Channabasweshwar Pharmacy College (Degree), Latur and SNJBS KKHA Arts, Science and Commerce College, Chandwad, Dist. Nashik (Maharashtra) entered into collaboration for various academic activities including student-teacher exchange, animal house facility and research work etc. Since then, a number of collaborative events are organized. The list of these events is as follows;

Sr. No.	Activity	Date of Activity	Venue	Total No. of Participants
1	Research paper Publication	03/2020	Channabasweshwar Pharmacy College (Degree), Latur and SNJBS KKHA Arts and Science College, Chandwad.	06
2	Research paper Publication	03/2020	Channabasweshwar Pharmacy College (Degree), Latur and SNJBS KKHA Arts and Science College, Chandwad.	06
3	Patent Grant	26/04/2021	Channabasweshwar Pharmacy College (Degree), Latur and SNJBS KKHA Arts and Science College, Chandwad.	04

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1. Research paper Published in Collaboration

VALIDATED RP–HPLC METHOD FOR ESTIMATION OF APIXABAN IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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VALIDATED RP-HPLC METHOD FOR ESTIMATION OF APIXABAN IN BULK AND PHARMACEUTICAL DOSAGE FORMS

Nalwar Yogesh S.[1],Imran Mujewar N.[1], Gholve S.B.[1], Giram Padmaja S.[2], Patil Arvind M.[3], Bhusnure Omprakash G. [4]*

[1]Toshniwal A.C.S. College, Dept. of Chemistry, Sengaon, (MS), India
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[3]S.N.J.B's Arts, Commerce and Science College, Dept. of Chemistry, Chandwad, Dist Nashik, (MS), India.
.[4]Channabasweshwar Pharmacy College, Dept. of Pharmaceutical Quality Assurance, Kava Road, Latur (MS), India.

Abstract : The methods having requisite precision, accuracy, specificity and robustness were developed and validated for quantitative determination of Apixaban in pharmaceutical dosage forms. The chromatographic column used was a reverse phase 250 µ 4.6 mm, 5 µm (particles) packing Inertsil® ODS-3V C_{18} HPLC column. The column and the HPLC system were kept at ambient conditions. The mobile phase was 0.02 M phosphate buffer pH 5.5 Acetonitrile (20:80 v/v) delivered at a flow rate of 0.8 ml/min. The injection volume was 20 µ l.The elute was analyzed by HPLC system in which UV detector was set at 279 nm.The response was linear range of 5-30 µg/ml (R2 =0.997).Validation of method was carried out fulfilling ICH guidelines. The methods were applied without any interference from excipients, for determination of drug in coated tablets. It is suggested that the proposed HPLC chromatographic method could be used routine quality control and dosage form assay of Apixaban.

Keywords:RP-HPLC, Apixaban, Method development & Validation, Stability Study.

I. Introduction

Apixaban is an anticoagulant for the treatment of venous thromboembolic events. . Chemically is an 1-(4 – methoxyphenyl) – 7 – oxo – 6 – [4 – (2 – oxopiperidin – 1- yl) phenyl] – 4, 5 – dihydropyrazolo [3, 4 – c] pyridine – 3 – carboxamide. (Figure 1).

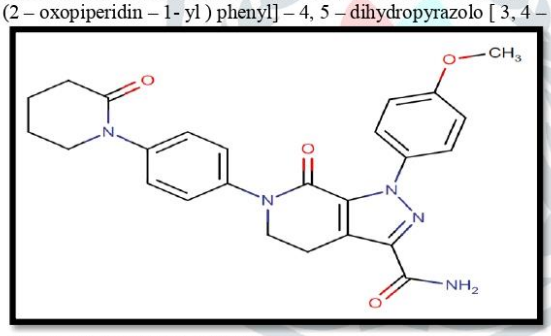

Figure 1: Structure of Apixaban

Its molecular formula is C25H25N5O4, and a molecular weight is 459.5. Apixaban is a white to pale-yellow powder and it is stored between 20 ^{0}C to 25 ^{0}C temperature. At physiological pH (1.2-6.8), apixaban does not ionize; its aqueous solubility across the physiological pH range is ~0.04 mg/mL. Apixaban dosage form is tablets(ELIQUIS) and they are available for oral administration in strengths of 2.5 mg and 5 mg of apixaban. Apixaban has been available in Europe since may 2012.The medical use of apixaban is to lower the risk of stroke and embolism in patients with nonvalvular a trial fibrillation. Apixaban is highly selective, orally bioavailable, and reversible direct inhibitor of free and clot-bound facto Xa. There are some methods of estimation of apixaban from human plasma by LC-MS3-9, but there is no assay method for apixaban by HPLC and UV Spectrophotometry. Further, apixaban is not officially reported in any pharmacopeia (USP, EP, JP & IP). The current HPLC method were developed and validated as per the ICH guidelines. The RP-HPLC method described here is simple, sensitive, and reproducible for apixaban determination in formulation with low background interfences. An attempt has been made to develop and validate to ensure their accuracy, precision and other analytical method validation parameters as mentioned in the below.[1]

II. Material Method:-

Chromatographic conditions

The chromatographic column used was a reverse phase 250 µ4.6 mm, 5 µm (particles) packing Inertsil® ODS-3V C_{18} HPLC column. The column and the HPLC system were kept at ambient conditions. The mobile phase was 0.02 M phosphate buffer pH 5.5 Acetonitrile (20:80 v/v) delivered at a flow rate of 0.8 ml/min. The injection volume was 20 µ l.The elute was analyzed by HPLC system in which UV detector was set at 279 nm.

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2. Research paper Published in Collaboration

Development and Characterization of Tamarindus Indica–Phospolipids complex as an effective phytoconstituents delivery system by QbD approach

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DEVELOPMENT AND CHARACTERIZATION OF *TAMARINDUS INDICA*-PHOSPOLIPIDS COMPLEX AS AN EFFECTIVE PHYTOCONSTITUENTS DELIVERY SYSTEM BY QbD APPROACH

Nalwar Yogesh S.[1] Gholve S.B.[1], Giram Padmaja S.[2], Patil Arvind M.[3],Gaikwad *Abhimanyu*[1], Bhusnure Omprakash G. [4]*,

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[4]Channabasweshwar Pharmacy College, Dept. of Pharmaceutical Quality Assurance, Kava Road, Latur (MS),

Abstract : The aim of the present study is to develop a complex of standardized *Tamarindus indica* (STI) and phospolipid with a goal to improve the bioavailability of its phytoconstituents. Tamarind is a flavonoid, glycoside that possesses different therapeutic activity.The poor solubility and dissolution rate limit its oral absorption and bioavailability. The phospholipid-STI complex was prepared using solvent evaporation method and characterized by various parameters like Solubility studies, Particle size determination, Infrared absorption (FTIR), Scanning electron microscopy (SEM), Entrapment efficiency etc. SEM reveal the reduction in crystallinity of extract in the complex. FTIR confirm the formation of phytophospholipid complex. The in vitro dissolution studies revealed a significantly higher efficiency of complex in releasing the STI in comparison to the pure STI, or the physical mixture. Phospholipid complex of STI may be of potential use in increasing the permeability and hence the bioavailability of tamarind. The result of the study revealed that the phospholipid complex may be considered as a promising drug delivery system that improves the absorption and bioavailability of plant constituents.

Keywords: Tamarindus Indica, Phospholipid Complex,Phytosomes, Qbd Approach.

I. INTRODUCTION

Tamarindus indica is an important medicinal plant and is cultivated all over the world of the family Fabaceae. T. indica fruit extracts contains many active ingredients such as Lauric acids, palmitic acids, oleic acids, linoleic acids, alkaloid, flavonoid, tannins, saponins, glycosides and terpenoids. Tamarind flavonoids have a large spectrum of biological activity including antibacterial, antifungal , antimicrobial and antiviral. (1,2)

Tamarind is frequently used in popular medicine, and over the past two decades their potential therapeutic properties have been largely investigated by in vitro and *in- vivo* assays. Differential experimental studies support the beneficial effects of dietary tamarind against many diseases, such as cardiovascular, neurodegenerative pathologies,due to the high content of polyphenols.(3)

phytosomes are more bioavailable as compared to simple herbal extracts owing to their enhanced capacity to cross the lipid rich biomembranes and finally reaching the blood.The phytosomes technique has emerged as one of the leading methods of improving bioavailabilty of phyto-pharmaceuticals having poor competency of solubilising and crossing the biological membranes.(4)

Phytosome is a patented technology of Indena where plant poliphenolics are complexed with phospholipids to improve bioavailability.(5-10)Phospolipids are lipid molecules where glycerol is bonded to two fatty acids.Phospolipid mainlyphospotidylcholine are lipophilic substances and readily form complex with polyphenolic compounds.Phospatidylcholine is a major structural constituent of all biological membranes. Phospotidylcholine is a major component of soya phospotidylcholine which provides free choline in the blood for the manufacture of acetylcholine; regulates digestive, cardiovascular and liver function.(11)

Tamarind shows low bioavailability because it is not soluble in water and is rapidly eliminatedfrom the body.The aim of this study is to develop a tamarind loaded phospolipid complex that could have potential to increase the bioavailability. The key objective of the present study is to develop the phytosomes of tamarind , to increase the solubility and bioavailability of drug, to prepare the tamarind phytosomes by specific method. The complex (TD-PC) tamarind phytosomes thus prepared was evaluated physico-chemically for drug loading, Chemical interaction(FT-IR), Thermal analysis (DSC), Crystallinity (XRD), surface morphology (SEM), Solubility and Dissolution rate study. The developed complex may be suitable to reduce the dose and frequency and hence reduce toxic or side effect of tamarind.

II. MATERIAL AND METHODS

Materials

Tamarind was purchased from Sunpure,Mumbai (India). Soya phospotidylcholine was purchased from LIPIDOME LIFESCIENCES, Kheda (Gujarat).All other chemicals and reagents were of analytical grade.

3. Patent Grant on 26/04/2021 in Collaboration

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पेटेंट प्रमाणपत्र
PATENT CERTIFICATE
(Rule 74 Of The Patents Rules)

पेटेंट सं. / Patent No.	:	384266
आवेदन सं. / Application No.	:	202121019027
फाइल करने की तारीख / Date of Filing	:	26/04/2021
पेटेंटी / Patentee	:	1.Dr. Arvind M. Patil 2.Dr. Rakesh S. Sancheti 3.Mrs. Minakshee A. Todarwal 4.Dr. Gotan H. Jain et al. et al.

प्रमाणित किया जाता है कि पेटेंटी को उपरोक्त आवेदन में यथाप्रकटित A NOVEL LIGAND, METAL COMPLEX AND PROCESS FOR SYNTHESIS OF METAL COMPLEX USING THE LIGAND नामक आविष्कार के लिए, पेटेंट अधिनियम, १९७० के उपबंधों के अनुसार आज तारीख 26th day of April 2021 से बीस वर्ष की अवधि के लिए पेटेंट अनुदत्त किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled A NOVEL LIGAND, METAL COMPLEX AND PROCESS FOR SYNTHESIS OF METAL COMPLEX USING THE LIGAND as disclosed in the above mentioned application for the term of 20 years from the 26th day of April 2021 in accordance with the provisions of the Patents Act,1970.

एकस्व कार्यालय THE PATENT OFFICE GOVT.OF INDIA भारत सरकार

अनुदान की तारीख : 14/12/2021
Date of Grant :

पेटेंट नियंत्रक
Controller of Patent

टिप्पणी - इस पेटेंट के नवीकरण के लिए फीस, यदि इसे बनाए रखा जाना है, **26th day of April 2023** को और उसके पश्चात प्रत्येक वर्ष मे उसी दिन देय होगी।
Note. - The fees for renewal of this patent, if it is to be maintained will fall / has fallen due on 26th day of April 2023 and on the same day in every year thereafter.

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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)	**1. Dr. Arvind M. Patil** **2. Dr. Rakesh S. Sancheti** **3. Mrs. Minakshee A. Todarwal** **4. Dr. Gotan H. Jain** **5. Dr. Sarika D. Shinde** **6. Dr. Omprakash G. Bhusnure**

hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of ~~my~~/our application numbered 202121019027 dated 26th April 2021 ~~is~~/are **Dr. Arvind M. Patil; Dr. Rakesh S. Sancheti; Mrs. Minakshee A. Todarwal; Dr. Gotan H. Jain; Dr. Sarika D. Shinde and Dr. Omprakash G. Bhusnure**

2. INVENTORS

INVENTOR (1)

(a) NAME: **Dr. Arvind M. Patil**

(B) NATIONALITY: Indian

(C) ADDRESS: S.N.J.B.'s KKHA Arts, Commerce and SPHJ Science College, Chandwad, Dist. Nashik, Maharashtra, India, 423101

Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Dr. Arvind M. Patil**

INVENTOR (2)

(a) NAME: **Dr. Rakesh S. Sancheti.**

(B) NATIONALITY: Indian

(C) ADDRESS: S.N.J.B.'s KKHA Arts, Commerce and SPHJ Science College, Chandwad, Dist. Nashik, Maharashtra, India, 423101

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Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Dr. Rakesh S. Sancheti**

INVENTOR (3)

(a) NAME: **Mrs. Minakshee A. Todarwal**

(B) NATIONALITY: Indian

(C) ADDRESS: S.N.J.B.'s KKHA Arts, Commerce and SPHJ Science College, Chandwad, Dist. Nashik, Maharashtra, India, 423101

Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Mrs. Minakshee A. Todarwal**

INVENTOR (4)

(a) NAME: **Dr. Gotan H. Jain**

(B) NATIONALITY: Indian

(C) ADDRESS: S.N.J.B.'s KKHA Arts, Commerce and SPHJ Science College, Chandwad, Dist. Nashik, Maharashtra, India, 423101

Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Dr. Gotan H. Jain**

INVENTOR (5)

(a) NAME: **Dr. Sarika D. Shinde**

(B) NATIONALITY: Indian

(C) ADDRESS: S.N.J.B.'s KKHA Arts, Commerce and SPHJ Science College, Chandwad,

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Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Dr. Sarika D. Shinde**

INVENTOR (6)

(a) NAME: Dr. Omprakash G. Bhusnure

(B) NATIONALITY: Indian

(C) ADDRESS: Channabasweshwar Pharmacy College, Kava Road, Latur, Maharashtra, India, 413512

Dated this 2nd July 2021

Signature: -

Name of the signatory: - **Dr. Omprakash G. Bhusnure**

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 July 2021.

Signature of the additional inventor(s) : -

Name: -

To, The Controller of Patent,

The Patent Office, at…**Mumbai**…

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