



**Research Publications in the Year 2020-2021**

S.NO.	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication
1	Simultaneous estimation of Ciprofloxacin and metronidazole in bulk and tablet formulation in bulk and tablet formulation by UV Spectrometer	K.Praveen, A.Veeshma, S.Priyanka,	Pharmaceutical Analysis	International journal of pharmaceutical sciences and research	2021
2	Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation	Venkateshwarlu E, Srinivasa Pramod J, Sai Kiran D, Sai Geethika P, Gireesh Kumar M, Manasa Sowmya K,	Pharmacy Practice	Indian Journal of Pharmacology	2021
3	Formulation and Evaluation of Oral Disintegrating Tablets of Salbutamol Sulfate	Y. Shravan Kumar, P. Samyuktha Rani, Ahamad Mohammad Saddam, Dr. B. Chandra Shekhar Reddy	Pharmaceutics	Journal of Pharmaceutical Analysis and Drug Research	2021
4	Formulation and Evaluation of Theophylline Lozenges	Y. Shravan Kumar, L. Pravalika	Pharmaceutics	Research Journal of Pharmacy and Technology	2021
5	Fabrication and Evaluation of Lidocaine Hydrochloride Loaded cubosomes	Rajani.T. GSN Koteshwar Rao, Alekhya M,	Pharmaceutics	Research Journal of Pharmacy and Technology	2021
6	Formulation and Evaluation of Salbutamol Sulphate Taste Masked Oral Disintegrating Tablets	M. Karnakar, S. Harika, M. Mounika and Y. Shravan Kumar	Pharmaceutics	International Journal of Pharmaceutical Sciences and nanotechnology	2021



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7	Drug Utilization Evaluation of Pantoprazole in Inpatients of Tertiary care Hospital	Charitha B, Karteeka B, Chandrashekar V, Sharvana Bhava B, Venkateshwarlu E	Pharmacy Practice	Indian Journal of Pharmacy Practice	2021
8	Cefotaxime Induced Staphylococcal Scalded Skin Syndrome: A Case Report	Shirisha J, Satish Ch, Shravani K, Venkateshwarlu E	Pharmacy Practice	Indian Journal of Pharmacy Practice	2021
9	Hypofractionated Versus Conventional Radiotherapy with Chemotherapy in Head and Neck Cancer: A Comparative Study	Bala Sankar R, Srinivas V, Sharavana Bhava B S, Venkateshwarlu E, Prakash Babu S	Pharmacy Practice	International Journal of Research and Pharmaceutical Sciences	2021
10	Potential approaches of Nanotechnology for cancer therapy: An insight	Vijay Mishra, Pavani Sriram	Pharamaceutics	International journal of Drug Delivery Technology	2021
11	Formulation and Evaluation of Clotrimazole Lozenges	Shravan Kumar Yamsani, Pravalika Lakkam and Sofia Fathima	Pharamaceutics	World Journal of Pharmacy and Pharmaceutical Sciences	2021
12	Formulation and Evaluation of Carvedilol Sustained Release Capsules by Semisolid Matrix Filling Technique	P. Priyanka , S. Harika , MD. Wajid , Y. Shravan Kumar	Pharamaceutics	Research Journal of Pharmacy and Technology	2021
13	Formulation and Evaluation of Valacyclovir Hydrochloride Effervescent Floating Tablets	Rajani T, Pavani S, Dharani A, Shravan Kumar Y	Pharamaceutics	International Journal of Advances in Pharmceutical. Biotechnology	2021
14	A case Report: Beckwith weidemenn syndrome	T.Anila Redy,B.S. Sharvana Bhava	Pharmacy Practice	Rapports De Pharmacie	2020



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15	Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation	Venkateshwarlu E, Srinivasa Pramod J, Sai Kiran D, Sai Geethika P, Gireesh Kumar M, Manasa Sowmya K,	Pharmacy Practice	Indian Journal of Pharmacology	2021
16	Simultaneous estimation of Ciprofloxacin and metronidazole in bulk and tablet formulation in bulk and tablet formulation by UV Spectrometer	A. Veeshma, S. Priyanka, K. Shirisha	Pharmaceutical Analysis	International journal of pharmaceutical sciences and research	2021
17	Fluorescence quantum dots : An insight on synthesis and potential biological application as drug carrier in cancer	S. Pavani, Asish Suttee	Pharmaceutics	Biochemistry and biophysics reports	2021
18	Ambispective study of adverse drug reactions in multi drug resistant tuberculosis patients in warangal, Telangana	Safurah Fatima, Nagesh adla, Rama Devi	Pharmacy Practice	Lung India	2021



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## SIMULTANEOUS ESTIMATION OF CIPROFLOXACIN AND METRONIDAZOLE IN BULK AND TABLET FORMULATION BY UV SPECTROPHOTOMETRY

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### Keywords:

UV, Simultaneous equation method,  
Q-absorbance ratio method,  
Ciprofloxacin, Metronidazole

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**ABSTRACT:** Three simple and economical UV-spectrophotometric methods have been developed and validated for simultaneous estimation of ciprofloxacin (CIP) and metronidazole (MET) in a tablet dosage form using distilled water as a green solvent. The proposed methods were; simultaneous equation method (method A), Q-absorbance ratio method (method B), and area under curve method (method C).  $\lambda_{max}$  of CIP & MET in distilled water were found to be 271 nm and 320 nm, respectively. The isoabsorptive point was observed at 290 nm. The linearity was obtained in the concentration range of 1-9  $\mu\text{g/ml}$ , and 2-18  $\mu\text{g/ml}$  for CIP and MET respectively by methods A, B & C. Validation parameters were carried out. All three methods were found to be linear, accurate, precise, and specific. Good results were achieved using distilled water as solvent due to its greater solubility, reproducible readings with maximum absorbance. Among the three methods, method C was found to be the most sensitive. Hence, this method can be recommended for the routine analysis of this drug combination.

**INTRODUCTION:** Ciprofloxacin (CIP) is chemically 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid Fig. 1. It is a fluoroquinolone antibiotic useful for the treatment of various infections caused by Gram-positive, Gram-negative organisms and against *Mycobacterium tuberculosis*. The bactericidal action of CIP results from inhibition of the enzymes topoisomerase 2 (DNA gyrase) and topoisomerase 4, which are required for bacterial DNA replication, transcription repair, and recombination<sup>1, 2</sup>. Metronidazole (MET) is designated chemically as 2-(2-methyl-5-nitro-1H-imidazole-1-yl) ethan-1-ol Fig. 2.

It is a prodrug unionized and the most useful antiprotozoal nitroimidazole derivative. It has been found to possess efficacy against obligate anaerobic bacteria due to their ability to intracellularly reduce MET to its active form, which then covalently binds to DNA, disrupts its helical structure, inhibiting the bacterial nucleic acid synthesis and results in bacterial cell death<sup>3, 4</sup>.

A survey of literature has revealed several analytical methods for the determination of CIP in pharmaceutical dosage form and biological fluids, including spectrophotometry<sup>5-9</sup>, spectrofluorimetry<sup>10</sup>, HPLC<sup>11-13</sup>, potentiometry<sup>14</sup>, electrical microtitration<sup>15</sup>, and HPTLC<sup>16</sup>. CIP in admixtures with MET<sup>17</sup> and ampicillin has been determined by NMR<sup>18</sup>. HPLC methods either with fluorescence detection or coupled with mass spectrometry (LC/MS) for determination of CIP in human plasma<sup>19, 20</sup>, and by SPE-UHPLC-PDA<sup>21</sup> have also been published. MET has been determined by several methods involving spectrophotometry<sup>22</sup>

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## Research Article

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## Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation

Srinivas Pramod Junutula, Sai Kiran Dubasi, Sai Geethika Reddy Padide, Gireesh Kumar Miryala<sup>1</sup>, Manasa Soumya Koppolu<sup>1</sup>, Sharvana Bhava Bandaru Sheshagiri, Venkateshwarlu Eggadi

### Abstract:

**AIM:** The current work establishes an easy, reliable technique for the estimation of serum Olanzapine concentration which correlates it clinically.

**SUBJECTS AND METHODS:** The work was agreed in 61 schizophrenic patients who were on olanzapine. Serum drug amount was estimated by normal-phase high-performance liquid chromatography and brief psychiatry rating scale was used to determine disease progression.

**RESULTS:** Samples provided 61 patients, 40 were under sub-therapeutic range, 16 were under therapeutic range and 3 were above the therapeutic range.

**CONCLUSION:** Therapeutic drug monitoring must be a part of clinical practice in psychiatric hospitals for optimizing the dose of an individual patient along with the correlation of serum concentration with the clinical assessment scales.

### Keywords:

High-performance liquid chromatography and therapeutic range olanzapine, schizophrenia, therapeutic drug monitoring

### Introduction

Olanzapine is benzodiazepine derivative which is used in the management of schizophrenia and also to treat modest to severe mania allied with manic depressive psychosis. Olanzapine was widely biotransformed in the hepatocyte, mainly through direct glucuronidation and CYP1A2 mediated oxidation followed by a lesser extent with CYP2D6. Olanzapine (5–20 mg) is recommended daily dose for schizophrenic patients.<sup>1</sup>

Therapeutic drug monitoring (TDM) of narcoleptics choose to optimize dosage decisions to maximize effectiveness and

stop unwanted effects, particularly while those are nonresponsive to management or exposed to undesirable effects through usual quantity for the reason that of demographic, illness, or treatment reciprocal action make difficult in treatment. TDM-assisted psychiatric treatment, while practice by physicians who have background of pharmacokinetics, is potentially useful and cost-effective. TDM is useful in determining drug noncompliance which is a major issue in psychiatric treatment. In many psychiatric hospitals, disease progression is assessed by using different psychiatric rating scales. This is widely used for initially diagnosed and relapse patients.<sup>2</sup>

Due to these reasons, there is a need to develop an easy and reliable method for determining serum Olanzapine concentration which

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# Formulation and Evaluation of Salbutamol Sulphate Taste Masked Oral Disintegrating Tablets

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## ABSTRACT

Salbutamol is a short acting, selective beta2-adrenergic receptor agonist used in the treatment of asthma and COPD. The aim of this study is to formulate oral disintegrating tablets of salbutamol sulphate to achieve rapid dissolution, absorption and further improving the bioavailability of the drug. Oral disintegrating tablets of salbutamol sulphate were designed with a view to enhance the patient compliance and provide a quick onset of action. The oral disintegrating tablets were prepared by using different synthetic polymers by direct compression method. Development of the formulation in the present study was mainly based on the concentration of superdisintegrants and the properties of the drug. Nine batches of tablets were formulated and evaluated for various parameters: drug content, weight variation, water absorption ratio, wetting time, *in vitro* disintegration, hardness, friability, thickness

uniformity, and *in vitro* dissolution. A fourier-transform infrared spectroscopy (FTIR) study showed that there were no significant interactions between the drug and the excipients. The prepared tablets were good in appearance and showed acceptable results for hardness and friability. The *in vitro* disintegrating time of the formulated tablet batches was found to be 14.39-32.41 sec and the drug content of tablets in all formulations was found to be between 87.48-99.96 %, which complied within the limits established in the Indian pharmacopeia. The study concluded that taste of the drug was masked with the help of sodium saccharin and flavor and the concentration of super disintegrating agent increases the disintegration time of tablets get decreases. The formulation (F9) had a minimum disintegration time of 14.39 sec and 99.96 % of the drug was released within 20 min.

**KEYWORDS:** Direct compression; Salbutamol sulfate; Crosspovidone; Crosscarmellose sodium; Sodium starch glycolate; Super disintegrant.

## Introduction

Salbutamol is a short acting, selective Beta2-adrenergic receptor agonist used in the treatment of asthma and COPD (Amperiadou et al., 1995). More than 50% of pharmaceutical products are orally administered for several reasons. Undesirable taste is one of the important major problem when the formulations prepared for oral purpose. Taste of a pharmaceutical product is an important parameter governing compliance (Sohi et al., 2004). Hence taste masking of oral pharmaceutical has become important tool to improve patient compliance and the quality of treatment especially in pediatrics. Hence formulation of taste masked products is a challenge to the pharmacist (Thoke et al., 2012).

Oral administration is the most popular route about 50-60 % of dosage forms (Talevi et al., 2018) are administered due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates), and most importantly patient compliance (Venkateswarlu et al., 2016, Pollothu et al., 2018). Solid oral delivery systems do not require sterile conditions and are therefore less expensive to manufacture (Mohalkar et al., 2014, Pande et al., 2016). One

important drawback of solid dosage forms is the difficulty in swallowing (dysphasia) or chewing in some patient's particularly pediatric and geriatric patients (Zakia et al., 2020). oral disintegrating drug delivery systems (oddds) offer several benefits such as easy administration to children and elderly patients having difficulties in swallowing (dysphagia) and in the case of tremors or mental retardation condition (Samvedna et al., 2018). Oral administration of oral disintegrating tablets (odt) donot require water, yet dissolve/disperse/ disintegrate in mouth in a matter of seconds, it have a pleasing mouth feel with an acceptable taste masking property and also leave minimal or no residue in mouth after administration (Heer et al., 2013, Bandari et al., 2014). The drug is released immediately when the tablet is placed on the tongue (Samvedna et al., 2018). They are also called as mouth-dissolving tablets, fast disintegrating tablets, fast dissolving tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet (Yadav et al., 2012, Hannan et al., 2016). The ODTS are in ever-increasing demand compared to liquid dosage forms due to the ease of handling, accurate dose and good stability during storage (Parkash et al., 2011). They improve the oral bioavailability of drugs as compared to





**RESEARCH ARTICLE**

## Formulation and Evaluation of Theophylline Lozenges

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### ABSTRACT:

Theophylline hard candies lozenges were prepared to provide slow release of medicament for the treatment of wheezing, shortness of breath, and breathing problems caused by asthma. It makes breathing easier by relaxing and opening air passage in the lungs. There are several dose forms like syrups, tablets, ODT's offered within the market however still there's would like for brand new dose forms that acts effectively and domestically for paediatric and people with difficulty in swallowing. The local acting mechanism of theophylline makes it more suitable to formulate as lozenges. The hard candy lozenges were formulated using sugar as a base Locust Bean gum, Kondagogu gum and Neem gum are used as natural polymers. The usage of corn syrup in the formulation made the lozenges smooth which helped in improving the elegance of the formulation. Stevia was used as sweetener. Sweeteners along with flavours are used to mask bitter taste of drug. The formulation of hard Candy lozenges was subjected to physico-chemical as well as in vitro drug release. Among all the formulations of hard candy lozenges F10 had shown in vitro drug release of 98.9% at the end of 30 minutes.

**KEYWORDS:** Theophylline, Stevia, Kondagogu gum, Locust Bean gum, Neem gum.

### INTRODUCTION:

Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, sweetened base, and are intended to dissolve slowly in the mouth.

Theophylline is used to treat wheezing, shortness of breath, and breathing problems caused by asthma, and other lung diseases. It is an anti-asthmatic and bronchodilator agent. It is readily absorbed through oral mucosa as oral bioavailability of Theophylline is more. Also, Theophylline is a heat stable drug which is ideal property for preparing lozenges.<sup>1,7</sup>

### MATERIALS:

Sugar, Liquid glucose, Theophylline (drug), Stevia, Neem gum, Locust Bean gum, Kondagogu gum, Citric acid, Colouring and Flavouring agents.

### METHODOLOGY:

#### Preformulations Studies:

Preformulation studies area unit primarily done to research the chemistry properties of drug and to determine its compatibility with different excipients.

#### Drug-Excipient Compatibility study:

Theophylline (DRUG) was mixed with all excipients, used in the formulation in different ratios and subjected to FTIR.

#### FT-IR:

A Fourier Transform - Infra Red Spectrophotometer (FTIR Spectrum BX series 2.19 version) equipped with spectrum v2.19 software was used to study the non-thermal analysis of drug-excipient (binary mixture of drug: excipient 1:1 ratio) compatibility. The spectrum for each sample was recorded over the 450-4000  $\text{cm}^{-1}$  spectral region with a resolution of 4  $\text{cm}^{-1}$ .<sup>3-6</sup>

#### Determination of $\lambda$ -max using UV Visible Spectrophotometer:

Determination of  $\lambda$ -max using UV Visible Spectrophotometer: Standard stock solution of Theophylline (1mg/mL) was prepared in methanol. For the selection of analytical wavelength solutions of drug Theophylline 100 $\mu\text{g}/\text{ml}$  was prepared by appropriate dilution of standard stock solution with distilled water and scanned in the spectrum mode from 200-300nm. The wavelength with maximum absorption was chosen for further analysis.

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**RESEARCH ARTICLE**

**Fabrication and Evaluation of Lidocaine Hydrochloride loaded Cubosomes**

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**ABSTRACT:**

Topical delivery of local anaesthetic drugs such as Lidocaine HCl using carriers and novel nanotechnology can enhance effective drug permeation through the skin into deeper layers and exhibit desirable duration of action. The present study was aimed to formulate and evaluate Lidocaine HCl loaded cubosomes (LHLCs) for sustained therapeutic topical action. Cubosomes emanated as favourable means for the delivery of the drug. LHLCs were prepared by top-down technique using lipid and polymer. Eight formulations of LHLCs were prepared using different concentrations of glyceryl monooleate (GMO) and Poloxamer 407 (P-407). Local anaesthetics create loss of sensation in particular region of the body by inhibiting impulse generation and propagation. Lidocaine HCl is most commonly used amino amide local anaesthetic. It is used as local, topical, intravenous, epidural, peripheral and spinal anaesthesia. The prepared cubosomal dispersions were evaluated to determine surface morphology, particle size, poly dispersibility index (PDI), zeta potential, entrapment ability, tissue distribution studies, and *in vitro* drug release studies. Scanning Electron Microscopic analysis confirmed that drug was encapsulated in bicontinuous structure. The maximum entrapment efficiency was found to be 89.85±1.1% with vesicle size as 228±2.1nm, charge as -5.68±2.7, PDI as 0.295 and 98.83%± 0.12 *in vitro* drug release at the end of 12 hr for F7 formulation, which was confirmed as optimized cubosomal dispersion.

**KEYWORDS:** Cubosomes, Lidocaine HCl, local anaesthetic, sustained drug delivery.

**1. INTRODUCTION:**

Skin is a tough barrier and allows only small quantities of drug molecules to penetrate inside. The outer most layer, Stratum corneum is highly lipophilic in nature and hence acts as rate limiting step in topical drug delivery<sup>1</sup>. Enormous innovations have been developed pertaining to novel transdermal drug delivery with prime aim of extended and targeted delivery of drugs<sup>2</sup>. There are different colloidal carriers such as micro particles, nano particles, micro and nano spheres, liposomes, sphinogosomes, cubosomes, transferosomes etc<sup>3</sup>. These carriers are used for transportation of various drug molecules which have difficulty in penetrating through skin and for poorly bio available drugs<sup>4</sup>.

They enable to sustain the effect of drug at constant rate following zero order kinetics with minimized undesirable side effects<sup>5</sup>.

Lidocaine HCl is a well known Local anaesthetic<sup>6</sup>. Topical anaesthetic agents are used in the treatment of pain associated with minor procedures and symptomatic relief in burns, joints, muscles, haemorrhoids, neuralgia and used in post-operative pains<sup>7</sup>. The half life of highly water soluble Lidocaine HCl is 1.5 to 2hr<sup>8</sup>. Most of the anaesthetics have tendency to bind back to plasma proteins in blood. This affects the duration of action of drug<sup>9</sup>. Nano structured lipid carriers such as Tocopheryl derivative induced systems were also proved to be effective in topical delivery of Lidocaine HCl<sup>10</sup>. Lidocaine HCl can be incorporated in vesicular carriers such as cubosomes, liposomes etc for extended release<sup>11</sup>. Due to greater stability of the cubosomes compared to liposomes which are prepared by phospholipids, the former is gaining prominence in topical drug delivery<sup>12</sup>.



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# Formulation and Evaluation of Salbutamol Sulphate Taste Masked Oral Disintegrating Tablets

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# Drug Utilization Evaluation of Pantoprazole in Inpatients of Tertiary care Hospital

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## ABSTRACT

**Objectives:** To review Pantoprazole drug use, prescribing patterns and promote appropriate pantoprazole use. **Methods:** The study is prospective and observational conducted in inpatients of a tertiary care teaching hospital [MGM hospital]. A total of 1012 cases were enrolled according to our plan of work i.e., inpatients who were under pantoprazole therapy were enrolled in two phases, phase-I (before intervention) and phase-II(after intervention) as we assessed inappropriate use of drug, intervention was developed and implemented and therefore pertinent use of drug is increased. **Results:** Inappropriate use of drug was found in phase-I and appropriateness in terms of rational use for indication, dose, dosing interval was improved in phase-II, this may be due to implementation of intervention. **Conclusion:** Rational use of pantoprazole in accordance with appropriate drug for indication, appropriate dose, dosing interval, duration of therapy for specific indication and particular individual was found to be low in phase-I and rational use was improved after intervention in phase-II by implementing criteria and standards rational drug therapy can be achieved. Rational use of pantoprazole should be increased.

**Key words:** Drug Utilization Evaluation, Pantoprazole, Proton pump inhibitors, Intervention, Indication, Rational use, Criteria and Standards.

## INTRODUCTION

Drug utilization evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). It involves a comprehensive review of a patient's medication and health history before, during and after dispensing in order to attempt to achieve appropriate therapeutic decision-making and positive patient outcomes. Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually and as populations, by striving to prevent the use of unnecessary or inappropriate drug therapy, prevent adverse drug reactions and improve overall drug effectiveness.<sup>1,2</sup> It is an ongoing empowered and organized quality improvement process, designed to

1. To amend drug use by developing criteria and standards.

2. To audit drug use.

3. To interpret prescription pattern.

Steps involved in Drug Utilization Evaluation is depicted in Figure 1

## DUE cycle

Pantoprazole is a first-generation proton pump inhibitor that constrain the activity of proton pump and are used to constrain gastric acid secretions in the treatment of ulcers and gastro esophageal reflux, preventing ulcer complications related to use of NSAIDs and corticosteroids, managing gastro esophageal reflux diseases and ulcer bleeding, prophylaxis of stress ulcer and preventing gastrointestinal risks in patients receiving anticoagulants.<sup>1</sup> Some other conditions where this drug is used include Helicobacter Pyloric eradication, Pyrosis [Heartburn], dyspepsia [OTC], Zollinger-Ellison syndrome.<sup>2</sup> The maximum recommended treatment duration for many

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# Cefotaxime Induced Staphylococcal Scalded Skin Syndrome: A Case Report

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## ABSTRACT

Staphylococcal scalded skin syndrome (SSSS) is as well called as Ritter von Ritterschein disease, Lyell disease, Ritter disease and staphylococcal necrolysis of the epidermis. More common in neonates and children of age less than five years and are at a greater risk of SSSS. To fight against SSSS, children should attain lifetime immunity in the form of antibodies against exotoxins of staphylococcal strains. Symptoms include fever and redness on the overall surface of skin. Within 24-48h, fluid-filled blisters appear on the body. We report a case of 2 years old male child developed SSSS after intravenous administration of Cefotaxime.

**Key words:** Staphylococcal scalded skin syndrome, Immunity, Exotoxins, Cefotaxime, Exfoliative, Cephalosporins.

## INTRODUCTION

Staphylococcal scalded skin syndrome is one of the major exfoliating skin infections. Mainly caused by *Staphylococcus* and the skin looks as if it has been burnt by a hot liquid. Due to the lack of immunity and underdeveloped renal clearance, there is a greater chance of SSSS in children.

Two exfoliating toxins A and B which are released from *Staphylococcus aureus*, but the mechanism for exfoliation is unclear until today. Beneath the granular cell layer, separation of the epidermis and red rash occurs when these toxins act at a remote layer. Two types of SSSS exist localized form superficial involvement of skin and a generalized form involvement of significant areas. Localized infection of *Staphylococcus aureus* in the skin, nose, mouth, throat, umbilicus and gastro intestinal tract (GIT). General malaise, irritability, fever, skin tenderness may be prominent. Other signs include facial edema, conjunctivitis and perioral crusting.

Cephalosporins are used as a prophylactic treatment in many patients because of their

$\beta$ -lactamase stability, lack of toxicity and broad-spectrum. Cefotaxime is a third-generation cephalosporin antibiotic. Here we discuss a case of SSSS due to Intravenous Cefotaxime administration.

## CASE REPORT

A two years old male child who was hospitalized in the Pediatric Department for fever since 3 days, facial puffiness, 2 episodes of vomiting containing food for 1 day, Swelling of legs and feet for 2 days. Then the patient was given Cefotaxime 280mg IV, Paracetamol 5ml syrup, Cetrizine 5ml syrup.

After two days, the patient developed pedal edema and rashes on legs. The physician stopped the medication and the patient was referred to dermatology. On general examination child was conscious, febrile. His pulse rate was 146/min and blood pressure was 90/50mmHg. Physical examination revealed multiple fluid-filled vesicles and bullae noted on the lower limbs and hyperpigmented lesions noted on the

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## Hypofractionated Versus Conventional Radiotherapy with Chemotherapy in Head and Neck Cancer: A Comparative Study

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### ABSTRACT

Head and neck cancers are a group of malignancies that arise from common anatomic sites which include the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, sinonasal cavities and from the salivary glands. Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50%. It has high recurrence rates and metastasis. It is a Prospective Observational, and Comparative Study carried out in 30 patients of loco-regionally advanced carcinoma of head and neck. The diagnosis of loco-regionally advanced cancers of head and neck was made following AJCC staging. The subjects were divided into two groups with 15 in each arm -Accelerated Hypo Fractionated Arm and Conventional Normal Fractionated Arm. All the patients were systematically interviewed, and clinical details of all the subjects were recorded. Among the 30 patients, the highest performance status of (83.3%) ECOG-1 was observed in both the groups when compared to ECOG-2, which is not statistically significant. Hypofractionated radiotherapy can achieve similar tumour response to conventionally fractionated radiotherapy in HNSCC, although with some increase in toxicity. However, to draw some reasonable conclusion, a study with a broader sample and longer follow-up needs to be performed.

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### INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer in the world and has a five-year survival rate of less than 50% (Xiong *et al.*, 2019; Zhao *et al.*, 2019). HNSCC has high metastasis and recurrence rates and includes the following

subgroups: oral squamous cell carcinoma (OSCC), nasopharyngeal carcinoma (NPC), and laryngeal squamous cell carcinoma (LSCC) (Zhao *et al.*, 2019; Huang *et al.*, 2019). HNSCC is associated with a variety of environmental factors as known risk factors, including smoking, alcohol abuse, and human papillomavirus (HPV) infection (Sailer *et al.*, 2019). The survival rate of patients with the disease has increased due to progress in surgical therapy, as well as radiotherapy and chemotherapy. Due to the lack of early clinical symptoms, many HNSCC patients are diagnosed with advanced cancer, the prognosis of HNSCC patients remains stagnant, with a considerable number of deaths due to recurrence and metastasis after chemotherapy and targets therapy (Liu *et al.*, 2019). Head and neck cancer is the sixth most common cancer and is responsible for almost 2,00,000 deaths around the world each year (Parkin *et al.*, 2002). The progression of HNSCC





## RESEARCH ARTICLE

# Potential Approaches of Nanotechnology for Cancer Therapy: An Insight

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### ABSTRACT

Cancer is one of the most severe threats to people all over the world. Cancer incidence and mortality are also on the rise. Chemotherapy, surgery, and radiation therapy are examples of traditional cancer treatment methods. Chemotherapy has been widely used in clinics due to its simple and effective process; however, the therapeutic potential of cancer chemotherapy is severely unsatisfactory due to side effects and drug resistance, non-specific distribution of medicines, multidrug resistance (MDR), and cancer heterogeneity. A drug delivery system (DDS) that combines chemotherapy with supplementary cancer management is required to overcome these limitations and improve cancer therapeutic efficiency. Because of nanomaterials' distinct physicochemical and biological properties, nanotechnologies have presented high potential in cancer therapeutics in recent years. Nanocarriers such as nanodiamonds, quantum dots, high-density lipoprotein nanostructures, liposomes, polymer nanoparticles, dendrimers, nanoconjugates, and gold nanoparticles are used in drug delivery of their physicochemical and optical properties, adaptability, sub-cell size, and biocompatibility. They provide an efficient means of transporting small molecules and biomacromolecules to diseased cells/tissues. In context to cancer, it provides a unique approach and comprehensive technology for early diagnosis, prediction, prevention, personalized therapy, and medicine. As a result, combinational therapy based on chemotherapy facilitated by nanotechnology is the current trend in clinical research, resulting in significantly improved therapeutic efficiency with minimal side effects to normal tissues. The review focuses on recent developments and approaches in nanotechnology for cancer treatment.

**Keywords:** Cancer, Drug delivery, Nanocarriers, Nanoparticles, Nanotechnology.

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### INTRODUCTION

Cancer is one of the leading causes of mortality worldwide. The pace of cancer is increasing with time because of factors like higher pollution, radiation, lack of exercise, and a balanced diet, including genetics.<sup>1</sup> Cancer control has been quite complex due to the distinctive pathophysiology of the cancer cells, which show therapeutic resistance and clinical diversity on the phenotypical and genetic levels. Any of these factors can lead to a mutation in cell DNA, including oncogenes, and causes cancer.<sup>2</sup>

The immortalization and longevity of discrete and amazingly replicated cells exceed all healthy functional cells and causes death ultimately. Initially, cancers start to spread to remote places throughout the body but are likely limited to a small area,<sup>3</sup> making cancer incurable. While our understanding of cancer biology has improved dramatically in the last 20 years, cancer is still the second leading cause of

death in the world. More than 10 million new cases and more than 5 million illness-related deaths are reported every year.<sup>4</sup> A cancer analysis was considered earlier terminal, although the prognosis is favorable at an early stage. A considerable number of cancer patients are asymptomatic until the final stages of the disease are reached. Chemotherapy, radiotherapy, and surgery are among the most common cancer treatments.<sup>5</sup>

Chemotherapy is widely used to inhibit the growth of fast-growing cancer cells by the systemic administration of cancer medicines to patients.<sup>6</sup> A high volume of distribution for low-molecular active ingredients leads to cytotoxicity from chemotherapy. The primary clearance from systemic circulation is another major limitation of chemotherapy. Small molecular chemicals are promptly excreted. They are washed away by macrophages from the body. They, therefore, persist for a short period in systemic circulation and cannot be interconnected with cancer cells, resulting in lower therapeutic

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## FORMULATION AND EVALUATION OF CLOTRIMAZOLE LOZENGES

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### ABSTRACT

Clotrimazole is formulated as lozenges to provide slow release medicament for the management of oral thrush. Clotrimazole is an azole antifungal that works by preventing the growth of fungus. Many dosage forms like syrups, tablets available in market but still there is a need for new dosage form which acts effectively and locally for paediatrics and people with difficulty in swallowing. So the present investigation has been taken up design prepare and evaluate hard candy lozenges to meet the need of improved bioavailability. The benefits of these prepared lozenges showed increase in bioavailability, reduction in gastric irritation, bypassing of first metabolism and increase in onset of action. The lozenges are prepared using sucrose as base; liquid glucose is used for transparency and smoothness; Hydroxy propyl methyl cellulose K15M (HPMC K<sub>15</sub>M) are used as polymers. Sodium saccharine are used as artificial sweeteners. Sweeteners along with flavours are used to mask the bitter taste of drug. All the formulations

prepared are subjected to various physicochemical parameters like weight variation, hardness, thickness, friability, content uniformity, and moisture content etc. the prepared formulations have a hardness of 8-11 kg/cm<sup>2</sup>, non-gritty and pleasant mouth feel. Some selected formulations are also tested for drug excipient interactions subjecting to Infrared Spectral analysis, *in vitro* release rate studies showed that the drug release for lozenges was maximum in formulation F6 (99.52±1.23%) after 25 minutes. The moulded lozenges can provide an attractive alternative formulation in allergic condition.

**KEYWORDS:** Clotrimazole, antifungal, lozenges, saccharine, K<sub>15</sub>M, liquid glucose.



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**REVIEW ARTICLE**

## Formulation and Evaluation of Carvedilol Sustained Release Capsules by Semisolid Matrix Filling Technique

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### ABSTRACT:

The objective of the study was to prepare semisolid capsules of poorly water-soluble drug Carvedilol using a combination of technologies involving solid dispersion preparation and converting it into semisolid matrix filled in hard gelatin capsule. Different excipients like Gelucire 44/14, poloxamer 188, gelatin, PVPK30, PEG6000 were used. Fifteen capsule formulations were prepared and assessed for their release characteristics. Lipid matrix formulations prepared with increasing amount of polymer showed a substantial decrease in release rate of drug in case of poloxamer188. Whereas gelucire 44/14, gelatin, PVPK30, and PEG6000 showed immediate release the mechanism of drug release from the test formulations were studied. The possible modification of carvedilol release kinetics by using poloxamer in the SSM was studied. Results indicate that poloxamer188 is an appropriate carrier for the development of sustained release drug delivery systems and Gelucire 44/14 a highly hydrophilic and lipophilic balance (HLB) excipient, acts as release enhancer in the different ratios studied. Among all the formulations Carvedilol formulation with poloxamer188 in the ratio of (1:3) showed sustained release. Release kinetics studies were performed. The formulation with poloxamer in 1:3 ratio follows first order and Higuchi order release kinetics governed by Fickian diffusion mechanism with  $R^2$  value 0.992.

**KEYWORDS:** Carvedilol, Gelucire44/14, Poloxamer188, Gelatin, PVPK30, PEG6000.

### INTRODUCTION:

Solid dispersion can be defined as "The dispersion of one or more active ingredients in an inert carrier or matrix at solid state"<sup>(1)</sup>. Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered as most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance, and cost-effective<sup>(2)</sup> manufacturing process<sup>(3)</sup>.

The goal in designing sustained delivery systems<sup>(4)</sup> is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery<sup>(5,6)</sup>. A single dose of a drug that is released over a sustained period of time to maintain a near constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use<sup>(7)</sup>. There are certain considerations for the preparation of sustained release formulations. If the active compound has a long half-life, it is sustained on its own<sup>(8)</sup>.

Carvedilol is a non-selective beta adrenoreceptor blocker, used in the treatment of hypertension<sup>(9)</sup>. The drug was selected as a model drug for the investigation because this drug has low molecular weight (carvedilol





Review Article

# Formulation and Evaluation of Valacyclovir Hydrochloride Effervescent Floating Tablets

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Valacyclovir hydrochloride, Effervescent, Floating, Tablets, HPMC K100 M, HPMC K 15 M, Sodium alginate, Xanthan gum

## ABSTRACT

The purpose of this research was to develop gastro-retentive drug delivery system of Valacyclovir hydrochloride to prolong gastric residence time with desired in vitro release profile. Valacyclovir hydrochloride is an Anti-viral drug with high solubility in gastric pH. In the present study, Valacyclovir hydrochloride floating tablets were prepared by effervescence method using sodium bicarbonate and citric acid as a gas generating agent. The tablets were formulated using direct compression method using polymers like HPMC K15M, HPMC K100M, Xanthan gum and Sodium alginate. Pre-compression parameters such as for angle of repose, bulk density, tapped density and hausner's ratio whereas the prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, floating lag time, total floating time, in vitro dissolution study and in vivo radiographic studies. FT-IR and DSC studies elucidated the compatibility of the drug with the polymers and other excipients used in the study. In Vitro release studies of the prepared tablets depicted to follow Zero order kinetics with R<sup>2</sup> value of 0.941 and Fickian diffusion where n value is < 0.5 and found to be the main mechanism of drug release. The manufacturing procedure was found to be reproducible and formulations were stable after one month of accelerated stability studies.

## 1. Introduction

Oral route is considered as the most common route of administration for drug delivery [1]. Effective oral drug delivery may depend upon the factors such as gastric emptying process, gastrointestinal transit time of dosage form, drug release from the dosage form and site of absorption of drugs [2]. Most of the oral dosage forms suffer from several physiological limitations such as variable gastrointestinal transit, variable gastric emptying time, non-uniform absorption profiles, incomplete drug release and shorter residence time of dosage form in stomach [3].

As a result, drugs with absorption window in the upper part of the small intestine undergo incomplete absorption [4]. Hence a beneficial delivery system would be one which possesses the ability to control and prolong the gastric emptying time and can deliver drugs in higher concentrations to the absorption site i.e. upper part of the small intestine [5]. Gastric retention of

drugs is one of the approaches used in the prolongation of gastric retention time with suitable therapeutic activity [6].

Valacyclovir Hydrochloride is an anti-viral drug used commonly in the treatment of infections caused by Herpes virus [7]. Valacyclovir HCl converts to acyclovir with L-valine by first-pass metabolism [8]. Plasma concentrations of unconverted valacyclovir are low with transient, generally becoming non-quantifiable by 3 hours after administration. Peak plasma valacyclovir concentrations are generally less than 0.5 mcg/mL at all doses [9].

Valacyclovir hydrochloride is suitable for floating drug delivery system as it undergoes hepatic metabolism which hinders with the oral bioavailability of the drug. It also has multiple dosage activity for a day that maintains stable drug plasma concentration [10].

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### A CASE REPORT: BECKWITH WEIDEMENN SYNDROME

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#### ABSTRACT

Beckwith-Weidemann-syndrome (BWS) is an overgrowth disorder usually present at birth, characterized by an increased risk of childhood cancer and certain congenital features. A minority (<15%) cases of BWS are familial, meaning that a close relative may also have BWS, and parents of an affected child may be at increased risk of having other children with BWS. While children with BWS are at increased risk of childhood cancer, most children with BWS do not develop cancer and the vast majority of children who do develop cancer can be treated successfully.

**Keywords:** Beckwith-Weidemann-syndrome, Macroglossia

#### INTRODUCTION

Patients were first noted to have abdominal wall defects, macrosomia, macroglossia, and enlarged adrenal glands. Since then, clinical presentation has expanded to recognize hemihypertrophy/lateralized overgrowth, hyperinsulinism, omphalocele, and organomegaly as classic features of BWS. Additionally, it is now recognized that there is a range of clinical features seen in patients with BWS. Presentation of BWS occurs on a spectrum ranging from isolated asymmetry to classic features of BWS. It is a pediatric cancer predisposition disorder caused by changes in the imprinted gene loci on chromosome 11p15 [1]. While most autosomal genes are expressed biallelically, imprinted genes are expressed either from the maternal or paternal allele. These genes are regulated by specific regions near the genes called imprinting control regions (ICRs), which contain epigenetic marks (methylation) that coordinate gene expression. BWS is caused by genetic or epigenetic changes that disrupt the parent-of-origin specific expression of these genes [2,3]. The imprinted gene regions involved in BWS are *H19*, *IGF2* and *CDKN1C/KCNQ1OT1*, all genes implicated in growth during early development. *H19* encodes a long noncoding RNA that is maternally expressed; it is believed to act as a tumor suppressor. *IGF2*, or insulin-like growth factor 2, is a paternally expressed protein-coding gene. *IGF2* is highly active during fetal development and acts as a growth promoter. *CDKN1C*, or cyclin-dependent kinase inhibitor 1C, is a gene that encodes a protein

implicated in cell cycle regulation. *KCNQ1OT1*, or potassium voltage-gated channel subfamily Q member 1 opposite transcript 1 is the antisense transcript of the protein-coding gene *KCNQ1*. *KCNQ1OT1* is implicated in regulating other growth genes [4]. Incidence is estimated to occur in 1 in 10,500 live births in the general population [5]. BWS is a congenital disorder that is commonly diagnosed in early childhood. Patients with BWS have an increased risk of developing embryonal tumors in childhood. Particularly, patients with BWS have an increased risk of developing hepatoblastoma before 4 years of age and Wilms tumor before 7 years of age [6]. Clinical features of BWS typically decrease with age. Regardless of specific presentation, all diagnosed children should be screened for tumor growth. Current screening recommendations are as follows: Ultrasound Screening, Full abdominal ultrasound every three months until age 4 years. Renal ultrasound every three months from age 4-7 years [7].

Alpha-fetoprotein (AFP) screening-AFP measurements every three months until age 4 years. Patients with Beckwith-Wiedemann syndrome (BWS) may require escalated care to manage persistent hypoglycemia. This may include treatment with diazoxide, octreotide, continuous feeds or in some cases partial pancreatectomy. [6] Consultation with experts in managing hyperinsulinism is recommended

#### MATERIAL AND METHODS

The Patient visited MGM Hospital with fever, headache and other associated symptoms. Caretakers consent was sought and explained about this case report publication. The Protocol and Written acceptance of them was submitted and got approved from Institutional Human Ethics Committee (IHEC).

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## Therapeutic drug monitoring of olanzapine: Easy and reliable method for clinical correlation

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### Abstract:

**AIM:** The current work establishes an easy, reliable technique for the estimation of serum Olanzapine concentration which correlates it clinically.

**SUBJECTS AND METHODS:** The work was agreed in 51 schizophrenic patients who were on olanzapine. Serum drug amount was estimated by normal-phase high-performance liquid chromatography and brief psychiatry rating scale was used to determine disease progression.

**RESULTS:** Samples provided 61 patients, 40 were under sub-therapeutic range, 18 were under therapeutic range and 3 were above the therapeutic range.

**CONCLUSION:** Therapeutic drug monitoring must be a part of clinical practice in psychiatric hospitals for optimizing the dose of an individual patient along with the correlation of serum concentration with the clinical assessment scales.

### Keywords:

High-performance liquid chromatography and therapeutic range, olanzapine, schizophrenia, therapeutic drug monitoring

### Introduction

Olanzapine is benzodiazepine derivative which is used in the management of schizophrenia and also to treat modest to severe mania allied with mania depressive psychosis. Olanzapine was widely biotransformed in the hepatocyte, mainly through direct glucuronidation and CYP1A2 mediated oxidation followed by a lesser extent with CYP2D6. Olanzapine (5–20 mg) is recommended daily dose for schizophrenic patients.<sup>1</sup>

Therapeutic drug monitoring (TDM) of neuroleptics choose to optimize dosage decisions to maximize effectiveness and

stop unwanted effects, particularly while those are nonresponsive to management or exposed to undesirable effects through usual quantity for the reason that of demographic, illness, or treatment reciprocal action make difficult in treatment. TDM-assisted psychiatric treatment, while practice by physicians who have background of pharmacokinetics, is potentially useful and cost-effective. TDM is useful in determining drug non-compliance which is a major issue in psychiatric treatment. In many psychiatric hospitals, disease progression is assessed by using different psychiatric rating scales. This is widely used for initially diagnosed and relapse patients.<sup>2</sup>

Due to these reasons, there is a need to develop an easy and reliable method for determining serum Olanzapine concentration which

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## SIMULTANEOUS ESTIMATION OF CIPROFLOXACIN AND METRONIDAZOLE IN BULK AND TABLET FORMULATION BY UV SPECTROPHOTOMETRY

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### Keywords:

UV, Simultaneous equation method,  
Q-absorbance ratio method,  
Ciprofloxacin, Metronidazole

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**ABSTRACT:** Three simple and economical UV-spectrophotometric methods have been developed and validated for simultaneous estimation of ciprofloxacin (CIP) and metronidazole (MET) in a tablet dosage form using distilled water as a green solvent. The proposed methods were; simultaneous equation method (method A), Q-absorbance ratio method (method B), and area under curve method (method C).  $\lambda_{max}$  of CIP & MET in distilled water were found to be 271 nm and 320 nm, respectively. The isoabsorptive point was observed at 290 nm. The linearity was obtained in the concentration range of 1-9  $\mu\text{g/ml}$ , and 2-18  $\mu\text{g/ml}$  for CIP and MET respectively by methods A, B & C. Validation parameters were carried out. All three methods were found to be linear, accurate, precise, and specific. Good results were achieved using distilled water as solvent due to its greater solubility, reproducible readings with maximum absorbance. Among the three methods, method C was found to be the most sensitive. Hence, this method can be recommended for the routine analysis of this drug combination.

**INTRODUCTION:** Ciprofloxacin (CIP) is chemically 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid Fig. 1. It is a fluoroquinolone antibiotic useful for the treatment of various infections caused by Gram-positive, Gram-negative organisms and against *Mycobacterium tuberculosis*. The bactericidal action of CIP results from inhibition of the enzymes topoisomerase 2 (DNA gyrase) and topoisomerase 4, which are required for bacterial DNA replication, transcription repair, and recombination<sup>1, 2</sup>. Metronidazole (MET) is designated chemically as 2-(2-methyl-5-nitro-1H-imidazole-1-yl) ethan-1-ol Fig. 2.

It is a prodrug unionized and the most useful antiprotozoal nitroimidazole derivative. It has been found to possess efficacy against obligate anaerobic bacteria due to their ability to intracellularly reduce MET to its active form, which then covalently binds to DNA, disrupts its helical structure, inhibiting the bacterial nucleic acid synthesis and results in bacterial cell death<sup>3, 4</sup>.

A survey of literature has revealed several analytical methods for the determination of CIP in pharmaceutical dosage form and biological fluids, including spectrophotometry<sup>5-9</sup>, spectrofluorimetry<sup>10</sup>, HPLC<sup>11-13</sup>, potentiometry<sup>14</sup>, electrical micro-titration<sup>15</sup>, and HPTLC<sup>16</sup>. CIP in admixtures with MET<sup>17</sup> and ampicillin has been determined by NMR<sup>18</sup>. HPLC methods either with fluorescence detection or coupled with mass spectrometry (LC/MS) for determination of CIP in human plasma<sup>19, 20</sup>, and by SPE-UHPLC-PDA<sup>21</sup> have also been published. MET has been determined by several methods involving spectrophotometry<sup>22</sup>

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## Fluorescent quantum dots: An insight on synthesis and potential biological application as drug carrier in cancer

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### ABSTRACT

Quantum dots (QDs) are nanocrystals of semiconducting material possessing quantum mechanical characteristics with capability to get conjugated with drug moieties. The particle size of QDs varies from 2 to 10 nm and can radiate a wide range of colours depending upon their size. Their wide and diverse usage of QDs across the world is due to their adaptable properties like large quantum yield, photostability, and adjustable emission spectrum. QDs are nanomaterials with inherent electrical characteristics that can be used as drug carrier vehicle and as a diagnostic in the field of nanomedicine. Scientists from various fields are aggressively working for the development of single platform that can sense, can produce a microscopic image and even be used to deliver a therapeutic agent. QDs are the fluorescent nano dots with which the possibilities of the drug delivery to a targeted site and its biomedical imaging can be explored. This review is mainly focused on the different process of synthesis of QDs, their application especially in the areas of malignancies and as a theranostic tool. The attempt is to consolidate the data available for the use of QDs in the biomedical applications.

### 1. Introduction

Quantum dots are semiconducting nanocrystals with intermolecular distance of approximately 2–10 nm. The use of QDs extends from the commonly seen items like lights, reflectors, photovoltaic devices and sign boards to the more sophisticated, delicate and precise medicines to be administered to humans. In case of medicines, QDs are useful as drug carriers and are also used as tools for diagnosis of diseases when seen under light of particular wavelength [1]. QDs can be synthesized by many well established documented procedures and uniqueness lies in

the fact that different QDs emit different emission spectra when excited under same wavelength. This is based on the composition of materials used for their synthesis and resultant particle size obtained for fluorescent dot [2]. The ease of conjugating QDs with drug delivery vehicles viz; a polymer, solid lipid nanoparticles, micelles, liposomes and carbon based nanomaterials allows the use of such fluorescent nano dots in the field of nano medicine [3]. Very recently the application of nanomaterials is seen in the areas of diagnosis as well as treatment for even complicated conditions like diabetes, cardiovascular ailments, neuro-muscular diseases and cancer. Due to the property of photo

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# Ambispective study of adverse drug reactions in multi-drug resistant tuberculosis patients in Warangal, Telangana

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## ABSTRACT

**Background:** Multidrug-resistant tuberculosis (MDR-TB) has become a global threat concerning to a risk of high mortality with the potential to cause adverse drug reactions (ADRs) which if not managed properly may affect patient compliance, resulting in below par treatment outcome. **Aim:** The aim of the study was to study, assess, and report the ADRs of patients diagnosed with MDR-TB. **Subjects and Methods:** An ambispective, observational study was conducted among confirmed cases of MDR-TB patients without any comorbidities during the period of January 2015–December 2018 in patients of age 15 years and above. **Statistical Analysis:** Data were analyzed descriptively using MS-Excel sheet 2013 and Chi-square test in GraphPad Prism 8.2.1. Results were expressed as either frequency, percentage, or mean  $\pm$  standard deviation. ADRs were evaluated for causality, severity, and preventability attributes. **Results:** In the sample size of 400 patients, 236 (ADR) were reported among 136 patients. The proportion of ADRs was higher in males ( $P = 0.0001$ ) and in the age group of 36–75 years ( $P = 0.0211$ ). Most commonly encountered ADRs include nausea and vomiting (35.31%) and arthralgia (14.04%), followed by peripheral neuropathy (8.93%) and giddiness (8.93%). Overall, 53% were of possible category and 60% of moderate level severity and 85% were unpreventable ADRs. **Conclusion:** Our study included 13 types of ADRs, of which most commonly reported were nausea and vomiting, arthralgia, and peripheral neuropathy and least common were psychosis, nephrotoxicity, and gynecomastia with a higher incidence in males. Majority of ADRs were moderate, unpreventable ADRs and had a possible relationship with the suspected drugs.

**KEY WORDS:** Adverse drug reaction, Causality, multidrug resistant tuberculosis, preventability assessment, severity

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## INTRODUCTION

Antimicrobial resistance has become a topical health and security concern for countries worldwide. In the course of previous years, it has become increasingly clear that global efforts to end tuberculosis (TB) will continue to face a major challenge with the widespread dissemination of TB strains that are resistant to the medicines used in its treatment.<sup>[1]</sup>

India (24%) is responsible for almost half of the world's cases of multidrug-resistant TB (MDR-TB).<sup>[2]</sup> Drug-resistant TB has been known from the time anti-TB drugs were first introduced for the treatment of TB. Currently, the World Health Organization estimated the incidence of MDR TB

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