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**DEVELOPMENT AND VALIDATION OF STABILITY-INDICATING
CHROMATOGRAPHIC METHOD FOR THE DETERMINATION OF
METFORMIN HCL AND CANAGLIFLOZIN AND ITS RELATED
IMPURITIES IN PHARMACEUTICAL DOSAGE FORM**

PATEL S^{1*}, JAGTAP K², SHAH U³ AND SHAH D⁴

- 1: Department of Pharmaceutical Quality Assurance and Pharmaceutical Chemistry, Nootan Pharmacy College, Sankalchand Patel University, SK Campus, Visnagar-384315, Gujarat, India
- 2: Department of Pharmaceutical Chemistry, Sal Institute of Pharmacy, Opp. Science city, Sola Bhadaj Road, Ahmedabad, Gujarat-380060
- 3: Department of Pharmaceutical Quality Assurance and Pharmaceutical Chemistry, Nootan Pharmacy College, Sankalchand Patel University, SK Campus, Visnagar-384315, Gujarat, India
- 4: Department of Pharmaceutical Quality Assurance and Pharmaceutical Chemistry, Nootan Pharmacy College, Sankalchand Patel University, SK Campus, Visnagar-384315, Gujarat, India

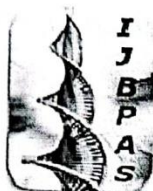
***Corresponding Author: Dr. Sejalben Patel: E Mail: sejupatel04@gmail.com**

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ABSTRACT

A simple, economic, selective and precise RP-HPLC method has been developed and validated for the estimation of related impurities of Metformin HCl and Canagliflozin in combined tablet. RP-HPLC method with gradient elution analysis was performed on Hypersil BDS C18 column (250mm X 4.6mm, 5µm) using mobile phase 0.05M Potassium Dihydrogen Phosphate buffer pH-5.0 and Acetonitrile in the ratio of (70: 30 v/v) at a flow rate of 1.0 ml/min and the detection wavelength was 290nm. The analytical method is validated according to ICH guidelines. The linearity was observed in the range of LOQ-



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**DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-
HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ANAGLIPTIN
AND METFORMIN HYDROCHLORIDE DRUG IN TABLET DOSAGE
FORM**

PATEL S*, PATEL KS, SHAH U AND DAYARAMANI R

Department of Pharmaceutical Assurance and Pharmaceutical Chemistry, Faculty of Pharmacy,
Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat, India

*Corresponding Author: Ms. Sejalben Patel: E Mail: sejupatel04@gmail.com

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ABSTRACT

A simple, rapid, sensitive & selective stability indicating RP-HPLC method is developed for the determination of anagliptin and Metformin HCL in tablet dosage form. A RP-HPLC analysis was performed on KROMASIL C₁₈ column and its size 250×4.6mm, 5µm with using mobile phase methanol and 0.05M potassium dihydrogen phosphate with buffer pH4 in ratio (30:70) at 220nm detection wavelength. The gradient was optimized with flow rate 1 mL/min. the completed analytical method validation was successfully carried out as per ICH guidelines. The recovery study was carried out at 80%, 100% and 120% level of working concentration and result were in the range 100.1-101.2% for Metformin HCL and 100.2-100.9% for Anagliptin. The linearity was proven in concentration range 5-15µg/mL for anagliptin and 25-75µg/mL for Metformin HCL. The limit of detection (LOD) was found to be 0.069µg/mL for anagliptin & 1.56µg/mL for metformin HCL. The LOQ value was found to be 0.209µg/mL for anagliptin & 4.716µg/mL for metformin HCL. All validation parameters was in accepted range as per ICH guideline. furthermore, forced degradation study was also performed at various stress condition such as acidic, basic, oxidative and photolytic as per protocol of ICH. The developed method can be successfully used for the estimation of Anagliptin & Metformin HCL in tablet dosage form.

Keywords: Anagliptin, Metformin HCL, stability indicating RP-HPLC method, validation



African Journal of Biological Sciences



3D Printed Orodispersible Film Using Semi-Solid Extrusion of Antihistamine Drugs

Bhumika J. Limbachiya^{1*}, Dr. Khushbu S. Patel², Sweta Patel³, Mehzaheen Imam⁴, Dr. Upasana M. Patel⁵, Pinal Patel⁶

^{1*}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat. & Assistant Professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

²Associate Professor, Department of Pharmaceutics, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat.

^{3, 4, 6}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat.

⁵Assistant Professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

***Corresponding Author:** Bhumika J. Limbachiya

^{*}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat. & Assistant professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.
Email: bjlimbachiya@gmail.com

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Abstract:

Orodispersible films (ODFs) present a promising avenue for personalized drug delivery systems, offering an alternative method to enhance consumer acceptance through features like rapid dissolution and administration without water. This study aimed to establish a platform for creating tailored treatments suitable for the on-the-spot production of ODFs using semi-solid extrusion 3D printing. The polymer of choice for ODFs was Hydroxypropyl Methyl Cellulose (HPMC), with Bilastine and levocetirizine hydrochloride as the model drug. This research endeavors to create orally disintegrating films (ODFs) loaded with drugs using a syringe extrusion 3D printer. Formulation with drug, characterization, Solubility study, identification, and calibration curve of both drugs has been done. The ODFs were formulated by dissolving drugs in a dispersion of polymers and other additives, which were then utilized for fabrication through 3D printing. Then disintegration time and drug Content (%) study was conducted in 0.1 N HCl at 37°C of both drugs and selected one drug which showed good results. Drug excipients compatibility study by IR spectroscopy was performed with and without technology in the fabrication of drug-containing ODFs, showcasing advancements in drug delivery systems.

Keywords: orodispersible film; 3D-printing; hydroxypropyl methylcellulose; Bilastine; Levocetirizine; pressure-assisted micro syringe.



African Journal of Biological Sciences



Exploring Feasibility Of Placebo Oral Formulation By Conventional And 3D Printing Method

Bhumika J. Limbachiya^{1*}, Dr. Khushbu S. Patel², Pinal Patel³, Dr. Upasana M. Patel⁴, Sweta Patel⁵, Mehzabeen Imam⁶

^{1*}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat & Assistant Professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

²Associate Professor, Department of Pharmaceutics, Faculty of Pharmacy Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat.

^{3, 5, 6}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat

⁴Assistant Professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

***Corresponding Author:** Bhumika J. Limbachiya

^{*}Research Scholar, Faculty of Pharmacy, Nootan Pharmacy College, Sankalchand Patel University, Visnagar, Gujarat & Assistant Professor, Department of Pharmaceutics, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

Email: bjlimbachiya@gmail.com

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Abstract:

Extrusion-based 3D printing technology represents a promising and relatively recent method with the potential to revolutionize the fabrication of pharmaceutical products across various dosage forms. Its distinct advantages over traditional manufacturing methods include enhanced precision in drug dosing, a critical factor for drugs requiring meticulous customization, such as those with a narrow therapeutic index. In this study, we successfully employed a syringe extrusion 3D printing technique to produce orodispersible films (ODFs) and compare their characteristics with those fabricated through the solvent-casting method. Different film-forming polymers like Polyvinyl Alcohol, Methocel and HPMC, PEG 4000, PEG 6000 & glycerin, and propylene glycol functioned as plasticizers. feasibility trials of film in 3d printer and by conventional method were performed. Mouth dissolving film was prepared successfully by 3D printing by pressure-assisted micro syringe method using HPMC K15 M and HPMC K100 M as polymer, Sucralose as sweetener, Citric Acid as saliva stimulating agent, PEG 400 and Glycerine as plasticizer, IPA and Water as solvent. So it can be concluded that mouth-dissolving film in both conventional methods and 3D Printing Methods. Formula by 3D printer by using a pressure-assisted micro syringe is ready for further trials with drug loading.

Keywords: 3D printing; syringe extrusion 3D printing; hydroxypropyl methylcellulose; orodispersible film

Effect of T3 loaded nanoparticles on AQP4 gene expression in mice stroke model

Hitesh Patel^{1*}, Jayvadan Patel^{2,3}, Anita Patel⁴

¹Department of Pharmaceutics, Sankalchand Patel University,
Visnagar, Gujarat, India

²Formulation Scientist, Aavis Pharmaceuticals, Hoschton, Georgia,
USA

³Professor Emeritus, Faculty of Pharmacy, Sankalchand Patel
University, Visnagar, Gujarat,
India

⁴Research Associate, Samrajya Aromatics Pvt. Ltd., Gandhinagar,
Gujarat, India.

Abstract

Ischemic brain strokes continue to rank among the leading causes of mortality and disability globally. A prompt intervention using strong neuroprotective medications is one potential method of pharmacological therapy for ischemic brain stroke patients. In the middle cerebral artery occlusion (MCAO) model of ischemic brain stroke, thyroid hormone (T3) has been demonstrated to protect against ischemic injury. Even though thyroid hormone may pass across the blood-brain barrier (BBB), we postulated that encapsulating it in nanoparticulate delivery vehicles would increase its efficacy in treating ischemic brain stroke. As an alternative to a thyroid hormone solution in the context of the MCAO stroke model, we investigated our hypothesis by creating thyroid hormone encapsulated in nanoparticles using biodegradable polymers and the environmentally friendly Supercritical Assisted Atomization (SAA) technique.

The primary advantage of our suggested use of thyroid hormones in ischemic stroke is that it makes substantial improvements possible in a life-threatening scenario by utilizing the body's hormones at sub-toxic levels. Based on, our investigation into the molecular processes behind thyroid hormone actions against edema in stroke patients, we have shown that in the transient-MCAO model, T3 and T2 both dramatically decreased the expression of AQP4. With their application in the treatment of hypothyroidism, thyroid hormones have a relatively well-established safety profile in humans. Our research adds to the small number of existing studies that examine AQP4 expression modulation as a potential strategy for brain edema mitigation. Our research is expected to contribute to the development of AQP4 expression modification as a potential treatment option for post-stroke brain edema.

Keywords: thyroid hormone, brain targeted nanoparticles, blood-brain barrier, supercritical fluid technique, anti-edema activity, ischemic brain stroke, AQP4.

I. INTRODUCTION

In India, ischemic stroke poses serious health risks to people. The absence of effective neuroprotective techniques in humans leaves stroke victims with permanent impairments brought on by the irreversible death of brain neurons (1). Brain edema is a major contributing factor to the sudden and high death rate following a stroke (2). This proposal aims to investigate the potential anti-edema and neuroprotective effects of thyroid hormones in cases of ischemic stroke. It has been stated in the literature that more than a thousand potential stroke drugs have been studied in the hopes of one day being used clinically (3). However, not a single molecule has been developed effectively into a workable, therapeutic medication. The neuroprotective qualities of endogenous hormones (progesterone, estrogen) or proteins (erythropoietin, superoxide dismutase) are of great interest (4-8). Our study expands on the idea of using endogenous neuroprotectants in place of exogenous substances. Our suggestion is predicated on the idea that thyroid hormone has anti-edema properties in cases of stroke.

Development of brain edema in ischemic stroke:

Brain ischemia, caused by factors like arterial blockage or cardiac arrest, results in insufficient oxygen and glucose supply, leading to ATP loss. When perfusion drops, cells lose potassium, and glial uptake partially buffers increased potassium. Sodium and chloride enter cells with passive water, causing cellular edema. This disrupts ionic balance, negatively affecting tissue perfusion. Early water accumulation is a sign of neuronal degeneration. Brain edema, seen after large strokes, is a dangerous consequence of ischemic brain injury, influencing survival after traumatic brain injury (9, 10). Breakdown of homeostatic mechanisms during ischemia causes severe dysregulation, leading to brain swelling and increased intracranial pressure (9-11). The hippocampus, particularly the CA1 region, is highly vulnerable to ischemia, with its pyramidal cells being the most sensitive (12). Astrocytes swell in the presence of excitotoxic glutamate concentrations, potentially impacting intracranial

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Enhancement of neuroprotective and anti-edema action in mice ischemic stroke model using T3 loaded nanoparticle

Hitesh Patel ^{1*}, Jayvadan Patel ^{2,3}, Anita Patel ⁴

¹ Department of Pharmaceutics, Sankalchand Patel University, Visnagar, Gujarat, India

² Formulation Scientist, Aavis Pharmaceuticals, Hoschton, Georgia, USA

³ Professor Emeritus, Faculty of Pharmacy, Sankalchand Patel University, Visnagar, Gujarat, India

⁴ Research Associate, Samrajya Aromatics Pvt. Ltd., Gandhinagar, Gujarat, India

*Corresponding Author: Hitesh kumar Patel

Email: aravpatel2009@gmail.com

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Abstract

Background: cerebral ischemia still represents one of the most common causes of death and disability worldwide. A prompt treatment using stroke medications is one potential method of pharmacological therapy for stroke patients. Thyroid hormone (T3) has been demonstrated to protect against ischemic damage. Despite the fact that thyroid hormone may pass through the blood brain barrier (BBB).

Objective: we hypothesized that the effectiveness of thyroid hormone treatment in stroke can be improved by encapsulation in nanoparticulate delivery system.

Methods: We tested our hypothesis by generating thyroid hormone loaded nanoparticles or brain-targeted nanoparticles using biodegradable polymer utilizing an environment-friendly Supercritical Assisted Atomization as an alternative to a thyroid hormone solution in the setting of stroke model. The biggest benefit of our proposed exploit of thyroid hormone in stroke is the fact that this strategy uses the body's endogenous hormone levels to afford significant improvement in a life-endangering situation. In our preliminary studied considerations, some tests were performed under operating conditions in a pressure range between 5 and 15MPa and temperature between 70 and 90°C.



Nanocarrier Mediated Transdermal Drug Delivery Systems for the Management of Psoriasis: A Review

Virendra Kumar Singh^{1*}, Hiteshkumar A Patel², Ramesh Singh³, Apurva Sahu⁴ and Bharat Mishra^{5*}

¹Research scholar, Department of Pharmacy, Nootan Pharmacy College, Visnagar, (Affiliated to Sankalchand Patel University), Gujarat, India.

²Associate Professor, Department of Pharmacy, Nootan Pharmacy College, Visnagar, (Affiliated to Sankalchand Patel University), Gujarat, India.

³ Professor, Department of Pharmacy, B.N College of Pharmacy, Sitapur Road, (Affiliated to AKTU), Lucknow, Uttar Pradesh, India.

⁴Assistant Professor, Department of Pharmacy, B.N College of Pharmacy, Sitapur Road, (Affiliated to AKTU), Lucknow, Uttar Pradesh, India

⁵Professor, Department of Pharmacy, Dr Shakuntala Misra National Rehabilitation University, Uttar Pradesh, India.

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*Address for Correspondence

Virendra Kumar Singh

Research scholar, Department of Pharmacy,
Nootan Pharmacy College, Visnagar,
(Affiliated to Sankalchand Patel University),
Gujarat, India.

E-Mail: virendrampharm@gmail.com

Bharat Mishra

Professor, Department of Pharmacy,
Dr Shakuntala Misra National Rehabilitation
University, Uttar Pradesh, India.

Email: bharatekash@gmail.com



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ABSTRACT

Psoriasis is an incessant autoimmune skin disease of inflammatory pathophysiology. It is expressed by prolific growth and abnormal differentiation of keratinocytes. The prevalence of psoriasis is in around 2-5% of the world population. The studies dictate that around 35% of people have moderate to severe psoriasis. Several approaches have been explored by researchers, taking in regard different anti-psoriasis drugs, but psoriasis treatment remains a challenge because of its chronic recurring nature and lack of perfect carrier for a safe and effective delivery of anti-psoriatic drugs. Currently nano carriers have gained prevalent purpose for unscathed and effective treatment of psoriasis. Novel nano carriers like liposomes, transferosomes, niosomes, ethosomes, SLN, NLC, microspheres, micelles, nanocapsules, dendrimers etc. have been thoroughly investigated. This review focuses on existing treatment options along with the recent developments in this direction.

Keywords: Psoriasis, Nanocarriers, Anti-psoriatic drugs, Delivery system, Nanoparticle.



Article

Beneficial effect of 5-HT1b/1d agonist on Parkinson's disease by modulating glutamate and reducing deposition of α -synuclein

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Authors:



Dr. Alok S. Tripathi
ERA College of Pharmacy ERA University



Needa
Fatima



Pankaj Tripathi
College of Pharmacy, Jazan University, Kingdom of Saudi Arabia



Rina
Jozi

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Abstract

The given investigation examined the neuroprotection role of 5-HT1b/1d agonist in reserpine induced Parkinson's disease (PD) in male Wistar rats. PD was induced in rats by reserpine at 5 mg/kg ip for 3 days and thereafter the rats were provided with the following treatments for 4 days, zolmitriptan (ZLM) group (30 mg/kg ip); STD group (levodopa + carbidopa, 200 + 5 mg/kg ip); ZLM + GA group (zolmitriptan, 30 mg/kg ip and glutamic acid, 1.5 mg/kg); ZLM + DX group (zolmitriptan, 30 mg/kg ip and dextromethorphan, 20 mg/kg ip). All the groups were then assessed for cognitive and motor functions at the end of the protocol. Moreover, oxidative stress parameters and histopathological changes were observed in rats of all treatment groups. Deposition of α -synuclein in the brain tissue was observed by silver staining. Data of this investigation revealed that motor and cognitive functions were improved in the ZLM-treated group compared with the negative control group, which was observed to be reversed in ZLM + GA group. Treatment with ZLM ameliorated oxidative stress and histopathological changes in the brain tissue of PD rats. Further, ZLM reduced the deposition of α -synuclein in PD rats, which reversed in ZLM + GA-treated group. This study concludes by stating that 5-HT1b/1d agonist can prevent neurodegeneration and reduce oxidative stress in PD rats. The probable underlying mechanism of such an effect of 5-HT1b/1d agonist could be by regulating the deposition of α -synuclein and reducing the expression of NMDA receptor.

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Does sildenafil citrate affect the pharmacokinetics of metformin in rats? Screening of mechanism through analytical and molecular docking approach
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Authors:

Anil Parmanand Dewani
Independent Researcher



Safia
O.
Rab



Pankaj Tripathi
College of Pharmacy, Jazan University, Kingdom of Saudi Arabia



Saurabh
Shrivastava

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Abstract and Figures

OBJECTIVE: In the present study, the effect of sildenafil on the pharmacokinetics of metformin was studied in experimental rats, and we also postulated the molecular mechanism by performing molecular docking studies. **MATERIALS AND METHODS:** Analysis of metformin and sildenafil (SIL) from rat plasma was done by high performance liquid chromatography. Optimum chromatographic separation and quantification of MET, SIL and Cetirizine was achieved on Phenomenex EVO C18 column with triethyl amine (0.3%). Methanol: Acetonitrile (70.05:25 v/v) as mobile phase maintaining flow rate of 1 ml/min, the detector was tuned at 224 nm. The extraction of MET and sildenafil from rat plasma was achieved by solid-phase extraction using Strata-X cartridges. The method was validated as per the ICH guidelines. For docking studies, the crystal structure of organic cation transporter 1 (OCT1) protein and multidrug and toxin extrusion (MATE) protein (5XJJ) were downloaded from the PubChem database. The docking study was performed by PyRx virtual screening software, and the results were analyzed by BIOVIA Discovery Studio. **RESULTS:** The validation of HPLC method was done, intraday and interday precision study of HPLC method demonstrated %RSD values less than 5%, the extraction recovery for MET and SIL were near to 80 % for low, medium and high QC samples. The plasma stability of MET and SIL showed % RSD values <10% for low, medium, and high QC samples. A sensitivity study for MET and SIL in rat plasma suggested a lower limit of quantification values of 8 and 10 ng/mL, respectively. The pharmacokinetic parameters were recorded, C_{max} of experimental and control rats was 611.2 and 913.2 ng/mL; t_{1/2} 1.66 and 1.98, AUC (0-4) 1637.5 and 2727.24, AUC (0-∞) 1832.38 and 2995.24 for MET. The results suggested that the C_{max} of MET in experimental rats (MET + SIL) was 33.07% lower than the control (MET only) and also the t_{1/2} was 0.32 h shorter. Docking analysis suggested a higher binding affinity of sildenafil with MATE protein (5XJJ) compared to OCT1, suggesting possible involvement of MATE family proteins for pharmacokinetic alterations of MET. **CONCLUSIONS:** The HPLC and solid-phase extraction method were developed and applied successfully for the pharmacokinetics of MET and SIL. Intake of SIL altered the pharmacokinetics of MET in rats. Molecular docking studies suggested the involvement of MATE family proteins for alterations of MET pharmacokinetics.

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