in the range of 111±2.3 mg.

4. Percentage moisture content: The prepared films were marked, then weighed individually and kept in a desiccator containing activated silica at room temperature for 24 hrs. The films were weighed again and again individually until it showed a constant weight. The percentage of moisture content was calculated as a difference between initial and final weight with respect to final weight. A small amount of moisture in patch type formulations helps maintain stability and prevents the formation of a dried and brittle film. A greater amount, however, can lead to microbial contamination during storage. The moisture content is determined by variations in the water content of the dried film and un-dried film. Percent moisture content is determined as follows

Percentage moisture content= Initial Weight-Final weight /initial weight X 100

The results of the moisture content varied in between 0.719 to 2.671 % . The moisture content values were optimum which could help the formulation remain stable and reduced brittleness during storage.

5. Percentage moisture uptake: A weighed film was kept in desiccators at normal room temperature for 24 hrs was taken out and exposed to 84% relative humidity (saturated solution of potassium chloride) in desiccators until a constant weight for the film was obtained. The percentage of moisture uptake was calculated as the difference between final and initial weight with respect to initial weight. This study can predict the moisture-absorbing capacity of a particular type of patch at various humidity levels.

Percentage moisture uptake= Initial Weight-Final weight / Final weight X100

The Percentage moisture uptake of Transdermal patches ranged from 0.650 to 2.551 which was optimum to protect the formulations from microbial contamination and also reduce bulkiness of films.

6. Drug content: A specified area of patch was dissolved in a suitable solvent in specific volume. Then the solution was to be filtered through a filter medium and

analysis of the drug was done with UV method. Good uniformity of drug content among the batches was 97.54±0.25.

7. The percentage elongation break- The test was determined by noting the length just before the break point, the percentage elongation can be determined from the below mentioned formula:

Elongation percentage = L1-L2 / L2 X100 Where, L1 is the final length of each strip and L2 is the initial length of each strip.

Table 2– Evaluationof prepared losartan potassium transdermal patch

Formulation Code	Thickness (mm)	Folding Endurance	Weight Uniformity (mg)	Moisture Content (%)	Moisture uptake	Drug Content (%)	Percent Elongation Break (%)
F1	0.22	57±2.9	111±2.3	2.150	1.990	97.54±0.25	90.2
F2	0.20	51±3.8	106±1.8	1.694	1.521	92.28±0.31	86.7
F3	0.15	48±2.5	110±2.0	0.719	0.650	91.23±0.31	84.3
F4	0.18	45±4.5	108±2.4	2.671	2.551	93.39±0.42	82.9
F5	0.21	41±3.4	98±2.5	2.042	2.054	84.26±0.21	80.4

Example 3: In vitro Diffusion study

In vitro diffusion studies were performed by using Frans diffusion cell with receptor compartment capacity of 100 ml. The cellulose acetate membrane was mounted between the donor and receptor compartment of diffusion cell. The prepared transdermal patch was placed on the cellulose acetate membrane and covered with aluminium foil. The receptor of the diffusion cell was filled with phosphate buffer pH 6.8. The whole assembly was fixed on a hot plate magnetic stirrer, and the solution in the receptor compartment was constantly and continuously stirred using magnetic beads, and the temperature was maintained at 37± 0.5^0C, because the normal skin temperature of human is 37^0C. The

samples were withdrawn at different time intervals and analysed for content spectrophotometrically. The receptor phase was replenished with an equal volume of phosphate buffer at each sample withdrawal.

Table no.3- In Vitro Diffusion study of Losartan Potassium Transdermal Patch

Time (hrs)	F1	F2	F3	F4	F5
1	15.99	13.21	10.89	9.56	8.03
2	22.07	21.95	20.43	18.21	15.41
3	27.34	25.17	23.56	20.18	18.91
4	30.45	27.67	24.32	22.32	20.54
5	37.32	33.87	30.54	28.78	26.41
6	45.21	43.67	39.76	38.84	35.35
7	49.23	47.34	45.87	43.74	40.54
8	56.57	54.31	49.15	47.59	45.75
9	63.67	61.45	59.16	56.29	53.36
10	72.56	69.67	65.28	63.76	61.15
11	76.67	74.34	73.26	71.51	69.37
12	83.16	81.57	79.87	77.43	74.76
13	87.23	85.45	83.76	81.54	79.47
14	92.54	89.56	87.47	85.32	83.67
15	95.41	92.32	90.16	88.56	85.87
16	97.21	94.32	93.56	90.88	88.67

The results from patches increase with increase in concentration of HPMC and ethyl cellulose. The formulation F1 exhibits maximum percentage release of value in 16 hrs. The drug release was increased linearly with the increasing concentration of HPMC and ethyl cellulose. The addition of HPMC to an insoluble film former tends to enhance the release rates.

Example 4: Comparative In-vitro diffusion study of prepared Transdermal patch and Gel of Losartan Potassium

It was determined by using Franz diffusion cell. Losartan Gel to single dose was placed in a donor compartment of diffusion cell. Receptor compartment was filled with pH 6.8 Phosphate buffer solution was stirred continuously at 350 rpm. Samples were withdrawn at specific time intervals and an equal volume of medium was replaced to maintain sink condition. The samples were analyzed by the UV-Visible spectrophotometer at 233 nm to determine the concentration.

Table 4: In-vitro diffusion study at pH 6.8 phosphate buffer for Optimized F1Transdermal patch and Losartan Potassium Gel

Time (Hrs)	F1 (%)	Losartan Potassium Gel (%)
1	15.99	8.54
2	22.07	13.51
3	27.34	16.24
4	30.45	19.31
5	37.32	23.76
6	45.21	27.97
7	49.23	36.51
8	56.57	47.86
9	63.67	53.42
10	72.56	60.31
11	76.67	67.39
12	83.16	72.84
13	87.23	74.16
14	92.54	76.86
15	95.41	79.17
16	97.21	80.13

The formulation F1 exhibits maximum percentage release of value in 16 hrs. An increase in Carbopol content was associated with a corresponding decrease in the drug release rate. This could be due to extensive swelling of the polymer which created a thick gel barrier for drug diffusion. It was observed that the Transdermal patch of Losartan potassium was able to release almost 97.21% of the drug release as compared to only 80.13 % drug release by the gel formulation. Therfore, the prepared Transdermal patch was concluded to be a more efficient formulation as compared to gel as it was able to provide sustained and complete release of drug for a longer period of time.

We Claim,

1. A transdermal patch of Losartan potassium comprising:
    i. 10 to 30 mg of Losartan potassium,
    ii. 10 to 800 mg of polymer,
    iii. other pharmaceutical additives.

2. The transdermal patch of Losartan potassium as claimed in claim 1 wherein, other pharmaceutical additives includes penetration enhancer, plasticizer, solvent.

3. The transdermal patch of Losartan potassium as claimed in claim 2 wherein, penetration enhancer is selected from dimethylsulfoxide (DMSO), ethanol, propylene glycol, polyethylene glycol, 2-Propanol, oleic acid, dimethylformamide, Lauric acid, Myristic acid, capric acid, Limonene, Menthol, Linalool, Carvacrol, dimethyl acetamide, isopropyl myristate, 2-Pyrrolidone, N-methyl-2-pyrrolidone, 1-decanol, 1-octanol, 1-hexanol, butane-1,2-diol, Urea, butylacetate, Cetyl lactate, sorbitan trioleate, sorbitan monopalmitate, cetyl trimethyl ammonium bromide, sodium lauryl sulphate, farnesol, carvone, menthone, nerolidol, Monoolein.

4. The transdermal patch of Losartan potassium as claimed in claim 2 wherein, plasticizer is selected from Glycerine, Glycerine triacetate, Glyceryltributyrate, Propylene glycol, Polyethylene glycol, Dibutyl phthalate, Diethyl phthalate, Dibutyl sebacate, Diethyl sebacate, Oleil oleate, Sorbitol, Triethyl citrate, Tributhyl citrate, Diethyl tartarate, Polyethylene glycol 600, Polyethylene glycol 3350, Polyethylene glycol 400, Polyethylene glycol 200.

5. The transdermal patch of Losartan potassium as claimed in claim 2 wherein, solvent is selected from Methanol, Ethanol, Isopropyl alcohol, Acetonitrile, ethyl acetate, chloroform, Acetone, dichloromethane, Toluene, Benzene, water.

6. A process of preparing transdermal patch of Losartan potassium comprising steps of:
    1. Dissolving Losartan potassium in solvent to prepare a drug mixture,
    2. Dissolving Polymers in solvent mixture to form a polymer mixture,
    3. Mixing drug mixture and polymer mixture thoroughly to obtain a solution,
    4. Adding permeation enhancers and plastisizers to the solution of step 3 and mixing thoroughly to obtain uniform solution,
    5. Casting films by pouring the uniform solution on desired size flat Teflon plates or glass petridish or any desired flat plate and allowing to evapourate the solvent to obtain transdermal patch.

Dated this 30th August 2021

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ABSTRACT

TRANSDERMAL PATCH OF LOSARTAN POTASSIUM

The present invention is related to transdermal patch of Losartan potassium and the process of preparing the same. Transdermal patch of Losartan potassium are made by solvent casting method and useful for treating Hypertension.

FORM 9

THE PATENTS ACT, 1970

(39 OF 1970)

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The Patents Rules, 2003

REQUEST FOR PUBLICATION

[See section 11A (2); rule 24A]

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1. Name, address and Nationality of the applicant (s)	~~I~~/ We 1. DR. SHUBHRAJIT MANTRY 2. MS. SAYALI SAKHARAM HANDE 3. DR. SUMIT ASHOK JOSHI 4. DR. GANESH YOGIRAJ DAMA 5. DR. SHRIRAM RAMESH PETHAKAR hereby request for early publication of ~~my~~/our application for patent No. 202121039262 dated 2021/08/30 under section 11A(2) of the act.

Dated this 8th day of September 2021.

2. To be signed by the applicant or his authorized registered patent agent. Name of the person who has signed	Digitally signed by, **Agent for the Applicant** Vijaykumar Shivpuje, IN/PA 1096, Sri Kripa, Akshay Nagar, Old Ausa Road, Latur, 413531, Maharashtra, India. To, The Controller of Patents, The Patent Office, At **Mumbai.**