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# Geethanjali College of Pharmacy

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Recognized Under UGC Section 2F & 12B of UGC Act, 1956, by DSIR-SIRO & HI/BI of MSME Certified by ISO 9001:2015
Cheeryal (V), Keesara (M), Medchal-Malkajgiri District, Telangana State - 501 301.

DATE: 21/07/2021

### Constitution of Research Review Club (RRC):

Review Ethical Committee provides a forum to remain up to date with literature and also offers an opportunity to learn methods of critically evaluating review and research articles. It usually organized around a define subject with a basic or applied a research and review article, manuscript and evaluation done by head of the Department.

#### Constitution of Research Review Club:

The following faculty members are nominated to be the members of Research Review Club:

#### **Research Review Club Members:**

S. No	Name	Members	Signature
1.	Dr. M. Ravi Kumar	Director	900
2.	Dr. Sunil Junapudi	Co-Ordinator	11.95
3.	Dr.M. Srinivas	Member	RO
4.	Dr. R. Siva Kumar	Member	620
5.	Dr. R. N. Kishore	Member	R. w. Diahon
6.	Dr. Bharat Bhushan	Member	Drahows a
7.	Dr. N. Anjaneyulu	Member	D. A.
8.	Dr. B. Rambabu	Member	of all.
9.	Dr. P. Neeraja	Member	Cartz
10.	Dr. Y. Shiva Kumar	Member	Usi -



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DATE: 15/7/2021

### **CIRCULAR**

All the faculty members are here by informed review article manuscript are forward to **ethical.gcpk@gmail.com** Research Review Club members evaluate the manuscript.



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DATE: 21/07/2021

### Minutes of Meeting

NATURE OF MEETING	REVIEW ETHICAL COMMITTEE	
VENUE	BOARD ROOM	
FREQUENCY OF MEET	ONCE IN A ACADEMIC YEAR	
CONVENED ON (DATE)	TIME: FROM 10 AM TO 1 PM	
LIST OF MEMBERS ATTENDED	Copy Attached	
COPIES CIRCULATED TO	All members of governing body	

### **Meeting Agenda**

- 1. To learn methods of critically evaluating review and research articles.
- 2. Review research Proposals involving Participants and their data to ensure that the agree the National and International Journal Guidelines.
- 3. It is mandate to ensure only support research of the highest Ethical standards.





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2.	Dr. Sunil Junapudi	Co-Ordinator	8
3.	Dr.M. Srinivas	Member	
4.	Dr. R. Siva Kumar	Member	G-30 Par
5.	Dr. R. N. Kishore	Member	R. N Dish
6.	Dr. Bharat Bhushan	Member	Braherthe
7.	Dr. N. Anjaneyulu	Member	D. Aug
8.	Dr. B. Rambabu	Member	N Di
9.	Dr. P. Neeraja	Member	Ceely
10.	Dr. Y. Shiva Kumar	Member	Ch



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### Research Review Club

### **Assigning of reviewers**

Title: Preparation and nutritive evaluation of Azolla pinnata pellets/granules as poultry feed

Author Name: Dr. R. Naga Kishore

I hereby assign proposed research or review article to the reviewers

Name of reviewer (1): Dr B. Rambabu

Mess.

Name of reviewer (2): Dr. M. Ravikumar

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# PREPARATION AND NUTRITIVE EVALUATION OF AZOLLA PINNATA PELLETS/GRANULES AS POULTRY FEED

AUTHOUR: Dr. R. Naga Kishore

**DESIGNATION: Associate Professor** 

COLLEGE: GEETHANJALI COLLEGE OF PHARMACY

#### **Abstract**

In the recent past, few studies have been carried out in chicken to assess the effect of *Azolla* meal and raw *Azolla* feeding on the performance of chicken. If we use unconventional feedstuffs like *Azolla* without reducing the performance, it will increase the profitability of broiler business. Hence, a study was carried out to evaluate the effect of dried *Azolla pinnata* vis-a-vis raw *Azolla* as choice feeding on the growth. Use of Azolla in broiler diets can improve the economic performance of broilers. Azolla is a free floating fern which can be regarded as a valuable food source. Azolla can be used as a plant protein source and provitamins for poultry nutrition. This plant with its thin roots is like a carpet that has been spread on the water surface. This plant's leaves are delicate, little and sensitive and have different colors depending on what point of time they have grown. Two formulations were prepared to enhance the shelf life of azolla and observed for their growth. Both formulations showed best results over 15 days of period. Further studies are necessary to improve the shelf life of azolla.

Keywords: Azolla pinnata, provitamins, poultry nutrition and formulations.



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### Research Review Club

#### REPORT

Title: "Preparation and nutritive evaluation of Azolla pinnata pellets/granules as poultry feed

Author Name: Dr. R. Naga Kishore

Name of reviewer (1): Dr B. Rambabu:

check Alignment.

Name of reviewer (2): Dr. M. Ravikumar:

Phormacenthical applications of the structure of

# PREPARATION AND NUTRITIVE EVALUATION OF AZOLLA PINNATA PELLETS/GRANULES AS POULTRY FEED

1R Naga Kishore, 2N Anjaneyulu, 3M Ravi Kumar 1Professor, 2Professor, 3Principal and Professor 1Geethanjali College of Pharmacy, 2Geethanjali College of Pharmacy, 3Geethanjali College of Pharmacy

#### Abstract

In the recent past, few studies have been carried out in chicken to assess the effect of Azolla meal and raw Azolla feeding on the performance of chicken. If we use unconventional feedstuffs like Azolla without reducing the performance, it will increase the profitability of broiler business. Hence, a study was carried out to evaluate the effect of dried Azolla pinnata vis-a-vis raw Azolla as choice feeding on the growth. Use of Azolla in broiler diets can improve the economic performance of broilers. Azolla is a free floating fern which can be regarded as a valuable food source. Azolla can be used as a plant protein source and provitamins for poultry nutrition. This plant with its thin roots is like a carpet that has been spread on the water surface. This plant's leaves are delicate, little and sensitive and have different colors depending on what point of time they have grown. Two formulations were prepared to enhance the shelf life of azolla and observed for their growth. Both formulations showed best results over 15 days of period. Further studies are necessary to improve the shelf life of azolla.

Keywords: Azolla pinnata, provitamins, poultry nutrition and formulations.

#### Introduction

Azolla is an aquatic fern, which resembles duckweed or mosses. It is addressed with other names like mosquito fern, duckweed fern, fairy moss or water fern. The name Azolla is derived from two Greek words, i.e. 'azo' means dry and 'ollya' means to kill. Therefore, this name Azolla indicates an important property of the fern that it would be killed by drought. Azolla is native to Asia, Africa, and America. Azolla is believed to float on the surface of the water with roots hanging underneath. These plants have leaves which are small in size and overlap on each other. The leaves or fronds are water repellent and sometimes red in color. This plant is popular as 'super plant' bosona of its great speed of growing and doubling its biomass within 2 or 3 days. Currently, the plant genus has 6 species of which A.pinnata is mostly found in Asia. The length of the roots for Azolla is around 1 to 2 cm and the leaf size is about 1 to 2 cm. The fern has a sporophytic cycle and is generally associated with cooler temperatures. The difference in the strain and environmental factors can alter the nutrient composition of Azolla. Azolla is consulted to favor the following nutrients, which is why it is greatly used as animal or livestock feed (For dairy animals, populary, sheep and goat). Dried Azolla has: Crude

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### Research Review Club

#### Assigning of reviewers

Title: A review of 1,2,4-Triazoles: synthesis and Pharmacological uses

Authors Name: B. Sandhya, Dr. R. Siva Kumar

I hereby assign proposed research or review article to the reviewers

Name of reviewer (1): Dr M. Srinivas

Name of reviewer (2): Dr. J. Sunil

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# A REVIEW OF 1,2,4-TRIAZOLES: SYNTHESIS AND PHARMACOLOGICAL USES

B. Sandhya\*, Geethanjali College of Pharmacy

Dr. R. Sivakumar, Geethanjali College of Pharmacy

### **ABSTRACT**

Heterocycle compounds are cyclic or noncyclic structure which contain one or more heteroatom. The heterocycle compounds containing nitrogen are widely used in medicinal chemistry. More than 75% drugs which are available in market contain nitrogen in heterocyclic moieties. Among these 1,2,4-triazole nucleus has attracted many researchers because of its simple, easy, cost effective method of synthesis and also mainly because of multidirectional biological activity (such as antibacterial, anticancer, analgesic, anticonvulsant, antioxidant, antiviral). The current review mainly aims on the synthesis methods and pharmacological uses of 1,2,4-triazole derivatives.

KEYWORDS: 1.2.4-triazoles, Synthesis, Pharmacological uses.



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Cheeryal (V), Keesara (M), Medchal-Malkajgiri Dist., Telangana State- 501301

### Research Review Club

### REPORT

Title: A review of 1,2,4-Triazoles: synthesis and Pharmacological uses

Authors Name: B. Sandhya, Dr. R. Siva Kumar

Name of reviewer (1): Dr M. Srinivas:

Satisfactory

Name of reviewer (2): Dr. J. Sunil:

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# A REVIEW OF 1,2,4-TRIAZOLES: SYNTHESIS AND PHARMACOLOGICAL USES

B.Sandhya\*, Geethanjali College of Pharmacy Dr.R.SivaKumar, Geethanjali College of Pharmacy Dr.S.Gayatri, Sri Ramachandra Institute of Higher Education and Research Dr.K.Mythili, Sri Ramachandra Institute of Higher Education and Research

#### **ABSTRACT**

Heterocycle compounds are cyclic or noncyclic structure which contain one or more heteroatom. The heterocycle compounds containing nitrogen are widely used in medicinal chemistry. More than 75% drugs which are available in market contain nitrogen in heterocyclic moieties. Among these 1,2,4-triazole nucleus has attracted many researchers because of its simple, easy, cost effective method of synthesis and also mainly because of multidirectional biological activity (such as antibacterial, anticancer, analgesic, anticonvulsant antioxidant, antiviral). The current review mainly aims on the synthesis methods and pharmacological uses of 1,2,4-triazole derivatives.

**KEYWORDS:** 1.2.4-triazoles, Synthesis, Pharmacological uses.

#### Introduction:

Triazole is an aromatic heterocyclic compound which is a five membered ring comprised of 2 carbon and 3 nitrogen atoms with molecular formula C<sub>2</sub>H<sub>3</sub>N<sub>3</sub>.. The triazoles are said to be the isosters of imidazoles in which the carbon atom of imidazole is isosterically replaced by nitrogen [1]. According to the position of nitrogen atoms, triazoles exist in two isomeric forms - 1,2,3-triazole (v-triazoles) and 1,2,4-triazole ((s-triazoles). The mobile protons at the ring nitrogen atoms of 1,2,3- and 1,2,4-triazoles are responsible for the tautomerism [2]. The 1,2,4-triuzole ring may exist in equilibrium between two forms: 111-form and 411-form an difficult to separate due to rapid interconversions.[3].

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#### Research Review Club

#### Assigning of reviewers

**Title:** "A Prospective Comparative Study on the Efficacy of Chlorxazone, Ibuprofen and Paracetamol versus Thiocolchicoside, Aceclofenac and Paracetamol in Patients with Acute Lower Backache: A Tertiary Care Hospital"

Author Name: Dr. R. Naga Kishore

I hereby assign proposed research or review article to the reviewers

Name of reviewer (1): Dr B. Rambabu

Name of reviewer (2): Dr. M. Ravikumar

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TITLE: A Prospective Comparative Study on the Efficacy of Chlorxazone, Ibuprofen and Paracetamol versus Thiocolchicoside, Aceclofenac and Paracetamol in Patients with Acute

Lower Backache: A Tertiary Care Hospital

AUTHOUR: Dr. R. Naga Kishore

**DESIGNATION: Associate Professor** 

COLLEGE: GEETHANJALI COLLEGE OF PHARMACY

#### **ABSTRACT**

#### **BACKGROUND:**

The combination of CNS acting muscle relaxants, non-steroidal medicine medication, and paracetamol are normally prescribed in management of mechanical low backache.

#### **AIM AND OBJECTIVES:**

To compare effectiveness of combination drugs chlorzoxazone + aceclofenac + paracetamol v/s thiocolchicoside + aceclofenac + paracetamol in subjects having low backache.

#### **MATERIALS AND METHODS:**

A total of one hundred patients between ages vary from eighteen (18) and sixty (60) years having mechanical low backache of ≤7 days length were categorised as groups. Group A type was prescribed with thiocolchicoside, paracetamol, & aceclofenac whereas Group B type was prescribed with chlorzoxazone, aceclofenac, & paracetamol orally doubly daily for seven days. The pain assessment, calculated by VAS and ODI. Readings were recorded on day one (baseline), and day seven.

#### **RESULTS:**

A significant pain reduction occurred on day seven in two groups. It was observed statistically that relief in pain varied in 2 groups, however clinically Group-B subjects shown better efficacy compared to Group-A.

#### **CONCLUSION:**

These findings confirm that chlorzoxazone, paracetamol, ibuprofen, is a preferable combination for patients having low backache.

#### **KEYWORDS:**

Drug combinations, mechanical low backache; muscle relaxants; non-steroidal inflammatory

drugs; VAS, ODI.

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**Title:** "A Prospective Comparative Study on the Efficacy of Chlorxazone, Ibuprofen and Paracetamol versus Thiocolchicoside, Aceclofenac and Paracetamol in Patients with Acute Lower Backache: A Tertiary Care Hospital"

Author Name: Dr. R. Naga Kishore

Name of reviewer (1): Dr B. Rambabu:

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Name of reviewer (2): Dr. M. Ravikumar:

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### A Prospective Comparative Study on the Efficacy of Chlorzoxazone, Ibuprofen and Paracetamol versus Thiocolchicoside, Aceclofenac and Paracetamol in Patients with Acute Lower Backache: A Tertiary Care Hospital

Athyala Divya<sup>1</sup>, Balaraju Ramya<sup>1</sup>, Muddapuram Manasa<sup>1</sup>, Varsha Madas<sup>1</sup>, Karthik<sup>2</sup>, R Naga Kishore<sup>1\*</sup>

Abstract: The combination of CNS acting muscle relaxants, non-steroidal medicine medication and paracetamol are normally prescribed in the management of mechanical low backache. To compare the effectiveness of combination drugs chlorzoxazone, ibuprofen and paracetamol versus thiocolchicoside, aceclofenac and paracetamol in subjects having low backache. A total of one hundred patients between ages vary from eighteen and sixty years having acute lower backache of ≤7 days length were categorized as groups. Group A type was prescribed with thiocolchicoside, paracetamol and aceclofenac whereas Group B type was prescribed with chlorzoxazone, aceclofenac and paracetamol orally doubly daily for seven days. The pain assessment, calculated by VAS and ODI. Readings were recorded on day one (baseline) and day seven. A significant pain reduction occurred on day seven in two groups. It was observed statistically that relief in pain varied in 2 groups, however clinically Group-B subjects shown better efficacy compared to Group-A. These findings confirm that chlorzoxazone, paracetamol, ibuprofen is a preferable combination for patients having low backache.

#### INTRODUCTION

Low back pain (LBP) is a considerable health problem in all developed countries and is most commonly treated in primary healthcare settings. It is usually defined as pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica). The most important symptoms of nonspecific low back pain are pain and disability. The diagnostic and therapeutic management of patients with low back pain has long been characterized by considerable variation within and between countries among general practitioners, medical specialists and other healthcare professionals. [1, 2] It is a major health and socio-economic problem [3] and is associated with high costs of health care, work absenteeism and disablement. [4] In general, LBP is managed with the short-term use of non-steroidal antiinflammatory drugs (NSAIDs) and centrally acting skeletal muscle relaxants. [5] Unfortunately, NSAIDs have gastric intolerance, whereas most of the centrally acting muscle relaxants have central nervous system depressant Sideeffects such as sedation, dizziness, impairment of coordination, mental confusion, weakness, etc. [6] Hence, these limiting factors demand a need for an ideal fixed-dose combination (FDC) which is devoid of effects on psychomotor performance, free of sedation and higher tolerability.

The visual analog scale (VAS) is a valid and reliable measure of chronic pain intensity. However, little work has been done to account the reliability of the VAG for the measurement of acute pain. The few studies that have explicitly assessed the reproducibility of VAS measures of

pain focused on chronic or postoperative pain and most examined the correlation between repeat VAS measures. <sup>[7]</sup> A study of a mechanical version of a VAS (a tool with a 10-cm ruler and a marker that the patient moves to the point indicating his or her intensity of pain) used by patients with pain found a correlation of 0.88 between two measures taken two hours apart. Studies that examined the correlation between a vertically oriented VAS for pain with a horizontally oriented VAS found correlations of 0.99 and 0.91 when they were given within 10 minutes of each other to patients with a variety of pain. <sup>[7,8]</sup>

The Oswestry Disability Index (ODI) is the most commonly used outcome-measure questionnaire for low back pain in a hospital setting. It is a self-administered questionnaire divided into ten sections designed to assess the limitations of various activities of daily living. Each section is scored on a 0-5 scale, with 5 representing the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage. Thus, for every question not answered, the denominator is reduced by 5. If a patient marks more than one statement in a question, the highest-scoring statement is recorded as a true indication of disability. The questionnaire takes 3.5-5 min to complete and approximately 1 min to score. [9,10]

Chlorzoxazone, a central muscle relaxant acts primarily at the level of the spinal cord and subcortical areas of the brain, where it inhibits multisynaptic reflex arcs involved in producing and maintaining alceletal muscle spasms. The exact mode of action is not clear, may be related to the sedative properties of the drug. The side-effect profile is similar to that of most other muscle relaxants, except for a limited number of reported cases of significant hepatotoxicity particularly by chlorzoxazone. [11]

Thiocolchicoside is a semi-synthetic derivative of colchicines, a natural glycoside that originated from flower seeds of superb gloriosa. [12] It has an affinity for the inhibitory glycine and gamma-aminobutyric acid (GABA)-A

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### Research Review Club

#### **Assigning of reviewers**

**Title:** Impact of COVID-19 on the Medical device industry

Author Name: S.D.Shalini

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Name of reviewer (1): Dr P. Neeraja

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Cheeryal (V), Keesara (M), Medchal-Malkajgiri Dist., Telangana State- 501301

TITLE: Impact of COVID-19 on the Medical device industry

**AUTHOUR: S.D.Shalini** 

**DESIGNATION: Assistant Professor** 

COLLEGE: GEETHANJALI COLLEGE OF PHARMACY

#### Abstract-

The main aim of this study is to review the effect caused by Covid 19 on the medical device industry and to study the challenges faced by the medical device industry in different countries such as India, the USA, European countries. In earlier May 2020, over 4.7 million people have been confirmed to be infected with the SARS-CoV-2 coronavirus, and governments are worried to get contain its spread. The high RO value (a measure of contagiousness-estimated to be between 2.0 and 3.02) of SARS-CoV-2 means that those infected copiously spread the virus and develop complications suddenly. As a result, health care systems are widespread, and the effective delivery of medical care to all patients has become challenging to the whole world. Improper seeking to early warning signals, less amount of stockpiling, lack of ease to testing kits and personal protective equipment (PPE), and country-wise variability in the approaches to testing kits, distribution of PPE, and timing and degree of social distancing measures are likely to get affect the spread of disease. As the COVID-19 pandemic continues to get imbalanced, medical device companies are finding it difficult to make précised decisions about their products, supply chains, and regulatory obligations in the advent of uncertainty. With a technique that leverages exemptions, production procedures that innovate to fill needs, and a communication plan that works across public and personal entities, which may navigate the chaos and support public health. Obligations from governing bodies and conversations with key decision-makers and regulatory authorities hold the key to the success of the medical device industry. At last, the implementation of several new regulations may be postponing as making many companies and regulatory agencies time to react to the crisis. However, there is no evidence to make this scenario be the deadline for suggestions.

Keywords-Medical device, Regulatory bodies, Surgical handling instruments.



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#### Research Review Club

### REPORT

**Title:** Impact of COVID-19 on the Medical device industry

Author Name: S.D.Shalini

Name of reviewer (1): Dr P. Neeraja: Maintain Consistency Cons

Name of reviewer (2): Dr. Y.Shiva Kumar:

va Kumar:

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### IMPACT OF COVID-19 ON THE MEDICAL DEVICE **INDUSTRY**

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<sup>1</sup>Assistant Professor, <sup>2</sup>Assistant Professor, <sup>3</sup> Assistant Professor, <sup>4</sup>Head of the Department, <sup>5</sup>Principal Department of Pharmaceutics, Geethanjali College of pharmacy, Cheeryal, Keesara-501301, India

Abstract: The main aim of this study is to review the effect caused by Covid 19 on the medical device industry and to study the challenges faced by the medical device industry in different countries such as India, the USA, European countries. In earlier May 2020, over 4.7 million people have been confirmed to be infected with the SARS-CoV-2 coronavirus, and governments are worried to get contain its spread. The high RO value (a measure of contagiousness-estimated to be between 2.0 and 3.02) of SARS-CoV-2 means that those infected copiously spread the virus and develop complications suddenly. As a result, health care systems are widespread, and the effective delivery of medical care to all patients has become challenging to the whole world. Improper seeking to early warning signals, less amount of stockpiling, lack of ease to testing kits and personal protective equipment (PPE), and country-wise variability in the approaches to testing kits, distribution of PPE, and timing and degree of social distancing measures are likely to get affect the spread of disease. As the COVID-19 pandemic continues to get imbalanced, medical device companies are finding it difficult to make précised decisions about their products, supply chains, and regulatory obligations in the advent of uncertainty. With a technique that leverages exemptions, production procedures that innovate to fill needs, and a communication plan that works across public and personal entities, which may navigate the chaos and support public health. Obligations from governing bodies and conversations with key decision-makers and regulatory authorities hold the key to the success of the medical device industry. At last, the implementation of several new regulations may be postponing as making many companies and regulatory agencies time to react to the crisis. However, there is no evidence to make this scenario be the deadline for suggestions.

Keywords: Medical device, Regulatory bodies, Surgical handling instruments.

#### Introduction:

A medical device is any device intended to be used for medical purposes. Medical devices benefit patients by helping health care providers diagnose and treat patients and helping patients overcome sickness or disease, improving their quality of life. Significant potential for hazards is inherent when employing a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country.

As a general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase. Medical devices vary in both their intended use and indications to be used. Examples range from simple, low-risk devices such as tongue depressors, medical thermometers, disposable gloves, and bedpans to complex, high-risk devices that are implanted and sustain life.

One example of high-risk devices is those with embedded software like pacemakers, and which assist in the conduct of medical testing, implants, and prostheses. The design of medical devices constitutes a serious segment of the sector of biomedical engineering.

#### II. Medical devices according to WHO

#### Medical Device - Full Definition

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or another similar or related article, intended by the manufacturer to be used, alone or together, for the citizenry, for one or more of the precise medical purposes(s) of:

- 1. Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
- 2. Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
- 3. Investigation, replacement, modification, or support of the anatomy or a physiological process,
- 4. Supporting or sustaining life,
- 5. Control of conception.
- 6. Disinfection of medical devices
- 7. Providing information utilizing in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the physical body, but which can be assisted in its intended function by such means.

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Cheeryal (V), Keesara (M), Medchal-Malkajgiri Dist., Telangana State- 501301

#### Research Review Club

### Assigning of reviewers

**Title:** Analytical Method Development and Validation for the Determination of Emtricitabine and Tenofovir Disoproxil Fumarate using Reverse Phase HPLC method in Bulk and Tablet Dosage form

Authors Name: Dr M. Srinivas

I hereby assign proposed research or review article to the reviewers

Name of reviewer (1): Dr. R. Siva Kumar

Name of reviewer (2): Dr. J. Sunil

Note: Correction manuscript please forward ethical.gcpk@gmail.com within one week

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#### TITLE

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE USING REVERSE PHASE HPLC METHOD IN BULK AND TABLET DOSAGE FORM

AUTHOR: Dr. M. Srinivas

**DESIGNATION: PROFESSOR** 

**COLLEGE: GEETHANJALI COLLEGE OF PHARMACY** 

#### **ABSTRACT**

Objective: A New method was established for simultaneous estimation of Emtricitabine and Tenofovir disoproxil fumarate by RP-HPLC method. Methods: The chromatographic conditions had been effectively advanced for the separation of Emtricitabine and tenofovir by way of using Edurasil ODS-3 C18(4.6 x 50mm, 3.5μm) column, go with the flow charge changed into 1ml/min, cellular segment ratio become Phosphate buffer (0.05M) pH four.6: ACN (30: 70) (pH become adjusted with orthophosphoric acid), detection wave period was 250nm. The device used turned into WATERS HPLC Auto Sampler, Separation module 2695, PDA Detector 996, Empower-software model-2. Results: Retention time of Emtricitabine and tenofovir were found to be 0.919 min and 1.732 min. The % purity of Emtricitabine and tenofovir was found to be 99.7 % and 99.04 % respectively. The system suitability parameters for Emtricitabine and tenofovir such as theoretical plates and tailing factor were found to be 1.56, 2744.20 and 1.19, 33.75.11. The linearity study for Emtricitabine and tenofovir was found in concentration range of 20µg-100µg and 30µg-150µg and correlation coefficient (r2) was found to be 0.999 and 0.999 % % RSD for intermediate precision was 0.6 and 0.69 respectively. The precision study was precise, robust and repeatable. LOD value was 2.98 and 2.96, and LOQ value was 9.98 and 9.96 respectively. Conclusion: The results of study showed that the proposed RP-HPLC method is a simple, accurate, precise, rugged, robust, fast and reproducible, which may be useful for the routine estimation of Emtricitabine and Tenofovir disoproxil fumarate in pharmaceutical dosage form.

Keywords: Emtricitabine, Tenofovir disoproxil fumarate. RP?HPLC



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#### Research Review Club

#### REPORT

**Title:** Analytical Method Development and Validation for the Determination of Emtricitabine and Tenofovir Disoproxil Fumarate using Reverse Phase HPLC method in Bulk and Tablet Dosage form

Authors Name: Dr M. Srinivas

Name of reviewer (1): Dr. R. Siva Kumar:

Satisfactory

Name of reviewer (2): Dr. J. Sunil:

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE USING REVERSE PHASE HPLC METHOD IN BULK AND TABLET DOSAGE FORM

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#### **ABSTRACT**

Objective: A New method was established for simultaneous estimation of Emtricitabine and Tenofovir disoproxil fumarate by RP-HPLC method. Methods: The chromatographic conditions had been effectively advanced for the separation of Emtricitabine and tenofovir by way of using Edurasil ODS-3 C18(4.6 x 50mm, 3.5μm) column, go with the flow charge changed into 1ml/min, cellular segment ratio become Phosphate buffer (0.05M) pH four.6: ACN (30: 70) (pH become adjusted with orthophosphoric acid), detection wave period was 250nm. The device used turned into WATERS HPLC Auto Sampler, Separation module 2695, PDA Detector 996, Empowersoftware model-2. Results: Retention time of Emtricitabine and tenofovir were found to be 0.919 min and 1.732 min. The % purity of Emtricitabine and tenofovir was found to be 99.7 % and 99.04 % respectively. The system suitability parameters for Emtricitabine and tenofovir such as theoretical plates and tailing factor were found to be 1.56, 2744.20 and 1.19, 33.75.11. The linearity study for Emericitabine and tenofovir was found in concentration range of 20µg-100µg and 30µg-150µg and correlation coefficient (r2) was found to be 0.999 and 0.999 % RSD for intermediate precision was 0.6 and 0.69 respectively. The precision study was precise, robust and repeatable. LOD value was 2.98 and 2.96, and LOQ value was 9.98 and 9.96 respectively. Conclusion: The results of study showed that the proposed RP-HPLC method is a simple, accurate, precise, rugged, robust, fast and reproducible, which may be useful for the routine estimation of Emtricitabine and Tenofovir disoproxil fumarate in pharmaceutical dosage form.

KEYWORDS: Emtricitabine, Tenofovir disoproxil fumarate. RP-HPLC.

#### INTRODUCTION

Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI) indicated for the treatment of HIV infection in adults or combined with tenofovir alafenamide for the prevention of HIV-1 infection in high-risk adolescents and adults.[1] Emtricitabine is a cytidine analogue. [2] The drug works by inhibiting HIV reverse transcriptase, preventing transcription of IIIV RNA to DNA. IUPAC Name: 4-amino-5-fluoro-1-[(2R,5S)-2-(hydroxymethyl) 1,3 oxathiolan-5-yl]-1,2dihydropyrimidin=?-one. Chemical C<sub>8</sub>H<sub>10</sub>FN<sub>3</sub>O<sub>3</sub>S. Molecular Weight is 247.247 g·mol<sup>-1</sup>. Emtricitabine is a white to off-white powder with a solubility of approximately 112 mg/mL in water at 25 °C. The log P for emtricitabine is -0.43 and the pKa is 2.65.

Tenofovir disoproxil fumarate (a prodrug of tenofovir), marketed by Gilead Sciences under the trade name Viread, belongs to a class of antiretroviral drugs known as nucleotide analogue reverse transcriptase inhibitors (nRTIs). This drug is prescribed in combination with other drugs for the management of HIV infection as well as for Hepatitis B therapy. Tenofovir belongs to a class of antiretroviral drugs known as nucleotide analog reverse transcriptase inhibitors (NtRTIs), which block reverse transcriptase, an enzyme necessary for viral production in HIV-infected individuals. This enables the management of HIV viral load through decreased viral replication. IUPAC Name (2E)-but-2-enedioic acid; bis({[(propan-2 yloxy) carbonyl]oxy} methyl){[(2R)-1-(6-amino-9H-purin-9-yl)propan-2yl]oxy} methanephosphonate. Chemical Formula is C<sub>23</sub>H<sub>34</sub>N<sub>5</sub>O<sub>14</sub>P. Molecular Weight is

635.51 g mol

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S.NO	TITLE	MANUSCRIPT RECEIVED DATE	REVIEW REPORT DATE	PUBLISHED	JOURNAL
1.	Preparation and nutritive evaluation of Azolla pinnata pellets/granules as poultry feed	11/8/2021	21/8/2021	NOV 2021, VOLUME 8	International Journal of Research and Analytical Reviews (IJRAR)
2.	A review of 1,2,4- Triazoles :synthesis and Pharmacological uses	6/8/2021	17/8/2021	Volume 8, Issue 4, Pg 214	International Journal of Research and Analytical Reviews (IJRAR)
3.	A prospective comparative study on the efficacy of Chlorzoxazone, Ibuprofen and Paracetamol versus Thiocolchicoside, Aceclofenac and Paracetamol in patients with acute lower back ache :A Tertiary Care Hospital	31/8/2021	10/8/2021	Vol. 2021, Issue 3	Invention Rapid: Pharmacy Practice
4.	Impact of COVID-19 on the medical device industry	28/7/2021	2/8/2021	OCT 2021, VOLUME 6 ISSUE 10, PG 16	International journal of Scientific Development and research (IJSDR)
5.	Analytical Method Development and Validation for the Determination of Emtricitabine and TenofovirDisoproxil Fumarate using Reverse Phase HPLC method in Bulk and Tablet Dosage form	26/7/2021	31/7/2021	Vol 18, Issue 10, 2021, Pg 254-260	European journal of Biomedical and Pharmaceutical sciences



