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# 3.3.1 NUMBER OF PAPERS PUBLISHED PER TEACHER FOR THE A.Y 2018-2019

S.No	Name of the author	Title of the paper	Title of the journal	Year of Publication	Citation index	Institutional affiliation as mentioned in the publication
1.	T S Mohamed Saleem K Jyothi S Chandra babu	A case report on Nevirapine induced exfoliative dermatitis	Pakistan Journal of Pharmaceutical Science	Vol.32, No.1, January 2019, pp.221- 222	Scopus ISI expanded IF: 0.86	Annamacharya College of Pharmacy, Rajampet Rajiv Gandhi Institute of Medical Sciences, Kadapa
2.	Meda Venkatasubbaiah, P. Dwarakanadha Reddy, Suggala V. Satyanarayana	Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital	Alexandria Journal of Medicine	Vol 54, No 4 2018	Elsevier Google Scholar	Research Scholar, JNTUA, AnanthapuramuDepartmentofPharmaceuticsAnnamacharyaCollegeCollegeofPharmacy,Rajampet,Department of Chemical Engineering, JNTUCollege of Engineering, Anantapuramu.
3.	S.Chand basha K.Ahamed Basha	Synthesis and antioxidant activity of some novel formazans	Asian journal of pharmaceutical analysis and medicinal chemistry	6(3), 2018, 123-126	Google Scholar	Department of Pharmaceutical Chemistry Annamacharya College of Pharmacy Rajampet
COLL	Dasari Vasavi Devi D Swarnalatha	Chemometric Assisted method development for Teneligliptin and	Asian Journal of Chemistry	30(12), 2018, 2704-2710	Scopus	Annamacharya College of Pharmacy Rajampet

#### LIST OF PUBLICATIONS FOR THE ACADEMIC YEAR 2018-2019

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			metformin by stability indicating RP-HPLC technique and its validation				
	5.	Dasari Vasavi Devi D Swarnalatha GV Subbareddy	ICH guideline practice: a validated stability indicating RP-UPLC method development and its application for determination of aliskiren and amlodipine in bulk and formulation	Rasayan J. Chem,	11 (3), 1300 - 1310 (2018)	Scopus	Annamacharya College of Pharmacy, Rajampet
	6.	P. ANITHA, J. BHARGAVI, G. SRAVANI, B. ARUNA, RAMKANTH S	Recent progress of dendrimers in drug delivery for cancer therapy	International Journal of Applied Pharmaceutics	Vol 10, Issue 5, 2018	Google Scholar	Department of Pharmaceutics, Annamacharya College of Pharmacy, Rajampet
ATA CO ATA CO Har Ba Mar S Raja	7. OLLEG	Malathi S. Mohan raghupathy S.,	Determination of hair growth stimulantion activityof acacia leuchopholea leaf extract on shavedsurface of skin	World Journal of Pharmaceutical Research	Volume 7, Issue 13, 718-723 2018	Google Scholar	Department of Pharmacology, Annamacharya College of Pharmacy, Rajampet
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8.	Vasavi devi dasari, Swarnalatha dugasani, venkatasubba reddy	on rats * Atomic absorption spectrophotometer – a versatile tool for the estimation of nickel	Pharmaceutical	12, (8), 187-190; 2019	Scopus , Google Scholar	Department of Pharmaceutical Sciences, Annamacharya College of Pharmacy, Rajampeta, Andhra Pradesh, India.
9.	gopireddy M. Syamala,, S. Angalaparameswari,, T. Vimalakannan,, C. Sumanjali,, T. Jyotshna	content in dronedarone Stability indicating method development and validation for the determination of haloperidol and benzhexol by RP- HPLC	International Journal of Research in Pharmaceutical Chemistry and Analysis	1(2), 52-58 2019	Google Scholar	Department of Pharmacology, Annamacharya College of Pharmacy. Rajampet, Andhra Pradesh, India.
10	S.Nalini, S.Chand Basha, T.S.M.Saleem	In-vitro Pharmacological Evaluation of sulforaphane from Brassica oleracea	TMR Integrative medicine	3(e19012), 1-6, 2019	Google Scholar	Department of Pharmaceutical chemistry Annamacharya College of Pharmacy, Rajampeta, Andhra Pradesh, India.



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#### REPORT

### A case report on Nevirapine induced exfoliative dermatitis

### Thattakudian Sheikuduman Mohamed Saleem<sup>1</sup>\*, Kakavakam Jyothi<sup>1</sup> and S Chandra Babu<sup>2</sup>

<sup>1</sup>Drug Information Centre, Department of Pharmacy Practice, Annamacharya College of Pharmacy, Rajampet, India <sup>2</sup>Department of General Medicine, Rajiv Gandhi institute of medical sciences, Kadapa, India

Abstract: Drug induced adverse drug reactions is more common in long term therapy particularly in immune compromised patients. Most of the drugs causing dermatological reactions like skin rashes, pruritus, steven johnson syndrome and exfoliative dermatitis. Nevirapine is the first line drug for human immunodeficiency virus (HIV) infection from the category of non-nucleoside reverse transcriptase enzyme inhibitor (NNRTI). In the present cases, we have reported the nevirapine induced severe exfoliative dermatitis. A patient admitted in the hospital with the symptoms of scaling on the skin and he received Nevirapine as a drug for his diagnosis of HIV for past three years. After clear examination exfoliative dermatitis was conformed and suspected with the cause due to Nevirapine. The drug was stopped and the patient was treated with drugs for symptomatic cure. The patient was recovered from his condition and other antiretroviral drugs were recommended for his treatment.

Keywords: Antiretroviral therapy, adverse drug reaction, erythroderma, HIV, skin rashes.

#### INTRODUCTION

Nevirapine is the first line drug for human immunodeficiency virus (HIV) infection from the category of non-nucleoside reverse transcriptase enzyme inhibitor (NNRTI). Hepatotoxicity and skin rashes are the most common adverse drug reaction of the drug nevirapine (Flexner, 2006; Aronson 2006; Safrin, 2009). In some case study it has been reported that the use of nevirapine produce the exfoliative dermatitis (ED) commonly called as erythroderma (Sharma et al., 2007; Bhandarkar et al., 2011; Rachamanti et al., 2014; Kumar and Kiran, 2014). ED is a skin disease with an inflammatory scaling which affect mostly on the cutaneous surface. Drug reaction is most important cause for the development of ED. The following drugs are reported with ED like Allopurinol, Nevirapine Carbamazepine, Codeine, Captopril, Diphenylhydantoin Gold, Antimicrobials etc (Rachamanti et al., 2014).

#### Case report

A 30 years old male was admitted in the Rajiv Gandhi Institute of Medical Science Hospital, Kadapa with complaints of scaling over the skin since nine days. He was diagnosed with HIV disease for last three years and received Lamivudine and Zidovudine as initial drug treatment with the dose of 150 and 300mg twice daily respectively. Then the drug treatment was changed to Nevirapine 200 mg as once in a day administration for first two weeks and twice daily from third week onwards. His past medical history with other drugs does not showing any evidence of dermatological diseases like

\*Corresponding author: e-mail: saleemcology@gmail.com

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psoriasis and a topic dermatitis. During his admission, after clear examination it was found that the lesions are erythmatous and scaly plaques present over the face, neck, trunk and back and involving more than 50% of the total body (fig. 1). No mucosal and genetalia involvement. Hair and nails are normal. The condition was diagnosed as drug induced ED and the suspecting drug was Nevirapine as causative by the Dermatologist. The laboratory investigation like RBS, Liver function tests shows normal values.CD4<sup>+</sup> T-cell count was350cells/mm<sup>3</sup>.

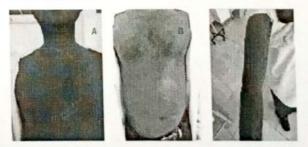


Fig. 1: Exfoliative dermatitis a) exfoliation and scaling on the trunk region, b) intense exfoliation over the stomach region, c) severe exfoliation and scaling over the upperlimbs.

#### Outcome and follow-up

After suspecting the condition the patient was advised to stop Nevirapine and started treatment for ED. He was prescribed with Dexamethasone injection (Decadron) 2cc, Avilinjection 2cc, Cetirizine tablet and Betamethasone ointment initially and after four days the injections were replaced with tablets along with vitamin supplements,

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#### **Original Article**

### Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital



Meda Venkatasubbaiah <sup>a,\*</sup>, P. Dwarakanadha Reddy <sup>b</sup>, Suggala V. Satyanarayana <sup>c</sup>

<sup>a</sup> Research Scholar, JNTUA, Ananthapuramu, Andrapradesh, India

<sup>b</sup> Department of Pharmaceutics, Annamacharya College of Pharmacy, Rajampet, Andrapradesh, India

<sup>c</sup> Department of Chemical Engineering, JNTU College of Engineering, Anantapuramu, Andrapradesh, India

#### ARTICLE INFO

Article history Received 2 July 2018 Revised 14 October 2018 Accepted 14 October 2018 Available online 29 November 2018

Keywords Adverse drug reaction Pharmacovigilance Reporting Causality

#### ABSTRACT

Objectives: To analyze and report adverse drug reactions (ADRs) in a tertiary care teaching hospital. Methods: This was an observational study, conducted to analyze and communicate the ADRs reported from July 2016 to June 2017 in a south Indian tertiary care teaching hospital. On daily basis, ADRs reported by healthcare professionals (HCPs) were analyzed and the reports that meet pharmacovigilance programme of India (PvPI) reporting criteria were communicated to PvPI through a specified updated Indian Pharmacopoeia Commission (IPC) suspected ADR reporting form. In this study, ADRs were summarised based on demographics, drug, incidence, type of reaction and its outcome. Causality, severity, seriousness, and predictability were assessed through WHO causality assessment scale, Hartwig and Siegel Severity Assessment Scale and PvPl criteria.

Results: A total of 254 ADRs communicated to PvPI through specified, updated IPC suspected ADR reporting form. The incidence of ADRs in both males and females was identical. The occurrence of ADRs in adult patients (71.26%) was significantly higher than other age groups. Of total ADRs, most of them were with Antibiotics (24.01%) followed by antipsychotics (11.42%). In causality assessment, a majority of ADRs (48.82%) were considered possibly related to the drug or treatment and 55.12% were mild in severity. Overall, 36.22% patients were recovered from ADRs. Most of the reported ADRs (54.33%) were probably preventable.

Conclusions: The results provided an insight to the HCPs on the importance of monitoring and reporting of ADRs. High-quality data gathered through a reporting system, most of the reported ADRs were probably preventable; the proper review of patient history and monitoring by HCPs can reduce the incidence of ADR. Our study results emphasize a need for establishing a pharmacovigilance centre to ensure the safe use of drugs

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#### 1. Introduction

The development of drugs in the last decades has brought remarkable benefits for the patients, at the same time the incidence of Adverse Drug Reaction (ADR) has raised remarkably. ADR is defined by World Health Organization (WHO) as "a

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response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function".12 It is universally accepted that "No drug absolutely free from side effects". From the literature it is observed that 5% of all hospital admissions were related to drug-induced problems and 10-20% of hospitalized patients are developing ADRs, it is estimated that ADRs are the fourth to the sixth leading cause of death.3

According to the WHO, "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long-term and short-term adverse effects of medicines".4-7 Pharmacovigilance aims at

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Abbreviations: ADR, Adverse Drug Reaction; AMC, ADR Monitoring centre; PvPI, Pharmacovigilance Programme Of India; WHO, World Health Organization; UMC, Uppsala Monitoring Centre; ICU, Intensive Care Unit; ENT, Ear Nose Throat; HCP, Health Care Professional: OBG, obstetrics and gynecology: DVL, Dermatology Venereology and Leprosy.

Peer review under responsibility of Alexandria University Faculty of Medicine. \* Corresponding author.

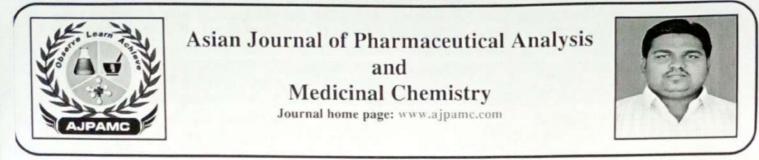
E-mail address: pharmachinna@gmail.com (M. Venkatasubbaiah).

Chand Basha S. et al. / Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry. 6(3), 2018, 123-126.

**Research Article** 

**CODEN: AJPAD7** 

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#### SYNTHESIS AND ANTIOXIDANT ACTIVITY OF SOME NOVEL FORMAZANS

S. Chand Basha\*1, K. Ahamed Basha<sup>1</sup>, R. J. Naveen Kumar<sup>1</sup>, K. Naga Lakshmi<sup>1</sup>

<sup>1\*</sup>Department of Pharmaceutical Chemistry, Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, Kadapa (Dist), Andhra Pradesh, India.

#### ABSTRACT

Various substituted formazan derivatives received considerable importance during last decade as they are covered with wide variety of biological and pharmacological activities and have a wide range of therapeutic importance. Based on this a series of new formazan derivatives has been synthesized. Phenyl hydrazine was added drop wise to mixture of various substituted Aromatic aldehyde in dilute acetic acid forms various substituted Phenyl hydrazones. The solution of substituted Phenyl hydrazones in pyridine was added to diazonium salt solution such as hetero aryl amine (2-amino pyridine, 2-amino pyrazine) forms a novel various coloured formazan derivatives. The synthesized compounds were characterized by physical studies, like solubility, melting point, TLC and subjected to spectral studies like IR, <sup>1</sup>H-NMR and mass spectroscopy. All the synthesized compounds were screened for *In-vitro* antioxidant activity was performed by the DPPH scavenging method by using Ascorbic acid as reference standard. Results suggested that electron withdrawing groups like nitro, chloro containing compounds shown potent antioxidant. Rest of the compounds showed mild to moderate activity.

#### **KEYWORDS**

Formazans, Hetero aryl amine and Antioxidant activity.

#### Author for Correspondence:

Chand Basha S, Department of Pharmaceutical Chemistry, Annamacharya College of Pharmacy New Boyanapalli, Rajampet, Andhra Pradesh, India.

Email: schandbasha20@gmail.com

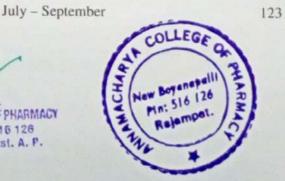
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#### INTRODUCTION

Formazans are characterized by intense colours, ranging from cherry red to a deep purplish black and contain the characteristic chain of atoms -N=N-C=N-NH-. Formazans are generally solids of relatively low melting points in spite of large the size of the molecules<sup>1</sup>. It is obtained from reduction of tetrazolium salts. Tetrazolium salts are colourless or faintly yellow compounds and they are reduced to deeply coloured compounds known as

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formazans. The formazan moiety is substituted with three phenyl groups at R, R', R" which is called 1, 3, 5-triphenyl formazan. They are often particularly soluble in chloroform and acetone; in water the solubility appears to be negligible, the solvent being colored.

#### MATERIAL AND METHODS

All chemicals were used of analytical grade from Sigma Aldrich and S.D. Fine Chem. Limited, and the solvents used were purified by standard methods. The synthesized compounds were evaluated for antioxidant activity by free radical scavenging DPPH method here ascorbic acid was used as reference standard.

#### **Experimental Procedure**

The schematic representation of synthesis of formazan derivatives was as follows,

#### Step 1

0.01 moles of phenyl hydrazine was added drop wise to a well-stirred mixture of 0.01 moles Aromatic aldehyde in dilute acetic acid (2ml in 10ml water) in a 100 ml conical flask at room temperature. The reaction mixture was further stirred for 1 hour and kept at room temperature for 30 minutes. The precipitated yellow crystalline mass was filtered and dried in an oven at 60°C. The crude product was recrystallized from rectified spirit with charcoal treatment. Benzaldehyde Phenylhydrazone was obtained as fine colorless needles, with melting point 156°C, and % yield was 80%.

#### Step 2

#### Preparation of Formazan derivatives

# Synthesis of 1-phenyl-3-phenyl-5 (aryl/hetero aryl) formazan derivatives

0.01mol of substituted aryl amine (2-amino pyridine) was dissolved in a mixture of 5ml concentrated hydrochloric acid and 5ml water taken in a100ml conical flask, with constant stirring. The reaction mixture was in ice bath until the temperature fell below 50°C separately, 1.6 g of sodium nitrite was dissolved in 7.5ml of water and chilled in ice bath below 50°C. The sodium nitrite solution was filtered to obtain a clear solution and then added drop wise to the aniline mixture with

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vigorous shaking and the temperature was not allowed to rise above 100°C. This diazonium salt solution of aryl and heteroaryl amine was filtered to obtain a clear solution and then added drop wise with continuous stirring to a solution of benzaldehyde phenyl hydrazone (0.01mol) in pyridine (20 ml), maintaining the temperature below 100ºC. The reaction mixture was allowed to stand for about 4 hours and was then poured in to 250 ml of ice-cold water with continuous stirring. The dark colored solid which separated out was filtered, washed successively with cold water, followed by hot water, finally with methanol and dried in air as well. The formazans thus synthesized were recrystallized from the mixture of chloroform and petroleum ether.

#### Step 3

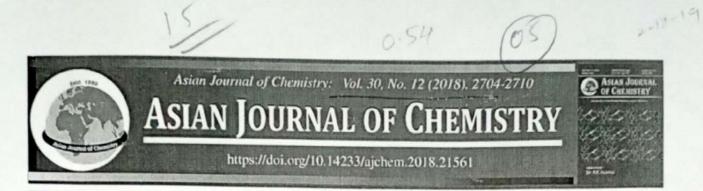
#### Preparation of formazan Derivatives

#### Synthesis of 1-phenyl-3-phenyl-5(aryl/hetero aryl) formazan derivatives

0.01mol of substituted aryl amine (2-amino pyrazine) was dissolved in a mixture of 5ml concentrated hydrochloric acid and 5ml water taken in a100ml conical flask, with constant stirring. The reaction mixture was in ice bath until the temperature fell below 50°C separately, 1.6 g of sodium nitrite was dissolved in 7.5ml of water and chilled in ice bath below 50°C. The sodium nitrite solution was filtered to obtain a clear solution and then added drop wise to the aniline mixture with vigorous shaking and the temperature was not allowed to rise above 100°C. This diazonium salt solution of aryl and heteroaryl amine was filtered to obtain a clear solution and then added drop wise with continuous stirring to a solution of benzaldehyde phenyl hydrazone (0.01mol) in pyridine (20 ml), maintaining the temperature below 100ºC. The reaction mixture was allowed to stand for about 4 hours and was then poured in to 250 ml of ice-cold water with continuous stirring. The dark colored solid which separated out was filtered, washed successively with cold water followed by hot water, finally with methanol and dried in air as well. The formazans thus synthesized were recrystallized from the mixture of chloroform and petroleum ether.

July - September

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#### Chemometric Assisted Method Development for Teneligliptin and Metformin by Stability Indicating RP-HPLC Technique and its Validation

DASARI VASAVI DEVI<sup>1,\*</sup>, DUGASANI SWARNALATHA<sup>2</sup> and GOPIREDDY VENKATASUBBA REDDY<sup>3</sup>

<sup>1</sup>Department of Pharmaceutical Sciences, Jawaharlal Nehru Technological University Anantapur, Anantapur-515 002, India <sup>2</sup>Annamacharya College of Pharmacy, Rajampeta-516 126, India <sup>3</sup>Jawaharlal Nehru Technological University Anantapur College of Engineering, Pulivendula-516 390, India

\*Corresponding author: E-mail: dvas.reddy@gmail.com

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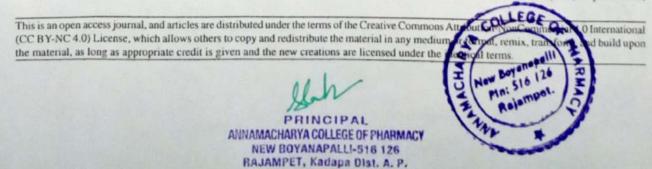
An innovative quality by design approach is presented through the development of an RP-HPLC method for the analysis of antidiabetic drugs teneligliptin and metformin in its drug substance and drug products. Response surface optimization of the design experiments has been employed using quadratic central composite design (CCD) for the optimization of method parameters using reverse phase high-performance liquid chromatography (RP-HPLC) on Discovery C8. 250 x 4.6 mm, 5 m with UV detection at 261 nm. For the interaction and quadratic effects of three factors namely change in mobile phase ratio, flow rate and wavelength on the selected response using CCD model. This was applied to simultaneously optimize the retention time, peak area and tailing factor of teneligliptin and metformin. The predicted optimum assay condition consisted of buffer [0.1 % orthophosphoric acid (OPA) solution] and acetonitrile taken in the ratio 37:63 as mobile phase at a flow rate of 0.94 mL/min. Using this optimum condition, a retention time for metformin and teneligliptin were 3.086 min and 4.065 min, respectively have been achieved. After establishing the optimal conditions for separation, validation parameters like linearity, accuracy, precision, LOD, LOQ and robustness have been determined which were based on ICH Q2 guidelines. Hence, the proposed method can be used for quality control of teneligliptin and metformin in its tablet dosage forms.

Keywords: RP-HPLC, Central composite design, Teneligliptin, Metformin.

#### INTRODUCTION

Quality of pharmaceutical products was considered as an important aspect by all regulatory bodies. The quality by design for the method development of the pharmaceuticals gives us more robust method. J.M. Juran, a well known quality expert developed the concept quality by design. Here, the appellant will plan the design space which had been undergoing regulatory analysis and consent [1-5]. International conference on harmonization in its Q8 pharmaceutical development, Q9 quality risk assessment and Q10 pharmaceutical quality system gives compelling conditions regarding quality of products. QbD basically aids to execute Q8 and Q9. Food and drug administration perspective of QbD is a systematic approach to product and process design and development [6-9]. QbD does not necessarily mean less analytical testing alternately, it means the right analysis at right time, and is based on science and risk assessment.

Pharmaceutical industries are adopting the concept of QbD, one can develop robust method which helps to follow ICH guidelines. Here components which enhance robustness are taken into consideration for the analytical method development in QbD environment. The method optimization was done using design expert software that follows a DOE approach [10]. Validation remains the formality as it is done in similar way to that of traditional method development in validation (ICH Q2) but in traditional method approach method validation after development i.e. it is like check box tool and in QbD, the validation parameter in ICH Q2 are consider as method intent. Diabeties, are a group of metabolous disorders in which there are elevated blood sugar level over an extended duration [11]. It causes many complicated situations which includes cardiovascular disease, stroke, chronic kidney disease, foot ulcer and even damage to the eyes by causing diabetic retinopathy if left untreated [12]. As per International Diabetes Federation (IDF) in year 2015,





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### ICH GUIDELINE PRACTICE: A VALIDATED STABILITY INDICATING RP-UPLC METHOD DEVELOPMENT AND ITS APPLICATION FOR DETERMINATION OF ALISKIREN AND AMLODIPINE IN BULK AND FORMULATION

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Dasari Vasavidevi<sup>1,\*</sup>, D. Swarnalatha<sup>2</sup> and G.V. Subbareddy<sup>3</sup>

 <sup>1</sup>Research Scholar, JNTUA, Anantapuramu- 515002 (A.P), India.
<sup>2</sup> Department of Pharmacognosy, Annamacharya College of Pharmacy, Rajampeta- 516126 (A.P), India.
<sup>3</sup>Department of Chemistry, JNTUA College of Engineering, Pulivendula-516390 (A.P), India.
\*E-mail : dvas.reddy@gmail.com

#### ABSTRACT

A novel, accurate, specific and robust reverse phase liquid chromatographic method was developed and validated for the simultaneous estimation of Aliskiren and Amlodipine besylate in bulk and tablet dosage form. A reverse phase stability indicating Ultra High-Performance Liquid Chromatography (UHPLC) method was developed on an SD  $3*100 \text{ mm x } 1.8 \mu$  column using isocratic elution of acetonitrile and 0.1% perchloric acid buffer (pH 2.6-2.8) in the ratio 60: 40 at a flow rate of 0.5 ml/min. The detection was carried out by using Acquity TUV ChA at 266nm. The total run time was 2.5 min and the retention time of amlodipine and Aliskiren were found to be 1.006 and 1.329 min respectively. According to ICH guidelines, forced degradation conditions were employed to establish the stability indicating method. The LOD and LOQ of Aliskiren and Amlodipine were found to be 0.17 µg/ml, 0.51 µg/ml and 0.03 µg/ml, 0.10 µg/ml respectively. The developed method was validated as per ICH guidelines for linearity, accuracy, precision, robustness and stability indicating studies and the method was successfully applied for the estimation of aliskiren and amlodipine in combined tablet dosage form. **Keywords:** Aliskiren, Amlodipine, UHPLC, Stability indicating.

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#### INTRODUCTION

Hypertension is a chronic disease associated with other disorders like diabetics and many cardiovascular diseases including stroke, myocardial infarction and congestive heart failure. It leads to morbidity and mortality, if left uncontrolled, hence it is essential to control and manage blood pressure.<sup>1,2</sup> There are several antihypertensive agents available with a different mechanism of action may play an important role in the optimal management of hypertension. It includes mono and combination therapy with β- blockers, diuretics, angiotensin- converting enzyme (ACE) inhibitors, angiotension II receptor blockers (ARB) and calcium channel antagonists.<sup>3,4</sup>

Aliskiren chemically, (2S,4S,5S,7S)-5-amino-N-(3-amino-2,2-dimethyl-3-oxopropyl)-4-hydroxy-7-[[4-methoxy-3-(3-methoxypropoxy)phenyl]methyl]-8-methyl-2-propan-2-ylnonanamidehemifumarate.<sup>5</sup> It is a non-peptide, first orally taken direct renin inhibitor simulating endogenous peptides approved for clinical use in the treatment of hypertension from the United States Food and Drug Administration (FDA).<sup>6,7</sup> It reduces plasma renin activity through high-affinity binding and specificity via aromatic side chains.<sup>8,9</sup> The drug substance is a single diastereoisomerx having 4 chiral centers, all S-configured, presented as a

white to slightly yellowish crystalline powder. The active is the hemifumarate salt of the corresponding amine, with a molecular weight of 609.8.

Rasayan J. Chem., 11(3), 1300-1310(2018) http://dx.doi.org/10.31788/RJC.2018.1133085

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**Review Article** 

#### RECENT PROGRESS OF DENDRIMERS IN DRUG DELIVERY FOR CANCER THERAPY

#### P. ANITHA, J. BHARGAVI, G. SRAVANI, B. ARUNA, RAMKANTH S.\*

Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, Kadapa, Andhra Pradesh 516126 Email: ramkanthsg@gmail.com

#### Received: 02 May 2018, Revised and Accepted: 14 Aug 2018

#### ABSTRACT

With the recent advances of nanotechnology, dendrimers are emerging as a highly attractive class of drug delivery vectors for cancer therapy. Dendrimers are multifunctional smart Nanocarriers to deliver one or more therapeutic agent safely and selectively to cancer cells. The high level of control over the synthesis of dendritic architecture makes dendrimers a nearly perfect (spherical) nanocarrier for site-specific drug delivery. The presence of functional groups in the dendrimers exterior also permits the addition of other moieties that can actively target certain diseases which are now widely used as tumor targeting strategies. Drug encapsulation, solubilization and passive targeting also equally contribute to the therapeutic use of dendrimers. Dendrimers are ideal carrier vehicles on cytotoxicity, blood plasma retention time, biodistribution and tumor uptake. In this review we highlight the advantages of dendrimers over conventional chemotherapy, toxicity and its management, following anti-cancer drugs delivered by using dendrimers and recent advances in drug delivery by various types of dendrimers as well as its diagnostic applications.

Keywords: Dendrimer, Cancer therapy, Nanocarriers, Drug delivery, Diagnostic applications

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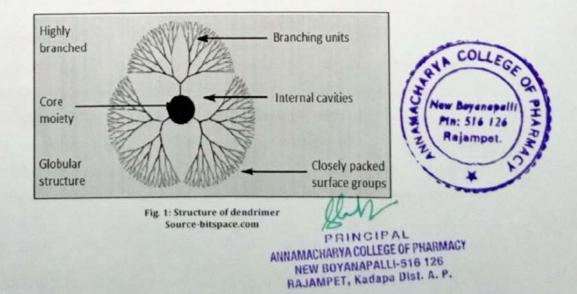
#### INTRODUCTION

Cancer is one of the world's most distressing diseases with no significant cure for several types of tumors [1, 2]. Cancer is principally a disease of cells identified by the loss of normal cellular growth, maturation and multiplication leading to disturbance of homeostasis. A brief consideration of the challenges facing an anti-cancer drug are-at first the drug must be able to seek out differences between a transformed cells from other healthy cells in the body. Secondly, they should provide sufficiently a high dose of toxic agent to kill the cell. Furthermore, it successfully cures a patient by eradicating each and every cancer cell [3]. However, conventional chemotherapeutic agents have several challenges such as low aqueous solubility, poor bio-distribution, unfavorable pharmacokinetics, narrow therapeutic index, poor membrane permeability, instability, rapid clearance, severe toxicity, and the emergence of multidrug resistance phenotypes.

Although, it has been observed that cancer chemotherapy is one of the best approaches to eradicate cancer and the success of chemotherapy mainly depends on the selection of optimum carrier system. These carriers include nanoparticles, nano tubes, nano rods, dendrimers, liposomes, solid lipid nanoparticles, microspheres etc.

Among all these, dendrimeric system appears to be promising in cancer chemotherapy, especially via ligand or Receptor-mediated endocytosis as it possess numerous properties [especially surface property] to target cancer and also to overcome all these limitations of conventional chemotherapeutic agents, there is an immediate need for developing safe and effective carrier vectors such as dendrimers that can protect the drug from degradation during transit and enhance targeting efficiency and also reduce adverse toxic effects caused by cytotoxic drugs [2].

Dendrimers are highly branched, nanosized, symmetric molecules with well defined, homogenous and monodisperse structure having diameter in 2-10 nm range. The word Dendrimer is based on the Greek words-"Dendron meaning tree or branch" and "merosmeaningpart" [3]. The structure of the denrimers is shown in fig. 1. The three component of dendrimer are central core, repetitive branching units and terminal groups. The "Generation number" of dendrimer is determined by the increase in a number of branching units which results in globar structure formation [4-7]. Palmerston Mendes L, Pan J, Torchilin VP 2017, has inferred in their review article that the presence of functional groups in the dendrimer's exterior also permits the addition of other moieties that can actively target certain diseases and improve delivery which is now widely used as tumor targeting [4]. The presence of unique properties makes them ideal carriers for the targeted delivery of therapeutic and diagnostic agents [8].





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**Research Article** 

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### DETERMINATION OF HAIR GROWTH STIMULANTION ACTIVITY OF ACACIA LEUCHOPHOLEA LEAF EXTRACT ON SHAVED SURFACE OF SKIN ON RATS

\*Malathi S.<sup>1</sup>, Mohanraghupathy S.<sup>2</sup>, Vanitha K.<sup>3</sup>, Sreekanth G.<sup>4</sup> and Nagendra T.<sup>5</sup>

Department of Pharmacology, Annamacharya College of Pharmacy, Rajampet,

Andhrapradesh.

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\*Corresponding Author Malathi.S Department of Pharmacology, Annamacharya College of Pharmacy, Rajampet, Andhrapradesh.

#### ABSTRACT

Herbal formulations always have attracted considerable attention because of their good activity and comparatively less side effects with synthetic drugs. The objective of present study involves preparation. The leaf extract of *Acaia Leucopholia* shown the best results in hair growth stimulation activity on rats. In this herbal Preparation the extract was taken from reflex condensation and the Preparation was applied topically on the skin of the rat. The test drug is compared with the standard drug Minoxidil which is a vasodilator and antihypertensive. The results when compared with the standard and test the test drug samples shown the ascending order results. The test sample – 3 has shown the equal result with the standard drug. Thus we

concluded that due to the presence of alkaloids in the plant leaf extract the plant has got the very good hair growth stimulating activity.

KEYWORDS: Acaia Leucopholia.

#### INTRODUCTION

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Hair is made up of dead cells. On our heads, we have hundreds and thousands of follicles, pore-like structures within the scalp that produce hair. Each follicle produces many hairs throughout our lifetime. Live hair cells are generated inside the follicle by the papilla.<sup>[1]</sup> As the new cells grow, the older cells die and are forced along the follicle towards the scalp. The **Couders et a** are compressed to form a protein called keratin. The hair shaft that we see is the keratin encreasing from the scalp. Finger-nails are made of keratin, too. Each hair consists of

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Research Article

### ATOMIC ABSORPTION SPECTROPHOTOMETER – A VERSATILE TOOL FOR THE ESTIMATION OF NICKEL CONTENT IN DRONEDARONE

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#### VASAVI DEVI DASARI1\*, SWARNALATHA DUGASANI2 VENKATASUBBA REDDY GOPIREDDY3

<sup>1</sup> JNTUA, Ananthapuramu, Andhr a Pradesh, India. <sup>2</sup>Department of Pharmaceutical Sciences, Annamacharya College of Pharmacy, Rajampeta, Andhra Pradesh, India. <sup>3</sup>Department of Chemistry, Jawaharlal Nehru Technological University Anantapur College of Engineering, Pulivendula, Andhra Pradesh, India. Email: dvas.reddy@gmail.com

#### Received: 04 May 2019, Revised and Accepted: 25 June 2019

#### ABSTRACT

Objective: The present investigation is to develop a validated analytical method for the determination of nickel content in dronedarone hydrochloride bulk drug by atomic absorption spectrophotometer (AAS).

Methods: Samples were analyzed after a preparation of sample solution by dissolving in suitable diluents of nitric acid and perchloric acid. In the present method, AAS with 0.2 nm slit width, nickel hollow cathode lamp with a wavelength of 232 nm has been employed.

Results: The system suitability parameters were performed to assess the system performance. The limit of detection and limit of quantification (LOQ) were found to be 0.051 ppm and 0.15 ppm, respectively. The percentage recovery at LOQ, 50%, 100%, and 150% levels of nickel in dronedarone was found to be 95.55, 109.33, 96, and 97.55, respectively.

Conclusion: With the developed method, the nickel content in dronedarone bulk sample was found to be 3.0 ppm.

Keywords: Dronedarone, Nickel, Atomic absorption spectrophotometer, Validation.

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#### INTRODUCTION

Dronedarone is a Class III antiarrhythmic drug recently approved by the US Food and Drug Administration in 2009 for the treatment of nonpermanent atrial fibrillation and atrial flutter [1]. The chemical name is N-[2-butyl-3[4-[3-(dibutylamino) propoxy]benzoyl]-1-benzofuran-5-yl] methanesulfonamide hydrochloride according to IUPAC. Its molecular formulae are  $C_{31}H_{44}N_1O_3S.HCI$  with a molecular weight of 593.22 g/mol [2]. Chemically, it is a benzofuran derivative containing heterocyclic compound which is a structural analog of amiodarone. DRO reduces the toxic effects in amiodarone by replacing the iodine group with a methanesulfonyl group [3]. Due to reduced lipophilicity, it has lower toxicity and superior pharmacokinetic characteristics than the amiodarone belonging to the same Class III antiarrhythmic drug [4]. DRO is crystalline in nature with a melting point of 149-153°C [5], with white to practically white, non-hygroscopic fine powder. It is a new active substance, and there is no official pharmacopoeial procedure available [6]. Literature overviews confess that drug was estimated by different analytical strategies such as spectrophotometric [7], highperformance liquid chromatography [8-17], and liquid chromatography mass spectrometry [18,19] in bulk drugs and formulation of dronedarone. From the review, it was found that there were no reported methods for the estimation of elemental impurity, i.e., nickel in dronedarone. Impurity profiling of pharmaceutical products was an extensive scope of concern. Rigid modulations are leaving behind for their effective use. Regarding the various regulatory guidelines, impurities are majorly organic or inorganic in nature (USP, ICH). To a great extent, we know about organic impurities, during the time inorganic impurities are procuring importance at recent times. The inorganic impurities, i.e., metal contamination, enter the standard reference materials and intermediates through crude materials, impetuses, reagents, solvents, and different supplies utilized for blend and for synthesis. This metal ions invaded possess the capability to decompose the materials of interest, which may sometimes prompt to potential noxious impacts, further to self-toxicity. Hence, it is necessary to monitor metal ion

contents in the standard reference material of drugs [20,21]. Various analytical strategies were utilized for the determination of inorganic metal impurities including titration, ion-exchange chromatography, capillary electrophoresis, and spectroscopic techniques such as flame photometry, fluorimetry, atomic absorption spectroscopy, and inductively coupled plasma. The titration strategies are not exact, whereas ion-exchange chromatography and capillary electrophoresis stabilization is a time-taking procedure and sensitivities are low when contrasted with atomic absorption spectrophotometer (AAS). For the above reasons, AAS has become a tool of choice for estimating metals. The present study was to carry out method development and validated using atomic absorption spectrophotometry to determine nickel content in dronedarone.

#### Chemicals and reagents

Nickel standard from Merck, nitric acid and perchloric acid from SDFCL chemicals, Milli-Q water, and API as a gift sample were used in the study.

#### Instrumentation and operating conditions

AAS of model AA-6300 (Shimadzu) equipped with fully integrated atomizers of Shimadzu make was used for the analysis. The system was regulated from an interfaced PC running Wizard software. Atomic absorption measurements were carried

out at 232 nm analysis wavelength, using nickel hollow cathode lamp, lamp current - 7 mA, slit width - 0.2 mm, burner height - 7 mm, oxidant flow - 15 L/min, acetylene flow - 1.6 L/min, lamp mode - BGC-D2, pre-spray time - 5.0 s, integration time - 5 s, and recommended flame - air acetylene.

#### Preparation of solutions

Preparation of nickel standard stock solution (solution A)

The 10 mL of 1000 mg/L concentrated nexter standard solution is taken into a 100 mL volumetric flask and dinte Groupers with Milli-Q

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# Stability indicating method development and validation for the determination of haloperidol and benzhexol by RP-HPLC

#### M. Syamala\*<sup>1</sup>, S. Angalaparameswari<sup>2</sup>, T. Vimalakannan<sup>3</sup>, C. Sumanjali<sup>4</sup>, T. Jyotshna<sup>5</sup>

<sup>1</sup>Department of Pharmaceutical Analysis, Krishna Teja Pharmacy College, Tirupati, Andhra Pradesh, India. <sup>2</sup>Department of Pharmaceutical Analysis, Jagan's college of pharmacy, Nellore, Andhra Pradesh, India. <sup>3</sup>Department of Pharmaceutical Analysis, P. Rami Reddy Memorial College of Pharmacy, Kadapa, Andhra Pradesh, India. <sup>4</sup>Department of Pharmacology, P. Rami Reddy Memorial College of Pharmacy, Kadapa, Andhra Pradesh, India. <sup>5</sup>Department of Pharmacology, Annamacharya College of Pharmacy. Rajampet, Andhra Pradesh, India.

#### ABSTRACT

A simple, Accurate, precise method was developed for the simultaneous estimation of the Haloperidol and Benzhexol in Tablet dosage form. Chromatogram was run through Kromasil (250mm 4.6mm, 5 $\mu$ ). Mobile phase containing Buffer and Acetonitrile and methanol in the ratio of 48:52 was pumped through column at a flow rate of 1.0 ml/min. Temperature was maintained at 30°C. Optimized wavelength for Haloperidol and Benzhexol was 220nm. Retention time of Haloperidol and Benzhexol were found to be 2.415 min and 2.820min. %RSD of the Haloperidol and Benzhexol were and found to be 0.6 and 0.2 respectively. %Recover was Obtained as 98.92% and 99.60% for Haloperidol and Benzhexol. LOD, LOQ values were obtained from regression equations of Haloperidol and Benzhexol were 0.42ppm, 1.27ppm and 0.04ppm, 0.14ppm respectively. Regression equation of Haloperidol is y = 24009x + 38704, and of Benzhexol is y = 40558x + 2880. Retention times are decreased and that run time was decreased so the method developed was simple and economical that can be adopted in regular Quality control test in Industries

Keywords: benzhexol; haloperidol; RP-HPLC.

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**Corresponding Author** 

Name: M. Syamala Email: <u>syamalamajjari@gmail.com</u>

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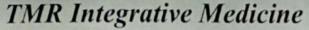
**Copyright**<sup>®</sup> **2019**, M. Syamala, et al. S Stability indicating method development and validation for the determination of haloperidol and benzhexol by RP-HPLC, Production and hosting by *Rubatosis Publications. All rights reserved.* 

#### INTRODUCTION

The phenomenal growth in chromatography is largely due to the introduction of the versatile technique called high-pressure liquid chromatography, which is frequently called high-performance liquid chromatography. Both terms can be abbreviated as HPLC. High-pressure liquid-solid chromatography (HPLC) is rapidly becoming the method of choice for separations and analysis in many areas. Most of the samples that are dissolved can be separated on some type of HPLC column<sup>[4]</sup>. Haloperidol is a psychotropic agent indicated for the treatment of schizophrenia. It also exerts sedative and antiemetic activity. Haloperidol principal pharmacological effects are similar to those of piperazine-derivative phenothiazines. The drug has action at all levels of the central nervous system-primarily at subcortical levels-as well as on multiple organ systems. Haloperidol has strong antiadrenergic and weaker peripheral anticholinergic activity; ganglionic blocking action is relatively slight. It also possesses slight antihistaminic and antiserotonin activity<sup>[9]</sup>. Trihexyphenidyl is an anticholinergic used in the symptomatic treatment of all etiologic groups of parkinsonism and drugpioduced extrapy-ramidal reactions (except andive dyshmesia). Triramidal reactions (except him hexyphenidyl possesses for acticholine ac and an-tihistaminic effects, although only the observer has been established as ineraper titally significant in the management of parkinsonism,

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### Clinical research

### In-vitro pharmacological evaluation of Sulforaphane from Brassica oleracea

#### Sodum Nalini<sup>1</sup>, Shaik Chand Basha<sup>2,\*</sup>, TS Mohamed Saleem<sup>3</sup>

<sup>1</sup>Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, India. <sup>2</sup>Department of Pharmaceutical Chemistry, Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, India. <sup>3</sup>Department of Pharmacology, Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, India.

\*Correspondence: Shaik Chand Basha M. Pharm, Department of Pharmaceutical Chemistry, Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, India. E-mail: schandbasha20@gmail.com

#### Highlights:

Sulforaphane shows significant anti-arthritic activity through in-vitro screening models and the activity was observed as concentration dependent against bovine serum albumin (BSA), egg albumin denaturation assay.

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