



Books and chapters in edited volumes/books published and papers published in national/ international conference proceedings per teacher during academic year 2017-18

Sl. No.	Name of the teacher	Title of the book/chapters published	Title of the paper	Title of the proceedings of the conference	Name of the conference	National / International	Year of publication	ISBN number of the proceeding	Page No
1	Mr. P.N.Mallikarjun		Design and Characterization of Controlled release matrix tablets of Glipizide using Avena Sativa Gum	70 th IPC	70th IPC Indian Pharmaceutical Congress	National	2018		<u>7</u>
2	Dr P.Chiranjeevi		RP-HPLC method for simultaneous estimation of Olmesartan medoxomil and amlodipine besylate in bulk and pharmaceutical formulation	70 th IPC	70th IPC Indian Pharmaceutical Congress	National	2018		<u>8</u>

3	Dr. T.Hemanth Kumar		Method Development and Validation of RP-HPLC Method for Simultaneous Estimation of Valsartan and Hydrochlorthiazide	70 th IPC	70th IPC Indian Pharmaceutical Congress	National	2018		9
4	Mr.P.Balakrishnaiah		In vitro Blood Coagulant Activity and Development of Hemostatic Wound Dressing From the Methanolic Fruit Extract of Mimusops Elengi linn	70 th IPC	70th IPC Indian Pharmaceutical Congress	National	2018		10
5	Yarguntla Srinivasa Rao*,		Simultaneous estimation of the Metformin and Canagliflozen in tablet dosage form by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	12

6	M Samba Murthy Raju*,		Simultaneous determination of Metoprolol Succinate and Cilnidipine in solid dosage forms by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	13
7	K Purna Naga Sree*,		RP-HPLC Method Development and Validation for the estimation of Olmesartan Medoxomil and Hydrochlorothiazide in tablets form.	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	14
8	Vasudha Dadi		RP-HPLC Method Development and Validation for the Simultaneous Estimation of Metroprolol succinate and telmisartan in pharmaceutical dosage forms	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	15

9	Cheepurupalli Prasad*		RP-HPLC Method Development and Validation for Simultaneous Estimation of Formoterol and Budesonide in pharmaceutical formulations	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17		2018	978-94-91107-06-5	16
10	Ponnam Chiranjeevi		Simultaneous Estimation of Drotaverine Hydrochloride and Paracetamol in Tablet Formulation by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17		2018	978-94-91107-06-5	17
11	Tatapudi Hemanth Kumar		Simultaneous Estimation of Metformin Hydrochloride and Nateglinide in Pharmaceutical dosage form by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17		2018	978-94-91107-06-5	18

12	P Bala Krishnaiah		Simultaneous Estimation of Ofloxacin and Ornidazole bulk and pharmaceutical formulations by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	19
13	Mr.K.Vara Prasada Rao		RP-HPLC Method Development and Validation for the Quantitative Determination of Etoricoxib in Pharmaceutical Dosage Form	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	20
14	Bora Ramarao		Simultaneous Estimation of Atorvastatin and calcium and Olmesartan medoxomil in Oral solid dosage form by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	21

15	Kanakaraju Adipalli		Simultaneous Estimation of Guaifenesin and Phenylephrine HCl in Combined Pharmaceutical dosage form by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	22
16	Mousami Maganti		Method Development and Validation for the Determination of Fulvestrant injection by RP-HPLC	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	23
17	Bheemarasetty Satya Kiran		RP-HPLC Method Development and Validation for the quantitative determination of Teriflunomide in pharmaceutical dosage form	Pharmaceutical technology challenges and cutting edge research in formulation of drugs	VISTA-2K17	National	2018	978-94-91107-06-5	24

release rate by conveniently varying the SAL-CG ratio in the matrix tablet. However, the variation in drug release rate was not linearly related to the ratio between these polymers and depended on the drug content and compressive force as well.

KEYWORDS: SODIUM ALGINATE, SUSTAINED RELEASE, CALCIUM GLUCONATE, WET GRANULATION

1A-120

FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF DOLUTEGRAVIR SODIUM

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ABSTRACT

The present study was aimed towards the development of sustained release matrix formulations of dolutegravir sodium. In this study the solubility and dissolution rate of poorly soluble drug was improved by solid dispersion technique using kollidoneVA64 as hydrophilic polymer. The solid dispersions of dolutegravir was prepared by employing physical mixing, kneading and solvent evaporation method. Solid dispersions prepared by various methods were evaluated by angle of repose, Carr's index, particle size, drug content and in vitro dissolution studies. The optimized solid dispersion was further formulated as sustained release matrix tablets using HPMCK15M and xanthan gum by direct compression technique. The prepared tablets of various dolutegravir sodium sustained release matrix tablets were evaluated for weight uniformity, hardness, friability and drug content. The drug release form the controlled release matrix tablets were evaluated by in vitro dissolution studies. The pure drug dolutegravir sodium along with optimized formulations was further characterized by FTIR, and DSC studies. The stability of the optimized formulation was checked by performing accelerated stability studies according to ICH guide lines.

KEY WORDS: DOLUTEGRAVIR, SOLID DISPERSIONS, MATRIX TABLETS.

1A-121

DESIGN AND CHARACTERIZATION OF CONTROLLED RELEASE MATRIX TABLETS OF GLIPIZIDE USING AVENA SATIVA GUM

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ABSTRACT

The main aim of the present work is to study the functionality of Avena Sativa gum (ASG) as a release retardant agent in the development controlled release matrix tablets of Glipizide. ASG extracted from oats (Avena Sativa) by an established method. FTIR studies were performed to find out the interactions between gum and drug. In this matrix tablets of Glipizide were prepared with ASG alone and in combination with PVP by wet granulation technique. The granules were evaluated for various post compression parameters and the granules showed satisfactory results. Tablets thus formulated were evaluated for various quality control tests like weight variation, hardness, friability etc. All matrix tablets were found to have better uniformity of weight and drug content with low SD values. The dissolution study proved that the ASG can be used as a matrix forming material for making controlled release tablets. The kinetic release data fitted into different mathematical models (Zero order, First order, Higuchi, Peppas and Hixson-Crowell). Most of the matrix formulations followed Higuchi or zero order kinetics. *in vivo* studies conducted for the optimised formulation using rabbits and the pharmacokinetic parameters were estimated.

KEY WORDS: GLIPIZIDE, AVENA SATIVA GUM (ASG), MATRIX TABLETS,

1A-122

DESIGN AND CHARACTERIZATION OF CONTROLLED RELEASE MATRIX TABLETS OF GLIPIZIDE USING AVENA SATIVA GUM

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ABSTRACT

Apremilast is approved by USFDA in September 2014 for treatment of Patients with active psoriatic arthritic and modarates to severe plaque psoriasis .The Present study described simple , accurate precise, robust development for estimation of apremilast by RP-HPLC method .

The chromatographic method standardized using C18 column (Inertsil ODS 3V,250 x 4.6mm, 5µm) and mobile phase containing 0.01M Ammonium acetate buffer pH 4 (pH adjusted with GAA) : Acetonitrile (30:70 v/v) at flow rate of 1ml/min the eluents were detected by PDA detector at 231 nm .The retention time was found to be 3.98 min. The system suitability parameters for apremilast such as theoretical plates and tailing factor were found within limits. The linearity study of apremilast was found in concentration range of 0.6 µg/ml- 3 µg/ml and correlation coefficient (r²) was found to be 0.999, % recovery was found to be at each level was 99.64%-100.15%

% RSD for interday and intraday precision was found within limits. The analytical method was validated and applied on marketed formulation.

KEY WORDS APREMILAST, RP-HPLC, VALIDATON, FORCE DEGRADATION

6A-96

STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF DIMETHYL FUMARATE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

The simple, rapid, specific, precise, accurate and reproducible stability indicating RP-HPLC method was developed for estimation of Dimethyl fumarate in bulk and capsule dosage form. An Inertsil ODS (150x4.6 mm, 5µ) column and a mobile phase containing Acetonitrile: Perchloric acid buffer (50:50% v/v) was used for this study. The flow rate was maintained at

1.0 ml/min; column temperature was fixed at 35°C and UV detection at 210 nm. The forced degradation studies were performed and method was validated as per ICH guidelines. The retention time of Dimethyl fumarate was found to be

3.5±0.02 min. The value of correlation coefficient between peak area and concentration was found to be 0.9987. The mean percent recovery of Dimethyl fumarate in capsules was found in the range of 95.0%- 105.0%. The results of forced degradation studies indicates that the drug was found to stable in basic, oxidative and photolytic conditions while degraded in acidic and thermal conditions. Thus, this method can be used for routine analysis of Dimethyl fumarate capsules and check their stability.

KEY WORDS: ANALYTICAL METHOD VALIDATION, RP-HPLC, CORRELATION COEFFICIENT, STABILITY INDICATING METHOD.

6A-97

RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF OLMESARTAN MEDOXOMIL AND AMLODIPINE BESYLATE IN BULK AND PHARMACEUTICAL FORMULATION

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ABSTRACT:

A simple, reproducible and efficient reverse phase high performance liquid chromatographic method was developed for simultaneous determination of Olmesartan medoxomil and Amlodipine besylate in bulk and pharmaceutical dosage form. Separation was achieved using a C-18 column having 250 mm x 4.6 mm i.d. with mobile phase containing acetonitrile and 0.1% orthophosphoric acid in the ratio of 60:40 v/v. The flow rate was 1 ml/min and effluent was monitored at 240 nm. The retention time for Olmesartan medoxomil and Amlodipine besylate were found to be 6.6 min and 7.6 min respectively. Linearity range was found to be 20-160 µg/ml for Olmesartan medoxomil with correlation coefficient 0.9981 and 5-25 µg/ml for Amlodipine besylate with correlation coefficient 0.9997. The developed method was found to be accurate, precise and selective for simultaneous estimation of Olmesartan medoxomil and Amlodipine besylate in bulk and pharmaceutical dosage form.

6A-98

STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF



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SOFOSBUVIR AND VELPATASVIR IN PURE AND PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple, accurate stability indicating RP-HPLC method has been developed and validated for the determination of sofosbuvir and velpatasvir in pure and pharmaceutical formulations. Method was developed using a mixture of acetate buffer and acetonitrile (85:15% v/v) as mobile phase at pH 3 using Shiseido C18 (250×4.6mm, 5 μ) column as stationary phase. The flow rate and the detection wavelength were 1ml/min and 245nm respectively. The retention times for sofosbuvir and velpatasvir were 3.277 and 6.517 minutes respectively. The linearity range of the method was found to be 10-60 μ g/ml for sofosbuvir and 2.5-15 μ g/ml for velpatasvir respectively. For accuracy the total recovery was found to be 99.07-100.27%. The %RSD was not more than 2% which proved the precision of the developed method. The developed method was validated as per ICH guidelines and the results of all the validation parameters were well within acceptable limits. The drugs were found to be stable and less prone to degradation when they are subjected to various stress conditions. The results obtained in this research work clearly indicated that the developed method is simple, selective, precise, accurate, robust, and rugged. Hence, this validated method can be applied for the simultaneous estimation of sofosbuvir and velpatasvir in commercially available formulation sample.

KEY WORDS: SOFOSBUVIR, VELPATASVIR, RP-HPLC, VALIDATION.

6A-99

METHOD DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF VALSARTAN AND HYDROCHLOROTHIAZIDE

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ABSTRACT:

A simple, reproducible and sensitive reverse phase high performance liquid chromatographic method was developed and validated for simultaneous determination of Valsartan and Hydrochlorothiazide in bulk and pharmaceutical dosage form. Separation was achieved using enable C18 G column having 10 mm×4.6 mm i.d. in with mobile phase in isocratic mode containing Acetonitrile and 0.1 % Orthophosphoric acid in the ratio of 10:90 v/v. The flow rate was 1ml/min and effluents were monitored at 265 nm. The retention time for valsartan was found to be 2.7 min and for Hydrochlorothiazide is 3.2 min. The linearity range for valsartan was found to be 20-160 μ g/ml with correlation coefficient 0.999. The linearity range for Hydrochlorothiazide was found to be 5-25 μ g/ml with correlation coefficient 0.999. The developed method was found to be accurate, precise and sensitive for estimation Valsartan and Hydrochlorothiazide in bulk and pharmaceutical dosage form.

6A-100

DEVELOPMENT AND VALIDATION OF NOVEL ANALYTICAL FOR SIMULTANEOUS ESTIMATION OF TOFACITINIB AND METHOTREXATE BY RP-HPLC

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Abstract.

Rheumatoid arthritis is an autoimmune disorder related to joints of body. The drug Tofacitinib in combination with the Methotrexate can be used for the treatment of Rheumatoid arthritis. The simple reverse phase High Performance liquid Chromatography method was developed for the determination of Tofacitinib and Methotrexate in combination. Tofacitinib is the recent advancement in treatment of rheumatoid arthritis. Methotrexate is anticancer drug but also used in the treatment of arthritis. The method was validated as per ICH guidelines. The separation was achieved on C₁₈ column (5 μ m, 4.6×150 mm analytical column) with flow rate 1ml/min. using methanol and the water as mobile phase in the ratio of 90:10. Column temperature was maintained 25°C and the observation were recorded at 293 nm. The method is linear in concentration range from 10-40 μ g/ml for Tofacitinib and Methotrexate in



were measured. Post compression parameters like swelling index, floating lag time, floating time were measured.

KEYWORDS: POLYHERBAL FORMULATION, FLOATING TABLET, ULCER.

3B-46

ABSTRACT

Gel formulation provides better application property and stability in comparison to cream and ointment. Topical gel drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. Skin is one of the most extensive and readily accessible organs on human body for topical administration and is main route of topical drug delivery system. Topical application of drugs offers potential advantages of delivering the drug directly to the site of action and acting for an extended period of time. Topical gels are intended for skin application or to certain mucosal surfaces for local action or percutaneous penetration of medicament or for their emollient or protective action. Gels are evaluated by following parameters such as pH, homogeneity, grittiness drug content, viscosity, spreadability, extrudability, skin irritation studies, in-vitro release, in Stability.

3B-47

DEVELOPMENT, CHARACTERIZATION AND ANTIOXIDANT ACTIVITY OF PICRORRHIZA PHOSPHOLIPID COMPLEX

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ABSTRACT

The aim of the present study is to develop a complex of Standardize Picrorrhiza Kurroa extract (SPE) and phospholipid with a goal to improve the bioavailability of its phytoconstituents. Kutkin is a glycoside, present in Picrorrhiza Kurroa known to possess various therapeutic properties. The poor solubility and dissolution rate limit its oral absorption and bioavailability. The picrorrhiza-phospholipid complex was prepared using solvent evaporation method and characterized by various parameters like solubility studies, particle size determination, infrared absorption (FTIR), Differential scanning calorimetry (DSC),

X-ray diffraction (XRD), Scanning electron microscopy (SEM), entrapment efficiency etc. SEM and XRD reveal the reduction in crystallinity of extract in the complex. FTIR and DSC confirm the formation of phyto-phospholipid complex. The in vitro dissolution studies revealed a significantly higher efficiency of complex in releasing picrorrhiza in comparison to the pure picrorrhiza extract, or the physical mixture. Phospholipid complex of picrorrhiza may be of potential use in increasing the permeability and hence the bioavailability of kutkin. We observed that complex was an effective scavenger of DPPH radicals and showed the strong antioxidant activity. The result of the study revealed that the phospholipid complex may be considered as a promising drug delivery system that improves the absorption and bioavailability of plant constituents.

KEYWORDS: PICRORRHIZA KURROA, PICRORRHIZA-PHOSPHOLIPID COMPLEX, PHOPHATIDYL CHOLINE, CHARACTERIZATION.

3B-48

IN VITRO BLOOD COAGULANT ACTIVITY AND DEVELOPMENT OF HEMOSTATIC WOUND DRESSING FROM THE METHANOLIC FRUIT EXTRACT OF MIMUSOPS ELENGI LINN

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ABSTRACT

Mimusops elengi is a small evergreen tree always grown as an avenue plant. This study aims at providing evidence for some of the biological activities of tannins. The preliminary screening of methanolic extract of fruits revealed the presence of alkaloids, flavonoids, tannins, saponins, glycosides, phenols. Different concentrations of plant extract varying from 2mg/ml to 10mg/ml were prepared. 1ml from each concentration was added to pre weighed micro centrifuge tubes and one tube is kept as control. 1ml blood freshly collected from healthy volunteers is added to each of the above said tubes. The time taken for blood coagulation was noted. Wound pads of size 3x3cm size were prepared using a sterile gauge and sterile absorbent cotton wool under sterile environment. Then the sterile wound pads were impregnated in varying concentrations of methanolic extract (2-10mg/ml). 2x2 cm long and deep incisions were made on the chicken and blood is allowed to flow. Then the prepared wound pads were placed on the incised areas. Time required for coagulating blood in micro centrifuge tubes decreases with increasing concentration of methanolic



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THEME

**PHARMACEUTICAL TECHNOLOGY
CHALLENGES AND CUTTING-EDGE
RESEARCH IN FORMULATION OF
DRUGS**



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ABOUT THE INSTITUTION

Vignan Institute of Pharmaceutical Technology (VIPT) is one of the constituent colleges of Vignan Institutions well known for quality education with Global standards and Indian values. VIPT was established in 2006 with a view to provide job oriented professional courses in Pharmacy. VIPT offers B. Pharmacy, M.Pharm., PharmD. Programs. The College is Affiliated to the JNTU Kakinada, approved by the All India Council for Technical Education (AICTE), Pharmacy Council of India (PCI), Govt. of Andhra Pradesh. The College is ISO 9001:2015 & ISO 14001:2015 & ISO 45001:2018 Certified for its safety and waste disposal methods employed. The infrastructure available makes the college a conducive academic learning that provides students with good quality education in a clean, comfortable environment. The college is presently one of the largest graduate, postgraduate and research institutions in Andhra Pradesh imparting quality Pharmaceutical Education.

ABOUT THE CONFERENCE

Vignan Institute of Pharmaceutical Technology, Visakhapatnam is organizing National Conference on "Pharmaceutical Technology challenges and cutting-edge research in formulation of drugs." during 14-15 September 2017. Considering the significance of new scientific and technological trends, their applications in the chemical and pharmaceutical industries, and developments in the biomedical sciences to enhance health advantages. It is intended to further investigate a number of study areas. The purpose of the conference is to serve as a forum for discussion of the research and advancements in the fields of chemical, biological, and pharmaceutical sciences. Many scholars will use this meeting as a springboard to share their work. Additionally, it offers a single platform for academics, research institutions, and industries to unite and present a chance for collaboration.

THEME

**PHARMACEUTICAL TECHNOLOGY
CHALLENGES AND CUTTING-EDGE
RESEARCH IN FORMULATION OF
DRUGS**



Simultaneous estimation of the Metformin and Canagliflozen in tablet dosage form by RP-HPLC

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A reverse phase high performance liquid chromatographic method (HPLC) has been developed for the simultaneous estimation of the Metformin and Canagliflozen in tablet dosage form. Sample was run through Standard Altima 150mm x 4.6 mm, 5 μ . Mobile phase (Buffer and Acetonitrile in the ratio of 75:25 v/v) was pumped through column at a flow rate of 1 ml/min. and the eluents were monitored at 283nm. The retention times (Rt's) of Metformin and Canagliflozen were found to be 2.294min and 3.376 min. Percentage RSD of the Metformin was found to be 1 and for Canagliflozen was 0.67 and the %Recoveries were gained as 100.47% for Metformin and 100.2% for Canagliflozen. LOD, LOQ values are from regression equations of Metformin and Canagliflozen were 0.321, 0.022ppm and 0.972, 0.067ppm resp. Regression equation of Metformin is $y = 1187.x + 811.2$, Canagliflozen is and $y = 22755x + 666.9$. The method was statistically validated and RSD was found to be less than 2% indicating high degree of accuracy and precision of the proposed HPLC method. Due to its simplicity, rapidness, high precision and accuracy, the proposed HPLC method may be used for determination of Metformin and Canagliflozin in tablet dosage form.

Keywords: Metformin, Canagliflozin, Acetonitrile, LOD, LOQ



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Simultaneous determination of Metoprolol Succinate and Cilnidipine in solid dosage forms by RP-HPLC

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A reverse phase high performance liquid chromatographic (RP-HPLC) method suitable for simultaneous determination of Metoprolol Succinate and Cilnidipine in solid dosage forms in has been developed and applied for dissolution studies. Chromatographic separation was performed and achieved using ELIPSE Phenomenax C18, 150X4.5 mm, 5 μ , column using a mobile phase consist of 0.1% OPA buffer (pH 3.0): Methanol (70:30%v/v). The effluent flow rate monitored at 1.0 mL/minute, injection volume was 10 μ L and detected by ultraviolet at 285 nm. The retention times of Metoprolol Succinate and Cilnidipine 2.590 and 4.047 minutes, respectively. The total run time was 6 minutes. The developed method has been validated for specificity, precision, linearity, accuracy, ruggedness and robustness. Additionally, the conditions of the dissolution test for Metoprolol Succinate and Cilnidipine tablets were presented by using: paddle at 50rpm stirring speed; medium volume of 900mL; temperature at 37 \pm 0.5 $^{\circ}$ C; and pH 6.8 phosphate buffer used as dissolution medium. The average percentage drug release was found to be in between 95% to 105% within 30 minutes for both drugs. The proposed analytical and dissolution method can be applied successfully for the quality control of commercial Metoprolol Succinate and Cilnidipine tablets and the comparison of in vitro dissolution of combination drug products.

Keywords: Metoprolol Succinate; Cilnidipine; Dissolution test; Method development



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RP-HPLC Method Development and Validation for the estimation of Olmesartan Medoxomil and Hydrochlorothiazide in tablets form.**K Purna Naga Sree*, Bommareddy Monica Krishna, Bothsa Akhil, Chanchala Alekya, Chitikala Jeevan Sarat**

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A new RP-HPLC method was developed and validated which was simple, accurate, less expensive and more rapid with isocratic mode for the estimation of Olmesartan Medoxomil and Hydrochlorothiazide in tablets form. It was achieved by using Inertsil ODS-3, 250 x 4.6 mm, 5 μ . The mobile phase used in this study was Buffer and acetonitrile in the ratio 67:33 v/v. The mobile phase was filtered through 0.45 μ membrane filter and degassed. The mobile phase was pumped from the solvent reservoir to column at a flow rate of 1.0 mL/min with injection volume of 10 μ L and run time 20 min at ambient temperature. The retention time for Olmesartan Medoxomil was 15.188 min and Hydrochlorothiazide was 4.345 min and U.V absorbance was maximum at 224 nm. The assay results comply with the label claim of the formulae. The proposed method is simple, selective, reproducible, sensitive and accurate with good precision. The present proposed system provides shorter analysis time and conserves mobile phase system. The method was proved to be superior to most of the reported methods. The proposed method was validated based on United States pharmacopoeia and ICH parameters. The parameters are accuracy, precision, linearity and range, specificity, ruggedness, robustness, system suitability, Forced Degradation Studies, filter validation and solution stability. The system suitability was checked and the %RSD, number of theoretical plates and tailing factor were found to be within the limits. In specificity no interference was observed due to placebo. The range of Olmesartan Medoxomil and Hydrochlorothiazide was found to be 0.050-0.150. The percentage recovery was found to be within the limits. In system precision and method precision %RSD was within limits. In ruggedness and robustness also the %RSD was within the limits. The proposed method can be successfully applied for routine analysis for estimation of Olmesartan Medoxomil and Hydrochlorothiazide in tablets.

Keywords: Olmesartan Medoxomil, Hydrochlorothiazide, RP-HPLC, Method Validation



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RP-HPLC Method Development and Validation for the Simultaneous Estimation of Metoprolol succinate and telmisartan in pharmaceutical dosage forms

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An accurate and precise RP-HPLC method was developed for the simultaneous estimation of Metoprolol succinate and telmisartan in pharmaceutical dosage forms. The chromatographic analysis was performed on X-Terra C8 (4.6mm x 100 mm, 5 μ m particle size) column with UV detection at 226 nm. The chromatogram was run through mobile phase consisting of sodium dihydrogen, ortho phosphate buffer (p^H 2.8) and methanol in the ratio of 35:65 v/v was pumped through column at a flow rate of 1.2 ml/min. Retention time of metoprolol succinate and Telmisartan were found to be 2.3 and 5.5 minutes. This method was the development and validation of simple, robust, ruggedness, stability indicating liquid chromatographic analytical method for the metoprolol succinate and telmisartan in pharmaceutical dosage forms.

Key Words: Metoprolol Succinate, Telmisartan, RP-HPLC.



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RP-HPLC Method Development and Validation for Simultaneous Estimation of Formoterol and Budesonide in pharmaceutical formulations

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A new, simple, accurate and reproducible RP-HPLC method developed and validated for Simultaneous estimation of Formoterol and Budesonide in pharmaceutical formulations. Separation of Formoterol and Budesonide was achieved using PHENOMEX, C18, 250X4.6, 5 μ m equivalent in an isocratic mode utilizing CH₃COONa: METHANOL (400:600 v/v) at a flow rate of 1.0mL/min and eluate was monitored at 289nm, with a retention time of 3.834 and 6.387 minutes for Formoterol and Budesonide respectively. The method was validated and there response was found to be linear in the drug concentration range of 50 μ g/ml to 150 μ g/ml for Formoterol and 50 μ g/ml to 150 μ g/ml for and Budesonide. The values of the correlation coefficient were found to 0.999 for Formoterol and 0.999 for Budesonide respectively. The LOD and LOQ for Formoterol were found to be 0.004 μ g/mL and 0.012 μ g/mL respectively. The LOD and LOQ for Budesonide were found to be 0.0817ppm and 0.2722 ppm respectively. This method was found to be good percentage recovery for Formoterol and Budesonide were found to be 100% and 100% respectively indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard with the sample so, the method specifically determines the analyte in the sample without interference from excipients of tablet dosage forms. The method was extensively validated according to ICH guidelines for Linearity, Accuracy, Precision, Specificity and Robustness.

Keywords: Formoterol ,Budesonide, RP-HPLC.



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Simultaneous Estimation of Drotaverine Hydrochloride and Paracetamol in Tablet Formulation by RP-HPLC

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A simple, rapid and precise RP-HPLC method has been developed and validated for the simultaneous estimation of Drotaverine Hydrochloride and Paracetamol in tablet formulation. Chromatography was carried out at ambient temperature on a Phenomenex C18 column (150×4.6 mm) with the isocratic mode using mobile phase as Methanol: water (25:75 v/v, p^H 5.9 adjusted with acetic acid) at a flow rate of 1.2 ml/min. The eluents were monitored at 274 nm. The retention times of Drotaverine Hydrochloride and Paracetamol were found to be 2.99 min and 3.15 min respectively. The linearity range of Drotaverine HCl and Paracetamol was found to be 10-100 ppm. The developed method was validated for specificity, precision, accuracy, robustness and ruggedness. All the validation parameters meet the acceptance criteria. This method could be used for routine analysis for simultaneous estimation for the above drugs.

KEY WORDS: Drotaverine HCl, Paracetamol, RP - HPLC



Simultaneous Estimation of Metformin Hydrochloride and Nateglinide in Pharmaceutical dosage form by RP-HPLC

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A new, simple, precise, accurate and reproducible RP-HPLC method developed and Validated for Simultaneous estimation of Metformin Hydrochloride and Nateglinide in pharmaceutical dosage form. Separation of Metformin HCl and Nateglinide was successfully achieved with Inertsil ODS, C18, (250 mm x 4.6 mm, 5 μ m) in an isocratic mode utilizing Phosphate Buffer : ACN : Methanol (30:60:10) at a flow rate of 1 mL/min and eluate was monitored at 221 nm, with a retention time of 2.420 and 4.270 minutes for Metformin HCl and Nateglinide respectively. The method was validated and there response was found to be linear in the drug concentration range of 14.4 μ g/ml to 33.2 μ g/ml for Nateglinide and 60 μ g/ml to 140 μ g/ml for Metformin HCl. The values of the correlation coefficient were found to 0.9998 for Metformin HCl and 0.9996 for Nateglinide respectively. The LOD and LOQ for Metformin HCl were found to be 2.81 μ g/ml and 8.52 μ g/ml respectively. The LOD and LOQ for Nateglinide were found to be 1.52 μ g/ml and 4.62 μ g/ml respectively. This method was found to be good percentage recovery for Metformin HCl and Nateglinide were found to be 99.34 % and 99.36 % respectively indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard with the sample. so, the method specifically determines the analyte in the sample without interference from excipient of tablet dosage forms. The method was extensively validated according to ICH guidelines for Linearity, Accuracy, Precision, Specificity and Robustness.

Keywords: Metformin HCl, Nateglinide, RP-HPLC



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Simultaneous Estimation of Ofloxacin and Ornidazole bulk and pharmaceutical formulations by RP-HPLC

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A new, simple, precise, accurate and reproducible RP-HPLC method developed and validated for Simultaneous estimation of Ofloxacin and Ornidazole bulk and pharmaceutical formulations. Separation of Ofloxacin and Ornidazole was successfully achieved on Inertsil 250X4.6, 5 μ m, C8 (4.6 x 250 mm, 5 μ m) in an isocratic mode utilizing 0.1% OPA: Methanol (50:50 v/v) at a flow rate of 1 mL/min and eluate was monitored at 227 nm, with a retention time of 3.819 and 6.456 minutes for Ofloxacin and Ornidazole. The method was validated and there was found to be linear in the drug concentration range of 50 μ g/ml to 150 μ g/ml for Ofloxacin and 50 μ g/ml to 150 μ g/ml for and Ornidazole. The values of the correlation coefficient were found to be 0.999 for Ofloxacin and 0.999 for Ornidazole respectively. The LOD and LOQ for Ofloxacin were found to be 0.180 μ g/ml and 0.599 μ g/ml respectively. The LOD and LOQ for Ornidazole were found to be 0.3074 μ g/ml and 1.0246 μ g/ml respectively. This method was found to be good percentage recovery for Ofloxacin and Ornidazole were found to be 99.59 % and 99.57 % respectively indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard with the sample so, the method specifically determines the analyte in the sample without interference from excipients of tablet dosage forms. The method was extensively validated according to ICH guidelines for Linearity, Accuracy, Precision, Specificity and Robustness.

Keywords: Ofloxacin, Ornidazole, RP-HPLC.

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RP-HPLC Method Development and Validation for the Quantitative Determination of Etoricoxib in Pharmaceutical Dosage Form

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A simple, rapid, precise & efficient RP-HPLC method has been developed and validated for the quantitative determination of Etoricoxib in pharmaceutical dosage form. The chromatographic separation was achieved by using column unisol ODS reverse phase (150×4.6 mm, 5 μm particle size) C₁₈ column. Mobile phase consists of mixture of pH 3.0 – 0.025M potassium dihydrogen phosphate buffer and methanol in the ratio of 60:40 v/v and was delivered at a flow rate of 1.5 mL/min, while the detection was monitored at a wavelength of 235 nm. The developed method showed excellent linear response ($r^2 = 0.999$) in the range of 9.6-57.6 μg/mL. The retention time for Etoricoxib was found to be 4.6 min. The percentage purity was found to be 99.6% and percentage recovery was found to be 99.6-100.1%. Forced degradation studies were conducted by using stress conditions such as acid stress degradation, alkali stress degradation, peroxide stress degradation, photolytic degradation, humidity and thermal degradation. From these studies, it was observed that the proposed acceptance criteria meet the requirements for acid, alkali and UV light degradation and it is stable even when more stress conditions like peroxide and thermal stress is applied. The proposed method was validated as per ICH guideline and can be concluded that the method is specific and peak purity characteristic passed. Thus, the method is fast, precise, specific and accurate and can be applied for estimation of Etoricoxib in pharmaceutical dosage forms in routine analysis.

Key words: Etoricoxib, RP-HPLC, Method Validation, Forced Degradation Studies.



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Simultaneous Estimation of Atorvastatin calcium and Olmesartan medoxomil in Oral solid dosage form by RP-HPLC

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A new, simple, precise, accurate and reproducible RP-HPLC method developed and validated for Simultaneous estimation of Atorvastatin calcium and Olmesartan medoxomil in Oral solid dosage form. Separation of Atorvastatin calcium and Olmesartan medoxomil was successfully achieved on a Inertsil ODS C₁₈ (250mm X 4.6mm X 5 μ Make: Waters) in an isocratic mode utilizing Orthophosphoric acid buffer (pH 2.5): Acetonitrile (40:60 % v/v) at a flow rate of 1 mL/min and eluate was monitored at 225 nm, with a retention time of 2.461 and 3.765 minutes for Olmesartan medoxomil and Atorvastatin calcium. The method was validated and the response was found to be linear in the drug concentration range of 50 μ g/mL to 150 μ g/mL for Olmesartan medoxomil and 50 μ g/mL to 150 μ g/mL for Atorvastatin calcium. The value of the correlation coefficient was found to be 0.999 and 0.999 for Olmesartan medoxomil and Atorvastatin calcium. The LOD and LOQ for Atorvastatin calcium were found to be 2.75 μ g/mL, 9.17 μ g/mL respectively. The LOD and LOQ for Olmesartan medoxomil were found to be 2.82 μ g/mL, 9.41 μ g/mL respectively. This method was found to be good percentage recovery for Atorvastatin calcium and olmesartan medoxomil were found to be 99.88 % and 100.05 % respectively indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard with the sample so, the method specifically determines the analyte in the sample without interference from excipients of tablet dosage forms. The method was extensively validated according to ICH guidelines for Linearity, Range, Accuracy, Precision, Specificity and Robustness.

Keywords: Olmesartan medoxomil, Atorvastatin calcium, RP-HPLC.



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Simultaneous Estimation of Guaifenesin and Phenylephrine HCl in Combined Pharmaceutical dosage form by RP-HPLC

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A new, simple, precise, accurate and reproducible RP-HPLC method was developed and Validated for Simultaneous estimation of Guaifenesin and Phenylephrine HCl in combined pharmaceutical dosage form. Separation was successfully achieved by using Inertsil ODS, C18, 250X4.6 mm, 5 μ m equivalent in an isocratic mode utilizing Sodium di hydrogen Phosphate Buffer: Acetonitrile (30:70 v/v) at a flow rate of 1.0 ml/min and elute was monitored at 232 nm, with a retention time of 3.497 and 2.353 minutes for Guaifenesin and Phenylephrine HCl respectively. The method was validated and there response was found to be linear in the drug concentration range of 130 μ g/ml to 390 μ g/ml for Guaifenesin and 5 μ g/ml to 15 μ g/ml Phenylephrine HCl. The values of the correlation coefficient were found to 0.9990 for Guaifenesin and 0.994 for Phenylephrine HCl respectively. The LOD and LOQ for Guaifenesin were found to be 2.81 μ g/ml and 8.52 μ g/ml respectively. The LOD and LOQ for Phenylephrine HCl were found to be 1.52 and 4.62 respectively. This method was found to be good percentage recovery for Guaifenesin and Phenylephrine HCl were found to be 99.70% and 98.85% respectively indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard with the sample so, the method specifically determines the Analyte in the sample without interference from excipient of tablet dosage forms. This method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in industries, approved testing laboratories, bio-pharmaceutical and bio-equivalence studies and in clinical pharmacokinetic studies in near future.

Keyword: Guaifenesin, Phenylephrine HCl, RP-HPLC.



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Method Development and Validation for the Determination of Fulvestrant injection by RP-HPLC

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A simple, specific and fast reverse phase high performance liquid chromatographic methods was established for determination of Fulvestrant injection. Optimum chromatographic separation was achieved by use of zorbax XDB C18; 150×4.6mm, 3.5µ with mobile phase consisted of a mixture of Mobile phase-A: water, acetonitrile and methanol (410:320:270) v/v, Mobile phase-B: Acetonitrile, methanol and water (490:410:100) v/v and at a flow rate of 2ml/min. Detection was carried out at 225 nm. Response was a linear function of concentrations over the range of 80–120µg/ml. Calibration curve was plotted and correlation co-efficient was found to be 0.999. The accuracy studies showed % recovery of Fulvestrant inj. in the range 99.7-102%. The method was validated in accordance with ICH guidelines.

Keywords: RP HPLC; Fulvestrant injection; Validation; ICH guidelines.



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RP-HPLC Method Development and Validation for the quantitative determination of Teriflunomide in pharmaceutical dosage form

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A simple, rapid, precise & efficient RP-HPLC method described for the quantitative determination of Teriflunomide in pharmaceutical dosage form. The chromatographic separation was achieved by using column Agela, C18, 150×4.6 mm, 5 μm. Mobile phase consists of mixture of pH 3.5 - 0.025M potassium dihydrogen phosphate buffer : ACN in the ratio of 65:35 v/v and was delivered at a flow rate of 1 mL/min, while the detection was monitored at a wavelength of 248 nm. The developed method showed excellent linear response ($R^2 = 0.999$) in the range of 39-72 μg/mL. The retention time for Teriflunomide was found to be 4.165 min. The percentage purity was found to be 99.6% and percentage recovery was found to be 100.1-100.5%. Forced degradation studies were conducted by using stress conditions such as acid stress degradation, alkali stress degradation, peroxide stress degradation, photolytic degradation, humidity and thermal degradation. From these studies, it was observed that the proposed acceptance criteria meet the requirements for acid and alkali degradation and it is stable even when more stress conditions like peroxide and thermal stress is applied. The proposed method was validated as per ICH guidelines and can be concluded that the method is specific and peak purity characteristic passed. Thus, the method is fast, precise, specific and accurate and can be applied for estimation of Teriflunomide in pharmaceutical dosage forms in routine analysis.

Key words: Teriflunomide, RP-HPLC, Method Validation, Forced Degradation Studies.



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